EXPORT OF HAZARDOUS PRODUCTS

HEARINGS

BEFORE THE

SUBCOMMITTEE ON INTERNATIONAL ECONOMIC POLICY AND TRADE

OF THE

COMMITTEE ON FOREIGN AFFAIRS HOUSE OF REPRESENTATIVES

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EXPORT OF HAZARDOUS PRODUCTS

THURSDAY, JUNE 5, 1980

HOUSE OF REPRESENTATIVES,
COMMITTEE ON FOREIGN AFFAIRS,
SUBCOMMITTEE ON INTERNATIONAL
ECONOMIC POLICY AND TRADE,
Washington, D.C.

The subcommittee met at 2:05 p.m. in room 2200, Rayburn House Office Building, Hon. Jonathan B. Bingham (chairman of the subcommittee) presiding.

Mr. BINGHAM. The Subcommittee on International Economic Policy and Trade will be in order.

Today the subcommittee begins hearings on the export of hazardous products. Efforts are underway in both the legislative and executive branches to deal with this problem. The subcommittee has before it H.R. 6587, a bill introduced by our colleague from Maryland, Mr. Barnes, to control the export of hazardous products.[1] An administration task force has been working for some time on a hazardous substances export policy. We will hear testimony from the administration next week.

Members have in their folders an inventory of current statutory authority in the area of hazardous product export controls, prepared by the administration, and a statement submitted by the Public Citizen Health Research Group. Without objection, both those documents will appear in the record.[2]

I would first like to welcome our colleague, fellow member of the subcommittee, and author of H.R. 6587, the gentleman from Maryland, Mr. Barnes.

STATEMENT OF HON. MICHAEL D. BARNES, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MARYLAND

Mr. BARNES. Thank you very much, Mr. Chairman. I very much appreciate the opportunity to lead off these hearings on H.R. 6587. As you know, it is a bill that I introduced last February to restrict the export of hazardous products from the United States.

I want to thank the chairman for his concern and leadership with respect to these very important issues and for scheduling this series of hearings.

[1] The text of H.R. 6587 appears in app. 1, p. 215.
[2] The inventory of current statutory authority appears in the Federal Register, Tuesday, Aug. 12, 1980, vol. 45, No. 157, p. 53756. The statement of the Public Citizen Health Research Group appears in app. 2 p. 220.

PURPOSE OF H.R. 6587

The purpose of this bill is very simple: It is to provide the citizens of foreign countries—particularly the less developed countries—the same opportunity to have protection from hazardous U.S. products that we provide our own citizens. Surprisingly, this country has no coherent policy against U.S. corporations using the less developed countries as dumping grounds for products we refuse to permit them to sell to our own people because of the hazards they pose to health. This practice of corporate "dumping" is injurious to the reputation of our country, to our foreign policy, and to the credibility of American products in the world market. It is disastrous for the people in the Third World—as congressional hearings, Government reports, an award-winning issue of Mother Jones magazine, and a draft report of an administration task force have all documented. Some quick examples include:

Exports of TRIS-treated children's sleepwear continued for more than a year after the Consumer Product Safety Commission banned their sale in the United States, following the discovery that the flame-retardant TRIS was carcinogenic.

Hundreds of thousands of baby pacifiers were exported in the 6 months between the issuance of final CPSC regulations prohibiting their sale in the United States and the effective date of those regulations.

Twenty-nine percent of the pesticides exported in 1976—161 million pounds—were not registered for use in the United States, and 20 percent of those—31 million pounds—were pesticides that had been banned by EPA because they posed unreasonable hazards to human life, wildlife, or the environment. The World Health Organization (WHO) has estimated that pesticides cause 500,000 human poisonings and 5,000 deaths each year. In one case, 14 million pounds of the pesticide Leptophos, which was never registered for domestic use by the EPA, were exported to 50 countries between 1971 and 1976. Egyptian farmers who used this pesticide were found to suffer from hallucinations and impairment of vision and speech.

Foreign-produced food, contaminated by banned pesticides exported by the United States, continues to seep back into the United States and other developed countries. The Food and Drug Administration (FDA) estimates that at least 10 percent of the food imported by the United States in 1979 contained residues of DDT and other banned pesticides. For instance, the highly toxic DDT pesticide is exported to food-producing nations such as Guatemala where the hazardous substance is sprayed on banana crops. The United States, in turn, imports Guatemalan bananas, and thus we experience indirect or boomerang effects of this proven disastrous chemical.

Medical products whose use is severely restricted in the United States because of potentially serious side effects are exported to and freely available in other countries without prescriptions, and with inadequate or flatly misleading labeling.

Contraceptives such as the Dalkon Shield intrauterine device and the injectable contraceptive Depo-Provera, which are banned in the United States, are sold abroad by their American manufacturers without any review whatsoever by the U.S. Government.

PROVISIONS OF H.R. 6587

There is currently no single statute in existence that attempts to deal with this dumping problem. Dumping is controlled only to the extent that the laws governing the domestic sale of potentially hazardous products happen to contain export provisions. Some of them do; some of them do not. Those that do often require nothing more than a simple notice to the importing country that the product has been restricted, without requiring full explanation of the reasons why, or approval of the importing country prior to export. Few of them concontain any control provisions, whereby our Government asserts its authority to review proposed exports to determine whether they are in the public interest. Under current law, companies can pretty much export whatever they can convince unsuspecting people abroad to buy.

My bill would provide such a control mechanism, and it would bring order out of this chaos in a very simple, a very straightforward way. It references several major domestic regulatory statutes governing hazardous substances, consumer products, flammable fabrics, pesticides, chemicals, foods, drugs, cosmetics, and poisons. And it says: Products regulated domestically under the laws may be exported only if their unrestricted sale is permitted in the United States, unless the Secretary of Commerce and the head of the appropriate regulatory agency concur in the following:

First, that the government of the importing country has requested the product.

Second, that the company has fully informed that government and the consignee of the U.S. restrictions on the sale of the product and of the hazards posed by the product; and

Third, that the potential benefits of the intended use of the product outweigh the possible hazards.

In the case of a product whose sale in the United States is permitted only under restrictions, those two officials would have to concur that its sale in the importing country would be subject to similar restrictions.

The product would not be exportable if it did not adhere to U.S. labeling requirements, or if the Secretary determined that these labeling requirements would be ineffective in protecting the public health of the importing country because of language barriers, illiteracy, or marketing practices in that country.

Finally, the bill would make it illegal to export an ingredient of a banned product for the purpose of manufacturing the banned product in another country.

POSSIBLE OBJECTIONS TO H.R. 6587

Let me try to anticipate a few possible objections to this bill. First, is the coverage of the bill too broad? I think not. It attempts to address only the most pernicious consequences of dumping practices: Biological damage to human life and the environment. Consciously excluded from its scope are numerous safety measures such as, for example, one requiring refrigerators to have doors that can be opened from the inside. It is not my purpose to apply U.S. standards to all exports, only to those which pose the most serious health problems.

Second, are there not cases where products banned in this country should be made available to the developing countries because of their special needs? The answer to that question is certainly yes. The bill does not prohibit that. It merely requires that a review and a conscious determination be made. This is not the current practice.

Third, does not this bill place the United States in the position of telling the developing countries what they can and cannot buy? It is certainly possible that, under the bill, our Government could decide that a product is simply too dangerous to export even if a developing country requests it; just as we attempt to control the export of nuclear fuels regardless of whether an individual country wants them. After all, we do have some responsibility for our own products and we should be prepared to exercise that responsibility in extreme cases. But generally, this bill would reinforce the capabilities of the developing countries to protect their people from unscrupulous marketing practices. Everyone on this subcommittee has spent enough time in the developing countries to know that most of them simply do not have the infrastructure necessary to assume the entire regulatory burden themselves. It is up to us to satisfy ourselves that the importing country has given its informed consent to the import before we permit a hazardous product to be exported from this country.

Finally, is this not another antitrade measure? Will it not further weaken our trade position? To this argument I respond with my most resounding "no", and I represent a district that is heavily engaged in the export of American-made products, and I am very concerned about increasing American exports. What is at stake here is the integrity of the label, "Made in USA." If we really want to improve our trade position, the last thing we should do is tolerate the export of health hazards that sully the reputation of our products. To those who argue that other countries are going to export hazardous products that we refuse to sell, I say, fine. Let them incur the wrath and distrust of the Third World as it increasingly recognizes that it is being used as the industrial world's garbage can.

Mr. Chairman, I will be listening with great interest and with an open mind to the comments that will be made on this bill during these hearings, and I am prepared to join with my colleagues on the subcommittee in making any necessary modifications in the bill. But I think the essence of the bill is something we will want to preserve: that products banned in this country because they are dangerous to Americans should not be exported because they are likewise dangerous to other people, and that the burden of proof is on those who seek exceptions to this general rule. Only by following that principle do we have any chance of stemming the flow of hazardous products abroad.

I want to thank you again, Mr. Chairman for working these hearings into the subcommittee's busy schedule and for giving me the opportunity to testify. I will be pleased to respond to any questions and, as always, I look forward to participating with you, Mr. Chairman, in the consideration of this important measure.

Mr. BINGHAM. Thank you very much, Mike. I commend you for bringing this important subject before the subcommittee.

EXPORTS OF DEPO-PROVERA

I would like to explore with you some of the questions that arise in my mind, and as it happens that I have become interested in the contraceptive Depo-Provera and we have had two hearings on population planning assistance, we can focus on that as an example.

You have mentioned Depo-Provera as a product which is banned in the United States. I am not sure "banned" is quite the proper word; it is not approved for sale by the FDA.

But, as you know, Depo-Provera's use has been approved by a committee of the WHO. The question arises whether there may be conditions in the Third World so different from the conditions that prevail in our country that different standards may apply.

According to its supporters, Depo-Provera is the best available contraceptive for use in the Third World because it is injected every few months, and it has been used now for 10 years or more in Thailand and other countries with great success. Since in many of those countries the risks involved in childbirth and having unwanted children are so much greater than in the United States, is it not possible that in a situation of this kind a different set of standards, or a different judgment, would be applied on balancing the risks?

Mr. BARNES. Absolutely. I think this is a good example of an instance in which the process that the legislation would set in motion could very well determine that the conditions are in fact different and that this particular domestically-produced product should be permitted to be exported.

The problem with the present situation is that there is no discussion, even, of that question. The merits are not weighed. The issue is not addressed. It seems to me that with a product such as this that has not been approved for use in our own country, before American manufacturers are permitted to export it, those judgments should be considered. The importing country—Thailand for instance, the example you cite—could very well request the product, could participate in an informed way in the decision with respect to whether or not the product should be exported from the United States. The decision might very well be in the affirmative. The bill does not exclude the possibility that that decision would be affirmative. It simply requires that that decision be made in a responsible way by officials in the United States who are taking into account not only the hazards, but also the needs of the importing country.

PARTICIPATION OF IMPORTING COUNTRY GOVERNMENT

Mr. BINGHAM. How do you envision that condition working in practice? In some cases exports are made to foreign governments, but I suppose in the majority of cases they are made to foreign consignees.

If the XYZ Trading Company in Zambia wants to import, let us say, Depo-Provera, will the company have to ask the Government of Zambia to make a formal request to the U.S. Government to import the product?

Mr. BARNES. That is the way I would envision it would work, and I think that is an appropriate mechanism. The government of the

country, particularly in democratic societies where governments are representative of their people, ought to be in a position to participate in the decision as to whether or not these products that have been found, for one reason or another, to be hazardous by agencies of the United States should be imported.

I can certainly envision a mechanism whereby the XYZ Trading Company in Zambia, wanting to import the product, would seek the approval and participation of its government by seeking a request from that government to the United States to permit the export of that product. That would require, then, that the government of the importing country be involved in the process, and I think that is wholly appropriate. They ought to be involved so that we know they are aware of what we are aware of. That is essentially the purpose of this legislation.

THIRD COUNTRY TRANSFERS

Mr. BINGHAM. What would you do about retransfers? What if XYZ Trading Company gets permission from the government of Zambia and then decides that the company would be better off selling it to Tanzania, or some other country?

Mr. BARNES. I have not thought that one through, Mr. Chairman; that is a very possible circumstance that you have raised. We would want to consider that.

Mr. BINGHAM. As you know, we worry a lot about transfers in the field of arms sales.

Mr. BARNES. Yes.

Mr. BINGHAM. It is something that has to be addressed, I think.

Mr. BARNES. I think it is. I think we will need to look at that and consider whether or not there is language that can address that question effectively.

Mr. BINGHAM. In your research on this, have you any idea of the amount of exports that would be affected?

Mr. BARNES. I do not have those numbers, Mr. Chairman. I hope and expect that these hearings will help us develop some of that record. I think witnessess who will be testifying later in the hearings are likely to be able to give us some of the specific numbers.

Mr. BINGHAM. Thank you very much.

Mr. BARNES. Thank you, Mr. Chairman.

Mr. BINGHAM. If you would take the chair, I would appreciate it, because as you know, we have the foreign assistance bill on the floor.

Our next witness is the gentleman from California, and I apologize to him for having to leave, but I leave him in good hands. Welcome.

Mr. BARNES [presiding]. We welcome to our subcommittee our distinguished colleague from California, Mr. Miller.

STATEMENT OF HON. GEORGE MILLER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. MILLER. Thank you, Mr. Chairman. Apparently copies of my testimony have not yet been sent to the subcommittee and I apologize. They will be forthcoming sometime today.

RELOCATION OF HAZARDOUS INDUSTRIES

The relocation of hazardous industries in lesser developed countries has become a topic of increasing concern since 1970. Two major factors which have influenced this trend of industrial relocations are the emergence of a series of laws in the industrialized nations to regulate pollution and workplace hazards, and shifts in the locations of certain raw materials.

Much of the early discussion of industrial flight has focused on the dumping of unsafe products on foreign consumers, and on ecological pollution by industry. I would suggest, however, that there is another facet of this growing dilemma, and that is the problem of worker safety.

Tax policies by the developed countries, including the United States, have contributed and encouraged the movement of high polluting, hazardous industries abroad. Certain industries have chosen to relocate abroad in order to avoid the cost associated with domestic pollution and safety controls. U.S. chemical firms, according to the industry estimates in 1974, spent 44 percent less on pollution controls abroad than they did in the United States.

Industry has confirmed this policy decision. H. B. Moreno, the vice president of Johns-Manville Corportation, the world's largest asbestos manufacturer, was quoted as opposing new worker safety exposure standards for cancer-causing asbestos because they might cause "a significant number of jobs to be shifted to foreign workers * * * solely because of unrealistic and unnecessary regulation." Note his presumption that foreign workers will be exposed to these health and safety hazards. Moreno's warning, incidentally, parallels similar concerns in a 1975 report of the National Institute of Occupational Safety and Health, and a report of the Raybestos-Manhatten Company. Raybestos did more than voice concerns: In 1974, the company bought 47 percent of a Venezuelan asbestos plant.

Much of the political pressure for policies which encourage overseas investment come from multinational corporations which have invested over $70 billion in developing countries. Corporate leaders have justified this heavy investment on the grounds that it generates great industrial and economic growth and because the comparatively low levels of pollution are so low that little harm will come from the early stage of industrial activity.

We should be suspicious of these arguments. The Wall Street Journal and the World Bank recently concluded that such investment has resulted in only minimal improvements in economic conditions and that the new wealth benefited only a select strata of the native population. Most of the people of the developing nations have not enjoyed any significant improvement in the quality of life of the average citizen.

Certain hazardous materials, such as DDT, which have been banned or severely regulated in the United States, have benefits which may outweigh environmental concerns in some developing nations. A cost-benefit study might show that DDT saved more lives by controlling malaria-spreading mosquitos than the number of lives

which would be imperiled through DDT exposures. These situations must be carefully examined on a case-by-case basis. The warning and labeling requirements of H.R. 6587 would put developing nations on notice of these dangers and allow them to make intelligent decisions about whether ot not to permit importation of the product.

But we must make a major distinction between environmentally unsafe products and industries which jeopardize the health and safety of workers.

It is impossible to justify the knowing exposure of workers, their families and neighbors to known carcinogens and other hazardous substances merely to make bigger profits.

It is impossible to justify a conscious decision to expose Brazilian, or Mexican, or African, or Asian workers to life-threatening hazards to which it is a serious crime to expose American workers.

Some countries may be willing to make this trade-off for economic development—but they should not have to. U.S. policies should not encourage and support this unconscionable strategy. We should recognize our moral obligation to assure that workers are adequately protected from life-threatening dangers in the workplace, wherever they may work, and certainly in those situations where adequate technology exists to assure safe working conditions.

It was not that long ago in our own history that manufacturers fled from States with strong labor and safety protections to States and regions where the safety requirements, workman's compensation costs, and insurance rates were low. Only a few years ago, a move was afoot in Congress to establish Puerto Rico as an industrial "free fire zone" where no U.S. environmental, labor protection, or tax laws would apply.

Having run out of areas in this country, manufacturers and distributors now look abroad to markets hungry for capital and material goods.

ASBESTOS INDUSTRY RELOCATION

Let us look at one example. The asbestos industry complained that it was unable to meet the safety requirements imposed in the mid-1970's by the Occupational Safety and Health Administration. A 1976 industry study predicted that American industry would lose ground to foreign competition from countries with weaker or nonexistent worker protection requirements.

This prediction has turned out to be somewhat accurate. Before 1970, nearly 100 percent of our imported asbestos textiles originated in Canada, Europe, or Japan, all of which regulate asbestos exposure relatively carefully, like the United States.

Testimony before numerous congressional committees, including reports of my own 2-year investigation, have illustrated that the domestic asbestos industry knew of the severe health dangers to which its workers were being exposed as long ago as the 1930's. Yet, for several decades, that industry perpetrated a cover-up of those dangers, with the result that millions of workers in the asbestos factories, shipyards, insulating companies, and millions of citizens in homes, public buildings, and schools have been exposed to this substance. Juries on opposite sides of this country in the last few months have confirmed this cover-up and have made major awards to injured worker who had not been adequately warned of the health threats.

Finally, after knowledge of the dangers from asbestos exposure became public—and over the vehement objections of the asbestos industry—minimal safety standards were established by OSHA in 1971. After the imposition of the OSHA standards, the importation of asbestos products increased dramatically, and the countries of origin dramatically shifted from those heavily regulating asbestos exposure to those with minimal controls or none at all.

In 1967, we imported no asbestos textiles from Mexico. A decade later, after 6 years of OSHA control, we imported 3 million pounds a year from Mexico which produces no raw asbestos itself. The increase in imports is solely because of the siting of new factories in Mexico because of lax worker safety protections.

The Pennsylvania-based AMATEX Corp., for example, opened a plant in Mexico which exported 2 million pounds of asbestos to the United States in 1975. An investigator who visited the AMATEX plant reported,

> Asbestos waste clings to the fence that encloses the brick plant and is strewn across the dirt road behind the plant where children walk to school. Machinery is caked with asbestos waste and the floor is covered with debris—and workers do not wear respirators.

The leading exporters of asbestos textiles are now Mexico, Taiwan, Brazil, and South Korea. Taiwan alone has exported 1 million pounds of asbestos textiles to the United States in 1976 and has no specific health requirements for asbestos workers; neither does South Korea.

IMPACT OF U.S. TRADE POLICY

One of the most disturbing points is that U.S. laws may be encouraging and supporting this shift of countries of origin. The leading asbestos exporters to the United States are 4 of the 5 greatest beneficiaries of the generalized system of preferences program (GSP) under which lesser developed nations are permitted to export certain items to the United States, in order to stimulate industrial development including asbestos textiles.

The GSP program may be encouraging the siting of hazardous industries in developing nations, as may other Federal tax and tariff policies.

GSP and other overseas development programs carry a heavy price tag. The exclusion of foreign earned income cost $360-million in 1978; DISC deferrals, $1.1 billion; deferrals of foreign corporate income, $615 million; and payments under the trade adjustment assistance act (to workers left jobless by plant closings due to foreign competition) cost $578 million in the period 1975–78.

The Congress should investigate this indirect, and perhaps unintentional, impact of trade policy.

We must emphasize the need for the strict enforcement of Executive Order 12114, signed in January 1979, which requires U.S. agencies undertaking overseas activity to notify affected nations of possible environmental or hazardous impacts. This principle should further be expanded to include private companies. Tax and tariff benefits ought to be denied to those who fail to exercise appropriate diligence in notifying foreign governments of such hazards, and to those who operate overseas plants in an unsafe manner.

A key aspect to this policy should be the support of the U.S. Government for international labor standards to provide basic health and safety protections, enforced by each individual nation. The 1974 trade act mandated the President to press for such standards in the recently completed Tokyo round of trade talks. This mandate was not adequately carried out.

I believe that Congressman Barnes' legislation provides the Congress with the opportunity to take a first step in the reduction in the proliferation of hazardous industries throughout the world. This legislation really requires American companies to put foreign governments on notice when hazardous products are being exported to that nation. I would urge that you insert such a provision in this bill during markup. Foreign governments, and especially those agencies responsible for health and safety, environmental controls, and labor protection ought to know as much about the potentially harmful effects of jobs in such factories as American workers.

I would personally prefer to see the elimination of all U.S. tax preferences and overseas investment incentives for companies which fail to provide the same level of protection to foreign workers as they do here in the United States. Failure to provide that protection, in effect, says that we believe that a foreign worker's life is less valuable and less worth protecting than an American life, and that is a chilling and indefensible view. The appropriate method for enforcement of such workplace standards should be international labor organizations, together with governments, as envisioned in the 1974 trade act.

The Congress must address this issue. It is clear that this is a matter for Government, and one which will not be adequately added by private industry. Just a year ago, international asbestos manufacturers met to discuss ways to undercut efforts to place warning labels on asbestos products bound for the European Continent "in fear of a negative influence on sales."

FOREIGN WORKER SAFETY STANDARDS

Concern for the lives, the safety, and the health of workers, whether they be Americans or not, is infinitely more important than "sales".

Preventing the needless poisoning or incapacitation of workers and their families is a moral and ethical imperative.

Militaristic and colonial imperialism in the 19th and early 20th century was a policy of exploiting underdeveloped nations for the raw goods needed by industrialized nations.

The corporate practices we have been discussing today, and which are often sanctioned and even encouraged by government policies, do not involve the looting of natural minerals, but the exploitation of the ecology and the human wealth of developing nations. Just as military imperialism was justified for its "civilizing" effects, so the dumping of dangerous industries and products has been rationalized because it stimulates economic development and modernization. Both concepts are immoral.

Such practices are immoral because they inherently assume that the resources and the people of the Third World should be sacrificed for the comfort and profit of major industrial powers.

They are immoral because they deny to foreign workers and consumers technological and medical protection, because it is cheaper to jeopardize their lives.

They are immoral because they value profit, or a product, or a process, over human life.

I recognize that there are some who argue that economics requires us to lessen our safety standards at home in order to more efficiently compete in the world community, I would respond: Let us use our knowledge and our ability to expand that level of safety to the rest of the world so that we will compete on the basis of the quality of the product, and not on the sacrifice to the worker who makes it.

Dumping hazards into the Third World is not only immoral but politically short-sighted, developing nations are awakening to the dangers, and are insisting upon better notification and safety controls. Several international organizations, including the Organization of American States, the United Nations environmental program, the U.N. Conference on the Human Environment, and the 1971 meeting of 31 African governments have called for the restriction of exports of banned materials and the movement of dangerous industries to countries with lesser safety standards.

I would suggest strongly that while dumping practices may serve the shortrun profit interests of multinational corporations, their long-term impact will be to foment the hostility of the Third World against these industrial interests and the governments which have aided and encouraged dumping practices, including our own.

H.R. 6587 offers the best opportunity we have at present to begin to institute these reforms in world commerce. We are not requiring testing; we are requiring that innocent people be informed of the results of testing which have documented serious dangers to health and safety. With the inclusion of my recommended language assuring warnings of hazardous industries and commercial practices, I support the enactment of H.R. 6587, and I congratulate the subcommittee for giving this problem and this legislation urgent consideration.

Thank you very much for the opportunity to testify.

Mr. BARNES. Thank you very much. You state very eloquently that the issue that this legislation addresses is a corollary to a range of issues that are equally important. Your comments could not be more timely. As you said, the foreign assistance legislation is on the floor even as we sit here.

The bells have indicated that there is a quorum call underway which will be followed immediately by a 5-minute vote on the Derwinski amendment relating to assistance for Syria. So, knowing that you and I have to go to the floor, we will recess the subcommittee for about 15 minutes and then resume.

I thank you very much, George.

Mr. MILLER. Thank you.

[Whereupon, a brief recess was taken.]

Mr. BARNES. We will resume the subcommittee hearing at this time. Let me first render the apologies of my colleagues on the subcommittee. Our committee, as was indicated earlier, has a bill under consideration right now on the floor, and all of my colleagues—on both sides of the aisle—on the subcommittee are engaged in debate.

I would be, too, if I were not here. So, all of them should be forgiven for their absence. I know that many of them are interested in these issues and their absence is not an indication of lack of interest.

Next, we have a panel of witnesses consisting of three consumer and environmental activists whose views we very much look forward to hearing.

I want to also say that the record, of course, of this hearing will be available to our colleagues.

We are particularly pleased that this hearing happens to coincide with a visit to our country by Mr. Anwar Fazal, a Malaysian national who is president of the International Organization of Consumers Unions. Mr. Fazal, we are delighted that we can take advantage of your presence in the United States to hear your views on this subject.

I am also pleased to welcome at this time Ms. Faith Campbell, who will testify on behalf of the Natural Resources Defense Council, and Ms. Jane Ives, who has done a good deal of work in this area and is testifying in her personal capacity.

If it is acceptable to the witnesses I would suggest that we hear all three of your statements and then perhaps discuss some of the issues. Any prepared statements will be entered in the record so you need not feel that you have to read through all of your statements. You are free to summarize if you wish. Mr. Fazal, welcome to the subcommittee.

STATEMENT OF ANWAR FAZAL, PRESIDENT, INTERNATIONAL ORGANIZATION OF CONSUMERS UNIONS

Mr. FAZAL. Thank you very much, Mr. Chairman. I think you should consider yourself extremely fortunate. I was at one meeting where there was only one person in the audience.

Mr. BARNES. And he was the next speaker.

Mr. FAZAL. He was the next speaker. [Laughter.]

Mr. Chairman, my name is Anwar Fazal. I am president of the International Organization of Consumers Unions—IOCU—and concurrently head the Office of Asia and Pacific of this organization. I am a Malaysian and live and work in the city of Penang in Malaysia. I have served as consultant on consumer protection matters with the Governments of Mauritius, Hong Kong and the Joint Food and Agricultural Organization and the World Health Organization Codex Alimentarius Commission.

I thank you and your subcommittee for this opportunity to share with you some perspectives on this urgent, complex and important issue of the export of hazardous products to other countries.

INTERNATIONAL HAZARDOUS PRODUCTS WARNING NETWORK

The first perspective I wish to share with you is that of IOCU. IOCU is a nonprofit, noncommercial foundation based in The Hague, Netherlands, and is the world center for consumer affairs. A democratically controlled organization, IOCU is supported by some 110 consumer organizations in nearly 50 countries, representing every continent and country at every stage of development. IOCU repre-

sents consumer interests at the United Nations and at various international fora.

As "the" international consumer organization, we have a very special and direct interest in this issue. I will, however, not repeat the extent of the problem; I think it is accepted that we have a serious problem and you have heard all the gory stories. Through your hearings, I expect, you will hear many more.

The practice of exporting hazardous products has been and is rampant and no particular country is exclusive in this unconscionable practice. Nor are many countries spared from it. Consumer groups from as diverse countries as Austria and Bangladash have voiced their concerns.

At every single major international consumer meeting organized by IOCU, voices from many lands have spoken on this issue. At the last World Consumer Congress held in London in 1978, the recommendation was made that IOCU seek to establish an "alert" system, a rapid exchange of information, and to increase pressure on national and international authorities concerned with this area.

In Jakarta, Indonesia, last year, at the Asia-Pacific Seminar on Consumer Testing and Research, at Hong Kong this year at the international seminar on "The Law and the Consumer," this subject was again raised. IOCU is committed to strengthening what it now calls the "international hazardous products warning network," sometimes referred to as the "consumer Interpol." This network, operated by IOCU, exchanges information rapidly between organizations and assists in affirmative action in the different countries where the problems occur.

It is a sad commentary on the state of affairs of the world that for many years there has been little action by responsible national and international authorities beyond pious statements and resolutions. Only now, in recent years—in recent months—has there been an awakening in Europe both in the EEC and in the OECD. Even the U.N. system has elevated it to the dignity of a problem and I understand an interagency group met in March this year.

Perhaps the greatest debate—and we hope the greatest action—will come from the United States. We salute the public-interest groups and the media for bringing to the fore the extent of the problem. This is, I think, part of the greatness of the United States that these kinds of issues can come to the fore and can be publicly articulated

We are most encouraged by the various proposals articulated by the various parts of the U.S. governmental system. We hope for the early realization of firm and affirmative measures and that the United States will provide the lead for international-level action. IOCU and particularly its members in developing countries will cooperate with likeminded groups in the United States to continue the pressure until a satisfactory procedure is established. On our part, we will strengthen our hazardous product warning network even further.

Let me share a further perspective, that of a Third World person who has spent the last 15 years in teaching, government service, and voluntary service in citizen action groups in the areas of population, environment, and consumer affairs in Third World countries.

What is the path we should take? There are no paths. This path will have to be made by walking.

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PRINCIPLES FOR EFFECTIVE GOVERNMENT ACTION

I believe that the approach for any effective action in this field by any government should be based on three guiding principles:

The first principle is that there should be no distinction between domestic and foreign consumers unless there are exceptional reasons for doing otherwise. As the chairman himself has mentioned, there will be exceptional circumstances. Some examples have been quoted, others can be quoted. For example, the promotion and use of infant formula in many Third World countries certainly creates a hazardous situation. IOCU has been associated with the excellent work done in the United States by INFACT and ICCR with whom we are working through the international baby food action network.

We are particularly also interested in the progress of the Dellums-Miller bills in this particular field which is again, as I mentioned, a similar problem where a product that may not be hazardous in the United States might in fact become hazardous in a Third World country.

The second important guiding principle is that the process for determining these exceptional circumstances should involve a procedure whereby the onus for proving the exceptional case should be with the manufacturer, the exporter, or the foreign government concerned. And, third—and I think this is extremely important—that there is adequate disclosure of information to public citizens groups both in the home and foreign country.

I think you put it aptly, Mr. Chairman, when you said there must be an informed, intelligent position taken. I think this is only possible if not just governments and manufacturers participate, but that citizens groups in both the exporting and importing country also participate.

Those of us who are in public-interest groups in the Third World will welcome affirmative action based on these principles. We believe it would go a long way to halt all this violence against the consumer.

Your bill, Mr. Chairman, is in the spirit of these principles. I believe that such an approach can deal with the issue of the "unholy alliances" that so readily develop between greedy businessmen and corrupt bureaucracies in many developing countries—a situation often compounded by a docile press, a general lack of information and technical skills, and discouragement of participatory forms of government.

There is again a tendency—and I think this is again an important aspect—to rely too easily and too quickly on mass medication and mass chemical use in place of more participatory, people-centered approaches to social and economic development. And these easy paths, these chemical paths, generate often false development and a society where cash register ethics prevail over basic social considerations.

Two thousand and five hundred years ago, Mr. Chairman, the Hittites of Anatolia—now in Turkey—had probably one of the earliest consumer codes. The code said simply: "Thou shall not bewitch thy neighbor's lard." That is, you should not practice fraudulent misrepresentation. The second principle is: "Thou shall not poison thy neighbor's lard." That is, you should not be able to kill your customer.

These two provisions are as valid today, and I am confident that the U.S. system has the ingenuity and courage to make a reality of these two principles for all consumers of its products, whether in the United States or abroad.

Then we can see the emergence of a consumer policy that no longer is just based on value for money but just as much, if not more, on value for people—people everywhere, their survival, their safety, and their health.

I thank you, Mr. Chairman, for this opportunity for sharing these perspectives with you.

Mr. BARNES. We thank you, Mr. Fazal, very much.

Ms. Campbell.

STATEMENT OF FAITH T. CAMPBELL, RESEARCH ASSOCIATE, INTERNATIONAL PROJECT, NATURAL RESOURCES DEFENSE COUNCIL, INC.

Ms. CAMPBELL. My name is Faith Campbell. I am representing the Natural Resources Defense Council, a public interest environmental protection organization in the United States with 45,000 members here and in 20 foreign countries.

We thank you for this opportunity to present our views. NRDC has been actively concerned about the shipment of products too dangerous to use in the United States since 1975. The prepared statement outlines some of our earlier actions.

We are particularly pleased, however, that you have brought this matter to the attention of the Foreign Affairs Committee because this places it in a new context, that of U.S. foreign policy and our relations with foreign countries, especially those of the developing world.

International concern about export of hazardous substances has increased greatly in the last few years. At both the 1977 and 1978 UNEP governing conferences of the United Nations Environment Program this problem was raised. At the former, Dr. J. C. Kiano, the Kenyan Minister for Water Development, warned that developing nations will no longer tolerate being used as dumping grounds for products that have not been adequately tested, and that their peoples should not be used as guinea pigs for determining the safety of chemicals.

Just this past winter, the U.N. General Assembly passed Resolution 34/173, which is attached to our statement, which calls upon exporting nations to discourage, in consultation with importing countries, the export of banned hazardous chemical products.

You yourself, Mr. Barnes, have already given quite a comprehensive list of a number of recurring incidents of dumping that have taken place over the last decade, and have pointed out—as has Mr. Fazal—the fact that many developing countries either have no legislation to help them deal with these chemicals coming into the country or, when they do have legislation, lack the technical and administrative capacity—and in some cases the honesty—to deal with the problem.

TOWARD A COMPREHENSIVE U.S. POLICY

As I mentioned, we have dealt with various aspects of the hazardous export problems since 1975, and our experience in dealing with individual pieces of legislation has made us strong supporters of the idea of a comprehensive approach governing all hazardous exports. Thus, we strongly support the concept in your bill and the administration's interagency hazardous substances export policy working group-proposed executive order. We see these two proposals as quite complementary.

Both would supplement existing laws with the application of appropriate controls under the Export Administration Act. Both would help to assure that importing countries were made fully aware of the hazards posed by these products. Both would permit the U.S. Government to prohibit export of those products where appropriate. Finally, both would provide a single focal point for improved monitoring and control of hazardous exports.

The question came up when you were testifying about the total volume of substances involved here. It is indeed necessary for us to get an estimate about the volume, but I have sincere doubts that anyone could provide it, even for pesticides, much less for the full range of products with which we are concerned at this time because no one has instituted such a system yet.

It is our opinion that the executive branch has ample authority under existing provisions of the Export Administration Act to impose controls over hazardous exports in order "to further significantly the foreign policy of the United States." Nevertheless, we do favor passage of an amendment to the Export Administration Act which would address specifically the hazardous export problem and streamline the process of placing a banned or hazardous product on the commodity control list.

COMMENTS ON THE PROVISIONS OF H.R. 6587

I will turn now to specific provisions of your bill, sir. We congratulate you on your initiative in introducing this bill. We are quite pleased with your interest in it. We feel that it could be strengthened in certain areas.

First, there should be more recognition of the need for a cooperative arrangement between the United States and the importing governments in controlling hazardous exports. As a general matter, the United States should unilaterally prohibit exports only after consultation with the importing country's officials; and then a judgment that the proposed export would pose a severe hazard to the health or the environment of the importing country. Furthermore, the primary objective of United States policy should be to assist and support foreign government officials in their own evaluation of the hazards. That does not say we should not reach our own decision.

In line with this suggestion, NRDC suggests some modifications in the criteria set out under paragraph 3. Basically, we feel that the criteria should require that the foreign government acknowledge receipt and consideration of the information provided by the exporter concerning the products's status in the United States and

possible hazards. We are somewhat troubled by criterion (iii) which calls for a benefit/risk assessment. We feel that the proper concern should be whether the proposed export poses severe risks to public health and the environment. In making this judgment, it would be reasonable to consider the countervailing benefit of the product, if any, and the capability of the importing government to assure its safe use.

Second, the bill should consider the impact of exported chemicals on the health and environment of the United States, the global commons, and third countries. As you have mentioned, exported pesticides return to us as residues on imported agricultural products. Chlorofluorocarbons, used anywhere in the world, destroy the ozone layer and thus threaten the American public. Other chemicals are transported by winds or water to either the United States or to innocent bystander countries.

Thus, we support the concept in the fourth draft, at least, of the administration's working group paper that the presence of severe risk to the health and environment of the United States, the global commons, and third nations should be considered as a separate ground for the prohibition of exports.

Third, the bill should consider the need to be more selective as to the goods which would be subjected to export controls. You already addressed that somewhat in your response to Mr. Bingham's question. I think it is quite clear that you do not intend to require a license for the export of all chemicals that are regulated under these 10 acts, but there will have to be some criteria set for determining what level of hazard is in the trigger.

We feel that an initial step in this area could be taken by the subcommittee requesting a list from the various agencies of the products regulated under their various jurisdictions and the level of risk associated with them.

Fourth, we would suggest that in the labeling of the exported product it would be appropriate to consider whether to require that some of the information at least be provided in the language of the recipient country. There is the problem of whether the label will actually appear on the final consumer product since most products are shipped in large bulk quantity.

Fifth, there is considerable need for better cooperation between the various U.S. agencies involved in management of hazardous products which are exported. Specifically, we cite the problem FDA has had in providing tests for residues when it does not know what chemicals are being used abroad; and OSHA's problems with devising worker safety tests for U.S. factories which are producing chemicals for export only and which EPA or another regulatory agency has not evaluated.

Of course, the Department of State has an important role in all this as the main channel of communication with the foreign government.

ADDITIONAL ELEMENTS OF A U.S. HAZARDOUS SUBSTANCE EXPORT POLICY

One of the probable increasing areas of toxic exports is the problem of toxic wastes. EPA is about to issue, or has already issued, very stringent regulations for disposal of waste in this country and this, we

feel, is likely to stimulate interest by U.S. corporations in foreign disposal of their wastes. We already had the incident which you referred to in your statement when you introduced the bill, of the Nedlog Corp. seeking out a foreign disposal site.

We encourage the subcommittee to consider including the Resource Conservation and Recovery Act under the rubric of this bill, and also ask it to urge the State Department and Commerce Department to move quickly in their own efforts to list certain hazardous wastes under the Export Administration Act.

Finally, we would add that there is great need for the United States to provide technical assistance to Third World countries in developing their own technical, scientific, and legal capabilities to monitor, evaluate, and regulate hazardous substances. The Foreign Affairs Committee is certainly in a position to consider what mechanisms best could be used to provide such assistance.

Thank you very much for this opportunity to present our views.

[Ms. Campbell's prepared statement follows:]

PREPARED STATEMENT OF FAITH T. CAMPBELL, RESEARCH ASSOCIATE, INTERNATIONAL PROJECT, NATURAL RESOURCES DEFENSE COUNCIL, INC.[1]

The Natural Resources Defense Council is pleased to submit this statement to the Subcommittee concerning the export of hazardous products from the U.S. NRDC is a public-interest environmental protection organization with 45,000 members in the United States and some 20 foreign countries. Through its International Project, NRDC has been actively concerned about the shipments abroad of products considered too dangerous or too little studied for use or sale at home. In 1975, NRDC joined a lawsuit against the Agency for International Development concerning the Agency's financing of pesticide exports, including some pesticides whose use was banned or severely restricted in the U.S. One result of the lawsuit was a dramatic change in AID policy on pesticide procurement. In 1977, the Agency announced that it would no longer permit the use in its projects of pesticides not registered with the EPA except following a detailed environmental analysis. That same year, NRDC presented testimony urging the adoption of an amendment to the Federal Insecticide, Rodenticide and Fungicide Act providing for tighter controls and better labeling on exports of banned or otherwise unregistered pesticides.

In July 1978, NRDC submitted a detailed statement to a House Government Operations Subcommittee calling for a comprehensive and consistent U.S. policy on exports of

[1] Jacob Scherr, Staff Attorney, and Nicholos A. DiPasquale, Intern, also participated in preparing the statement.

regulated hazardous products. Early this year, NRDC reviewed EPA's implementation of the export notification requirements under the Toxic Substances Control Act. In testimony on April 15, 1980, before the Subcommittee on Consumer Protection and Finance of the House Committee on Government Operation, NRDC made a number of recommendations as to steps EPA must take to improve its present procedures.

NRDC is very pleased that this Subcommittee of the Foreign Affairs Committee has decided to address the problem of hazardous exports. In past Congressional discussions, the problem has been viewed almost exclusively as an "environmental" or "consumer" issue. These hearings hopefully will place the problem in the broader context of U.S. foreign policy and relations with other nations, particularly those in the developing world.

The export of banned products has become a matter of international concern over the last few years. At the 1977 meeting of the UNEP Governing Council, Dr. J. C. Kiano, the Kenyan Minister for Water Development, warned that developing nations will no longer tolerate being used as "dumping grounds for products that had not been adequately tested" and that their peoples should not be used as "guinea pigs" for determining the safety of chemicals. He urged that

"Unless a product has been fully tested and certified, and widely used in the countries of origin, it should not be used for export."*

Kenya is not alone, but one of many developing countries whose citizens are most vulnerable to exports of hazardous drugs, pesticides, and other products. In January 1980, the United Nations General Assembly passed Resolution 34/173 on the exchange of information on banned hazardous chemicals and unsafe pharmaceutical products. The Resolution calls upon exporting nations to discourage, in consultation with importing countries, the exportation of banned hazardous chemical products. A copy of the General Assembly Resolution is attached.

The continued export of hazardous products from the United States poses needless and severe risks to public health and the environment of foreign countries and threatens our nation's image within the international community. The potential for injury is significant as illustrated by the recurring incidents during the last decade of the "dumping" of American hazardous products overseas:

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* The Standard, Nairobi, Kenya, May 11, 1977 at 3.

* In 1971, Iraq placed an order for 95,000 tons of wheat and barley seeds with the American grain trading firm Cargill. The seeds were treated with methyl mercury, a fungicide whose use had been banned by many developed countries following mercury poisoning epidemics in Pakistan, Guatemala, Japan, and the American Southwest. The poisoned seeds were widely distributed throughout Iraqi countryside, where they were used not for planting, but for baking into breads and cake. An estimated 6,000 people died and another 100,000 suffered serious, often irreparable, injury.

* In 1975 alone, the U.S. exported over three million pounds of Leptophos, a pesticide never registered by the Environmental Protection Agency for domestic use. Over half of the pesticide went to Egypt, a country with no procedure for regulating pesticides. Use of Leptophos in Egypt resulted in the death of a number of farmers and 1,000 water buffalos, and illness in rural communities.

* U.S. companies continued to sell 2, 4, 5-T abroad after its EPA registration for most domestic uses was suspended in 1970. The herbicide is similar to Agent Orange, the defoliant used by the U.S. in Vietnam and later found to cause birth defects and (infant) death. In Colombia, a rash of miscarriages and deformed babies during the early 1970's has been tentatively linked to use of 2, 4, 5-T there.

* In total, 15% of U.S. pesticide exports in 1975 were comprised of products never registered by or cancelled or suspended by EPA.

* In April 1977 the Consumer Product Safety Commission banned the sale or distribution of tris-treated baby sleepwear because the fire retardant was found to be carcinogenic. Several million dollars' worth of the sleepwear was exported to foreign countries, primarily third world nations, before the CPSC belatedly prohibited this practice a year later.

* In December 1979, it was revealed that a Colorado firm, the Nedlog Technology Group, had offered the President of Sierra Leone up to $25 million for the rights to dispose of U.S. hazardous wastes there. Press reports of the offer touched off student protests in Sierra Leone and a strong, adverse reaction from other West African countries, including Nigeria and Ghana. In February, it was reported that President Stevens had rejected the proposal.*

* The Sierra Leone incident might be just the tip of an iceberg. EPA is now implementing tough new regulations on hazardous waste disposal and local public opposition to siting disposal facilities is growing. The result may be a frantic worldwide search for countries willing to serve as America's waste dumps. Apparently, Chile, Haiti, Liberia, Nigeria and Senegal have already been approached.**

The hazardous export problem is a symptom of a much deeper dilemma facing the developing world. As is true of many advanced technologies, the use of chemicals has spread throughout the world much faster than the capability to assure their safe use. Some developing countries have enacted virtually no legislation to govern the importation, domestic use and disposal of potentially toxic chemicals, and few maintain any facilities for monitoring the effects of the products on health or the environment. Even where decent laws are on the books, many governments lack the technical and administrative capacity to implement them.

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* Washington Post, February 25, 1980, at A-10.

** See Sunday Star-Ledger (Newark, NJ), February 10, 1980; Science, February 29, 1980, at 962.

The communications between officials of the ministries who manage importation and distribution and officials of health ministries, who are at least likely to appreciate the significance of potential hazards, may be minimal. By permitting the uncontrolled export of hazardous chemical products, the U.S. and other producing nations have demonstrated a lack of sensitivity to the difficulties faced by health and environmental officials in developing countries.

Towards a Comprehensive U.S. Policy

During the last two years, the United States has begun to respond to the problem of hazardous exports. Unfortunately, progress has been sporadic and piecemeal. There remains a patchwork of inconsistent export provisions in U.S. regulatory statutes and varying levels of concern about exports in the responsible federal agencies. While the State Department has become more aware of the foreign policy implications of such exports, the U.S. Government is at present powerless to stop them.

We strongly support the basic approach taken by Congressman Barnes in H.R. 6587 and by the Administration's Interagency Hazardous Substances Export Policy (HSEP) Working Group in a proposed Executive Order. Both would

supplement existing laws with the application of appropriate controls under the Export Administration Act. Both would help to assure that importing countries were made fully aware of the hazards posed by the importation of dangerous products from the U.S. Both would permit the U.S. Government to prohibit, where appropriate, any exportation of such goods. Both would provide a single focal point for improved monitoring and control of hazardous exports.*

It is our opinion that the Executive Branch has ample authority under existing provisions of the Export Administration Act to impose controls over hazardous exports in order "to further significantly the foreign policy of the United States." Nonetheless, we do favor passage of an amendment to the Export Administration Act, which would address specifically the hazardous export problem and streamline the process of placing a banned or hazardous product on the commodity control list. The existing provisions under the Act for imposing "foreign policy" controls are rather cumbersome and potentially very time-consuming. The

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* NRDC remains concerned about the adequacy of the implementation of existing export notification procedures. A GAO report issued last summer found that EPA's practice of notifying foreign nations about pesticide registration decisions "neither complies with the intent of the legislation nor adequately recognizes foreign nation's desire to be more fully informed about U.S. regulatory actions. General Accounting Office, "Better Regulation of Pesticide Exports and Pesticide Residues in Imported Foods is Essential," at 62 (CED-79-43, June 22, 1979). Our own review earlier this year of EPA's procedures for notifying foreign governments of exports of PCB's and chlorofluorocarbons found their implementation to be seriously inadequate. See Statement of Faith T. Campbell before the Subcommittee on Consumer Protection (footnote continued on next page)

Federal Government must be able to move quickly to stop the inevitable rush to dump a banned product overseas.

Comments on the Provisions of H.R. 6587

NRDC congratulates Congressman Barnes on his initiative in proposing the first comprehensive legislation on hazardous exports. It is a solid proposal, which we believe could be strengthened and made more effecitve.

First, there should be more recognition of the need for cooperation between United States and importing countries in controlling hazardous exports. The United States should not be seen as trying to impose our own health and environmental standards on our trading partners.

There is validity to the claim that other nations have different problems and assessments of risks and benefits. There is also validity to the concern that many countries are ill-equipped to evaluate technical data and implement effective regulations. As a general matter, the U.S. should unilaterally prohibit exports only after consultation with host country officials and a judgment that the proposed export would, nonetheless, pose a severe hazard to the health or the environment in the importing country. The primary objective of U.S. policy should be

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(footnote continued)

and Finance Concerning Export of Chemicals Regulated under the Toxic Substances Control Act, April 15, 1980.

to assist and support foreign health and environmental officials, not to bypass or overrule them.

In this regard, NRDC suggests some modifications in the criteria set out under Paragraph 3 of the proposed new subsection on "Export of Hazardous Goods." The first and second criteria as now drafted would not assure that the importing government officials are provided an opportunity to evaluate the hazards posed by a particular export. Any request for the export of a product should include an acknowledgment prepared by the foreign government of the receipt and consideration of information provided by the exporter concerning the product's status in the United States and possible hazards.

Criterion (iii), calling for the Secretary of Commerce and the head of the responsible regulatory agency to make a benefit/risk assessment of the proposed export, is the most troublesome. Besides being inappropriate, the preparation of such assessments is very difficult, even in the United States. The proper concern should be whether the proposed export poses severe risks to public health and the environment. In making this judgment, it would be reasonable to consider the countervailing benefit of the product, if any, and the capability of the importing government to assure its safe use. This standard would

stop the export of banned products, such as tris-treated baby garments, defective baby pacifiers, and adulterated drugs. It would permit the U.S. to stop an export where, despite the request of the foreign government, there remains substantial concern about the health and environmental risks. One example here would be restricted pesticides posing severe risks to unskilled applicators and farmworkers.

Second, the amendment should consider the impacts of exported chemicals on the health and environment of the United States, the global commons, and third countries. Pesticides shipped abroad have come back to the United States as residues on imported coffee, tomatoes, and other agricultural products. Some chemicals, such as chlorofluorocarbons which deplete the ozone layer, threaten the upper atmosphere and the U.S. environment, no matter where in the world they are employed. Chemicals are carried by winds or water across national borders, with the potential for injuring an "innocent bystander" country. NRDC agrees with the Administration's HSEP Working Group that the presence of severe risks to the health and environment of the U.S., the global commons, and third nations be considered as a separate ground for a prohibition of exports.

Third, the amendment should consider the need to be more selective as to the goods which would be subjected to export controls. As presently worded, the amendment would cover a very wide range of products regulated under ten different federal statutes. Some of the regulatory requirements are extremely technical and address relatively minor risks. Should bicycles be placed on the Department's list of commodities requiring validated export licenses because in order to sell a bicycle in the U.S., it must be equipped with a rear reflector? This is of course an extreme example, but one which has been raised during the course of the discussion of U.S. policy on hazardous exports. The amendment should establish a procedure and criteria for identifying those products posing substantial risks to human health and the environment and for placing them on the commodity control list. The Subcommittee could take a very useful step in this regard by requesting each of the relevant agencies to prepare and submit lists of those products within their jurisdiction which are now not permitted to be sold in the U.S. or subject to licensing, use or similar restrictions.

Fourth, in regard to labeling of exported products, the proposed amendment would help to assure that at least the initial importer has access to the information and

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warnings given to consumers in the United States. It would be appropriate to consider whether some or all of this information must be provided in the language of the recipient country. The Federal Insecticide, Rodenticide and Fungicide Act has a similar labeling requirement, pursuant to which EPA has already issued regulations. NRDC supports the extension of full U.S. labeling to all exported products. It is not clear whether the labeling requirement would go beyond the exporter to include consideration of the adequacy of the labeling on the actual product sold in the foreign country. If so, we are very concerned about the capability of the Secretary of Commerce to make such determinations.

Fifth, the bill should consider the need for coordination among the various agencies concerned about hazardous exports. The Department of State has a role to play in acting as a channel of communication with foreign governments and in helping to assess the hazards posed by particular exports in other countries. There should be a formal mechanism for the gathering and sharing of information on hazardous exports among the regulatory agencies. Information provided to the Food and Drug Administration about exports of banned pesticides to other countries should help the FDA set priorities for testing for residues of such pesticides on imported agricultural products. Given

the sad experiences with U.S. plants manufacturing Leptophos and Kepone for export only, it might be worthwhile to pinpoint such facilities for scouting by the Occupational Safety and Health Administration or EPA.

Additional Elements of a U.S. Hazardous Substance Export Policy

Earlier in this statement, we mentioned the increased prospects for massive shipment of U.S. hazardous toxic wastes to developing countries. The State Department is sensitive to the charges that the U.S. may be "exporting Love Canals," and apparently some steps have been taken to place hazardous wastes on the commodity control list and thereby to require validated licenses for such exports.* While it would be appropriate to suggest additions to the Barnes bill to address this related problem, we encourage the Subcommittee to urge the State Department and Commerce Department to move ahead as quickly as possible to list hazardous wastes and to guarantee that such exports proceed only after very careful evaluation of proposals and close consultations with importing governments.

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* At its April meeting in Nairobi, the United Nations Environment Programme Governing Council adopted a decision calling upon member states to develop notification procedures and controls on international transfers of hazardous wastes.

Another element of the hazardous export problem which has received insufficient consideration is the need to provide technical assistance to importing countries. Many developing nations lack the technical, scientific and legal capabilities to monitor, evaluate and regulate chemical substances. Even in cases where scientific information is available, there may be a lack of resources and expertise necessary to make reasoned assessments. A review should be undertaken of the assistance for institution building and manpower development available through bilateral or multilateral channels. There should be encouragement for the development of international training and exchange activities within each federal regulatory agency to improve the capability of importing countries to effectively utilize information provided to them under notification or licensing procedures.

Once again, NRDC is pleased to have this opportunity to present our views on the hazardous export issue and H.R. 6587. We would be pleased to provide the Subcommittee with additional details or documentation it may desire.

Thank you.

[The attachment referred to follows:]

ATTACHMENT

Thirty-fourth session
Agenda item 12

RESOLUTION ADOPTED BY THE GENERAL ASSEMBLY

[on the report of the Third Committee (A/34/829)]

34/173. Exchange of information on banned hazardous chemicals and unsafe pharmaceutical products

The General Assembly,

Aware that the exportation of banned hazardous chemicals and unsafe pharmaceutical products could have serious and adverse effects on the health of peoples in the importing countries,

Recognizing the urgent need to take concrete measures to prevent the adverse effects on health on a world-wide basis and, to that end, mindful of the importance of objective information about banned hazardous chemicals and unsafe pharmaceutical products,

1. Urges Member States to exchange information on hazardous chemicals and unsafe pharmaceutical products that have been banned in their territories and to discourage, in consultation with importing countries, the exportation of such products to other countries;

2. Requests the Secretary-General, in co-operation with the United Nations agencies and bodies concerned, especially the World Health Organization, to assist Governments in exchanging information and to submit a report to the General Assembly at its thirty-fifth session, through the Economic and Social Council, about the experience of Member States and the United Nations agencies and bodies concerned.

106th plenary meeting
17 December 1979

Mr. BARNES. Thank you very much.
Ms. Ives.

STATEMENT OF JANE H. IVES, ENVIRONMENTAL ANALYST, ABT ASSOCIATES, INC.

Ms. IVES. Mr. Chairman, my name is Jane Ives and I am an environmental analyst with Abt Associates, a social science and economic research firm in Cambridge, Mass. I am also a doctoral candidate in the faculty of Economics at the University of London, England, studying the regulation and administration of occupational health-care policies in the chemical industry in the United States and Europe.

I appreciate the opportunity to address the Subcommittee on International Economic Policy and Trade.

Mr. Miller and Mr. Barnes have clearly identified the problem at hand; my testimony, therefore, will focus on the issues and initiatives of public and private groups, with regard to the problem of hazardous product export.

EXPORTATION OF HAZARDS CONFERENCE

In November of 1979 I organized and managed with Mr. Barry Castleman in New York City an International Conference on the Exportation of Hazardous Industries, Products and Technologies to Developing Countries. The Conference, which was sponsored by the new directions program of the University of Connecticut Health Center, was held in conjunction with the annual meeting of the American Public Health Association and focused on the public policy issues involved in the exportation of hazardous and polluting industries to nonregulating Third World countries to avoid the high costs of worker protection and environmental control in regulated, industrial nations. This Conference was cosponsored by the U.S. Environmental Protection Agency; the National Institute for Occupational Safety and Health; several national public interest groups, academic institutions, and public health associations; and labor unions.

Among the national and international participants were Mr. Herman Rebhan, General Secretary, International Metal Workers Federation, Geneva, Switzerland; Dr. Gustavo Molina-Martinez, Colombia, South America; Mr. Birger Viklund, Worklife Research Center, Stockholm, Sweden; Dr. Zafrullah Chowdhury, Dacca, Bangladesh; Dr. Anthony Robbins, Director, National Institute for Occupational Safety and Health, Maryland; Mr. Stanley W. Eller, Director, Occupational Safety and Health Department, International Chemical Workers Union, Akron, Ohio; Dr. William McCarville, Monsanto Co., St. Louis, Mo.; and Dr. Geraldine Cox, Vice President, Technical Director, Chemical Manufacturing Association, Washington, D.C.

These and other noted speakers and panelists examined regulatory processes in the United States, Europe and developing countries and discussed specific case studies involving the exportation of hazardous asbestos mining operations to foreign countries for the purpose of evading environmental and health regulations; benzidine dye manufacturing, as well as the use of pesticides in Latin America.

The Conference concluded with the adoption of five resolutions which support the following:

1. The proposal of Dr. Anthony Robbins, Director of the National Institute for Occupational Safety and Health, to study occupational health hazards, internationally, and to report the findings of the International Labor Organization and other national and international organizations.
2. The formation of an ongoing hazard export study group to examine the problems of the exportation of hazardous industries, products, and technologies to developing countries; runaway shops; and the reimportation of hazardous products.
3. The formation of an international conference of scientists, workers, union representatives, and other governmental and nongovernmental organizations, to study and discuss the effects of industrial hazards.
4. The right of people to know the generic identity and hazards of the substances with which they work; and the required labeling of substances in several languages.
5. The right of workers to have complete access to all their medical records, as well as health and safety test data, in their own language.
6. The establishment of a national health service to provide quality health care services to workers.

"ECONOMY OF HAZARD EXPORT"

As a result of my research and organizing efforts, I am aware of the major policy and public health issues as they affect a wide variety of banned products regulated under many different legal authorities. According to various Conference participants, hazardous and polluting industries are exporting their products and factories and moving to nonregulating Third World nations to avoid the high costs of worker protection and environmental control in regulated, industrialized nations, like the United States.

Accordingly, the "economy of hazard export" is emerging as a driving force in new plant investment in hazardous industries and products, because U.S. companies spend half as much in developing nations for air and water pollution control as they do in the United States, when the percentage of capital spending for such control is compared.

In July 1978, the congressional hearings before the Subcommittee on Commerce, Consumer and Monetary Affairs of the House Committee on Government Operations pointed out several instances in which American firms continued to export substances that had been banned or strictly limited for use in the United States. Several examples from Government reports and recent studies suggests the complexity, scope and, persistence of this problem.

In 1976, the Consumer Product Safety Commission banned pacifiers causing infants to choke to death. In 1979, 120,000 pacifiers were exported to Australia that did not meet U.S. regulations.

In April 1977, the Consumer Product Safety Commission banned domestic sales of TRIS-treated sleepwear after the carcinogenic hazard of the substance was discovered. Exports of these garments continued for over a year.

According to the Washington Post, the marketing of infant formulas, banned birth control devices and drugs continues to flourish. Again, pharmaceutical firms forbidden to sell Depo-Provera, an injectable birth control drug, in the United States, now exports it from a Belgian subsidiary. The food and drug administration banned Depo-Provera because it is suspected of causing cancer and birth defects.

Aldrin, dieldrin, heptachlorand chlordane, banned in the United States but made for export, comes back to this country on cacao from Ecuador, coffee from Costa Rica, sugar and tea from India.

Recently, various companies in the United States have approached Senegal, Nigeria, Liberia and Sierra Leone about setting up facilities to process and dispose of toxic wastes.

According to the Washington Post, "the African West Coast has become a prime target for disposing of U.S. waste since Federal and State regulators have begun to crack down on disposal here".

While it was generally agreed at our Hazard Export Conference that there is not, as yet, a mass exodus of polluting and hazardous industries to "nonregulating countries," there was widespread concern that if the trend continues unopposed it will surely worsen in the new decade.

SHARING INFORMATION

Foremost is the need to develop and share vital information worldwide about industrial hazards. Our conference representatives recommended the implementation of a global information service, designed to monitor the global movement of hazardous industries, products, and technologies. It was widely agreed that as individual nations gain control of pollution and workplace hazards through the development of institutions, laboratories, regulations, compensation laws, and appropriate civil and criminal codes, the problems of hazard export will be met.

In conclusion, the U.S. Government, U.S. manufacturers, and consumers should support H.R. 6587 to amend the Export Administration Act of 1979 so as to protect the health and welfare of all consumers and maintain a positive and trusting relationship with other governments.

The exportation of hazardous industries, technologies and products tends to undermine our relations with foreign governments and will, eventually, adversely affect our position in foreign markets.

As a result of our Conference findings, I strongly urge your subcommittee and the administration's ad hoc working group to consider, study, and promote further action on the larger problem of the exportation of hazardous industries and technologies.

Thank you for the opportunity to testify.

Mr. BARNES. Thank you very much.

VOLUME OF TRADE AFFECTED

There have been several comments today, and Ms. Campbell indicated that maybe nobody really knows the answer. But, do any of you have any figures on the dimensions of the problem that we are dealing with? What volume of trade, if you know, would be affected by export controls or notification procedures on hazardous products?

If we would institute export licensing procedures, do you have any guesses what number of license applications we would be talking about each year? Has anybody seen any statistics that are reliable on it?

Ms. CAMPBELL. Mr. Barnes, in 1977, when we were dealing with the pesticide bill, FIFRA, we attempted to find out the volume or even percentage of banned or nonregistered pesticides that were being sent abroad.

In 1975, nonregulated pesticides made up about 15 percent of U.S. pesticide exports, which were in the 500 billion pound range. I have no idea whether the percentage has changed in the last 5 years.

The problem is that none of the statistics are kept on that basis. The Bureau of Customs can easily tell us the total volume of pesticide exports, or in some cases even individual pesticides, such as DDT, which have separate Customs identification numbers. But the identification numbers have never been broken down for each individual chemical or on the basis of whether the chemical is registered for use in the United States or not.

So, I believe that one of the main purposes of the bill, as we indicated, would be to centralize some form of data gathering on this problem. Perhaps the industry could tell you if they went back and reworked their own figures. I am sure they do not keep their own export figures on that basis at this time because no one has asked them the question.

Mr. BARNES. Mr. Fazal, have you seen any figures internationally on the dimension of this problem in conferences you have participated in?

Mr. FAZAL. The answer is, no. It is in fact a jungle, really, this whole area. The extent of the problem is such that if anybody wanted to do such a study the information would be very difficult to get, largely because of the secrecy that very often prevails in a lot of these kinds of operations.

We find that very often even to trace a product that has been found to be hazardous is a great difficulty. We do not very often get the cooperation from governmental authorities, the cooperation from industry that might have been involved in this area. There are attempts to disguise, very often, the particular product through use of fancy names; through constant changing of names; through change of documentation and so on. I think a kind of constant vigilance will always have to be maintained in this field because if not, the "goose" will get away with many things in this field.

RANGE OF PRODUCTS AFFECTED

Mr. BARNES. Obviously, one of the problems with this kind of legislation is defining what you are talking about. I would be interested in your collective judgment on how we can best define the products that we want to be covered. The bill simply references several domestic regulatory laws. Is that the way to do it? Is it too narrow an approach, too broad an approach? How would you recommend that we define the classes of products that really present the most serious problems?

Ms. CAMPBELL. Mr. Barnes, I believe that the reference to the domestic legislation is essential as a beginning point, but is not suffi-

cient in itself. There would have to be some criteria in the legislation that would define what level of regulation we are talking about. For example, again with FIFRA which I am familiar with, EPA's regulation of pesticides varies from some user instructions on widely used chemicals to outright bans on all uses of a particular chemical. Of course, most of the pesticides were somewhere in the middle with certain uses allowed and certain uses not allowed; and varying restrictions on worker exposure or the weather conditions under which you can use it.

So, certainly, that kind of detail could not be worked into the legislation, but you would have to state that it would vary according to the stringency of the agency's regulation of the domestic use of the product, and then work closely with EPA, or FDA, or the respective agency in working out between the Commerce Department and the agency what they felt was appropriate for their particular type of product.

It is going to be a difficult question to work out. I think it can be worked out with some threshold determined with the agency's cooperation at a relatively early date. So, as you proceed with marking up the bill you could put something in.

I would add that it will be important for you, with your strong personal interest in this bill, to press all the agencies, Commerce, EPA, FDA, on the criteria they use in advising you as to what the threshold should be. From our experience—I hope Mr. Fuller is going to forgive me—the thing has been that EPA, for example, has not had a great deal of concern about the impact of U.S. chemicals abroad. It has not been part of its congressionally determined mandate and it has not been aggressive in this area at all. So, they are—from my point of view—likely to put the threshold a little lower than I would want it. But they are the experts on threshold, so we have to take their word for it to some extent.

LEVEL OF INTERNATIONAL CONCERN

Mr. BARNES. Mr. Fazal, you went through this to some extent in your testimony, but how is this problem really being perceived in the international community right now? You mentioned that concerns have been raised in Austria and Bangladesh. Were you meaning to suggest that those were single instances, or that there really is a very broad concern internationally in the international community about this question now?

Mr. FAZAL. There is very, very broad interest. I mentioned in my testimony the interest of the EEC in this field. They are actively working in this area; and the OECD is actively working in this area. The United Nations has an interagency committee.

We would not be having this kind of concern by so many international intergovernmental agencies if there was no problem. That is one indication of the worldwide concern of this problem.

I gave you two countries where there has been concern, and I selected Austria and Bangladesh because they are so very different. A country like Austria, which is considered a very well developed country, has also the problem that many goods have been dumped, and the consumer organization there has expressed its concern to the government.

If you take another example, a country that is near mine, Indonesia, the report by Mother Jones magazine in this field got first-page bold headlines; it was the main story of the day in the leading English newspaper in that country. It was entitled—I do not have the exact title—something like "Third World Victims of U.S. Faulty Products." So you can see the kind of importance that in fact this issue is being given in the fifth or sixth-largest country in the world, and a developing country at that.

Thank you, Mr. Chairman.

CONFLICTS WITH FOREIGN REGULATORY STANDARDS

Mr. BARNES. Thank you. In testimony the subcommittee is going to receive later are references to conflicts that exist with other countries' regulatory standards. My question is, is it feasible for us to develop a list of countries that have effective enforceable standards that we would accept in lieu of our own for purposes of exports to those countries; or is this a problem that ought to be dealt with on a case-by-case basis?

Mr. FAZAL. My reaction would be not to do such a list. The kinds of issues that are involved are very fluid and I think one must operate on a case-by-case kind of basis. I think the procedure you have suggested provides for that.

Mr. BARNES. Are we capable—perhaps Ms. Campbell can respond to this—of making the determinations that are required by this law? One of the concerns is that there would be lengthy bureaucratic delays in making the determinations. What is your judgment about our capability of reaching the judgments that this legislation would require to be reached, in a reasonable period of time, without disrupting trade?

Ms. CAMPBELL. Mr. Chairman, it would have to be done in consultation with the government of the importing country, I believe. Again because of the current lack of explicit congressional mandate in the international area, EPA's international affairs office is not now equipped to evaluate the impact of a particular chemical in a particular country, and whether that country's regulatory mechanism is adequate.

However, I believe that within a short time of enactment of this legislation EPA or the other regulatory agencies and the Commerce Department could work out a mechanism of consultation with foreign governments that would give them fairly quickly the kinds of answers they would need to make the determination. It will require some new knowledge on their part, which I am quite confident they can obtain.

Ms. IVES. I think that it should also be in consultation with international organizations such as WHO and the OECD, and they should provide a vital link with the kind of information that can be obtained in developing countries, in South America and in Europe. There are a number of people who would be more than willing to provide this kind of linkage, if given the opportunity to work with the U.S. Government.

Mr. BARNES. Let me ask one more question—I do not know if you are familiar with both—what are the main differences between

what this legislation proposes, and the approach of the administration's ad hoc task force?

Ms. CAMPBELL. Mr. Chairman, NRDC has seen the fourth draft of the administration's proposal but not the final draft. So, I would hesitate to comment now. But we expect to get a chance to see the fifth draft fairly soon. Then we could send in to you an analysis of the differences.

Mr. BARNES. Very good. I want to thank all three of you very much for taking the time to be here today and present this very helpful testimony to the subcommittee. If you would like to make additional views known, please do forward them to the subcommittee and we will make them part of the record of this hearing.

Mr. Fazal, again I want to particularly thank you for being here. I think we are fortunate that we scheduled the hearing while you were in this country and I am very grateful you could come to Washington to give us the benefit of your thoughts. Thank you very much.

Mr. FAZAL. Thank you very much.

Ms. CAMPBELL. Thank you.

Mr. BARNES. Our final witness is Dr. Howard Bauman, vice president of science and technology of the Pillsbury Co.

Mr. Bauman, I hoped to have other industry witnesses present, but no one else consented to testify. So, you are our industry "panel."

We very much appreciate your appearance and the subcommittee looks foreward to having the benefit of your views. Again, your statement will be entered in the record in full and you may summarize it if you wish.

STATEMENT OF HOWARD E. BAUMAN, VICE PRESIDENT OF SCIENCE AND TECHNOLOGY, THE PILLSBURY CO.

Mr. BAUMAN. Mr. Chairman, we certainly welcome the opportunity to testify on H.R. 6587. My name is Howard E. Bauman, I am vice president of science and technology of the Pillsbury Co. in Minneapolis, Minn.

I would like to add that one of my main jobs within the Pillsbury Co. is to make sure that all the ingredients, the packaging and labeling of our food products that are either produced anywhere in the world or exported anywhere in the world, conform to the regulations and laws of those countries.

I would like to point out that the Pillsbury Co. is an international marketing company. We participate in three segments of the food industry: Agri-products, restaurants, and consumer foods. The Pillsbury Co. recognizes the concern which has prompted this bill and, I might add, we support this concern. However, we feel it is important that certain facts be pointed out to the subcommittee that we believe are essential in the evaluation of this bill. I will testify only to the effects of this bill on food exports, which is our business, and the only area I really feel competent to talk about. Nonfood exports that are covered by this bill will, I am sure, be addressed by others—at least I hope they will be.

OBJECTIONS TO H.R. 6587

We oppose the bill as written since it would be overly restrictive, potentially detrimental to the exports of foods and commodities, and could result in large amounts of unproductive and unnecessary paper-

work. I should also point out that most food products are perishable within some degree of time and this could also be a problem if we encounter bureaucratic delays in dealing with products.

Another point which you alluded to earlier: This bill automatically assumes that our regulatory actions are always recognized, believed, and accepted by other countries. As the subcommittee is undoubtedly aware, there is a dispute within the scientific community worldwide as to certain actions that our Food and Drug Administration has taken. Some products that have been sharply curtailed, banned, or require special labeling in the United States are not contrary to the laws and regulations of other countries. I have used a few examples here to point out where there is a conflict.

For instance, F.D. & C. Red No. 2, a food coloring, has been banned as a food coloring in the United States and F.D. & C. Red No. 40 is our currently accepted red color. On the other hand, Canada, Brazil, India, Poland, Thailand, and the United Kingdom and at least 32 additional countries do not accept F.D. & C. Red No. 40 as a food color but do accept F.D. & C. Red No. 2. So, therefore any red product that we sell outside of the United States—except for two areas in Australia—must contain Red No. 2; otherwise, we cannot sell the product.

Another example is cyclamate, which has been banned in the United States but is permitted for sale in Canada, France, Switzerland, and other countries. The bill does state that it would be illegal to export an ingredient for another food product if that ingredient has been banned. Well, cyclamate is produced in this country and sold in these other countries where it is permitted. So, there is another problem.

The Food and Drug Administration has proposed a ban on saccharin, which has been stayed by the U.S. Congress. However, saccharin alone or as an ingredient in certain products is, like the previous examples, permitted for sale in Canada, the United Kingdom, and other countries, and even in this country as yet.

Now, another type of issue: It is not permitted under current U.S. regulations to add green color to processed peas—I am talking from our Green Giant side now—without what we call "crepe labeling" and that is, artificially colored peas. This is an acceptable commercial practice in France, the United Kingdom, the Netherlands, and some other countries. It is impossible to sell a product in England, for instance, like processed green peas, that is not colored; they just will not buy it. It puts us totally in an anticompetitive position.

Further, I think there could be a potentially broad interpretation of this bill by regulatory agencies, judging from what they have done in the past. It is conceivable that current regulations that allow a food additive up to a specific content level would prohibit our company or any other company from exporting a product containing an additive in excess of the U.S. limitation. I have cited another example here: The use of sulfite as a preservative in dried fruit. It will vary, the quantity that is needed, depending on the type of climate that the food has to be kept in. In this country it is limited to 200 to 300 parts per million. France, the United Kingdom, Portugal, India, Pakistan and many other countries permit up to 2,000 parts per million. I just question whether it would be possible under H.R. 6587 to export a dried fruit containing in excess of 300 parts per million of sulfite to these foreign countries.

I might add here that the food, drug, and cosmetic law does contain export language, and we are quite satisfied with the way that handles the items. It does list areas where you do have to get some type of permission in order to export a product. But the vast majority of our regular food products that we produce in this country, or produce for sale in other countries, must conform to the laws and regulations of the country to which we are exporting. That is not too difficult because most countries have regulations covering food, either some they have written themselves or those they adopted

As an example, I recently had some dealings with Venezuela, and they have adopted the U.S. regulations; if it is approved here, we can sell the product there. It varies from country to country. Some may use the Codex Alimentarius, the FAO listings as a basis for accepting ingredients for food, or food additives; some will accept the EEC regulations. So, it is not totally devoid of a great deal of control at this point in time.

We also feel that in labeling we could run into some real problems because most countries like to control what is said on their own labels, as we like to control what is said on our labels. Any country that exports a product into the United States must comply with our labeling regulations, and I think it is only fair that we comply with theirs.

So, for instance, the warning statement that we have on saccharin-containing products now would not be accepted in these other countries; it does not conform with their labeling requirements. I do not think we can impose that, they just will not accept it.

I think this bill could even affect current commodities regulations which establish maximum levels. I picked out one naturally occurring toxicant called aflotoxin in commodities such as peanuts, corn, and cottonseed which can differ from regulations of other countries. This regulation, to a great deal, depends on what levels they have internally in the crops they grow in their own countries and how they want to control it. Any time we make a shipment we have to certify that the product—whatever we are shipping—does not exceed certain tolerances, and in most cases we have to include tests that go along with it to prove this. So, even in the commodity area it is not a question of dumping. For instance, all of the grain we ship out has to go through USDA grading and certification, and then it is put in bond before it is even loaded onto the ship. So, there are controls in this area that are currently being used.

I would like to add that it is the policy of our company both to act in a responsible fashion in exporting food products and to comply with the rules, law, and regulations of the importing country.

We think this bill could be detrimental to the export of food products and commodities from the United States as it is currently written. We ask the subcommittee to proceed with caution and explore the potentially adverse position that this bill may create for U.S. food exporters.

I think it is something that should be looked at very carefully now, especially during the current recession when an aggressive export policy is needed.

I thank you for the opportunity to testify.

ASSIGNING REGULATORY RESPONSIBILITY

Mr. BARNES. Thank you, Mr. Bauman. A couple of questions, if I may. Do you think that it is the responsibility of our Government to

concern itself with protecting the citizens of other countries from hazardous products whose sale we restrict or prohibit in this country; or should we simply not consider that part of the responsibility of this Government and leave it to the host government, the importing country? Or, if you feel that it is part of our responsibility, how would you suggest we carry out that responsibility; how would we best implement it?

Mr. BAUMAN. First of all, I will agree, there is a responsibility. I think it is how we separate out the hazards and how we deal with the laws and regulations of the foreign countries.

What bothers me about the bill most, it is like a big net that has been thrown out and everything has been dragged into it without really attempting to differentiate between degrees of hazard. For some of those that I cited, for instance, you will find many scientists who say there is no hazard. You will find some others that say, yes, there is a hazard, but it is remote. But there is a possible hazard.

I think you have to separate that from something that is truly hazardous, and there are items that I think should be sharply controlled. I am not sure how that should be dealt with. I think it can be worked out, I would like to see more industries testify on behalf of their own types of products.

Mr. BARNES. I would, too.

Mr. BAUMAN. I think we can differentiate in food products where hazards might exist and where maybe specific controls ought to be established.

REGULATORY CONFLICTS

Mr. BARNES. Do you have in mind, or do you think you could formulate, any specific suggestions for modifying this bill so that it prevents dumping but does not reach the kinds of cases that you talked about, where it is really just a conflict between our regulatory standards and the regulatory standards of another nation that might be altogether reasonable, looking at it from their perspective? Do you think it is possible for you or your company, or perhaps an industry group with which you are associated, to come up with some specific suggestions for modifications, maybe even some language that we could look at?

Mr. BAUMAN. Certainly.

Mr. BARNES. The subcommittee could consider that, and that would be very helpful.

[The following information was subsequently provided:]

THE PILLSBURY CO.,
Minneapolis, Minn., July 15, 1980.

To: The Subcommittee on International Economic Policy and Trade.

On June 5, at a hearing of the Subcommittee on International Economic Policy and Trade, I agreed to submit an amendment to H.R. 6587 that would deal with problems that The Pillsbury Company foresaw in this legislation regarding the export of food products and commodities. It appears to us that a major problem exists in attempting to cover all types of exports in one bill. Food products and commodities are not as hazardous to public health as toxic chemicals, etc. Pillsbury would prefer to see food products and commodities segregated within the bill and dealt with separately. We recommend the language similar to that found in the Food, Drug and Cosmetic Act, Section 801(381)(d)(1):

"A food, drug device or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it—

"(A) accords to the specifications of the foreign purchaser,

"(B) is not in conflict with the laws of the country to which it is intended for export,

"(C) is labeled on the outside of the shipping package that it is intended for export, and

"(D) is not sold or offered for sale in domestic commerce.

"This paragraph does not authorize the exportation of any new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 512."

Most countries have laws governing food and food additives, and therefore, under export considerations we suggest that food products, commodities or ingredients shipped to a country having such laws conform to the laws of that country. For those countries who do not have food and drug laws, we suggest that the Food and Drug Administration determine the regulations that the importing country would like used by the exporter. Some countries, not having their own formal regulations, conform to the regulations of other nations; i.e., Codex Alimentarius standards, the U.S. Food, Drug and Cosmetic regulations, or the food and drug laws of the European Economic Community. Other countries request that the FDA or the USDA verify that the product to be exported complies with U.S. regulations.

This approach should assure relatively free movement of food products, commodities and ingredients, and also assure that the regulations of the exporting country do not indirectly supersede the laws and regulations of the importing country.

Sincerely,

HOWARD E. BAUMAN.

Mr. BARNES. Are you familiar with the work of the administration's ad hoc task force on hazardous substances, do you have any sense of what they are up to, and do you have any comments?

Mr. BAUMAN. Not lately. I have been able to scan through their draft four. Information on what they have been doing has not been, though, prevalent throughout the industry. I think they are attempting to do what I alluded to, that is, narrow it down a little bit more into separating the real hazards from potential and perceived hazards, and those that we really do not have to be concerned with. If they continue to proceed in that direction, I think it may be a good way of dealing with it. But I would like to see their new draft.

Mr. BARNES. We hope to be seeing it shortly.

The Pillsbury Co., you said, participates in three segments of the food industry: Agriproducts, restaurants, and consumer foods. Does the agriproducts end of it get into chemicals and fertilizers, any of those things that have been addressed today?

Mr. BAUMAN. No; we are entirely a food and feed company. Our agriproducts deals a great deal in commodities, food commodities.

Mr. BARNES. Right. Well, I thank you very much for testifying. I think your comments are very helpful. I really would encourage you to give us any specific recommendations you might have and particularly if you can coordinate those efforts with others in your industry and in the exporting community generally it will, I think, be very helpful to those of us on the subcommittee who will have to make the decisions.

Mr. BAUMAN. I will make a point of doing that.

Mr. BARNES. Thank you, Mr. Bauman, I would appreciate it very much, and I appreciate your being here this afternoon.

Mr. BAUMAN. Thank you, sir.

Mr. BARNES. We will recess these hearings on this legislation until 1 week from today.

[Whereupon, at 3:55 p.m., the subcommittee adjourned, to reconvene at 2 p.m. on Thursday, June 12, 1980.]

EXPORT OF HAZARDOUS PRODUCTS

THURSDAY, JUNE 12, 1980

HOUSE OF REPRESENTATIVES,
COMMITTEE ON FOREIGN AFFAIRS,
SUBCOMMITTEE ON INTERNATIONAL
ECONOMIC POLICY AND TRADE,
Washington, D.C.

The subcommittee met at 2:16 p.m. in room 2200, Rayburn House Office Building, Hon. Jonathan B. Bingham (chairman of the subcommittee) presiding.

Mr. BINGHAM. Today the subcommittee resumes its hearings on the export of hazardous products. We will consider H.R. 6587, the bill introduced by Congressman Barnes of the subcommittee, and the administration's policy.

We are most interested in the administration's views of these matters. This afternoon we will hear executive branch testimony.

Our witnesses are the Honorable Robert Harris, a member of the Council on Environmental Quality; the Honorable Homer Moyer, General Counsel of the Department of Commerce; Mr. William Hayne, Deputy Assistant Secretary of State for Environment, Health and Natural Resources, and Ms. Susan King, Chairperson of the Consumer Product Safety Commission.

The Food and Drug Administration and the Environmental Protection Agency have been invited to have representatives present in case questions arise specifically involving those agencies.

We welcome all of our witnesses and ask Mr. Harris if he would care to begin.

STATEMENT OF ROBERT HARRIS, MEMBER, COUNCIL ON ENVIRONMENTAL QUALITY, AND COCHAIRMAN, INTERAGENCY WORKING GROUP ON A HAZARDOUS SUBSTANCES EXPORT POLICY

Mr. HARRIS. Thank you, Mr. Chairman.

My name is Robert Harris. I am a member of the Council on Environmental Quality.

With me today, in addition to other administration witnesses, is Katherine Gillman, on my right, who is the Senior Staff Member for International Affairs of the Council and Edward Cohen, on my left, who is the assistant to Esther Peterson, Special Assistant to the President for Consumer Affairs.

I appreciate the opportunity afforded to us to comment on this legislation and to discuss with you some efforts that we are making to develop a hazardous substances export policy for the administration.

There can be no question that the dumping of toxic materials abroad to bypass stringent regulations at home is morally indefensible. It is not hard to imagine a future backlash from the Third World countries resulting from outrage at what they may consider a callous disregard for their health and well-being.

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It was in 1978, with the banning of TRIS-treated sleepwear, that the working group was formed and began its deliberations. At that time, as you probably remember, TRIS-treated sleepwear was banned by the Consumer Product Safety Commission. During the following months, TRIS-treated sleepwear was exported abroad.

As you know, TRIS-treated sleepwear was shown to cause cancer in laboratory animals and also to cause sterility and testicular atrophy in exposed animals.

In the early summer of 1978, the working group was convened by Esther Peterson, Special Assistant to the President for Consumer Affairs. The group included the State Department, the Departments of Agriculture, Commerce, Energy, Health, Education and Welfare, Justice, Defense, Labor, and Treasury, and the Environmental Protection Agency, the Consumer Product Safety Commission, the Export-Import Bank, the Overseas Private Investment Corporation, ACTION, the Nuclear Regulatory Commission, the Office of Management and Budget, the Council on Environmental Quality and other White House groups.

In July of 1978, that same summer, hearings were held before the Subcommittee on Consumer and Monetary Affairs of the House Committee on Government Operations.

These hearings demonstrated that many banned products were being shipped overseas with apparent unconcern by the U.S. Government. It became obvious that TRIS-treated sleepwear was not the only substance that had been banned, or significantly restricted for use in the United States, that was being exported to other countries.

Furthermore, importing countries had asked for restraint in exporting hazardous substances.

For example, a United Nations Environmental Program Resolution in May 1977 asked nations not to permit the export of hazardous substances without the knowledge and consent of the importing country.

POLICY CONSIDERATIONS

The working group, in its efforts to develop a Government hazardous-substances export policy, concluded that the following should be taken into consideration in developing such policy:

First, as a nation exporting substances banned in our country, the United States has a moral obligation to recognize and assist in controlling the potential effects of the substances on the health and safety of citizens abroad and in the world environment.

Second, nations differ substantially in their economic and cultural characteristics and, as a result, in their need for hazardous substances.

It is difficult for us to say, in the United States, what is an acceptable or an unacceptable risk for other nations. We feel that information is the key to preventing unwanted products from entering other countries from the United States.

Third, economic and diplomatic ties with other countries could be strained if we permit unrestrained export of hazardous substances.

Fourth, although there may be short-term gains in unrestricted trade, there may be long-term damage to the label "Made in the U.S."

Fifth, excessively restrictive limitations on export of hazardous substances could place the United States at a competitive disadvantage and, in fact, hurt our balance of payments.

Sixth, an export policy should be administratively simple and inexpensive to implement.

Seventh, the practical effect of unilateral U.S. actions could be substantially diminished if foreign facilities and firms were to become alternative suppliers.

And finally, the United States should attempt to protect American citizens against the danger to their health and safety and damage to the world environment that may arise from exporting banned substances.

DEFINING HAZARDOUS SUBSTANCES

As I indicated at the outset, the working group has been deliberating for the last 2 years and has developed a policy that is consistent with the considerations that I have just listed.

Over this 2-year period, there have been countless working sessions, there have been four drafts, and there have been consultative meetings with the chemical industry, the pesticide industry, the consumer product industry, the drug industry, and consumer, environmental, health, and labor representatives.

The working group has reached a general consensus on the desirable principles for a policy controlling the export of banned hazardous substances which we will soon develop in a fifth draft for further review by the public.

The principles which underlie this policy are as follows: First of all, we define a "banned substance" as one that is banned or severely restricted by existing statutes in the United States. Substances that are not registered or approved for use or manufacture in the United States but require such registration or approval are also included in the definition, and are covered by some aspects of the policy.

The policy pertains to pesticides, chemicals, food additives, drugs, cosmetics, medical devices, electronic products, and consumer products.

The policy further defines a banned substance by reference to the sections of statutes under which regulations banning or severely restricting these substances take place.

HAZARDOUS SUBSTANCES EXPORT NOTIFICATION

With such a definition, we believe that under most circumstances, our international responsibilities for control of the export of banned substances could be met by an effective notification system.

To achieve a notification system, first of all, we will develop an annual summary of all regulatory activities in the United States that result in banning or severely restricting substances.

Important pending regulatory activity will also be included in the annual summary. The summary will be made available to foreign countries and should help to provide the information necessary for them to make judgments about whether or not they wish to receive shipments of such products from the United States.

As you are well aware, many statutes, such as the Consumer Product Safety Act, the Federal Hazardous Substances Act, the Flammable Fabrics Act, the Federal Insecticide, Fungicide, and Rodenticide Act, require certain notification of the export of substances which are regulated under those acts.

These existing laws require notification tied to the actual shipment, either each shipment or the first shipment of the year, for most categories of substances with which we are concerned.

Our experience with these laws is minimal. Specifically, under the Toxic Substances Control Act, only two substances so far are subject to shipment notification, and the new provisions under the Federal Insecticide, Fungicide, and Rodenticide Act are just now being implemented.

Shipment notification rules have just been published by the Consumer Product Safety Commission. Accordingly, the working group takes no position with respect to these provisions at this time.

After some more experience with these procedures and with the new annual summary described above, we can review the various shipment notification procedures and make appropriate recommendations to the Congress. However, we do believe that the existing notification requirements of these statutes can be more consistent and can be systematized.

We, therefore, envision a notification system led by the State Department, which makes uniform the issuance of such notification to foreign governments.

This system will provide a central location where foreign officials can turn for information on exports of hazardous products and other regulatory actions pending on such products.

HAZARDOUS SUBSTANCES EXPORT CONTROLS

With respect to a very small number of particularly hazardous substances, the working group believes that there are some substances which may warrant something more than notification.

Because of the degree and nature of the hazard that these substances may entail, their export could pose serious foreign policy problems for the United States. The export of such products can be controlled under the existing authority of the Export Administration Act.

As you know, the act authorizes the President to, and I quote:

> Prohibit or curtail the exportation of any goods, technology, or other information subject to the jurisdiction of the United States, or exported by any persons subject to the jurisdiction of the United States, to the extent necessary to further significantly the foreign policy of the United States, or to fulfill its declared international obligations.

This is a section 6(a)(1).

Mr. BINGHAM. Excuse me, Mr. Harris.

Mr. HARRIS. Yes, sir.

Mr. BINGHAM. We are going to have to interrupt for a vote.

The subcommittee will be in recess for 10 minutes.

[Whereupon, a brief recess was taken.]

Mr. BINGHAM. The subcommittee will resume its session.

Mr. HARRIS. We believe that under this section of the Export Administration Act of 1979, the President has authority to control the export of banned hazardous substances in appropriate circumstances. There are, of course, very detailed procedures which must be followed in invoking this authority, and the act would only be used in very limited circumstances.

A task force, chaired by the Department of State and including the Department of Commerce, the Environmental Protection Agency, the Consumer Product Safety Commission, the Food and Drug Ad-

ministration, the Special Trade Representative and other relevant agencies would consider the substances that are banned or severely restricted in this country candidates for inclusion on the commodity control list.

In selecting these candidates, the task force would consider, on the basis of available, existing information, the type, extent, severity, likelihood, and duration or irreversibility of alternatives to the substance, the importance of its beneficial use, the availability of the substance from other sources and other relevant matters.

If the State Department concludes, based on the advice of the task force, that the export of a banned substance would be detrimental to our foreign policy and export control would benefit the foreign policy of the United States, then it would recommend to the Commerce Department that it be placed on the commodity control list.

The Commerce Department would apply the appropriate criteria and procedures of sections 2, 4, and 6 of the act in evaluating the State Department's recommendation. The act also mandates consultation with affected industries identified by the Secretary of Commerce.

In addition to the prior consultation requirements, the act requires that when controls are imposed, expanded, or extended, the President immediately notify the Congress of such action and report on his findings and reasons for imposing those controls.

Once a banned hazardous substance has been placed under export control, an exporter must apply to the Department of Commerce for a validated license to export the substances.

An export license would not be recommended by the Department of State unless it determines, following appropriate consultations, that the export is not contrary to U.S. foreign policy interests, and the importing foreign government has no objections.

The State Department would set up a system for its embassies and missions to consult its appropriate officials in foreign countries when imports of banned substances on the commodity control list are proposed. The Commerce Department already has in effect standard procedures for the processing of export licenses.

In conclusion, these unilateral actions which I have just outlined will not stand alone. This policy must be a part of a larger effort of international cooperation in developing hazardous substances alert systems, labeling requirements, in developing a clearinghouse for information and other international arrangements for the control and dissemination of information regarding hazardous substances.

Furthermore, we believe that what I have just outlined will achieve the broadest objectives of H.R. 6587 under the existing authority of the Export Administration Act of 1979 and, therefore, H.R. 6587 is neither necessary nor desirable.

I am attaching to my testimony a critique of this proposed legislation as well as the opinion of the Justice Department which concludes that the President has the authority to control hazardous substances under the Export Administration Act of 1979.[1]

This concludes my testimony. I will be more than happy to anwer any questions that you may have at this time, or after the other administration witnesses have testified.

[Mr. Harris' prepared statement follows:]

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[1] The Justice Department opinion appears in Vol. 45, No. 157 of the Federal Register, Tuesday, Aug. 12, 1980, p. 83768.

PREPARED STATEMENT OF ROBERT HARRIS, MEMBER, COUNCIL ON ENVIRONMENTAL QUALITY, AND COCHAIRMAN, INTERAGENCY WORKING GROUP ON A HAZARDOUS SUBSTANCES EXPORT POLICY

Mr. Chairman and Members of the Subcommittee:

Thank you for your kind invitation to testify this afternoon on behalf of the Administration's Interagency Working Group on a Hazardous Substances Export Policy. I commend the Subcommittee for undertaking this examination of an issue which we believe warrants national attention -- the export from this country of products which are banned or severely restricted for domestic use.

As you know, two years ago, the Administration formed an ad hoc interagency working group to consider Federal policy governing the export of hazardous substances, meaning substances which are banned entirely or banned for most significant uses in this country.* I am here today to report on the progress of our work and to suggest considerations that should be taken into account in defining a policy. The other Administration witnesses appearing are members of the Interagency Working Group who will present testimony on subjects that are within the particular expertise of their agencies.

The catalyst for convening the Working Group was the national and international controversy over U. S. exports of TRIS-treated children's sleepwear, which has been effectively banned for sale in the United States. The export of TRIS-treated sleepwear was not an isolated

* You will note that this is a different and narrower definition of hazardous substances than those used in other contexts (such as the pending "Superfund" legislation). It refers only to products and materials that cannot be sold or used domestically, or are so severely restricted as to be virtually banned.

incident. Hearings held by the Subcommittee on Commerce, Consumer and Monetary Affairs of the House Committee on Government Operations in July, 1978, identified other instances in which American firms exported substances that had been banned, or banned for most uses in this country. I should point out that since there are only limited controls on the export of banned substances, there are no mechanisms for systematically monitoring or valuing such exports. As a result, we are unable to estimate the precise dollar value of banned hazardous substances exported from this country.

Several examples, drawn from the Congressional hearings and other sources, suggest the scope of the problem. After the Consumer Product Safety Commission banned the domestic sale of TRIS-treated sleepwear, approximately 2.4 million pieces valued at $2.1 million were reported to have been shipped abroad. Many of these shipments were to developed countries such as France and Australia, where consumer groups reportedly promoted use of the TRIS-treated sleepwear because of its flame-retarding characteristics. Apparently, even in these technologically sophisticated countries, there was ignorance about the potential health hazards associated with this sleepwear which has led to the ban on their use in the United States.

Pesticides such as dieldrin, chlordane, heptachlor, and strobane were still exported freely after they had been suspended or cancelled for most uses in the United States.

Another powerful and hazardous pesticide, leptophos, which was never registered by EPA for domestic use, was manufactured in the United States principally for export. Between 1971 and 1976, nearly 14 million pounds were exported to 50 countries. In 1971 and 1972, a number of Egyptian farmers were found to be suffering from hallucinations and impairment of vision and speech after using leptophos, and 1,200 water buffalo were reported to have died from exposure to the pesticide. The leptophos episode is very widely known throughout the world, and is still often alluded to by representatives of other countries as a regrettable incident which does not reflect credit on the United States.

A recent incident that might have had a still more damaging effect on our reputation abroad was the attempted export, not of a hazardous substance, but of a hazardous waste. Several months ago, an American firm explored the disposal in Sierra Leone of toxic chemical wastes. Because of their potentially serious threat to the environment and human health, very careful disposal of these wastes is required under U. S. law. The American firm proposing disposal of wastes to Sierra Leone had offered the Sierra Leone government $25 million to accept the shipment. The U. S. State Department acted immediately to warn the Sierra Leone government of the potential dangers of the plan. Shortly afterward, the plan was publicly exposed, citizens of Sierra Leone and other African countries vigorously objected, and the plan was abandoned.

While these examples are anecdotal, they do indicate the need for a tighter rein on the export of banned hazardous substances. While I am convinced that many U. S. firms would not and do not dump unsafe products on unsuspecting foreign populations, the temptation to dispose of inventories of these products has, in some circumstances, apparently been irresistible.

In my judgment, U. S. manufacturers have a strong stake in maintaining a positive attitude among foreign governments and consumers towards products bearing the label "Made in the USA." Sale abroad of substances banned for sale in our own country or a seeming lack of concern by the U. S. government for their harmful effects would undermine foreign confidence in American-made products. Such sales may result in the loss of export trade, possible long-term loss of foreign markets, and an adverse impact on our balance of payments. Thus, a tighter control over the export of banned substances is not contrary to our national interest in promoting exports; it is consistent with it.

The Working Group recommends the following considerations which we believe should be taken into account in establishing a policy to govern the export of banned substances:

First, as a nation exporting substances banned for use at home, the United States has a moral obligation to recognize and assist in controlling the potential effect of these substances on the health and safety of citizens abroad and on the world environment. Our leadership in the world as an industrialized nation brings with it a corresponding

responsibility of leadership in controlling the exports of banned hazardous substances.

Second, nations differ substantially in their economic and cultural conditions and in their use of, and need for, hazardous substances. It is difficult to make decisions on the acceptability of risks for another nation. Let me illustrate this point with an example. DDT was banned for general use in the United States in 1972 and is widely known for its adverse environmental effects. However, for many years, it was considered a low-cost and effective pesticide for killing malaria-carrying mosquitoes. The United States does not suffer from pandemic malaria, but many other nations do; the disease afflicts over 200 million people in lesser-developed countries. In those countries where this life-threatening disease is rampant, where mosquitoes have not developed resistance to DDT, and where there is no better alternative, the use of DDT may be appropriate. If the government of a sovereign nation is properly informed of the potential adverse effects of a particular substance, it can more appropriately make the essential benefit-risk determinations for its own population than can the United States government.

Third, U. S. relations with other countries could be harmed by unrestrained export of substances which are banned or banned for most significant uses in the United States. If the United States does not exercise special vigilance over the exports of these materials, our economic and

diplomatic ties with other countries could be jeopardized. Citizens and governments of foreign countries receiving these banned hazardous products directly, or via their use by neighboring countries, may develop increasingly hostile attitudes towards the U. S. and its products.

Fourth, as I mentioned earlier, the unrestrained export of banned hazardous products could undermine the confidence of foreign buyers in U. S.-made goods, and could jeopardize U. S. sales abroad. While there might be a brief short-run advantage to certain firms in exporting substances that are banned at home -- or perhaps a minor benefit to our balance of trade -- these sales may in the long-run do significant harm to our trading position by tarnishing the image of U. S. products abroad.

Fifth, excessively restrictive limitations on the exports of products which a foreign government may decide it needs could place U. S. firms at a competitive disadvantage and undermine the confidence of foreign buyers in the reliability of U. S. firms as suppliers. Such limitations could also place significant economic burdens on this nation, including adverse effects on the balance of trade payments, on output and jobs, and perhaps on domestic competition if smaller firms suffer disproportionately from reduced ability to compete in foreign markets.

Sixth, an export policy should be administratively simple and inexpensive to implement, and should recognize the complexities of international commerce. We have established in our country a sophisticated system of regulation designed

to prevent the distribution of certain hazardous substances to U. S. consumers. Our policy governing the export of these banned hazardous substances should be built upon the domestic system of regulation. For your information, and in response to your request, I am attaching to my testimony a summary of the principal statutes authorizing domestic regulation of potentially hazardous substances, which are relevant to this policy.

Seventh, the United States should encourage and participate actively in international initiatives to develop consistent policies to govern the exports of banned substances and to encourage the sharing of data, analyses, and information. The practical effect of unilateral United States actions to control export of banned substances could be substantially diminished if foreign facilities and firms were to become alternative suppliers of substances which U. S. policy seeks to control. While the witnesses from the State Department will describe in greater detail our international efforts, I would just point out that the fora for these initiatives include the Organization for Economic Cooperation and Development (OECD), the World Health Organization (WHO), the Food and Agricultural Organization (FAO), Codex Alimetarius Commission (a UN body), the United Nations Environment Programme (UNEP), and the International Labor Organization (ILO).

Eighth, the United States should attempt to protect American citizens against dangers to their health and safety and damage to the world environment that may arise

from exporting banned substances. The export of banned hazardous substances can have a direct effect on U. S. citizens through the re-importation of the original substances or their traces or derivatives; through the illegal diversion into domestic commerce of restricted products originally produced for export only, or through the transport of banned hazardous substances back to this country via the air or oceans. For example, an FDA spot-check (examining about one percent of shipments) of imported raw agricultural commodities in 1977 and 1978 found that about 10 percent of the shipments tested contained residues of unregistered or severely restricted pesticides. Of course, it cannot be said that all of these pesticides emanated from the United States. However, to the extent that they did originate here, they may be coming back to haunt us.

As I mentioned in the beginning of my testimony, the interagency Working Group has been considering the issue of banned hazardous substances exports for almost two years. There have been several meetings of the full Working Group, countless working sessions among members of the Working Group, and a succession of four separate draft reports. In addition, we held a series of consultation meetings with representatives of the chemical, pesticide, consumer product, and drug industries, and with consumer, environmental, health and labor organizations. We have found this to be a highly complicated issue because of the sometimes conflicting policy

considerations which must be taken into account. Nonetheless, the Working Group has reached a general agreement on desirable principles for a hazardous substances export policy. Our next step will be to prepare a final draft report that discusses these principles in some detail and refine it in consultation with affected interests. I would like to describe these principles to you.

For the purposes of this policy, a "hazardous substance" is one which is banned entirely or banned for most significant uses in the United States. It is a pesticide, chemical, food (including meat products or poultry), food additive, drug, cosmetic, medical device, electronic product or consumer product for which a Federal agency has taken any of the following types of regulatory actions in order to protect against actual or potential threat to health or safety of the United States public or to the environment:

(1) Final rulemaking or adjudicatory action (including emergency or interim binding action) which denies or revokes approval for, or prohibits, the manufacture, production, use, disposal or sale in the United States of a hazardous substance;

(2) Final rulemaking or adjudicatory action (including emergency or interim binding action) which serves to prohibit most significant uses in the United States;

(3) Withholding or absence of registration or approval for any hazardous substance for which Federal law requires Federal agency registration

or approval before manufacture, production, use, sale or disposal in the United States.

A difficult aspect of developing a policy in this area is the formulation of a precise definition of the substances which should be included. To prevent any ambiguity, we recommend a definition which identifies the products subject to the policy by referring in the definition to specific provisions of specific statutes.

With such a definition, we believe that in most circumstances, the international responsibilities of the United States could be met by an effective hazard notification system. Recently enacted law requires notification of the export of many of these substances. In addition, the Working Group recommends the publication each year of a summary of U. S. regulatory actions taken during the course of the year which ban or very strictly limit hazardous substances for domestic use. Also included would be summaries of important pending regulatory actions and additional information on both final and proposed actions.

This annual report would compile in one up-to-date document a summary of U. S. regulatory actions concerning hazardous substances of interest to the world community. It would inform foreign governments of regulatory actions the previous year that were not included in the latest annual report, and for which some governments may not otherwise have received a notification. It would give foreign governments notice of prospective regulatory

actions so that they could monitor the progress of a proceeding if they so desired. Furnished with this information, a foreign government could take whatever regulatory action it deemed appropriate at the same time the U. S. regulatory action takes place.

The summary would serve another useful purpose. It would be a "hazard alert" for foreign governments for products that they may be importing from other countries. It could, we believe, be an important factor in curtailing international trade of banned and highly dangerous hazardous substances.

The Working Group also believes it is desirable for regulatory agencies, at their discretion, to notify foreign governments immediately of important regulatory actions banning the use of hazardous substances.

Existing law requires notification tied to actual shipment (either each shipment, or the first shipment of the year) for most categories of substances with which we are concerned. Our experience with these schemes is minimal. Specifically, under TSCA only two substances so far have been subject to shipment notification, and the new provisions under FIFRA are just now being implemented. The CPSC regulations implementing shipment notification have been issued but not yet published. Accordingly, the Working Group takes no position with respect to these provisions at this time. After some more experience with these procedures, and after instituting the new annual notification procedure and the export controls described above, we can review these various shipment notification procedures and make appropriate recommendations to the Congress.

In the meantime, however, some steps can be taken administratively to make notification of shipment more uniform. We believe to the extent possible under existing law, that notification of shipment should regularly occur through the State Department and that it should be the responsibility of the State Department to forward the notification to the appropriate government officials of the country of destination and to the U. S. embassy in that country. Of course, the U. S. regulatory agency responsible for the notification could also make direct contact with its counterpart in the foreign country; in the case of some laws, agencies are required to make this notification. By making the notification procedure more uniform, we believe the likelihood will be greater that the notification will end up in the right hands of the foreign government. In addition, regularizing the process will ensure that there will be one location to which foreign officials can turn to obtain information on exports of hazardous substances.

With respect to a very small number of particularly hazardous substances, the Working Group believes there are some substances which may warrant something more than notification. Because of the degree and nature of the hazard that these substances may entail, their export could pose serious foreign policy problems for the United States. The export of such products can be controlled under the existing authority of the Export Administration Act.

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As you know, the Act authorizes the President to "... prohibit or curtail the exportation of any goods, technology, or other information subject to the jurisdiction of the United States or exported by any persons subject to the jurisdiction of the United States, to the extent necessary to further significantly the foreign policy of the United States or to fulfill its declared international obligations." Section 6(a) (1)).

We believe that under this section of the Export Administration Act of 1979, the President has authority to control the export of banned hazardous substances, in appropriate circumstances. There are, of course, very detailed procedures which must be followed in invoking this authority, and the Act would only be used in very limited circumstances.

A task force, chaired by the Department of State and including the Department of Commerce, the Environmental Protection Agency, the Consumer Product Safety Commission, the Food and Drug Administration, the Special Trade Representative, and other relevant agencies, would consider from the substances that are banned or severely restricted in this country candidates for inclusion on the Commodity Control List. In selecting these candidates, the Task Force would consider, on the basis of available, existing information, the type, extent, severity, likelihood and duration or irreversibility of detrimental effects, the potential detrimental effects on neighboring countries and the global commons, the availability of alternatives to the substance, the importance of its beneficial use, the availability of the substance from other sources, and other relevant factors.

If the State Department concludes, based on the advice of the Task Force, that the export of a banned substance would be detrimental to our foreign policy and export control would benefit the foreign policy of the United States, then it would recommend to the Commerce Department that it be placed on the Commodity Control List.

The Commerce Department would apply the appropriate criteria and procedures of Sections 3, 4, and 6 of the Act in evaluating the State Department's recommendation. The Act also mandates consultation with affected industries identified by the Secretary of Commerce. In addition to the prior consultation requirements, the Act requires that when controls are imposed, expanded, or extended, the President immediately notify the Congress of such action and report on his findings and reasons for imposing those controls.

Once a banned hazardous substance has been placed under export control, an exporter must apply to the Department of Commerce for a validated license to export the substances. An export license would not be recommended by the Department of State unless it determines, following appropriate consultations, that the export is not contrary to U.S. foreign policy interests and the importing foreign government has no objections. The State Department would set up a system for its embassies and missions to consult its appropriate officials in foreign countries when imports of banned substances on the Commodity Control List are proposed. The Commerce Department already has in effect standard procedures for the processing of export licenses.

These unilateral actions which I have described are just one part of what should be a broader program to promote international cooperation on trade of hazardous substances throughout the world. We believe there is a need for international agreements for notification of the export of hazardous substances that are banned in the country of origin; comprehensive adoption of uniform, readily understandable hazard labeling for substances in international commerce; improved worldwide hazard alert systems, and clearinghouses for information on health and safety risks in the world place; and other common standards and practices related to the export of hazardous substances. These steps could lead to the formulation of an international convention governing hazardous substances exports.

A common international effort is important for several reasons. Common policies governing exports of banned and highly dangerous hazardous substances, subscribed to by all countries, would help to ensure that U.S. firms located abroad, or firms of other nations, would not become alternative suppliers of these substances. Consistency among nations and hazard notification labeling would be more effective than widely varying national programs, because the procedures would be more universally understood; more accurate because it would be based on broad international experience; and less burdensome to industry because firms would not have to respond to multiple varying requirements. Moreover, countries like the United States that took responsibility for export of hazardous substances would not be penalized economically.

Through international cooperation, on-going technical assistance programs for developing countries can be focused toward helping these countries establish adequate standards for health and safety, develop competent regulation, and effectively use available information. Differences among countries in needs and desires for assistance must be recognized. International cooperation will more likely flourish if it is built on existing structures, and is mindful of resource constraints that affect the ability of developing countries to contribute to the effort.

With the agreement in principle that has been reached by the Interagency Working Group, we will proceed to develop a final draft report and then refine it in consultation with interested parties. The recommendations that I have outlined will, we believe, go a long way toward meeting our goals. We entirely agree with the broad objectives of H.R. 6587, but we believe these goals can be accomplished under existing authority, and that enactment of the bill is neither necessary nor desirable. I am attaching for the Subcommittee's information a more detailed critique of this legislation. I am also submitting an opinion from the Office of Legal Counsel of the Department of Justice which concludes that the President may control the export of hazardous substances, in appropriate circumstances, under the authority of the Export Administration Act of 1979.

Our policy will put the United States in a strong position to persuade other industrialized nations to control the distribution of highly dangerous hazardous products throughout the world. I commend the subcommittee for its interest in this subject and I will be pleased to answer your questions.

[The critique referred to follows:]

WORKING GROUP COMMENTS ON H.R. 6587

The Working Group on Hazardous Substances Export Policy strongly supports the objectives of H. R. 6587. However, we recommend against enactment of the bill because we believe first, that the Executive Branch already has adequate authority to achieve the bill's goals, and second, that the policy proposals now being developed by the Working Group will accomplish its aims more effectively.

Our principal difficulties with H. R. 6587 are as follows:

1. H. R. 6587 would require U. S. government agencies to assess the costs and benefits of hazardous substances in foreign countries. In general, we believe it is inappropriate for the United States to make these cost-benefit analyses for our trading partners since this may be seen as an imposition of our own values and standards on others. In addition, most U. S. government agencies do not have the resources to make such analyses. It is difficult enough to make cost-benefit analyses for the use of such substances at home. To require them for exports would place very heavy burdens on regulatory agencies.

It is appropriate, we believe, for the United States to fully inform importing countries of the facts about hazardous substances which have been banned for use (or banned for most significant uses) in the United States. For some substances whose export could pose serious foreign policy problems for the United States because of the degree and nature of the hazard they entail, export controls under the Export Administration Act are desirable. The Executive Branch has the authority under the Act to impose controls.

2. As we understand its definitions, H. R. 6587 could impose export controls on a very large universe of substances. It defines as "hazardous" all goods "subject to registration, licensing or use requirements or similar restrictions" under 11 acts. Under this definition, export controls might be established on all pesticides and all drugs, and perhaps on a very large class of chemicals, as well as banned substances. The Working Group has found it a difficult problem to define the hazardous substances which are banned for all or most uses. We believe our proposed policy solves the problem, both by our generic definition and by reference to regulatory action under specific sections of relevant statutes.

3. We believe that export controls under the Export Administration Act should be applied only to a carefully selected sub-group of the larger universe of "hazardous substances" which have been banned or severely restricted for use in this country. Without this selection, export controls might be applied to substances or products whose export would not represent any foreign policy problem to the United States. An example is bicycles without rear reflectors. We believe that full disclosure of the facts about such exports is in most cases sufficient protection for our trading partners and our foreign policy interests.

The recommendations of the Working Group would, we believe, provide an effective and flexible system for controlling extremely hazardous exports that seriously threaten the environment and human health of other countries that are not acceptable to the governments of important nations and that pose serious threats to our foreign policy interests.

Members of the Working Group have also found other provisions of H. R. 6587 undesirable because they believe:

- o The bill would greatly restrain U. S. exports more than is necessary to accomplish its legitimate objective;
- o Section 2(5), forbidding the export of goods that could possibly be used in the manufacture of a substance that is prohibited for export is undesirable and burdensome. Many goods have both hazardous and non-hazardous uses, and it would be next to impossible to enforce this provision once the goods reach the importing country;
- o Section 2(4) requiring the Secretary of Commerce to determine whether warnings, instructions for use, and other information about hazardous substances is likely to be effective in importing countries would place a difficult, perhaps impossible, burden on the Secretary;
- o Section 2(3) divides responsibility for imposing export controls between the Secretary of Commerce and the relevant regulatory agency, rather than reserving the final decision to the Secretary of Commerce in consultation with the Secretary of State. The result could be inconsistency and an unpredictable export policy.

Mr. BINGHAM. Thank you very much, Mr. Harris.
Mr. Moyer.

STATEMENT OF HOMER MOYER, GENERAL COUNSEL, DEPARTMENT OF COMMERCE

Mr. MOYER. Thank you, Mr. Chairman.

The Department of Commerce welcomes the opportunity to address the important matter of developing an effective policy on the export of hazardous substances and, specifically, on H.R. 6587.

Mr. Chairman, the Department of Commerce shares the concerns of Congressman Barnes, the sponsor of this bill, about the negative health, environmental, and foreign policy consequences which can be occasioned by the indiscriminate export of hazardous substances.

We also agree that an effective policy in this area is an important part of a responsible U.S. export policy. Moreover, we agree, indeed, nearly 2 years ago, we proposed that the appropriate vehicle for instituting such a policy is the Export Administration Act.

In our judgment, however, the Export Administration Act of 1979 already contains sufficient authority to impose controls on the export of hazardous substances and there is, therefore, no need for additional legislation. This view has been twice concurred in by the Department of Justice, both before and after the 1979 amendments to the act.

As the testimony of my colleagues indicates, the working group chaired by Esther Peterson has, at some length, considered this issue, and has recently agreed upon desirable principles for a hazardous substances export policy.

The Department of Commerce would, under either the working group or under H.R. 6587, administer controls on the export of hazardous substances.

My brief remarks will, accordingly, focus on that portion of the working group proposal rather than on the annual notification system or efforts to obtain an international agreement.

FOREIGN POLICY EXPORT CONTROLS

Under our proposal, the export of particularly hazardous substances would be controlled under section 6 of the Export Administration Act of 1979, the foreign policy controls section.

As I have indicated, we believe that there presently exists sufficient authority to impose such controls. Additions to the Commodity control list and decisions on individual license applications would, of course, be made in accordance with the various requirements of section 6 as amended last year.

The substances for which export controls could be proposed would be that list of substances banned entirely or banned for most significant uses in the United States. This category would be defined, as Mr. Harris has described, in terms of certain specified types of regulatory actions.

After consideration by an interagency task force, the State Department would recommend to the Commerce Department additions to the commodity control list where it concludes, considering all relevant factors, that exportation of the substance to certain destinations

would be detrimental to our foreign policy. Additions to the list would be made in accordance with the provisions of section 6(k) of the act.

Once a hazardous substance has been placed on the commodity control list, an exporter must apply to Commerce for a validated license to export that substance.

The general statutory criterion for decisions on individual license applications will be whether denial of the license for export will further significantly the foreign policy of the United States.

The factors to be considered would include those factors specified in section 6 of the act as well as a large number of other relevant factors that are enumerated in my statement.

[The list of factors follow:]

The type, extent, and severity of risk posed by the substance.
The likelihood of its having a detrimental effect. The number of people likely to be detrimentally affected.
The duration, permanence, or irreversibility of the detrimental effect.
Destination.
The use to which exported product is intended to be put.
Views of the importing country.
Whether the host country government is itself the importer.
Benefits to be gained by the export (not a formal risk benefit analysis).
The extent to which the substance is freely available from alternative sources.
Availability of similar nonhazardous alternatives.
Precautions the importer intends to take with the substance.
Any dangers inherent in alternative substances presently being used.
Effect the hazardous substance might have on neighboring countries.
Possible reaction of other countries.
Results of Congressional consultations.
Results of consultations with industry representatives and other concerned parties.
The results of international efforts to curb the export of the substance.
Any other relevant factors.

Mr. MOYER. Prominent among those would be the views of the importing country. It is my understanding that the State Department would not recommend issuing a license over the objection of any importing country.

Given the very small number of products that would be included on the commodity control list, the resource requirements of administering this program would be minimal. Likewise, we assess the impact of this policy on our export trade to be negligible.

With that brief summary, Mr. Chairman, I should be happy to answer any questions the subcommittee might wish to ask.

Thank you.

Mr. BINGHAM. Thank you very much, Mr. Moyer.

Mr. Hayne.

STATEMENT OF WILLIAM ALSTON HAYNE, DEPUTY ASSISTANT SECRETARY FOR ENVIRONMENT, HEALTH AND NATURAL RESOURCES, DEPARTMENT OF STATE

Mr. HAYNE. Thank you, Mr. Chairman.

We welcome the opportunity to appear before the subcommittee to discuss the international efforts undertaken, or supported by the Government of the United States, regarding the export of hazardous substances and products.

My colleagues have addressed, or will address other aspects of the subject of the export of hazardous products raised in your letter to Secretary Muskie on May 22.

The Department of State is most sympathetic to the overall thrust of H.R. 6587. We are, indeed, concerned about the foreign policy implications of adverse consequences to public health and the environment abroad which can be traced to the unregulated export of hazardous substances and products from the United States.

I would add to my prepared statement that it is not just a question of foreign policy with which we are concerned, but also the possible adverse effects on health and the environment abroad. We have been very active in the working group.

With your permission, Mr. Chairman, I will summarize my statement and submit the full text for the record.

Mr. BINGHAM. Please do. Without objection, the full statement will appear in the record.

Mr. HAYNE. Thank you.

OECD ACTIVITIES

We have been very active in the Organization for Economic Cooperation and Development (OECD) with respect to the Toxic Substances Control Act. The Environmental Protection Agency, the Department of Commerce and others have worked with us.

In the OECD, we are trying to harmonize with other developed countries the regulations affecting trade in new, and sometimes existing, chemicals. This would apply to several areas such as good laboratory practices. We hope in this way to avoid trade barriers.

This exercise, however, governs trade mainly between developed countries rather than between the less developed and developing countries.

Even now, under the Toxic Substances Control Act, as other witnesses have mentioned, there is some provision for notification. As I believe the first witness mentioned, the United Nations' environmental program (UNEP) has a provision urging that people in other countries be careful of their exports. In 1979, the U.S. Government introduced a resolution calling for countries to act responsibly in exporting toxic or hazardous substances. I have attached a copy of that resolution to my testimony.[1]

For some time now we have also been notifying countries of pesticides exports.

USEFULNESS OF NOTIFICATION INFORMATION

If I can speak from my own experience when serving abroad in countries receiving these products from the United States, I have often been concerned that the form of notification was not always in the most useful form. I believe all of our administration witnesses are aware of the need to improve this process.

As other witnesses have mentioned, there is the difficult problem, of which we are all aware, of comparing the benefit risk ratio for other countries. We cannot apply our own standards.

[1] The resolution is retained in subcommittee files.

Given a choice, for example, between malaria and DDT, the World Health Organization and OECD governments usually prefer to take the DDT.

EXPORT OF HAZARDOUS WASTES

One aspect of the work which has come to the fore rather rapidly concerns the export of hazardous wastes as distinct from hazardous products.

I am sure that others are aware of the proposals within the last few months for the export from the United States to countries in Africa and also in the Caribbean toxic wastes which are now being controlled in the United States.

We have no means of finding out about these exports, or of controlling them, but we have asked all of our embassies abroad, to inform us if they hear of any exports coming from the United States.

What we have done on the cases about which we do know, is to inform the local governments of the prospective shipments of the wastes involved, of the risks involved, and to tell them also that we would make it public. So far, this has resulted in a cancellation of the proposals.

In the case of wastes as well as in the case of products, we find that the Export Administration Act is applicable. In the former case we have moved a little further and a little faster than we have on the hazardous products.

We are now in the process, I think, where the Department of State will address a formal request to the Department of Commerce asking for the application of this act to the export of hazardous wastes.

We will use as a guide the items which the Environmental Protection Agency has listed under the Resource Conservation and Recovery Act as automatically triggering this new process.

This completes my prepared testimony, Mr. Chairman. I would be happy to answer questions.

[Mr. Hayne's prepared statement follows:]

PREPARED STATEMENT OF WILLIAM ALSTON HAYNE, DEPUTY ASSISTANT SECRETARY FOR ENVIRONMENT, HEALTH AND NATURAL RESOURCES, DEPARTMENT OF STATE

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

THE DEPARTMENT OF STATE WELCOMES THE OPPORTUNITY TO APPEAR BEFORE THE SUBCOMMITTEE TO ADDRESS THE SUBJECT OF THE INTERNATIONAL EFFORTS UNDERTAKEN, OR SUPPORTED BY THE GOVERNMENT OF THE UNITED STATES REGARDING THE EXPORT OF HAZARDOUS SUBSTANCES AND PRODUCTS. MY COLLEAGUES WILL ADDRESS OTHER ASPECTS OF THE SUBJECT OF THE EXPORT OF HAZARDOUS PRODUCTS, RAISED IN YOUR LETTER TO SECRETARY MUSKIE ON MAY 22.

THE DEPARTMENT OF STATE IS SYMPATHETIC TO THE OVERALL THRUST OF H.R. 6587. WE ARE INDEED CONCERNED ABOUT THE FOREIGN POLICY IMPLICATIONS OF ADVERSE CONSEQUENCES TO PUBLIC HEALTH AND ENVIRONMENT ABROAD, WHICH CAN BE TRACED TO THE UNREGULATED EXPORT OF HAZARDOUS SUBSTANCES AND PRODUCTS FROM THE UNITED STATES. TO THAT END, WE HAVE BEEN ACTIVELY ENGAGED IN THE FORMULATION OF THE HAZARDOUS SUBSTANCES EXPORT POLICY BY THE ADMINISTRATION'S AD HOC WORKING GROUP, ESTABLISHED BY MRS. PETERSON. INDEED, THE DEPARTMENT OF STATE WOULD PLAY AN ACTIVE ROLE IN THE IMPLEMENTATION OF THAT POLICY AS CHAIRMAN OF AN INTERAGENCY TASK FORCE, IN WHICH THE DEPARTMENT OF COMMERCE, AS ADMINISTRATOR OF THE EXPORT ADMINISTRATION ACT, AND OTHER INVOLVED DEPARTMENTS AND AGENCIES WOULD PARTICIPATE.

I WOULD LIKE TO TURN TO OUR INTERNATIONAL EFFORTS, TO DESCRIBE FOR YOU THE PROGRAMS CURRENTLY UNDERWAY WHICH

ADDRESS VARIOUS ASPECTS OF THIS PROBLEM. FOR CONVENIENCE, THE ISSUE MAY BE DIVIDED INTO TWO IDENTIFIABLE COMPONENTS: 1) TRADE AMONG DEVELOPED COUNTRIES, AND 2) TRADE BETWEEN DEVELOPED AND LESS DEVELOPED COUNTRIES. EACH ASPECT OF THE ISSUE RAISES DIFFERENT QUESTIONS, WHICH ARE BEING ADDRESSED IN DIFFERENT MULTILATERAL FORA.

THERE HAS BEEN AN INCREASING U.S. AND INTERNATIONAL CONCERN ABOUT THE EFFECTS OF TOXIC OR HAZARDOUS CHEMICALS ON HEALTH AND THE ENVIRONMENT. AS ONE ASPECT OF THIS CONCERN, COMPREHENSIVE MEASURES ARE BEING INTRODUCED (OR CONSIDERED) BY THE U.S. AND OTHER INDUSTRIAL COUNTRIES TO DETERMINE WHETHER NEW (AND SOMETIMES EXISTING) CHEMICALS ARE HAZARDOUS TO HEALTH AND THE ENVIRONMENT AS A PRECONDITION FOR APPROVAL OF PRODUCTION, MARKETING, AND IMPORTATION. IF SUBSTANTALLY DIFFERENT, SUCH NATIONAL CONTROL MEASURES, TESTS AND STANDARDS COULD BECOME NON-TARIFF TRADE BARRIERS --INTER ALIA SERIOUSLY IMPEDING THE GROWTH OF U.S. CHEMICAL EXPORTS IN WHICH THE U.S. CURRENTLY ENJOYS A LARGE TRADE SURPLUS. INTERNATIONAL HARMONIZATION EFFORTS, FOCUSED IN THE CHEMICALS PROGRAM OF THE ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD), ARE BEGINNING TO BEAR FRUIT. THE WORK OF DEVELOPING HARMONIZED GUIDELINES FOR TESTING NEW CHEMICALS HAS BEEN LARGELY COMPLETED, AND BY THE END OF THIS YEAR IS EXPECTED TO RECEIVE OECD COUNCIL REOCOMMENDATION FOR MEMBER COUNTRY ADOPTION. HOWEVER, MAJOR POINTS OF DIFFERENCE STILL REMAIN TO BE RESOLVED.

ANOTHER ASPECT OF THIS PROBLEM INVOLVES THE NOTIFICATION OF OECD GOVERNMENTS OF DOMESTIC REGULATORY ACTIONS ON TOXIC OF HAZARDOUS CHEMICALS. UNDER THE LEAD OF THE GOVERNMENT OF CANADA, AN EXPANDED INFORMATION EXCHANGE PROGRAM HAS BEEN DEVELOPED. THIS WILL ADDRESS CONSIDERATIONS FOR THE DEVELOPMENT OF EXPORT AND IMPORT NOTIFICATIONS OF TOXIC OR HAZARDOUS SUBSTANCES. THE U.S. GOVERNMENT STRONGLY SUPPORTS THIS PROGRAM, IN LIGHT OF OUR STATUTORY RESPONSIBILITIES UNDER SECTIONS 12 AND 13 OF THE TOXIC SUBSTANCES CONTROL ACT. THIS ISSUE WILL BE EXPLORED IN DETAIL AT THE FALL MEETING OF THE OECD ENVIRONMENT COMMITTEE'S CHEMICALS GROUP.

MORE CONTROVERSIAL QUESTIONS, IN THE SENSE OF APPROPRIATE U.S. AND INTERNATIONAL COURSES OF ACTION, HAVE ARISEN OVER OTHER ASPECTS OF INTERNATIONAL TRADE IN TOXIC AND HAZARDOUS SUBSTANCES. IN THE 1977 AND 1979 MEETINGS OF THE UNITED NATIONS ENVIRONMENT PROGRAM (UNEP) GOVERNING COUNCIL AND LAST NOVEMBER, IN THE UN GENERAL ASSEMBLY, RESOLUTIONS WERE PUT FORWARD BY THE DEVELOPING COUNTRIES CALLING FOR COUNTRIES TO ACT RESPONSIBLY IN EXPORTING TOXIC OR HAZARDOUS SUBSTANCES. THE UNITED STATES HAS SUPPORTED THESE INITIATIVES.

THE UNITED NATIONS ENVIRONMENT PROGRAM RESOLUTIONS RECOGNIZE THE PROBLEMS OF THE HEALTH OF PEOPLE AND OF THE ENVIRONMENT AS DIRECTLY RELATED TO THE CAPABILITIES OF COUNTRIES IN FORMULATING AND DEVELOPING APPROPRIATE PROTECTIVE PROGRAMS AND STRENGTHENING THEIR CAPABILITIES FOR EVALUATING CHEMICALS, FOODS, DRUGS AND

COSMETICS. COPIES OF THESE RESOLUTIONS ARE APPENDED TO MY TESTIMONY FOR THE RECORD. IN ADDITION, IN THE UNITED NATIONS GENERAL ASSEMBLY, AT ITS 34TH SESSION LAST FALL, THE ECONOMIC AND SOCIAL COUNCIL REPORTED ON THE EXCHANGE OF INFORMATION ON BANNED, HAZARDOUS CHEMICALS AND UNSAFE PHARMACEUTICAL PRODUCTS. A REPORT ON THE EXPERIENCES GAINED BY MEMBER STATES ON THE EXCHANGE OF INFORMATION ON HAZARDOUS CHEMICALS AND UNSAFE PHARMACEUTICAL PRODUCTS THAT HAVE BEEN BANNED IN THEIR JURISDICTIONS; AND TO DISCOURAGE, IN CONSULTATION WITH IMPORTING COUNTRIES, THE EXPORTATION OF SUCH PRODUCTS TO OTHER COUNTRIES. A COPY OF THIS RESOLUTION IS ALSO APPENDED TO MY TESTIMONY FOR YOUR INFORMATION.

WHILE THIS ISSUE LARGELY RELATES TO INDUSTRIAL CHEMICALS, SIMILAR QUESTIONS SURROUND THE EXPORT OF AGRICULTURAL CHEMICALS, PARTICULARLY PESTICIDES. THERE HAVE BEEN NUMEROUS REPORTS, PARTICULARLY IN DEVELOPING COUNTRIES, OF WIDESPREAD SICKNESS AND DEATH CAUSED BY EITHER MISAPPLICATION OF PESTICIDES BY UNTRAINED PERSONNEL OR BY EXPOSURE TO CONTAMINATED MATERIALS. UNLIKE OTHER COUNTRIES, THE U.S. FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT REQUIRES THAT FOREIGN GOVERNMENTS BE NOTIFIED WHENEVER SIGNIFICANT REGULATORY ACTIONS ARE TAKEN BY THIS GOVERNMENT ON SPECIFIC PESTICIDE FORMULATIONS, AND EXPORTS OF UNREGISTERED PESTICIDES TAKE PLACE.

VARIOUS ENVIRONMENTAL GROUPS HAVE PROPOSED THAT PESTICIDES (AND, FOR THAT MATTER, INDUSTRIAL CHEMICALS) SHOULD NOT BE EXPORTED IF THEY CANNOT BE USED IN THE U.S. PROBLEMS WITH

THIS APPROACH INCLUDE LDC BENEFIT-RISK EQUATIONS THAT MAY BE DIFFERENT THAN OURS. GIVEN A CHOICE BETWEEN MALARIA AND DDT USE, FOR EXAMPLE, THE WORLD HEALTH ORGANIZATION AND THE LDC'S GOVERNMENTS HAVE SUPPORTED THE LATTER. SIMILARLY, PARTICULAR USES OF PESTICIDES IN DEVELOPING COUNTRIES IMPORTANT TO THEIR NATIONAL ECONOMY, E.G., RELATED TO THE PRODUCTION OF PALM OIL AND BANANAS, FOR WHICH OBVIOUSLY NO REGISTRATION OF PESTICIDE FORMULATIONS EXIST IN THE U.S. HOWEVER, RESIDUES OF ANY SUCH PESTICIDES MUST BE AUTHORIZED BY "TOLERANCES" ESTABLISHED BY EPA ONLY UPON A FINDING THAT THE RESIDUE WILL NOT RENDER THE FOOD OR COMMODITY "UNSAFE". THESE QUESTIONS COULD BE REVIEWED EFFECTIVELY WITHIN THE CONTEXT OF THE HAZARDOUS SUBSTANCES EXPORT POLICY, AND WOULD BE TAKEN INTO ACCOUNT IN ITS IMPLEMENTATION.

IN THE MEANTIME, ONE PROBLEM SIMILAR TO THOSE CONSIDERED THE PETERSON STUDY, BUT NOT COVERED BY THE HSEP--THE EXPORT OF HAZARDOUS WASTES--HAS RECENTLY COME TO THE FORE AS A PRIORITY ISSUE. FACED WITH INCREASING COSTS AND GOVERNMENT REGULATORY CONTROLS ASSOCIATED WITH THE DISPOSAL OF HAZARDOUS (NON-NUCLEAR) WASTES IN THE U.S., SOME U.S. COMPANIES ARE NOW CONSIDERING LESS DEVELOPED COUNTRIES AS POTENTIAL DISPOSAL SITES. THE USG IS CONCERNED ABOUT THIS DEVELOPMENT BECAUSE OF POTENTIAL UNFAVORABLE ENVIRONMENTAL AND HEALTH CONSEQUENCES ARISING FROM SUCH EXPORTS, ESPECIALLY TO DEVELOPING COUNTRIES WHERE ADEQUATE DISPOSAL PROGRAMS HAVE NOT YET BEEN DEVELOPED. RECENT EVENTS HAVE ALSO REVEALED

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THAT FOREIGN PUBLIC REACTION TO SUCH EXPORTS CAN BE DETRIMENTAL TO THE INTERESTS OF THE UNITED STATES.

THE DEPARTMENT HAS ALERTED A LARGE NUMBER OF U.S. EMBASSIES, IN COUNTRIES WHERE THE ISSUE COULD BE RELEVANT, TO REPORT ANY INFORMATION AVAILABLE NOW OR IN THE FUTURE CONCERNING POTENTIAL OR ACTUAL MOVEMENT OF HAZARDOUS WASTES TO DEVELOPING COUNTRIES FROM THE U.S., AND OTHER DEVELOPED COUNTRIES. IN THE CONTEXT OF KNOWN U.S. DISPOSAL OFFERS TO SIERRA LEONE AND HAITI, OUR EMBASSIES HAVE EMPLOYED A "NOTIFICATION" POLICY ADVISING THOSE GOVERNMENTS:

-- THAT THE U.S. IS CONCERNED ABOUT THE POTENTIAL HEALTH AND ENVIRONMENTAL RISKS WHERE ADEQUATE HAZARDOUS WASTE DISPOSAL PROGRAMS ARE LACKING.

-- THAT WE STAND WILLING TO SHARE SPECIFIC INFORMATION ON THOSE RISKS AND MAKE THAT INFORMATION PUBLIC.

-- THAT IT WOULD BE IN THE GOVERNMENT'S OWN INTEREST TO OBTAIN FULL INFORMATION FROM POTENTIAL EXPORTERS, PARTICULARLY ON THE NATURE, VOLUME AND TOXICITY OF THE WASTES AND EVALUATE THE RISK INVOLVED BEFORE CONCLUDING ANY AGREEMENT.

AS A RESULT OF THESE EFFORTS, ONE U.S. COMPANY HAS DROPPED ITS CONSIDERATION OF SIERRA LEONE, CHILE AND SOMALIA AS POSSIBLE DISPOSAL SITES. BUT THE ULTIMATE OUTCOME OF PROPOSALS BY OTHER COMPANIES TO HAITI IS UNCERTAIN, AND THERE MAY BE ADDITIONAL COUNTRIES THAT HAVE BEEN APPROACHED OF WHICH WE ARE UNAWARE.

In learning from our experiences in the export of hazardous wastes, the U.S. Government sponsored a draft resolution at the last Governing Council meeting of the United Nations Environment Program. The resolution requests that the Executive Director, in cooperation with competent organizations in the United Nations system, as well as others, develop guidelines for the safe and appropriate disposal of hazardous chemical wastes and pertinent measures concerning their transboundary transport, and to report on his progress at its ninth session in 1981. A copy of the resolution is also appended to my testimony.

Domestically, the Department has convened two interagency meetings to address the export of hazardous wastes. In attendance were representatives of the Environmental Protection Agency, Council on Environmental Quality, the Department of Commerce and the Office of the Special Trade Representative. The issue was whether the Export Administration Act could be used to control the export of hazardous wastes. We have been informed by Commerce that the Export Administration Act can be used and they have asked us to obtain the views of the Justice Department. Subsequently, we are notifying Commerce to have hazardous wastes, as defined by the Environmental Protection Agency, and the Department of Transportation placed on the Commodity Control

LIST, AS PROVIDED UNDER SECTION 6(K) OF THE EXPORT ADMINISTRATION ACT.

MR. CHAIRMAN, THAT COMPLETES MY PREPARED STATEMENT. WE HAVE OUTLINED AN EXTENSIVE INTERNATIONAL EFFORT UNDERTAKEN BY THE UNITED STATES IN THE EXPORT OF HAZARDOUS PRODUCTS. IN ADDITION, WE HAVE REVIEWED FOR YOU OUR DOMESTIC AND INTERNATIONAL PROGRAMS ON HAZARDOUS WASTES. WE WOULD BE PLEASED TO CONSULT WITH YOU AND MEMBERS OF YOUR STAFF ABOUT OUR PROGRESS. CERTAINLY IF THE NEED ARISES FOR ADDITIONAL LEGISLATION WE WILL SO APRISE YOU OF OUR CONCERNS. IN BEGINNING TO ESTABLISH THE GROUNDWORK FOR THE IMPLEMENTATION OF THE HAZARDOUS SUBSTANCES EXPORT POLICY, WE HAVE NOTIFIED A NUMBER OF OUR POSTS ABROAD AND DIRECTED THEM TO REVIEW WITH HOST GOVERNMENTS OUR POLICIES AND PROVIDE US WITH THEIR REACTIONS. WE WILL, OF COURSE, BE PLEASED TO PROVIDE THEM TO YOU WHEN THEY BECOME AVAILABLE. I SHALL BE PLEASED TO ANSWER ANY QUESTIONS THE SUBCOMMITTEE MAY HAVE. THANK YOU.

Mr. BINGHAM. Thank you.

The final witness is Ms. Susan King, Chairman of the Consumer Product Safety Commission.

STATEMENT OF SUSAN B. KING, CHAIRPERSON, CONSUMER PRODUCT SAFETY COMMISSION

Ms. KING. Thank you, Mr. Chairman.

I am Susan King, Chairperson of the Consumer Product Safety Commission (CPSC).

With me today is Andrew Krulwich, General Counsel of the CPSC and just last week elected Chairman of the OECD's working party on product safety.

If it is acceptable to you, I would like to summarize roughly two-thirds of the prepared text, and ask that the full text be incorporated into the record; and then focus on the latter portion of the written text because I think it does report on some new developments.

Mr. BINGHAM. Without objection, the entire statement will appear in the record.

Ms. KING. Thank you very much.

We would like to compliment Congressman Barnes for introducing H.R. 6587 because it does, again, focus important public attention on a matter of enormous concern to a lot of us—the dumping of seriously hazardous products in other countries.

As others at the table have said, we also believe dumping is bad foreign policy and bad economic policy for many of the reasons that have been outlined here.

However, CPSC notes also that it is a complex question, this question of the export of products which have been either banned or are in violation of standards set by this country.

By way of illustration of the various factors that have to be taken into consideration in approaching an export policy, we set out three examples with which we have had familiarity arising under our own statutes ranging from bicycles which are in violation of the U.S. standard because they do not have reflectors, to TRIS-treated children's garments. These raise very different questions. We believe that they need to be treated differently in balancing a number of factors.

WHITE HOUSE POLICY

We agree with the White House policy that it requires some flexibility in response. We would also acknowledge, from our own experience in the product safety area, that there are legitimate trade interests to be considered, and make the point that certainly the vast majority of businesses and manufacturers and private companies with which we deal want to comply with the law and ask that the law be clear, that it be equitable in its terms and reasonable as it applies to them.

We have been an active participant in the hazardous product working group for the last 2 years.

We strongly support the draft as it now stands. We have had a lot of input into the draft and strongly endorse the flexible approach that is put forward in that policy, as it has been outlined by Mr. Harris.

I would make the point that an Executive order does not extend to independent regulatory agencies, such as the Consumer Product Safety Commission.

We would have some interest in seeing that any export policy which is developed be introduced in and considered by Congress in order to have Government-wide application.

CPSC POLICY

I would turn very briefly to the policy and the statutes under which the Consumer Product Safety Commission now works because we are one of the few agencies in Government that does have a comprehensive system, including an export notification system, which was established by Congress in late 1978.

Very briefly, the Commission can prohibit the export of goods which are produced for domestic commerce if the goods are in violation of an agency standard or ban. We have authority to ban the export of them.

Products that are manufactured solely for export can be banned by the Commission in accordance with the congressional mandate only if the Commission makes a finding that such products pose a serious hazard to U.S. residents by, for example, the reimportation of such goods.

And finally, we have a system of export notification now in place. We have issued final rules implementing our export policy and expect that they will be published in the Federal Register shortly.

The rules require that any person who seeks to export a product which is in violation of a standard or ban established by the Consumer Product Safety Commission must notify the Commission of the intent to export 30 days prior to such export. In that notification, they must supply us with information concerning the country of destination, the consignee and a full description of the goods.

We then notify the recipient government of the intended export and the nature of the standard or ban that applies to the product, and describe, in some detail, the nature of the noncompliance with such standard or ban.

We have had an excellent response to this program, but it has not been in place very long. We have had a positive response from over 60 foreign governments who have enthusiastically responded, and who want us to notify them. They have identified the governmental offices that should receive such notices. We are very pleased with the results of that thus far.

There is an example of how the notification system works spelled out in the testimony. I will not go into it here, but I think that in our own experience in the last 18 or 20 months with regard to the export notification system in place at CPSC, in most instances, we agree that the interests of the United States are best served by a system which gives the best possible information to other countries so that those countries can make an informed decision.

In some instances, of course, the nature of the hazard is so serious, the potential threat to the environment, or to U.S. residents, by reimportation or environmental contamination, is such that we believe there should be an opportunity for the Government itself to prohibit the export of such serious and dangerous products or substances.

OECD EFFORTS

If I may, I would like to turn to page 8 of the prepared text and talk a bit about the Consumer Product Safety Commission's involvement in the OECD work.

As you know, we do not believe that the question of the export policy is a one-way street. It is clearly a two-way street, a two-way agreement.

Consumer products are a very significant factor in international trade. There are times when the United States needs and wants to know about the potential entry of hazardous products or substances into this country.

In that context, we are very pleased by the new interest throughout the world in establishing some form of broad import-export notification system.

As I indicated, among the most interested are countries who participate in the Organization for Economic Cooperation and Development. I would note also that the European community and the United Nations have also begun to look at the problem.

There has been a great deal of concern expressed by many Third World countries who are often the unsuspecting victims in the export of seriously hazardous products or substances.

And finally, there are a number of private consumer organizations, such as the International Organization of Consumer Unions, who have taken up this cause, and who are helping focus attention on the most serious abuses.

I would indicate only that in 1969, OECD established a committee on consumer policy. One of its most active and productive subcommittees or working party has been the working party on product safety.

Last week Esther Peterson, Andrew Krulwich and I, along with Jim Tarrant from the Department of State, attended 4 days of meetings during which Mr. Krulwich was elected Chairman of the Consumer Policy Committee's working party on product safety.

Having taken on this responsibility, CPSC will be working, in particular, on the proposed expansion of the OECD notification system.

Let me explain the existing system very briefly. For several years, the Consumer Policy Committee of OECD has had a system of voluntary notification by which member countries share information on product safety standards and bans.

Under this system, information has been exchanged on products that are vital to CPSC priorities such as chain saws, products containing asbestos, toys and numerous other children's products.

The international system has worked very well so far, but as the concern about the export and the movement of hazardous products across national boundaries has grown in recent years, so has the interest in strengthening and improving the existing system.

There were several important steps taken at the OECD meeting last week to expand the information sharing program.

The Consumer Policy Committee specifically approved the extension of the existing notification system to include additional products that had not been previously covered, such as automobiles and tires, and specifically indicated that products that pose a long term or chronic, unsuspected hazard would be covered by the notification system.

Also products subject to recall, either voluntary or mandatory, would be covered. New product safety research undertaken by member countries would be included in the system, as would standards and bans at the proposal stage as well as at the time they are finalized.

There was also considerable effort to consider ways in which the OECD Consumer Policy Committee could most effectively notify non-OCED member countries of product safety activities.

There is great interest in using contacts with other international organizations, both governmental and nongovernmental, as well as direct contact with governments for purposes of achieving the most effective notice.

There is also interest in providing some sort of mechanism, over time, by which we will be able to evaluate the effectiveness of the notices, and what response is taken by member governments or receiving governments in response to the information that they have gotten.

Most significant right now is the contemplated next step of the working party on product safety. Until now, this entire information sharing program has focused on information concerning standards and bans.

As a result of last week's meeting, the working party on product safety will be considering, as its number one priority, the development and implementation of the export notification system.

Such a system would give an importing country sufficient information about the intended shipment of potentially hazardous products to permit the receiving government to stop the shipment, if such action is deemed appropriate.

This motion, which CPSC and the U.S. delegation strongly supported, passed the committee unanimously.

Let me emphasize that it was not the Consumer Product Safety Commission acting alone at an OCED meeting in Paris.

We have worked very closely with the U.S. mission in Paris. The positions that have been developed, as set forth, are coordinated by the Department of State. The White House, as I indicated, has provided a great deal of leadership and quite strong support in this effort.

We believe that the OECD action last week represents real progress for the export notification system.

This is not to say that it is easy to establish such a system. The difficulties that we have encountered in the development of a uniform export-import policy for the United States alone are, obviously, multiplied many times in the international forum.

There are different legal systems, statutory bases and policy considerations in the participating countries to be taken into account.

The complexities are apparent when you add to those concerns other concerns about spiraling inflation, competing national interests in protecting foreign trade positions, and the need to assure the protection of valid trade secrets and confidential business information.

Nonetheless, the OECD countries and others are very aware of the basic issues at stake here, and there is new willingness to explore solutions which we find both positive and very encouraging.

This last round of meetings convinced us of the commitment of our major trading partners in exploring the possibilities of a broader system of export notification.

We believe that such a commitment is essential for this system if it is to ever work as it should, without discrimination against manufacturers in America, or against that country which is taking the lead in making more health and safety information available to others.

Ultimately, the appropriate home for a comprehensive, or worldwide export notification system might very well be the United Nations. For now, however, we believe that the most fruitful arena is the OECD. These organizations will continue to play an active role. We hope that our experience and commitment will benefit the process.

We will be glad to answer any questions also, Mr. Chairman.

Thank you.

[Ms. King's prepared statement follows:]

PREPARED STATEMENT OF SUSAN B. KING, CHAIRMAN, CONSUMER PRODUCT SAFETY COMMISSION

MR. CHAIRMAN, IT IS A PLEASURE FOR ME TO APPEAR BEFORE THIS SUBCOMMITTEE ON BEHALF OF THE CONSUMER PRODUCT SAFETY COMMISSION TO DISCUSS U.S. POLICY REGARDING THE EXPORT OF PRODUCTS DEEMED TOO HAZARDOUS TO BE SOLD IN THIS COUNTRY. THE ENTIRE SUBJECT OF EXPORT POLICY IS VERY IMPORTANT TO OUR AGENCY.

FIRST, I WOULD LIKE TO CONGRATULATE REPRESENTATIVE BARNES FOR INTRODUCING THE BILL BEFORE THE SUBCOMMITTEE, H.R. 6587, AND FOCUSING ATTENTION ON AN INCREASINGLY TROUBLESOME QUESTION. AS THE SUBCOMMITTEE KNOWS, "DUMPING" OF UNSAFE OR DANGEROUS GOODS HAS RECENTLY BECOME A MAJOR CONCERN IN A NUMBER OF COUNTRIES. ONE NATIONAL MAGAZINE HAS CALLED DUMPING THE "CORPORATE CRIME OF THE CENTURY."

THERE IS NO QUESTION THAT FOR THE UNITED STATES TO EXPORT SERIOUSLY DEFECTIVE OR DANGEROUS PRODUCTS TO UNSUSPECTING AND OFTEN UNDERDEVELOPED COUNTRIES IS BAD FOREIGN POLICY. IT IS INCONSISTENT WITH THIS COUNTRY'S BELIEF THAT HUMAN LIFE SHOULD BE PROTECTED.

DUMPING IS ALSO BAD ECONOMIC POLICY. ONE SHIPMENT OF DANGEROUS PRODUCTS BEARING AN AMERICAN LABEL CAN QUICKLY UNDERMINE FOREIGN BUYERS' LONG-STANDING CONFIDENCE IN THE SAFETY AND INTEGRITY OF AMERICAN GOODS.

DUMPING CAN ALSO HAVE AN IMPACT HERE AT HOME. IF MANUFACTURERS BELIEVE THAT A READY MARKET EXISTS ABROAD FOR DESIGN OR PRODUCTION "MISTAKES," OR PRODUCTS THAT ARE, FOR WHATEVER REASON, SERIOUSLY DEFECTIVE, IT MAY REDUCE THE INCENTIVE FOR SAFETY IN THE DOMESTIC MARKETPLACE. THE U.S. CONSUMER LOSES IN THIS SITUATION. SO DOES THE U.S. MANUFACTURER OF THE SAFE PRODUCT. HE MAY FIND HIMSELF AT A DISADVANTAGE AT HOME AND ABROAD, CREATING, IN EFFECT, AN INDIRECT SUBSIDY FOR THE MANUFACTURER OF UNSAFE GOODS.

HAVING SAID THIS, LET ME ACKNOWLEDGE THAT "DUMPING" IS TOO SIMPLE -- AND PERHAPS TOO PEJORATIVE -- A TERM TO DESCRIBE A COMPLEX PROBLEM.

MANY TYPES OF PRODUCTS POSING VARYING LEVELS OF HAZARDS ARE REGULATED UNDER A BEWILDERING ARRAY OF LAWS IN THIS COUNTRY. THE PRODUCTS REGULATED BY CPSC ALONE RANGE FROM TOYS TO POWER TOOLS TO HOUSEHOLD SUBSTANCES CONTAINING POTENTIALLY TOXIC OR CANCER-CAUSING CHEMICALS. WE CONSIDER A VARIETY OF FACTORS IN MAKING HEALTH AND SAFETY DECISIONS WHICH WILL AFFECT U.S. CONSUMERS. OUR OWN EXPERIENCE INDICATES THAT IN WORKING TO DEVELOP A UNIFORM POLICY AS TO HAZARDOUS EXPORTS, MANY OF THE SAME CONSIDERATIONS ARE RELEVANT. AMONG THESE ARE THE NATURE AND SEVERITY OF THE HAZARD POSED BY THE PRODUCT, THE NEED FOR THE PRODUCT, THE AVAILABILITY OF SUBSTITUTES, THE COST OF THE REGULATION, ETC.

LET ME GIVE YOU A FEW EXAMPLES:

- CPSC HAS A SAFETY STANDARD FOR BICYCLES. WHILE BIKES WITHOUT REFLECTORS WOULD BE BANNED IN THIS COUNTRY, IT IS HARD TO SAY WE SHOULD BE WORRIED BY THE EXPORT OF SUCH U.S. PRODUCTS TO COUNTRIES IN WHICH THERE IS NO AUTOMOBILE OR NIGHTTIME TRAFFIC.

- OUR STANDARD REGULATING THE FLAMMABILITY OF CLOTHING MAY RAISE MORE COMPLICATED QUESTIONS. SUPPOSE A U.S. MANUFACTURER DEVELOPS A GARMENT PARTICULARLY SUITABLE FOR VERY COLD CLIMATES BUT WHICH IS SO FLAMMABLE THAT IT CANNOT BE SOLD HERE. CONFLICTING, COMPETING INTERESTS ARISE WITH REGARD TO SUCH EXPORTS -- THERE IS A DEMONSTRATED HUMAN RISK, BUT THERE MAY ALSO BE A SERIOUS NEED FOR SUCH PRODUCT IN SOME COUNTRIES, AND PERHAPS NO ADEQUATE OR AVAILABLE SUBSTITUTE. HERE THE TRADEOFFS FOR THE IMPORTING COUNTRY CAN GET VERY DIFFICULT.

- A FINAL EXAMPLE IS THE PRODUCT WHICH HAS SO MUCH POTENTIAL FOR HARM THAT, REGARDLESS OF THE COURSE THE IMPORTING NATION MIGHT CHOOSE, BASIC HUMANITARIAN CONSIDERATIONS SUPPORT THE CONCLUSION THAT EXPORT SHOULD BE PROHIBITED ALTOGETHER.

I WOULD PUT ONE PARTICULAR CPSC EXPERIENCE IN THE LAST CATEGORY. TRIS-TREATED CHILDREN'S SLEEPWEAR WAS REMOVED FROM THE U.S. MARKET AFTER TESTS DETERMINED THAT TRIS COULD BE

ABSORBED INTO THE HUMAN BODY AND POSSIBLY CAUSE CANCER. CPSC SUBSEQUENTLY ALSO BANNED EXPORT OF TRIS-TREATED GARMENTS. IN A CASE LIKE TRIS, THE OBLIGATION OF THE UNITED STATES NOT TO EXPOSE OTHER NATIONS TO A CANCER-CAUSING SUBSTANCE OUTWEIGHS WHATEVER INTEREST AN IMPORTING COUNTRY MIGHT HAVE IN IMPORTING A PRODUCT OR A MANUFACTURER MIGHT HAVE IN CUTTING HIS LOSSES.

A WORKABLE EXPORT POLICY FOR THIS COUNTRY MUST TAKE INTO ACCOUNT BOTH THE COMPLEXITIES OF THE PROBLEM AND THE DISTINCTIONS WE OURSELVES MAKE IN RESPONDING TO DIFFERENT PUBLIC HEALTH AND SAFETY HAZARDS. IT IS ALSO IMPORTANT TO RECOGNIZE THAT THE VAST MAJORITY OF AMERICAN PRODUCERS AND MANUFACTURERS WANT TO, AND WILL, COMPLY WITH THE LAW. TO ENCOURAGE SUCH COMPLIANCE, WE MUST SEEK TO MAKE THE POLICY AS REASONABLE, AS CLEAR AND AS EQUITABLE AS POSSIBLE.

WHITE HOUSE POLICY

CPSC HAS BEEN AN ACTIVE PARTICIPANT IN THE HAZARDOUS SUBSTANCES EXPORT POLICY WORKING GROUP WHICH HAS SPENT MANY MONTHS DEVELOPING A DRAFT PROPOSAL. WE STRONGLY SUPPORT THIS WHITE HOUSE EFFORT TO DEVELOP A UNIFORM EXPORT POLICY. WE ALSO SUPPORT THE CURRENT DRAFT THAT HAS BEEN DISCUSSED IN SOME DETAIL TODAY.

THE KEY ELEMENT OF THE WHITE HOUSE POLICY, WE BELIEVE, IS ITS FLEXIBILITY. IT RECOGNIZES THAT NOT ALL HAZARDS

POSE THE SAME DEGREE OF RISK, AND THAT OTHER COUNTRIES' PRIORITIES ARE NOT NECESSARILY THE SAME AS OURS. THE POLICY PROVIDES FOR A SERIES OF GRADUATED RESPONSES, RANGING FROM SIMPLE U.S. NOTICE OF EXPORT TO THE FOREIGN GOVERNMENT, TO NOTIFICATION WITH ACKNOWLEDGEMENT FROM THE FOREIGN GOVERNMENT, TO A POSSIBLE BAN ON EXPORT -- DEPENDING ON THE SEVERITY OF THE HAZARD.

THERE WAS AGREEMENT AMONG ALL THE AGENCIES WHO PARTICIPATED IN DEVELOPING THE POLICY THAT IT SHOULD BE BASED PRIMARILY ON INFORMED CHOICE, WITH FULL DISCLOSURE OF RELEVANT FACTS TO IMPORTING COUNTRIES. IT WAS AGREED THAT EXPORT CONTROLS WOULD APPLY ONLY IN THOSE RELATIVELY SMALL NUMBER OF CASES WHERE THERE WAS A "SEVERE HAZARD" TO THE GLOBAL COMMONS, TO AN INNOCENT BYSTANDER NATION, OR TO THE UNITED STATES. A RECOMMENDATION THAT A "SEVERE HAZARD" EXISTS AND EXPORT CONTROLS SHOULD BE APPLIED WOULD BE MADE BY AN INTER-AGENCY TASK FORCE COMPOSED OF THE STATE DEPARTMENT, COMMERCE DEPARTMENT, AND RELEVANT REGULATORY AGENCIES.

CPSC POLICY

LET ME BRIEFLY EXPLAIN THE STATUTORY SYSTEM UNDER WHICH WE NOW FUNCTION. THE CONSUMER PRODUCT SAFETY ACT AND OTHER ACTS ADMINISTERED BY CPSC PROHIBIT THE EXPORT OF PRODUCTS WHICH VIOLATE AN AGENCY STANDARD OR BAN IF THOSE PRODUCTS HAVE EVER BEEN IN DOMESTIC COMMERCE. IT WAS UNDER THIS AUTHORITY THAT CPSC PROHIBITED THE EXPORT OF TRIS-TREATED CHILDREN'S SLEEPWEAR.

UNTIL 1978, CFSC DID NOT EXERCISE AUTHORITY OVER PRODUCTS MANUFACTURED AND LABELED SOLELY FOR EXPORT. THAT YEAR, CONGRESS AMENDED THE STATUTE TO PROVIDE A COMPREHENSIVE SYSTEM OF EXPORT NOTIFICATION FOR NON-COMPLYING CONSUMER PRODUCTS.

AGENCY REGULATIONS HAVE BEEN ISSUED TO IMPLEMENT THE CONGRESSIONAL MANDATE. THEY REQUIRE:

- 30-DAY ADVANCE NOTICE TO CPSC BY ANY PERSON WHO INTENDS TO EXPORT ANY PRODUCT WHICH FAILS TO COMPLY WITH A PRODUCT SAFETY STANDARD OR BAN

- NOTICE BY CPSC TO THE COUNTRY OF DESTINATION, INCLUDING SHIPMENT DATES, NAME OF CONSIGNEE, AND INFORMATION REGARDING THE RELEVANT STANDARD OR BAN AND THE NATURE OF NON-COMPLIANCE

AS A MATTER OF POLICY, CPSC TREATS PRODUCTS RECALLED UNDER A VOLUNTARY OR MANDATORY RECALL ACTION THE SAME AS IT TREATS THOSE SUBJECT TO A STANDARD OR A BAN, I.E., REQUIRING NOTICE OF INTENT TO EXPORT AND PROVIDING INFORMATION TO RECIPIENT GOVERNMENTS.

BY PROVIDING SUCH INFORMATION, CPSC HOPES TO ASSURE THAT FOREIGN COUNTRIES WILL BE ABLE TO MAKE INFORMED CHOICES ABOUT WHETHER TO PERMIT ENTRY INTO THEIR COUNTRY OF PRODUCTS NOT PERMITTED IN THE UNITED STATES FOR HEALTH OR SAFETY REASONS. IN PASSING THE 1978 ACT, CONGRESS SAID THAT:

"... THE UNITED STATES GOVERNMENT HAS AN OBLIGATION TO SHARE THE RESULTS OF ITS SAFETY RESEARCH WITH COUNTRIES WHICH PURCHASE U.S. EXPORTS. SUCH A POLICY NOT ONLY AFFIRMS THIS NATION'S COMMITMENT TO HUMAN RIGHTS, BUT ALSO STRENGTHENS U.S. DIPLOMATIC RELATIONS AND LONG-RANGE EXPORT PROSPECTS. (H.REP. NO. 95-1164, ACCOMPANYING H.R. 12442 (MAY 15, 1978). P.7)."

CONGRESS RECOGNIZED THAT INFORMED CHOICE WOULD NOT ALWAYS BE APPROPRIATE. THE AMENDMENTS ALSO AUTHORIZE THE COMMISSION TO PROHIBIT THE EXPORTATION OF CERTAIN PRODUCTS WHICH MIGHT POSE A HAZARD TO U.S. RESIDENTS, FOR EXAMPLE, FROM REIMPORTATION.

WHILE WE HAVE NOT YET HAD A GREAT DEAL OF EXPERIENCE WITH OUR NOTIFICATION REGULATIONS, I WOULD LIKE TO GIVE THE SUBCOMMITTEE SOME IDEA OF HOW THE SYSTEM WOULD WORK IN PRACTICE. LATE LAST YEAR, WE WERE NOTIFIED BY A U.S. EXPORTER OF ITS INTENT TO SHIP NURSERY LAMPS TO CANADA. THESE LAMPS COULD NOT BE SOLD IN THIS COUNTRY BECAUSE THE DECORATIVE FIGURINES ON THE LAMP WERE COVERED WITH BRIGHTLY COLORED PAINT WHICH CONTAINED HIGH AMOUNTS OF LEAD WELL IN EXCESS OF THE U.S. STANDARD. WE IMMEDIATELY WROTE THE CANADIAN GOVERNMENT TELLING THEM OF THE IMPENDING EXPORT. CANADA REQUESTED MORE INFORMATION ABOUT THE HAZARDS POSED BY LEAD IN PAINT, AND EVENTUALLY TOLD THE EXPORTER THAT THE INCOMING GOODS WOULD BE REFUSED. I MIGHT ADD THAT THE MINISTRY OF CONSUMER AND CORPORATE AFFAIRS OF THE CANDADIAN GOVERNMENT MADE A

SPECIAL POINT OF EXPRESSING APPRECIATION TO US FOR THE NOTIFICATION. IT PROVIDED CANADA WITH THE INFORMATION AND THE OPPORTUNITY TO EXERCISE A CHOICE THAT OTHERWISE WOULD NOT HAVE BEEN POSSIBLE.

IN MOST INSTANCES, OUR OBJECTIVES ARE BEST SERVED BY PROVIDING FOREIGN GOVERNMENTS WITH THE BEST INFORMATION ON WHICH TO BASE THEIR DECISION. I THINK SUCH AN APPROACH ANSWERS CRITICISMS ABOUT THE UNITED STATES BECOMING THE "WORLD'S NANNY" OR TOO PATERNALISTIC, WHILE STILL ASSURING THAT OUR COUNTRY, AS A GENERAL RULE, WILL NOT BE EXPORTING HAZARDOUS PRODUCTS TO UNINFORMED TRADING PARTNERS.

THE RESPONSE OF OTHER GOVERNMENTS TO OUR NOTIFICATION PROGRAM HAS BEEN UNIFORMLY POSITIVE. SIXTY COUNTRIES, REPRESENTING ALL OF OUR MAJOR TRADING PARTNERS AS WELL AS AFRICAN AND LATIN AMERICAN COUNTRIES, HAVE GIVEN US INSTRUCTIONS ON THE APPROPRIATE OFFICE TO CONTACT WITHIN THEIR GOVERNMENTS. THEIR GOVERNMENTS HAVE EXPRESSED GREAT INTEREST IN AND ENTHUSIASM FOR THE PROGRAM. OUR EFFORTS NOW WILL BE AIMED AT MAKING SURE THAT MANUFACTURERS AND EXPORTERS ARE FULLY AWARE OF THEIR NEW OBLIGATIONS.

OECD

I DON'T WANT TO LEAVE WITH YOU THE IMPRESSION THAT WE DO ALL THE WORK HERE. CONSUMER PRODUCTS ARE A VERY SIGNIFICANT FACTOR IN INTERNATIONAL TRADE, AND EXPORT NOTIFICATION

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IS A TWO-WAY STREET. THERE ARE TIMES WHEN THE U.S. NEEDS AND WANTS TO KNOW ABOUT THE POTENTIAL ENTRY OF HAZARDOUS PRODUCTS OR SUBSTANCES INTO THIS COUNTRY. IN THAT CONTEXT, WE ARE HEARTENED BY THE NEW INTEREST THROUGHOUT THE WORLD IN ESTABLISHING SOME FORM OF BROAD IMPORT/EXPORT NOTIFICATION SYSTEM. AMONG THE MOST CONCERNED ARE THE COUNTRIES WHO PARTICIPATE IN THE ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD). THE EUROPEAN COMMUNITY (EC) AND THE UNITED NATIONS HAVE ALSO BEGUN TO LOOK AT THE PROBLEM OF EXPORT DUMPING, AS HAVE THE THIRD WORLD COUNTRIES, WHO ARE OFTEN THE UNSUSPECTING VICTIMS. FINALLY, THERE ARE PRIVATE CONSUMER ORGANIZATIONS, SUCH AS THE INTERNATIONAL ORGANIZATION OF CONSUMER UNIONS (IOCU), WHO HAVE TAKEN UP THIS CAUSE.

LET ME TALK HERE A LITTLE ABOUT THE OECD PROGRAM SINCE IT IS THE MOST ADVANCED TO DATE AND THE ONE WITH WHICH WE ARE MOST FAMILIAR. OECD WAS ORIGINALLY ESTABLISHED IN 1948 AS AN OUTGROWTH OF THE MARSHALL PLAN PROGRAM. ITS 24 MEMBER COUNTRIES NOW WORK TOGETHER TO PROMOTE ECONOMIC GROWTH AND COOPERATION. SEVERAL SPECIALIZED COMMITTEES ON ENERGY, SCIENCE, TECHNOLOGY, AND ECONOMIC POLICY CARRY OUT THE WORK OF THE ORGANIZATION.

IN 1969, OECD CREATED A COMMITTEE ON CONSUMER POLICY (CCP) WHICH QUICKLY BECAME A LEADER AMONG INTERNATIONAL CONSUMER ORGANIZATIONS. CPSC HAS LONG BEEN ACTIVE IN THE CCP.

JUST LAST WEEK, WE ATTENDED FOUR DAYS OF MEETINGS DURING WHICH THE GENERAL COUNSEL OF CPSC WAS DESIGNATED CHAIRMAN OF THE COMMITTEE'S WORKING PARTY ON PRODUCT SAFETY. HAVING TAKEN ON THIS RESPONSIBILITY, WE WILL BE WORKING, IN PARTICULAR, ON THE PROPOSED EXPANSION OF THE OECD NOTIFICATION SYSTEM FOR HAZARDOUS PRODUCTS.

FOR SEVERAL YEARS, THE OECD/CCP HAS HAD A SYSTEM OF VOLUNTARY NOTIFICATION BY WHICH MEMBER COUNTRIES SHARE INFORMATION ON PRODUCT SAFETY STANDARDS AND BANS. UNDER THIS SYSTEM, INFORMATION HAS BEEN EXCHANGED ON PRODUCTS VITAL TO CPSC PRIORITIES, SUCH AS CHAIN SAWS, ASBESTOS, TOYS AND NUMEROUS OTHER CHILDREN'S PRODUCTS. THE SYSTEM HAS WORKED WELL SO FAR. BUT AS CONCERN ABOUT HAZARDOUS PRODUCTS HAS GROWN, SO HAS INTEREST IN IMPROVING IT.

IMPORTANT STEPS WERE TAKEN AT THE MEETING LAST WEEK TO EXPAND THIS OECD INFORMATION-SHARING PROGRAM. THE CONSUMER COMMITTEE SPECIFICALLY APPROVED EXTENSION OF THE EXISTING NOTIFICATION SYSTEM TO INCLUDE:

- ADDITIONAL PRODUCTS, SUCH AS AUTOMOBILES AND TIRES, AND PRODUCTS WHICH MAY POSE LONG-TERM OR LATENT, UNSUSPECTED CHRONIC HAZARDS;
- PRODUCTS SUBJECT TO A RECALL, EITHER VOLUNTARY OR MANDATORY;

- NEW PRODUCT SAFETY RESEARCH UNDERTAKEN BY MEMBER COUNTRIES;
- STANDARDS AND BANS AT THE PROPOSAL STAGE (I.E., BEFORE BEING FINAL);
- CONSIDERATION OF WAYS TO MOST EFFECTIVELY INFORM NON-OECD MEMBER COUNTRIES OF PRODUCT SAFETY ACTIVITIES. CONTACT WITH INTERNATIONAL ORGANIZATIONS, BOTH GOVERNMENTAL AND NON-GOVERNMENTAL, AS WELL AS DIRECT CONTACT WITH COUNTRIES, WILL BE IMPORTANT TO ACHIEVING THE MOST EFFECTIVE NOTICE;
- A MECHANISM TO PROVIDE FEEDBACK TO OECD FROM MEMBER COUNTRIES AS TO RESPONSES TAKEN AS A RESULT OF PRODUCT NOTIFICATIONS. THIS WILL PERMIT ON-GOING EVALUATION OF BOTH THE NOTICE AND THE RESPONSE ASPECTS OF THE SYSTEM.

MOST SIGNIFICANT IS THE CONTEMPLATED NEXT STEP. UNTIL NOW, THE SYSTEM HAS BEEN LIMITED TO INFORMATION ON STANDARDS AND BANS. NOW, AS A RESULT OF LAST WEEK'S MEETING, THE WORKING PARTY ON PRODUCT SAFETY WILL BE CONSIDERING, AS ITS NUMBER ONE PRIORITY, THE DEVELOPMENT AND IMPLEMENTATION OF AN EXPORT NOTIFICATION SYSTEM. SUCH A SYSTEM WOULD GIVE IMPORTING COUNTRIES SUFFICIENT INFORMATION ABOUT THE INTENDED SHIPMENT OF POTENTIALLY HAZARDOUS PRODUCTS TO PERMIT THE RECEIVING GOVERNMENT TO STOP THE SHIPMENT, IF SUCH ACTION IS DEEMED APPROPRIATE. THIS MOTION, WHICH CPSC AND THE U.S. DELEGATION STRONGLY SUPPORTED, PASSED UNANIMOUSLY.

THIS REPRESENTS REAL PROGRESS TOWARD AN EXPORT NOTIFICATION SYSTEM. THIS IS NOT TO SAY IT WILL BE AN EASY TASK. THE COMPLEXITIES AND DIFFICULTIES ENCOUNTERED IN DEVELOPING A UNIFORM EXPORT POLICY FOR THE U.S. ALONE ARE MULTIPLIED MANY TIMES IN AN INTERNATIONAL FORUM. THERE ARE DIFFERENT LEGAL SYSTEMS, STATUTORY BASES AND POLICY CONSIDERATIONS IN THE PARTICIPATING COUNTRIES TO BE TAKEN INTO ACCOUNT. ADD TO THAT CONCERNS ABOUT SPIRALING INFLATION, COMPETING NATIONAL INTERESTS IN PROTECTING FOREIGN TRADE POSITIONS, AND THE NEED TO ASSURE THE PROTECTION OF VALID TRADE SECRETS AND CONFIDENTIAL BUSINESS INFORMATION, AND THE COMPLEXITY IS MORE APPARENT. NONETHELESS, THE OECD COUNTRIES AND OTHERS ARE VERY AWARE OF THE BASIC ISSUES HERE AND THE NEW WILLINGNESS TO EXPLORE SOLUTIONS IS POSITIVE AND ENCOURAGING.

THE LAST ROUND OF OECD MEETINGS CONVINCED ME OF THE COMMITMENT OF OUR MAJOR TRADING PARTNERS TO EXPLORING THE POSSIBILITIES FOR A BROADER SYSTEM OF EXPORT NOTIFICATION. SUCH A COMMITMENT IS ESSENTIAL FOR THE SYSTEM TO WORK AS IT SHOULD, WITHOUT DISCRIMINATION AGAINST MANUFACTURERS IN AMERICA OR AGAINST COUNTRIES THAT TAKE THE LEAD IN MAKING IMPORTANT HEALTH AND SAFETY INFORMATION AVAILABLE TO OTHERS.

ULTIMATELY, THE APPROPRIATE HOME FOR A COMPREHENSIVE OR EVEN WORLDWIDE EXPORT NOTIFICATION SYSTEM MIGHT BE THE UNITED NATIONS. FOR NOW, THE MOST FRUITFUL ARENA IS THE OECD. THE AGENCY WILL CONTINUE TO PLAY AN ACTIVE ROLE THERE, AND WE HOPE OUR EXPERIENCE AND COMMITMENT WILL BENEFIT THE PROCESS.

I BELIEVE THIS IS A COMPREHENSIVE STATEMENT OF WHAT CPSC IS DOING, AND I WOULD BE PLEASED TO ANSWER ANY QUESTIONS.

Mr. BINGHAM. Thank you.

ADMINISTRATION OBJECTIONS TO H.R. 6587

I do not have a clear idea as to the administration's specific objections to H.R. 6587.

Mr. HARRIS. I have attached to my testimony some of our objections. Perhaps I could mention a couple, and then Ms. Gillman or Mr. Cohen could add to it if I leave out something.

First of all, we do not believe that we should be in a position of doing a rigorous cost benefit analysis for the use in other countries of chemicals or consumer products or other substances that are banned or restricted in the United States. That is, it would place the regulatory agencies in an untenable position of having to decide whether or not the benefits accruing to citizens of another country. outweigh the risk posed in those circumstances. An explicit cost benefit analysis, we think, would be an unworkable and undesirable requirement and very burdensome.

Second, as I read it, there would be a ban on export of chemical intermediates, and perhaps on other products that are used in the manufacture of banned substances in the United States.

I wonder, again as I read it, whether certain chemical intermediates that might be used in the manufacture or in the synthesis of a banned pesticide would be banned for export; and yet, that intermediate might be used in hundreds of desirable products in manufacturing in other countries.

In addition, we are concerned that this bill encompasses a very large universe of substances and products. We believe that this would be undesirable and unnecessary.

What we are proposing and developing in this hazardous substances export policy that I have been discussing is a less ambitious and, I think, equally effective program that would encompass far fewer substances and products and chemicals and, in fact, a program that would adequately prevent the export of products that would have adverse implications for our foreign policy interests.

Mr. BINGHAM. What effect do you think passage of legislation like the Barnes bill would have on the international negotiations?

Ms. KING. As far as the Consumer Product Safety Commission and the working party on product safety goes, I think the effect would probably be negligible because the reach of the Barnes bill may much more heavily impact in the area of chemicals and pesticides and items that are not strictly consumer products.

I think the State Department might want to respond to that. I think that your work would be more directly impacted.

Mr. HAYNE. Mr. Chairman, with respect to the work that is going on in the Toxic Chemicals Control Act, I do not think that there would be much effect because that controls imports more than exports.

We have also proposed to OECD that we do try to develop a common export policy. I can see some reasons for not putting into effect ourselves too strict a policy until we get the other countries at least to move a certain distance in the same direction.

Thank you.

Mr. BINGHAM. Well, I am not sure I follow that because I understand that the Barnes bill would only apply to products which are presently prohibited.

Are you suggesting that it would go beyond that?

Mr. HAYNE. Mr. Chairman, it is my understanding that the provision of the Barnes bill would provide for export controls on certain items that are not now controlled.

Mr. BINGHAM. Well, we will pass that for the moment.

I recognize Mr. Lagomarsino.

Mr. LAGOMARSINO. Thank you, Mr. Chairman.

I have a number of questions. I think they would take longer than 5 minutes.

I ask unanimous consent to submit the questions for the record.

Mr. BINGHAM. Without objection.[1]

Mr. LAGOMARSINO. Let me just ask this question, and any one or all of you may answer.

U.S. GOVERNMENT'S RESPONSIBILITY

To what extent do you believe that the regulation of hazardous substances as called for both in the regulation that we are proposing in the Executive order and/or in the bill is the responsibility of the U.S. Government rather than the importing country government?

Mr. HARRIS. Well, we believe that the responsibility lies both here in the United States and on the shoulders of the importing country, depending on the circumstances.

As I have outlined here, there are clearly situations where the exportation of products manufactured in the United States would not be in the foreign policy interests of this country because they would cause adverse health effects to, say, Third World peoples, or damage to their environment. They may represent severe hazards and severe risk, and the country importing the product would neither know nor be aware of this, nor able to evaluate or identify that information that is relevant to make such a determination for itself. This would likely come back to haunt us.

Also, there are situations, and that has been discussed by a previous witness, where such an exportation would harm citizens in the United States. For example, certain pesticides that are banned in the United States yet may be exported to countries that use them on food crops then imported by the United States.

In fact, the FDA has identified, as I recall, residues of unregistered pesticides on about 5 to 10 percent of the imported agricultural product shipments it has tested.

Mr. LAGOMARSINO. Would that be so even though, as I understand it, in many cases, the company that would be exporting these materials, or some other company, could manufacture exactly the same product in that other country, or in those other countries?

Mr. HARRIS. Yes. That is right.

NEED FOR INTERNATIONAL COOPERATION

That is why I think we are emphasizing that. This is simply one step in the effort to, if you will, get our house in order, and to set an example for the international community. It is essential that we have cooperation with other nations.

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[1] The questions and responses appear in app. 4, p. 241.

Mr. LAGOMARSINO. Yes. That was going to be my next question. Several of you did comment on it.

It is rather obvious that such regulations would not be very effective unless we had comparable action by at least our allies, people who are capable of manufacturing such products.

Mr. HARRIS. Precisely.

EFFECTIVENESS OF LEGISLATION

Mr. LAGOMARSINO. How likely is it that this legislation would do exactly what it is intended to do?

Mr. HARRIS. The Barnes bill?

Mr. LAGOMARSINO. Yes.

Mr. HARRIS. I assume that it would do what it is intended to do in the sense of its intentions being to prevent the export of substances from the United States that may harm our interests and that have foreign policy implications, detrimental implications to the United States.

On the other hand, because of the large universe that this bill would cover, the opposite may, in fact, be true. That is, the bill would create a restriction, or an impediment to exportation of certain products that other countries need, desire, want and, in fact, are in their best interests to import as well as in our best interests to export. So it is difficult for me to say if, indeed, this were law that the benefits would outweigh the cost.

Mr. LAGOMARSINO. Because of the fact, that as you described before, what could occur is that a company from the United States could manufacture that product elsewhere, or in some other country.

Mr. HARRIS. Or there would be certain export restrictions, and the fact may be that a certain product is needed and is perhaps even desirable in other countries, or the restrictions would place the American manufacturer at a disadvantage competitively.

BASIS FOR INFORMED DECISIONS

Mr. LAGOMARSINO. It kind of runs throughout what most of you said that by saying that the United States must establish standards to apply to hazardous substances, at least insofar as those that are going to be exported are concerned, the other countries are not capable of making a competent decision on their own behalf.

Now, what countries do you believe are not capable of making such a decision? [Laughter.]

You need not name them.

Ms. KING. May I respond to that?

Mr. LAGOMARSINO. Surely.

Ms. KING. I would like to come back to a more general principle here, that no one can make an informed choice without the information. What has run through the statement of everyone here and through the introductory remarks made by Congressman Barnes with regard to his bill is that central to all of this is a notification system which provides full and complete information on which a decision, an informed decision, can be based, and that includes information not just about the

product but the nature of the risk and the rationale underlying the standard.

It also argues for a strong U.S. commitment to the work that is going on in the international arena for the sharing of information among countries and not just among exporters and importers. As the State Department has indicated, there is a great deal of work going on in the area of chemicals and toxic substances.

Mr. LAGOMARSINO. Thank you.

Mr. BINGHAM. We will have to take another recess.

[Whereupon, a brief recess was taken.]

Mr. BINGHAM. The subcommittee will resume its session.

I understand that you want to add to your previous comments, Ms. KING.

Ms. KING. We have lost Mr. Lagomarsino.

Mr. BINGHAM. He will not be able to return.

Ms. KING. The basic point that I think needs to be remembered here is that people cannot make choices as I indicated, without accurate, adequate, and timely information in a very comprehensive fashion. That is really the key to this whole endeavor.

Whether one begins with a presumption of a ban, or whether one begins with a presumption of notice, they are all based on the concept of information sharing. The question that we believe is critical in any policy that is developed is to permit flexibility, which takes into account the nature and the severity of the hazard, the irreversibility of the damage, perhaps the availability of alternatives or substitute products—a whole variety of questions need to be considered.

In the consumer safety area, as I indicated, the issues may be quite different even under our own statutes, and they certainly would be quite different from factors that would be considered in the environmental, pesticide, or food and drug area.

There are fewer instances of life-threatening consumer products than there are in the chemical area.

For example, notification, in most instances, in the consumer product safety area is an adequate response because it does permit informed choice on the part of the receiving government.

Just to repeat what I said prior to the break, the fact that there is activity going on in the international arena, that the information is available to as many countries as possible and to many international organizations like the United Nations and the World Health Organization and, in addition, to international consumer organizations, reduces a problem to which Mr. Lagomarsino referred—the possibility of purchase of the same product from other countries. If one is aware of the hazard and deems the hazard to be a very serious one, perhaps the receiving government would choose not to purchase it from any country.

Worldwide dissemination of information is what is very important regardless of which approach, or from which end of the continuum one begins in developing a bill.

I think we have indicated that these are different approaches. They are not. It is starting at two different ends of the continuum and drawing intentions within the continuum.

Thank you.

Mr. BINGHAM. Did you want to add to that?

OBJECTIONS TO H.R. 6587

Mr. HARRIS. Well, I would like to simply say that in your question about what our objections were with respect to the Barnes bill, perhaps we did not make that clear although I did, in my testimony, say that we certainly agree with the objectives and goals of this proposed legislation.

If it would be all right, I would like to ask Ms. Gillman to discuss and elaborate a little bit on some of the technical details of this bill to which we object, or that we think might be altered or changed in a beneficial way.

Mr. BINGHAM. Certainly.

Would you identify yourself, please.

STATEMENT OF KATHERINE GILLMAN, SENIOR STAFF MEMBER FOR INTERNATIONAL AFFAIRS, COUNCIL ON ENVIRONMENTAL QUALITY

Ms. GILLMAN. Mr. Chairman, I am Katherine Gillman, senior staff member for International Affairs for the Council on Environmental Quality.

We do have some technical problems with the bill. For example, the definition of "hazardous substances" in the bill we think could be interpreted as covering a very large universe of substances, all of which would be put on the commodity control list, but that is a rather technical thing which I think can be solved and agreed upon fairly easily.

I think the difference is in approach, and it is not a vast gulf, but the difference in approach is that the Barnes bill would take all of the banned substances, all of the substances which are banned from use, and place export controls over those whereas the working group's proposal would be somewhat more flexible. We would be able to select from that universe of banned substances, and substances that are banned for most uses, substances to put on the commodity control list. As Ms. King has pointed out, there might be some consumer products, for example, which we do not regard as life threatening, or as any threat to the foreign-policy interests of the United States. One example is the export of bicycles that do not have adequate reflectors.

We find that it would be an advantage to have the flexibility to select from that large universe of substances a more limited group to put on the commodity control list.

We think that our system, too, would enable us to deal with unforeseen situations that might arise—such as life-threatening situations where products suddenly become banned, suspended, canceled, or whatever—and that we would be able to act quickly.

So, as I say, I think it is a continuum, as Ms. King said. It is coming to the same problem with the same general outlook, but with a somewhat more restrained and more flexible approach on the part of the working group.

UNIVERSE OF PRODUCTS

Mr. BINGHAM. You used the term "universe of products." Several witnesses have used that term.

How large is this universe?

Ms. GILLMAN. It is a little difficult to say exactly. We have tried to make a count.

It is not as big as you might think. As we define it in the working group, the pesticides which are banned, or which are banned for most significant uses, amount to between 30 and 60. The ones that are being made for export only, if you look at the generic pesticides, number about 25.

Then when you get to the consumer products, it is a little more complicated because what you are talking about is not just banned products, but products that do not meet the standards of the Consumer Product Safety Commission. So it is a little hard to count them, but we think that there are between 30 and 50 products and standards which are in question.

When you get to the Food, Drug and Cosmetics Act drugs are not in the picture because unapproved drugs cannot be exported anyway under the present Food, Drug and Cosmetics Act. But there is a goodly number, probably a couple of hundred classes of foods and cosmetics, which are adulterated or misbranded, or that do not meet the standards and which, therefore, would be considered to meet the definition of "banned hazardous substances."

Now, according to our proposal, all those would not necessarily be listed on the commodity control list. They would be the substances from which the task group would consider and recommend some of them, a few of them, to be placed on the commodity control list.

Mr. MOYER. Mr. Chairman, I might elaborate on this point, because we are talking about different sets of universes. This goes to the first question asked, which is really a threshold question.

As I read the Barnes bill, the universe it would define, particularly in paragraph 2 where it talks of the subject of registration, licensing, or use requirements, is an enormous universe. Pesticides alone, for example, I am told, number in the tens of thousands.

So what we are talking about in terms of the universe upon all of which H.R. 6587 would impose certain notification requirements is a very large universe indeed.

The universe about which we are talking, in terms of the working group proposal, is a universe that numbers somewhere in the hundreds.

From that universe, the most particularly hazardous substances would be taken as candidates for inclusion on the commodity control list and, therefore, the validated license requirement so that the threshold universe, if that is the appropriate term, is very different indeed in the two proposals.

I might add that there is an obvious calculus at work here in that there is more than one variable. The way in which one defines the universe affects, obviously, the appropriateness of the measures, or controls to be imposed be they notification, inclusion on the commodity control list, or some other measure. The types of measures taken with respect to a very large universe would be different from those taken for a smaller universe. This is an issue that was enormously time consuming in our considerations.

The universe defined here—which we understand to be very large—is inappropriately large for the notification types of requirements specified in the bill.

Mr. BINGHAM. Mr. Barnes.

Mr. BARNES. Thank you very much, Mr. Chairman.

First of all, I want to thank the chairman for scheduling these hearings and for his concern and leadership on the issues relating to exports generally and, specifically, the subject matter before us.

Second, I want to thank all of the witnesses for taking the time to prepare their testimony and to be here today.

I found it very helpful to assess your comments on the bill which was introduced this past winter.

The bill was intended to serve essentially as a vehicle to raise this issue and to give us the opportunity to get answers to a series of questions that still have to be answered. Some of these have been discussed already this afternoon.

How many products are we talking about? What is the impact of them?

What is the potential financial impact upon exporters of the restrictions that might be imposed?

INTENT OF SPONSORS OF H.R. 6587

The fact that the bill is essentially a first draft is reflected by the fact that you have caught a couple of areas that need to be more clearly delineated.

You noted earlier, Mr. Harris, the potential problem that this act would be interpreted to prohibit the export of an ingredient even if that ingredient might be used overseas for some wholly admirable purpose.

That was not our intention, although I can see that is the way this reads. So clearly, that would have to be cleaned up in the next draft.

The intent was to prohibit the ingredients being exported separately, and then overseas being used to create the product whose export might have been prohibited under the statute had the ingredients been exported as the product.

Whether or not that situation can be reached through legislation is another question, but that was the purpose of the language in that section.

Similarly, Mr. Moyer has read paragraph 2 to suggest that what we are talking about here is placing on the commodity control list 10,000 pesticides, or every conceivable product in the United States that is, in any way, so involved.

I see how you read that language—"subject to registration, licensing, or use requirements," et cetera.

That is not the intent of those of us in Congress who have been working on the legislation. It is our purpose to reach those products which have been found to be hazardous, and not to raise a whole new standard of whether a product which is subject to registration or regulation might be hazardous to export. That is not the purpose here at all. I think we can all agree that language can be found to reach the purposes of the bill.

The reason I go through all of that is simply to suggest that the disagreements that have emerged with respect to the legislation may not be as great as might be perceived by a casual listener to these proceedings.

But I think we do have some differences, one of which is how fast we are going to move on this, and when we are going to see some action on what everyone here has agreed is an important issue in the foreign policy of the United States.

STATUS OF WORKING GROUP'S REPORT

The working group has been working for a couple of years, and we have an indication today that sometime fairly soon, we will see the results of that effort.

When will we see that?

Mr. HARRIS. Let me first say that which I first indicated at the beginning, that Ms. Peterson, of course, has been chairing this group and, unfortunately, she could not be with us today because she is ill.

Her assistant, Ed Cohen, to my left, has been working diligently on this for the past 2 years. I would like him to answer that.

STATEMENT OF EDWARD COHEN, DEPUTY SPECIAL ASSISTANT TO THE PRESIDENT FOR CONSUMER AFFAIRS

Mr. COHEN. Thank you, Bob.

Mr. BARNES. There is a phrase that is used for what you just did.

Mr. COHEN. Yes, "Pass the buck."

I think the point is a fair one: 2 years is a long time. But I think that there are reasons for this rather lengthy process.

As you have gathered from this group, we consider the exportation of hazardous products to be an exceedingly difficult and sensitive problem.

First, the eight factors that must be taken into account in developing a policy, as listed by Mr. Harris in his testimony, are not necessarily consistent. When inspected separately, these factors not only do not lead one to the same conclusion, but some of them are, in fact, conflicting. Quite frankly, when you have a task group composed of 20 agencies, the weight that each one of those eight factors is to be given is not always clear. So it is of no surprise that there have been differences of opinion among the agencies in trying to reach an agreement.

Second, midway through this process, there was a substantial change in the fabric of the laws which governed the export of hazardous or banned products.

Among these changes are amendments to the Consumer Product Safety Act, the Flammable Fabrics Act, the Federal Hazardous Substances Act, and FIFRA. Naturally, it requires some reassessment.

And finally, we have engaged in a consultation process which has taken a substantial amount of time.

There are interest groups, such as labor, business, consumers, and environmentalists who are interested in what we are doing, and who have asked that we consult them. Obviously, this process takes time.

Let me respond directly to your question. Within the working group, I believe we have reached an agreement on a policy in principle.

We are in the process of drafting what will be the fifth and, hopefully, the final draft of our working paper. Upon finishing this, hopefully within a week, we will engage in additional, and preferably

final, consultations. We will then move the report forward to the decisionmaking people in the administration.

So I guess the bottom line to your question as to when we will be finished is, hopefully, by the end of this summer.

Mr. HARRIS. I would just say that although Esther Peterson has acted as the chairperson of this group, she now says that she cochairs it with CEQ. So I do not want to shirk that responsibility. I want to say that we are committed to that task. If that is the way that it is to be implemented by the end of the summer, we are committed to do that. I see no reason why we cannot meet that.

Mr. BARNES. Well, thank you.

Let me just say that some of us are equally eager to see this process move forward, and maybe the legislative process will grind forward as well because I think, as Ms. King has pointed out, that there may be some areas where legislation is required.

DECISION TO NOTIFY IMPORTER OR TO DENY EXPORT

Let me examine the basic philosophical difference that I gather some of you have with respect to what the working group is doing, and what this legislation proposes.

The bill takes the position that anything that has been banned in the United States ought to be subjected, before export, to a relatively simple process as defined in the bill to make sure that the other country has been notified, and that the agency that banned the product in the United States is allowed to participate in the decision as to whether or not the export would be permitted.

Some of you seem to be making a distinction between "serious hazards" and "nonserious hazards."

If the universe we are talking about is as small as 30 pesticides, maybe 30 to 50 consumer products, maybe a total of a couple of hundred foods and cosmetics, would it not make sense to simply say, as a policy, that these products will not be exported. Those that have been banned simply will not be exported unless the tests in the bill have been met.

Why is it that we need to, within that relatively small universe, categorize them?

On page 13 of your testimony, Mr. Harris, you said that you would assume that the Export Administration Act "would only be used in very limited circumstances." That is, anything beyond mere notification.

Why do we not go beyond notification for the whole universe and permit, on a case-by-case basis, the decision to be made that indeed, bicycles without reflectors are perfectly acceptable in a rural area where the only danger is a water buffalo?

That is not something that is going to be a difficult decision to make.

Mr. HARRIS. Well, I can give a few comments on that. Perhaps Mr. Moyer would also like to respond to that.

We do envision notification of these banning actions and actions that restrict the use of products through an annual report. We think that for most of these substances and products, this will be adequate. Indeed, in order for this task force to decide which substances will be singled out as representing a special case and placed on the commodity

control list, they will have to consider all of the substances which have been banned, or severely restricted. So there will be some consideration of these. And so I would, I think, have to answer it in that way.

Mr. Moyer, would you?

Mr. MOYER. I would add that our proposal would, in many repsects, do precisely that.

In other words, those substances selected for inclusion on the commodity control list which would, presumably, be the most hazardous of the regulated, severely restricted substances, would therefor require validated licenses.

That could mean one of two things. Licenses might not be issued under any circumstances, which amounts to, obviously, an export ban.

Alternatively, they would be considered on a case-by-case basis taking into account all of the circumstances, if the export is within the framework of the Export Administration Act.

There is the flexibility and, indeed, our intention would be to do, with respect to those substances, what you describe, namely, in the worst cases, put the substances on the commodity control list and, in those cases, prohibit export.

In certain cases, that could be done without regard to the views of an importing country. A decision could be made that a substance is so hazardous that it simply would not be exported.

Mr. BARNES. Mr. Chairman, I know that my time has expired.

I know that Mr. Pease has some questions.

Mr. BINGHAM. Would you want to yield to Mr. Pease? We can come back to you.

Mr. BARNES. I will yield to Mr. Pease for some questions.

Mr. PEASE. Thank you, Mr. Chairman, and thank you, Mr. Barnes.

I first would like to welcome the panel, particularly Ms. King for whom I have long had a very high regard.

It is a pleasure to see you here in your official capacity.

I would like to ask some questions. I am not nearly as expert in this field as Mr. Barnes is. I am seeking information.

I was late in appearing. I apologize for that.

PRESENT HAZARDOUS SUBSTANCES EXPORT POLICY

Will someone tell me succinctly what the administration's policy is now on the export of hazardous materials?

[No response.]

Mr. PEASE. Silence means no policy?

Mr. HARRIS. Well, what we have been asked to do here is to discuss with you and to give you a status report of the development of such a policy.

We are nearing the final stages of the development of an administration policy on the export of hazardous substances.

We have arrived, through a 2-year period of discussions and negotiations among ourselves, at a consensus, represented by my testimony, on those points that we feel should be included in the administration policy. We hope that that policy will be finalized and will be acted upon within the next couple of months.

Mr. PEASE. Thank you.

Would it be fair to say then that at the moment, there is no official policy in place?

Mr. COHEN. There is a policy in place, as far as various statutory requirements for notification and, in some circumstances, authority to prohibit the export of certain products.

There are also a variety of initiatives in the international arena which the State Department has outlined. These, in sum and substance, constitute U.S. policy.

I think that those are the two centers of the administration policy at the moment.

Mr. PEASE. Can someone make an estimate of what proportion of the problem of hazardous materials being subject to export is currently covered by legislation of one kind or another?

Mr. MOYER. With respect to bans or validated license requirements for particular exports the most prominent existing control is the FDA area with respect to foods, drugs, and cosmetics.

There are now no export controls within the meaning of the Export Administration Act in place.

The notification provisions that are in place are varied, and they are in at least five different statutes and presently in three different forms. Those are the existing notification procedures that are now a matter of law and being followed.

Mr. BINGHAM. Would you yield?

Mr. PEASE. Yes; I would be happy to yield.

Mr. BINGHAM. I understood you to say earlier that under the existing FDA procedures, drugs banned or not approved by FDA may not be exported.

Mr. MOYER. That is correct.

Ms. GILLMAN. That is right. That is correct.

Drugs that are not approved in the United States, as a general rule, cannot be exported.

Furthermore, under the Toxic Substance Control Act, there are two classes of chemicals that may not be exported at all, which is PCB's, which may not be exported for any use, and fluorocarbons, which may not be exported for certain uses.

So there are export bans for at least two classes of chemicals under the law, and I think, as Ms. King has pointed out, there are certain circumstances under which consumer products may be banned for export.

Mr. PEASE. Is it the expectation that the administration policy, when it is finally adopted, will require legislation?

Mr. HARRIS. No. We think that this policy can be adopted under the current Export Administration Act of 1979. This act, in fact, gives the authority to do precisely what we are proposing to do.

FOREIGN POLICY CONCERNS

Mr. PEASE. Would the State Department witness agree that the export of hazardous goods from the United States is injurious to the foreign policy of the United States and to the reputation and the credibility of the United States as a responsible and moral partner in the community of nations?

In other words, have we had complaints from other nations about the export of hazardous materials?

Mr. HAYNE. To my knowledge, sir, we have had no official complaints, though this may have happened over the period of years, and I would not necessarily be familiar with it.

Of course, we hear complaints from within the United States by American groups, and there may be similar complaints from other private groups in other nations.

I would like to go back to your previous question. You asked about our policy.

I believe I mention in my testimony the question of the export of hazardous wastes that we have to face.

There being no regulations or laws which could prohibit that, we, nevertheless, established a policy on this by asking all of our embassies to report and unilaterally adopt a policy of notifying foreign governments of the risk which they faced and informing them also that we would make the information public.

In other words, we mean that we are against the unregulated export of anything to a destination which cannot adequately control it.

So I must say we are very much in accord with the objectives of this piece of legislation.

Mr. COHEN. May I add, Mr. Chairman, that while we are carefully saying there have been no official protests by the community of nations, Esther Peterson has done some international travel with regard to the work of OECD.

At about every location to which Mrs. Peterson goes she is approached on the issue of the export of hazardous or banned products from this country, such as, for example. TRIS-treated sleepwear to the European Community, leptophos to Egypt, and there are other examples in our report.

Mr. PEASE. But we have had no government-to-government complaints as far as you know?

Mr. HAYNE. None that I know of, sir, but I would not necessarily be in a position to answer that.

Mr. PEASE. All right.

Would you agree then, in that case, that the export of hazardous goods constitutes an injury to the foreign policy of the United States?

Mr. HAYNE. I think it well might do so in the circumstances about which we have talked. And even if we do not receive an official complaint, if it damages our reputation, or if it damages the health and the environment of other people, it would injure our foreign policy.

POLICY OF OTHER INDUSTRIALIZED NATIONS

Mr. PEASE. Is there any other nation, Western nations especially, which has in place some sort of policy regarding the export of hazardous goods, Germany, France, Great Britain?

STATEMENT OF ANDREW KRULWICH, GENERAL COUNSEL, CONSUMER PRODUCT SAFETY COMMISSION

Mr. KRULWICH. The possibility of international controls, or consideration of international systems on export controls, are under active consideration at OECD, at the European Economic Community, as well as in the U.N.

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These are programs that are at various stages of consideration and various stages of development, but it is a very actively debated issue in the international community at this time.

I am not aware of any programs that are actually in place in the countries, though.

Mr. PEASE. Has there been any testimony on the effect of restrictions such as the ones about which we are talking on U.S. exports, which we are trying to promote?

Mr. MOYER. Congressman Pease, I mentioned in my testimony that the total impact of the policy that we have proposed, which is described in Mr. Harris' testimony, would be negligible because the export bans would apply only to those very seriously hazardous substances.

VIEWS OF IMPORTING NATIONS

Mr. PEASE. Has question been raised about the responsibility of our Government versus the responsibility of the government of the importing nation regarding the protection of the health of their people?

That is a philosophical question, I guess.

Ms. KING. The notification system with which we are now operating in the Consumer Product Safety Commisson has been very graciously and eagerly received by the foreign governments that we have contacted and that have responded to us.

The point that we made in the testimony is that this is a two-way street, and the United States has an active national interest in promoting a broader exchange of information so that we are not the only country in the position of gathering information; and U.S. manufacturers should not be penalized for being willing to make information available to the government for transmission to other governments.

We believe that it is in everyone's interest to promote a much broader exchange of information.

Mr. PEASE. Would that argument then be in favor of a general policy of notification rather than restrictions on exports?

Ms. KING. From our own perspective, we have said, and I think that everyone at the table agrees, that there are instances in which the export of a product may pose such a serious hazard either to the people of the receiving country, to the neighboring countries, to the general environment, or perhaps even to U.S. citizens or U.S. residents by way of reimportation that it is imperative, we think, that there be the opportunity and the authority for the exercise of discretion to ban exports, and to ban exports totally, when that is deemed to be appropriate.

Mr. PEASE. Yes.

Ms. KING. The case of TRIS-treated children's sleepwear is very clearly an example of that.

There was an international uproar in response to U.S. manufacturers seeking to export TRIS-treated products after the products had been banned from the U.S. marketplace. The Consumer Product Safety Commission did take action to ban the export of those garments

I must say that without a more comprehensive system than exists today, it is difficult for a very small agency to police the worldwide market; international cooperation is very, very important.

Mr. PEASE. Thank you.

In the discussions that are going on in the international fora, is there any discussion of the, again, general philosophical question of the tradeoffs, particularly in the LDC's of progress versus safety?

In other words, in some of these situations I can envision where the entire atmosphere is so primitive and unsafe that it is almost laughable to think of adding protection as well from some minor substance that might be exported.

Ms. KING. If I may respond briefly to that; I am sure others would like to as well. Obviously, that is a point of great concern that is very often raised in the industrial and agricultural chemicals area where you have very serious competing interests which may involve life-and-death questions. The question here is one of balancing, surely.

The first and most important aspect of this is the ability of the importing government to have adequate and full information on which to base a decision. Likewise, the U.S. Government should have similar flexibility to decide whether to ban the export of a particular product because what may be a risk here may be the norm for the population of the individual importing country.

Secondly, I do not think that we would find, over time, nor do the developing countries have to find, that economic growth and stability are inconsistent with health and safety and environmental protection.

Had we known 20 years ago some of the things we know now, we might not be faced with some of the problems we now face.

Many developing countries have at hand information which will enable them to make much more informed choices than we were able to make. And I think that some of the mistakes that have been made in the past do not have to occur again.

This should be encouraging in terms of the developing countries.

Mr. PEASE. Well, again, that seems sensible if the stress is on notification rather than the banning of exports because if we ban exports of hazardous goods, we are taking the decisions out of the hands of the receiving country.

Ms. GILLMAN. The emphasis, I do not think in any of these policies or in Mr. Barnes' bill, is not on the banning of exports.

I think the emphasis in his bill and in some of our policy, too, is along the lines of the resolutions passed twice under the United Nations' environmental program by the governing council in which the Third World countries themselves asked for protection by the industrialized countries: Not to export banned hazardous substances without the knowledge and consent of the importing country.

So I think that Mr. Barnes' approach, and our approach, too, takes that into account.

Mr. PEASE. Well, I am happy to hear that because I think, for example, of pesticides. It is one thing to ban a pesticide when you have a population in the United States that is not in danger of starvation. It is another thing to ban it in some under developed country where a pesticide may make a difference in having a harvest or not having a harvest at all of some basic crop.

Mr. HARRIS. May I respond to that?

Mr. PEASE. Surely.

Mr. HARRIS. I think that perhaps it has been said by others, but there are clearly going to be close calls in decisions that will be difficult to make for the very reasons that you point out.

I think we recognize that we do not want to get into a position of disallowing the export from this country of something that may not be acceptable to us, but may be clearly acceptable to another country under their economic and social condition, such as a medical device that if they had to do without they would not have anything, an X-ray machine that does not pass inspection here, as an example. But I think that in many, many, many of these cases we are talking about situations where the exporting of certain products is merely an action of dumping these products, and a banning action would more than likely reduce our economic position and have an adverse effect on the companies involved. I think that the TRIS-treated sleepwear is an example of that.

There are products where there are alternatives, and there are such alternatives at the same cost, or perhaps even at reduced cost.

As to pesticides, as an example, some pesticides are extraordinarily hazardous. Effciency has not been demonstrated for certain pesticides; in many other cases, there are pesticides to which there are alternatives which are equally or more efficient than a product that is being banned.

And finally, I think it is clear, for me, anyway, that we do have a responsibility, a moral obligation, not to allow an export that will injure the health, safety, or the environment of another country, and that we have that responsibility, certainly, in those countries that do not have an apparatus for evaluating, a health minister, or the ministries, or an agency that can evaluate the reams of data that are produced on substances or particular chemicals.

That situation is not one of their wanting that product, but of simply not responding, let us say, to information, not knowing how to respond to it.

I think we have an obligation, where we know that a product will be damaging and where there are alternatives, to exercise that responsibility and disallow the exportation of the product.

Mr. PEASE. Well, I was with you up there until the end.

What you are saying, it seems to me, is that if the LDC is not in a position to make a judgment, that we ought to make the judgment for the LDC. We ought to make the decision on the tradeoffs between whether we will allow a particular pesticide or whether there will be a crop of corn in that country the next year.

Is that what you are saying?

Mr. HARRIS. No; I think that none of these actions that would be taken, at least under our policy, would be done outside of consultation with the country and if, indeed, the officials in that country wanted the product, then, in all likelihood, it would not be banned, or disallowed.

Mr. PEASE. What you were saying: You were setting a situation where there was no one with whom to consult who knew anything in the receiving country.

Well, I have been playing somewhat the devil's advocate here this afternoon.

I think it is pretty difficult for anybody to be opposed to some kind of restrictions on the export of hazardous goods, and I would not expect a flood of witnessess to come in and oppose this bill.

But we hear a lot the expression about something having "a chilling effect."

We hear from businessmen, time and time again, who are involved in the export business that they have to go through a lot of rigamarole in order to export, and many of them make the decision not to bother.

Many U.S. corporations that could effectively compete overseas do not try because they think it is more trouble than it is worth. That may be real or imagined.

But to the extent that we add another application form, another review process, and so on, we do, I think, run the danger of discouraging U.S. firms from trying to export overseas.

So I think it is worthwhile to try to examine the tradeoffs, to try to examine how many different kinds of products would be subject to the application and review procedure and all the rest versus how many or what percentage of that number is likely to provide a genuine risk, to examine what the real cost would be versus the benefit. That is really the reason I have been asking these questions this afternoon.

I am grateful to the chairman for indulging me in doing so.

Mr. BINGHAM. Thank you, Mr. Pease.

Mr. Barnes.

Mr. BARNES. We have kept the witnesses for almost 2½ hours now. I have some other questions. Perhaps I could submit those in writing, and see if the witnesses would be prepared to give us some responses.

Mr. BINGHAM. I suggest that the gentlemen continue for at least 5 minutes.

Mr. BARNES. If the chairman is prepared to stay a few minutes, I will ask a few questions.

Let me make one comment, and that is with respect to this point that my colleague from Ohio raises about the capability of the LDC's to make these judgments.

Last week we had testimony from the President of the International Organization of Consumer Unions who was presenting the international perspective on this issue and commenting about the view relating to the exportation of hazardous goods from developed countries, and the view of those in less developed countries.

He showed us some clippings about the attitude toward the United States because of certain actions that have been taken in this area, and he specifically addressed this question that the gentleman from Ohio raises by saying that a bill like this, or the concept of this bill is necessary in the developed countries to deal with what he called the "unholy alliances that so readily develop between greedy businessmen and bureaucracies in many developing countries. That situation is often compounded by a general lack of information and technical skills and the general discouragement of participatory forms of government."

What I guess he is suggesting is that we do not have a Consumer Product Safety Commission in every country of the world with commissioners as dedicated as Ms. King and others to protecting the citizens of the United States, and it is not unrealistic to recognize that as we develop a policy which is humane and responsible and consistent with our foreign policy.

Let's move to what that policy will be if it ends up being the policy that is being developed in the working group, which we hope we will see very soon.

EXPORT OF PRODUCTS RECALLED FROM DOMESTIC MARKET

What happens under the policy, as you envision it, when a product which is already on the market is banned, as in the TRIS case? Would it still be exportable until this interagency process is completed, and it produces a decision to put this on the commodity control list, or would there be a stay of exports?

What would the process be?

Ms. KING. In the case of TRIS, that specific example, until there is a fully developed policy such as the working group is preparing now, the Consumer Product Safety Commission does have statutory authority to move in this area with regard to a product over which we have jurisdiction.

Maybe we can pick a different example.

Mr. MOYER. Let me respond, if I may, because under our proposal, the action would be under the Export Administration Act, and it would simply apply to items on the commodity control list. It would impose foreign policy controls on a particular substance.

That is a step that can be taken very rapidly when the needs so require. So there need not be a lengthy delay between the discovery—to follow up on your example of a particular hazard associated with a substance or a product already on the market—and action to control the exports.

EXPORT OF HAZARDOUS WASTES

Mr. BARNES. In the community that I represent, we have a problem with where to put our sludge, and it has been suggested, I take it from reading the newspapers, by people who are otherwise serious individuals, that we export it to Haiti.

What would the administration's policy be with respect to hazardous waste?

We presently have this policy of notification of our embassy personnel, but how would the new procedures work as envisioned under the program being developed, Mr. Hayne?

Mr. HAYNE. Are you speaking of sludge in particular now?

Mr. BARNES. No. I just used that as an example.

Mr. HAYNE. I know more about D.C. sludge than I care to admit. I have someone with me who knows even more.

Mr. HAYNE. It is a perfectly respectable project. It could be of benefit to everyone concerned.

The Haitian project, I believe, has been canceled. This same sludge, I believe, is going to Antigua if that works out.

Mr. BARNES. Well, what would the policy be with respect to hazardous waste, generally, under the new procedures which are envisioned?

Mr. HAYNE. We intended, at this point, to separate these because we were moving more quickly with hazardous waste than we were with hazardous products. They both would come under the Export Administration Act.

We expect to get something in place with respect to hazardous waste possibly within a month.

Mr. HARRIS. So right now hazardous wastes are not included in the draft policy.

RESTRICTIONS OF EXPORTS DURING POLICY IMPLEMENTATIONS

Mr. BARNES. Under the draft policy, what happens while you are considering which items get placed on the commodity control list?

Is there a danger that there would be some sort of rush to dump, by manufacturers, the products that might conceivably end up being banned from export? Is that problem considered?

I might defer to others about what length of time it might take to effect some action on this. But there would be some period of time that would be required before a product would be considered for the commodity control list.

I assume that during that period of time, there is nothing in the policy that would prevent its exportation.

Mr. MOYER. I might say, generally, that one of the attractions of the Export Administration Act, and the foreign policy controls, is the flexibility that it affords, and that includes the flexibility to move very quickly in response to a particular situation as well as the flexibility to consider the particular circumstances of a particular product on a case-by-case basis.

As to the hypothetical that you pose, if that situation arose, we would have the flexibility there to move very quickly to deal with it.

Mr. BARNES. We have a vote under way, but let me ask: Is there any distinction in the policy that you are developing between products that have simply not yet been approved for domestic use, and those products which have been affirmatively disapproved, where action has already been taken? How is that addressed?

Ms. GILLMAN. The way that that is addressed is that there are only two classes of products that are like that. One is drugs, for which exportation comes under the Food, Drug and Cosmetics Act. At the moment, you cannot export unapproved drugs. Thus, in this regard, what we are really talking about as a practical matter, is unregistered pesticides.

The way the policy would address unregistered pesticides, of which we believe there are about 25 generically now being exported, is that only they would be among the substances which could be considered for commodity control, but only under very unusual circumstances.

These would be pesticides which had not been regulated, for which there was no regulatory record. So only if something really terrible came along, would the State Department and the Commerce Department be likely to say that such pesticide should be on the commodity control list.

In addition, there is another group of pesticides which are rather anomalous because they have been very stringently regulated. This would include a pesticide such as Dieldrin, which is registered but only for very, very limited use in the United States.

Now, those pesticides would be on the list of substances from which certain ones might be placed on the commodity control list, and it is kind of an anomaly that such pesticides actually, some of them, now escape the notification provisions of FIFRA. But they would be on the group of prohibited and significantly prohibited substances from which the group could choose as candidates for the commodity control list.

Did you want to add something, Ed?

Mr. COHEN. I will make one additional point: This small group of pesticides which is registered for extremely narrow purposes is not addressed, one way or another, in your bill. There are approximately 17 of those.

Mr. BARNES. I see.

VALIDATED EXPORT LICENSE PROCEDURE

Let me ask one question about the procedures.

As I understand the process that is envisioned by the working group, it is going to be a rather cumbersome process.

An application would first go to Commerce, then to State, then through an interagency process chaired by State. Then State would make a recommendation to Commerce, and then Commerce would make the determination.

Is that sort of the way it would work?

Mr. COHEN. There are two separate processes. The first process is placing a particular product on the commodity control list itself, and that is preceded by taking a universe of products—that is, those which are subject to definition—and having this interagency task force chaired by State determine which of those pose such severe hazards that they may result in adverse foreign policy ramification for the United States.

That determination is made by the State Department and is based on the advice of the task force. The recommendation is made to Commerce that a particular product should be placed on the commodity control list. Commerce would then proceed with its established procedures for placing a product on the list.

The second process occurs when an exporter wants to export a particular product which appears on the commodity control list. In order to accomplish that, application is made for a validated export license. The State Department is asked, during the course of considering that application, to consult with the foreign government.

So there are two separate processes: First, placing it on the list. Second, responding to an application for an export license.

Mr. BARNES. All right.

Thank you very much, Mr. Chairman.

Mr. BINGHAM. I have two or three quick questions.

EXISTING STATUTORY AUTHORITIES

You have mentioned the TRIS-treated garments which have been banned. Under what authority were they banned?

Ms. KING. The Federal Hazardous Substances Act.

Mr. BINGHAM. Which provides for the ban on export of hazardous substances?

Ms. KING. Yes. The TRIS-treated garments were removed from the domestic market in 1977, I believe, April 1977.

After they were removed from the domestic market, the Commission voted, in June of 1978, to prohibit their export. This action was possible because the garments had, in fact, moved in domestic commerce.

Mr. BINGHAM. I see.

You have mentioned that products can be banned for safety reasons under the Export Administration Act.

Have there been any such cases to date?

Mr. MOYER. There has been none so far.

Mr. BINGHAM. And finally, as I mentioned the other day, I am interested in this question of Depo-Provera, which has been approved by WHO but not by FDA.

Does that come under the automatic ban of the provision on exportation of drugs not approved by FDA?

Ms. GILLMAN. It cannot be exported. Under the law, it cannot be manufactured or exported from the United States.

Mr. BINGHAM. In your task force, have you considered this question of standards adapted by U.S. agencies that might be different from those adopted by an international agency such as WHO?

Ms. GILLMAN. We did not consider asking for changes in legislation. Our policy was developed under the framework of the existing law.

Mr. BINGHAM. I want to thank you very much.

The hearing is adjourned.

[Whereupon, at 4:35 p.m., the subcommittee adjourned, to reconvene at the call of the Chair.]

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EXPORT OF HAZARDOUS PRODUCTS

TUESDAY, SEPTEMBER 9, 1980

HOUSE OF REPRESENTATIVES,
COMMITTEE ON FOREIGN AFFAIRS,
SUBCOMMITTEE ON INTERNATIONAL
ECONOMIC POLICY AND TRADE,
Washington, D.C.

The subcommittee met at 2:15 p.m., in room 2255, Rayburn House Office Building, Hon. Jonathan B. Bingham (chairman of the subcommittee) presiding.

Mr. BINGHAM. The Subcommittee on International Economic Policy and Trade will be in order.

Today the subcommittee continues its hearings on the export of hazardous products. The subcommittee has held two hearings on the bill introduced by our colleague, Congressman Barnes, and on an early draft of the administration's hazardous substances export policy. A new draft of the administration's policy has now been published for public comment in the Federal Register.[1]

The main purpose of today's hearing is to offer those citizens who wish to do so an opportunity to comment on the policy in a public hearing.

That's all I have to say at this point.

Mr. LAGOMARSINO. I have nothing.

Mr. BINGHAM. Mr. Barnes, do you have a statement?

Mr. BARNES. Yes, Mr. Chairman. Thank you. A brief statement.

Mr. Chairman, I am extremely pleased that we are continuing our hearings on the need to establish a Federal policy to control the export of hazardous goods. As I said before, I find it totally unacceptable that this country allows the selling to less developed countries without adequate restrictions products such as pesticides, toxic substances, contaminated foods, dangerous contraceptive devices, known carcinogens, and other products that we have determined are hazardous to the health of our own citizens.

The problem is clear: The United States needs to take swift action to control these exports which are injurious to our national integrity, our reputation as a responsible trading partner, and our duty to protect the lives and health of our friends worldwide.

For far too long, the United States has not taken into account the injury done to our foreign policy when we consider our export policy. Given the country's current balance-of-trade deficit, and the general

[1] See Federal Register, Tuesday, Aug. 12, 1980, vol. 45, No. 157, p. 53754.

economic situation as a whole, we must do all we can to enhance the value and respect of the label "Made in the U.S.A."

In introducing H.R. 6587, I have proposed what I believe is a firm response to the current hazards to the public health and the environment. The bill corrects the current maze of laws applying to individual product categories. It addresses the current lack of uniformity. It provides what we need for controlling those exports—a strong public mechanism for saying that these exports will be permitted only when the producers of hazardous products obtain export licenses from the Government.

My thinking in the past has been that a simple notification procedure is not sufficient. Notification is not control, and notification allows for the kind of slippage which is extremely troubling.

I am pleased that we have before us today the Carter administration's final version of its proposed policy to address this problem. During our June hearings, the administration clearly articulated its agreement with the principles in the bill, and indicated there is no question that the dumping of toxic materials abroad to bypass stringent regulations here at home is indefensible.

However, the administration also argued that there is no need for additional legislation to accomplish this goal. The administration position is, as I understand it, that the appropriate vehicle for instituting the needed policy is the Export Administration Act of 1979, which already contains Presidential authority to impose controls on the export of hazardous products.

I want to say at the outset that I approach this hearing today with an open mind on the proposed Presidential order. I think that our hearings today can and must address two serious and crucial questions:

First, we need to have a full and complete discussion of the strength, depth, and coverage of the proposed order. The administration has been working on this proposal for over 2 years. I have read the report of the interagency working group, and I am impressed with it. It is a good-faith effort, and I commend those who have worked so continuously to solve this problem.

Nevertheless, it is obviously also a product of many compromises, and I have not yet decided whether the proposed order precludes the need to redraft the legislation which I had earlier introduced, for possible introduction next year.

Second, we must address the institutional question of the constitutional role of the Congress, as a legisative body, versus that of the President, as the Executive. There are both advantages and disadvantages to resolving the problem of exporting hazardous goods through Presidential order. It is swift, flexible, and nearing completion.

But, on the other hand, it is not as durable as a public law. Will the problem persist for decades to come? Will the Executive mechanism survive budget cuts and program reshuffles? These are questions which demand our attention, and I am optimistic that the hearings today will help us to answer them.

Again, Mr. Chairman, I thank you for scheduling these hearings. I commend you for it, and I thank you for the time to make this opening statement.

Mr. BINGHAM. Thank you, Mr. Barnes.

I am gratified that we have so many visitors today. In view of the crowd, and the fact that you are obviously very uncomfortable, staff will explore the possibility of moving this hearing down to the main committee room, where we would all have plenty of room.

Our colleague, Mr. Gibbons, a member of the Ways and Means Committee, has submitted a brief statement which he has asked me to submit for the record, and without objection, that will appear in the hearing record.

[Mr. Gibbons' statement follows:]

STATEMENT OF HON. SAM M. GIBBONS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Mr. Chairman, I want to commend you for scheduling today's special hearing to evaluate the Administration's proposed hazardous substances export policy.

I was alarmed and gravely concerned to learn of the dumping of dangerous products on less developed countries that are not in a position to set safety standards or have the necessary tools to control imports. The exportation of any product considered unsafe for Americans should be forbidden. Such practice should be condemned. It seems to me that allowing such exports to continue will only damage our reputation as fair traders.

It would be unconscionable on our part to stand back and allow this traffic in hazardous products to continue. How can we expect to develop markets for our products abroad if the products we export are toxic and deadly? I strongly urge the Administration to forge an export policy that protects the health and safety of consumers wherever they may be and preserve the integrity of the label "Made in U.S.A." Dumping of defective medical devices, lethal drugs, toxic pesticides, contaminated foods, can hardly be considered good business. As a member of the House Trade Subcommittee I support action to halt such practices.

Thank you for allowing me to submit this statement for the record.

Mr. BINGHAM. In view of the large number of witnesses today, I will urge the witnesses to be as brief as possible and summarize their statements where possible.

I am told that we can move to the full committee room, but we have to vacate it by 4:30. By that time, perhaps the interest will have subsided. And we can come back up here at that time. So we will adjourn now to room 2172 on the first floor.

[Whereupon, a brief recess was taken.]

Mr. BINGHAM. Our first witnesses this afternoon are Mrs. Esther Peterson and Mr. Robert Harris, cochairs of the administration's Interagency Working Group on a Hazardous Substances Export Policy.

Welcome, once again, Mrs. Peterson and Mr. Harris. I understand you have a joint statement. Will you proceed as you see fit.

STATEMENT OF ESTHER PETERSON, COCHAIRPERSON, INTERAGENCY WORKING GROUP ON A HAZARDOUS SUBSTANCES EXPORT POLICY

Mrs. PETERSON. Thank you. I do appreciate the opportunity to appear before you. As the cochairman of the task force, I want to say that I have with me people who assisted in the preparation of the working group's report. They are Mrs. Gillman, on my left; Edward Cohen, on my right; and Andrew Krulwich, who is here from the

Consumer Product Safety Commission, and has been handling some of the work on the OECD.

We are particularly grateful for your interest in helping us with this. I also wanted to say at the beginning that I view this hearing, as I hope you do, as one to catch up on where we were before. The reasons for undertaking this initiative were described and well established in our previous testimony. Therefore, I will not repeat that today.

What I want to do is to state where we are and what the principles are, so we can proceed from there—so we can get your help and assistance for the working group that will be having to put all this together.

When Dr. Harris testified before the subcommittee in June, the working group had reached an agreement in principle on the policy. I am pleased to say that our agreement in principle has been translated into a revised report, which has now been published in the Federal Register for public comment. The report contains a detailed listing of existing statutory authority and procedures and proposes a policy to govern the export of banned or significantly restricted products from the United States.

POLICY CONSIDERATIONS

I must say, in all candor, Mr. Chairman, this has been a very difficult problem to grapple with, and one which has required a delicate balancing of considerations, and taken far too long a time, but a process through which we felt we had to go.

I would like to reiterate briefly what those considerations we took into account are.

First, as a nation exporting banned or significantly restricted substances, the United States is obligated to recognize and assist in controlling the potential effects of these substances on the health and safety of citizens abroad and on the world environment.

Second, nations differ substantially in their economic and cultural conditions, and in their use of and need for hazardous substances. It is difficult for one nation to make decisions on the acceptability of risks for other nations. Such assessment requires extensive information regarding economic, political, and social conditions which our regulatory agencies may not have and may not be able to readily obtain.

Third, U.S. relations with other countries could be harmed by the unrestrained export of substances which are banned, or significantly restricted, in the United States.

Fourth, export of these products could undermine confidence of foreign buyers in U.S.-made goods and could jeopardize their sale abroad.

Fifth, excessively restrictive limitations on the export of products which a foreign country may decide it needs, could place U.S. firms at a competitive disadvantage and harm U.S. relations with the government of that country.

Sixth, excessively restrictive limitations could also place significant economic burdens on the U.S. economy, including adverse effects on the balance of trade and payments, on output and jobs, and perhaps on domestic competition.

Seventh, an export policy should be administratively simple and inexpensive to implement, and should recognize the complexities of international commerce.

Eighth, the United States should encourage and participate actively in international initiatives to develop consistent policies for hazardous substance exports, and for the sharing of data, analyses, and information. The effectiveness of unilateral U.S. action could be substantially diminished if foreign facilities or firms were to become alternative suppliers of substances which U.S. policies seek to control.

And ninth and last, the United States should attempt to protect citizens in our country against the dangers to their health and safety of importing hazardous substances and their derivatives or residues, and of damage to the world environment.

These were the considerations that were taken into account by the working group as it developed the policy that we are working on.

And, Mr. Chairman, the report and proposed policy which appear in the Federal Register very closely reflect the proposal as Dr. Harris described it to the subcommittee in June. That policy contains the following components:

HAZARD NOTIFICATION

First, in most circumstances, we believe that the international responsibilities of the United States are fulfilled by an effective system of hazard notification. Existing regulatory statutes already require notification of the export of many banned or significantly restricted substances.

However, we believe that these notifications of shipments can be more effective if a more uniform procedure is followed by all Federal agencies. Thus, our proposal provides that notification of shipments would occur through the State Department, and that it would be the responsibility of the State Department to forward the notification to the appropriate government officials of the country of destination through the U.S. Embassy in that country.

U.S. regulatory agencies could also make direct contact with their counterparts in the foreign country if they wish to, or if they are required to do so by law.

In addition, the policy would make the content of the notification more uniform.

We believe that regularizing the notification process will increase the likelihood that the notification will end up in the appropriate hands in the foreign government.

Also, foreign officials will know that there is one location with the U.S. Government where they can turn to for information on hazardous substances.

SUMMARY OF REGULATORY ACTIONS

A second feature of the proposed policy is the publication each year of a summary of U.S. regulatory actions taken during the course of the year regarding banned or significantly restricted hazardous substances for domestic use. The summary would also include proposed regulatory actions to ban or significantly restrict substances that were pending

before agencies at the close of the year and that were of significant international interest.

We believe the summary would serve to alert foreign governments to the hazards of substances that they might be importing from other countries. It would thus be an important factor in curtailing international trade of banned and highly dangerous hazardous substances.

It would also allow a foreign government to take regulatory action that it might deem appropriate near the same time that U.S. regulatory action takes place.

EXPORT CONTROLS

And third, the working group proposal recognizes that in some very limited circumstances, additional safeguards are needed to assure good and stable relations with other nations in the world community. The failure to exercise special vigilance over the export of some banned or significantly restricted products which are particularly hazardous could adversely affect our economic and diplomatic relations with other countries.

This additional control would be exercised under authority that now exists under section 6(a) (1) of the Export Administration Act of 1979.

This section authorizes the President, and I quote:

> * * * to prohibit or curtail the exportation of any goods, technology, or other information, to the extent necessary to further significantly the foreign policy of the United States or to fulfill its declared international obligations.

The authority contained in this subsection is to be exercised by the Secretary of Commerce, in consultation with the Secretary of State and such other departments and agencies as the Secretary of Commerce considers appropriate. It is to be implemented by means of export licenses issued by the Secretary.

The working group's policy provides that the Secretary of Commerce require a validated export license for those prohibited and significantly restricted products which, if exported, would prove detrimental to the foreign policy interests of the United States. The products on which these export controls would be imposed would be chosen in the following manner:

An interagency task force, chaired by the State Department, and composed of the Department of Commerce, the Environmental Protection Agency, the Consumer Product Safety Commission, the Food and Drug Administration, the Office of the U.S. Trade Representative, and the Council on Environmental Quality, would consider which substances covered by the policy should be subject to export controls.

The task force would advise the State Department as to which of the listed products should be considered candidates for inclusion on the commodity control list, because of the especially severe hazards that their export would pose.

In so doing, the task force would consider, to the extent possible within the limits of available information, the type, extent, and severity of the potential detrimental effects of each substance proposed for inclusion on the commodity control list by a member of the task force; the likelihood of the effects; the duration of the effects; the

ability of foreign countries to avoid or mitigate the effects; the availability of the substance from sources other than the United States; the availability of other substances or methods that would serve the same purpose as the substance to be exported; and the importance of the beneficial uses of the substance (not intended to require rigorous quantitative analysis of costs and benefits).

The function of the regulatory agencies on the task force is to provide technical advice to the State Department on the basis of available information compiled in the course of previous regulatory proceedings.

With the benefit of this advice, the State Department would identify, subject to the concurrence of the Secretary of Commerce, those relatively few banned or significantly restricted substances which should be included on the commodity control list, because controls on their export would further significantly the foreign policy of the United States, or would fulfill the declared international obligations of the United States.

The act mandates a number of procedural and substantive requirements which must and would be met in invoking foreign policy controls.

Once all of these statutory requirements for imposing export controls were met, and the hazardous substance has been placed on the commodity control list, an exporter would have to apply to the Commerce Department for a validated license before exporting that substance.

The act sets forth specific statutory deadlines for processing applications. The Department of Commerce would make the decision on whether to grant the license, in consultation with the Federal agency with domestic regulatory authority, the State Department, and any other relevant agency.

Historically, the Commerce Department has rarely, if ever, granted export licenses over State Department objections. In this context, the Commerce Department would continue to give great weight to the State Department recommendations. The State Department would not recommend issuing a license unless it had determined that the export would not be detrimental to United States foreign policy interests, and that the State Department, after appropriate consultations, had received no objections to the export from the government of a foreign country to which the banned or significantly restricted product is being sent.

Other factors to be considered by the Department of Commerce in acting on an application for a validated export license might include: The type of hazardous substance, the destination of the export, the proposed use to which the product will be put, whether the foreign government is the importer, the nature and type of hazards involved, the number of people potentially affected by the hazard, the benefits to be gained by the export—again, this would not be a rigorous quantitative analysis of the cost and benefits—the availability of alternative sources of the substance, the availability of nonhazardous alternatives, precautions the importer will take with the substance, the dangers inherent in alternative substances presently being used, the effect the substance might have on neighboring countries, the potential reaction of other countries, results of consultations with industry

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representatives and other concerned parties, and the results of international efforts to curb the export of the substance. Actual experience in evaluating applications might reveal other factors that should be considered. The Commerce Department would propose and receive comment on regulations governing its consideration of applications for export licenses for hazardous substances.

We believe the procedures that I have outlined in my text, provide a systematic and coherent scheme for exercising authority which now exists in the Export Administration Act.

INTERNATIONAL ACTIVITIES

The fourth component of our proposed policy would be enhanced efforts by the State Department and other Federal agencies, in consultation with the State Department, to seek international agreement in the following areas:

(a) Notification of the export of hazardous substances.

(b) Comprehensive adoption of uniform, readily understandable hazard labeling for substances in international commerce.

(c) Improved worldwide hazard alert systems and clearinghouses for information on health and safety risks in the workplace.

(d) Other common standards and practices related to the export of hazardous substances.

These steps could lead to the formulation of an international convention governing hazardous substances exports.

Common policies governing hazardous exports subscribed to by all countries would help to assure that firms in other nations of U.S. multinational firms located abroad would not become alternative suppliers for hazardous substances. It would also assure that countries like the United States that take responsibility for hazard exports would not be penalized economically.

EVALUATION

And, finally, our proposal provides for an annual evaluation of the effectiveness of this policy.

While this proposal is substantially similar to that which Dr. Harris described last June, there are several points which I believe should be highlighted.

SUBSTANCES INCLUDED

As you may recall, in June we spent a significant amount of time discussing the importance of a precise definition of the substances which would be included within this policy. Dr. Harris indicated that our proposal would contain very precise definitions identifying the products subject to the policy by referring to specific provisions of specific statutes. That, Mr. Chairman, has proved to be an arduous task, but it is now complete, and I am attaching to my testimony a copy of our definition for the information of the subcommittee.[1]

Since Dr. Harris' testimony in June, we have made two modifications in the scope of our definition. One of these changes, and perhaps one

[1] See Federal Register, Tuesday, Aug. 12, 1980, vol. 45, No. 157, p. 53754.

of the most difficult dilemmas faced by the working group, was how to address the problem of unregistered pesticides.

The working group concluded that pesticides for which registration had never been sought would not be candidates for export controls, since U.S. regulatory agencies would not have readily available health and safety test data drawn from regulatory procedures.

Thus, data on which to make decisions on whether to impose export controls might well be lacking. However, in the case of unregistered pesticides for which a tolerance has been denied or revoked, data from regulatory proceedings do exist. Thus, unregistered pesticides in this category would be considered for export controls.

For example, the very powerful and very hazardous pesticide, Leptophos, which was never registered by EPA for domestic use, would be a candidate for export controls, if it were still being manufactured, because EPA denied a tolerance for residues of Leptophos on foods, under authority of the Food, Drug and Cosmetic Act.

It is important to recognize that a pesticide may be unregistered, not because it poses a health, safety or environmental problem, but simply because there is no need or market for the pesticide in this country.

The other modification in the definition relates to "medicines and medical supplies." Section 6(f) of the Export Administration Act excludes from the Secretary's authority under the foreign policy provisions export controls on "medicine or medical supplies."

The working group has asked the Office of Legal Counsel of the U.S. Department of Justice for a legal opinion as to the particular classes of products regulated by FDA which are covered by this term as used in the Export Adiminstration Act.

Mr. Chairman, I believe that we have made substantial progress since your last hearing. We have continued to encourage broad participation from inside and outside Government in the process of developing a hazardous substance export policy. Over 20 agencies are represented on our working group, each bringing a distinct interest and perspective to our efforts.

We have consulted numerous times with industry and labor organizations and consumer, health, environmental, and other public interest groups.

As you know, we are now providing these organizations and groups an opportunity to comment on our revised fifth draft report, a copy of which was published in the Federal Register.

Several commentators have asked for an extension of the 30-day period, assuring us that more detailed and constructive comments would be prepared. Based on these assurances, we have decided to extend the period an additional 30 days, until October 13, 1980.

While this process has moved much more slowly than many of us would have liked, I am pleased with our product. I look forward to the close of the Federal Register comment period, so that we can proceed to conclude this effort.

I thank you for your attention. I would be happy to try to answer your questions.

Mr. BINGHAM. Thank you very much, Mrs. Peterson. I understand you don't have separate statements?

Mrs. PETERSON. No, we put this together as a basic statement for all of us. We thought, however, you could ask questions to any one of us.

EXPORT ADMINISTRATION ACT AUTHORITY

Mr. BINGHAM. Thank you. How was it that the task force centered its attention on the Export Administration Act and its foreign policy control provisions as a mechanism for application in this type of situation? In the debates and committee reports, and all the other background having to do with the Export Administration Act, I think it was clear that Congress had in mind different types of situations when we authorized foreign policy controls. I don't think the Congress really had in mind using foreign policy controls in this type of situation.

Mrs. PETERSON. I think that we had not anticipated the impact of some of the experiences that we have had with the export of hazardous products, and therefore that had not been an item of focus during the time of the debate.

Also my present feeling is that if we can find existing authority to accomplish our objectives then we should utilize what already exists.

So I think we should try to use existing authority to the extent possible. I don't know if Mr. Harris has something to add to that.

STATEMENT OF EDWARD COHEN, DEPUTY SPECIAL ASSISTANT TO THE PRESIDENT FOR CONSUMER AFFAIRS

Mr. COHEN. Mr. Chairman, there is some indication in the committee report of this committee that the export of certain types of products could adversely affect our foreign policy interests and that the act could be used to place export controls on those products. I refer specifically to the reference in the committee report on the export of thumbscrews.

Mr. BINGHAM. Well, as one of the members involved, I can assure you what was in our minds was not that they were inherently dangerous instruments, but that they were instruments of political repression that we wouldn't want to be associated with in terms of exports.

However, I understand what you say, Mrs. Peterson, about preferring to use existing legislative tools, if possible. It does strike me that it may turn out that this particular legislative tool is not particularly well geared to——

Mrs. PETERSON. We have the possibility of agreement within the agencies on the use of the act and I think we have to explore all of those routes.

INDUSTRY RESPONSE

Mr. BINGHAM. Could you tell me what kind of response you have been getting from industry in regard to the proposed draft policy?

Mrs. PETERSON. Well, I think there has been tremendous interest from industry on this. We have had substantial contact but it has been procedural, rather than substantive. One of the reasons I felt we should extend the comment period is because the requests came largely from industry for more time, with the assurance that they would give us constructive, substantive comments. That's one reason

I felt very strongly that we should extend it, so I'm looking forward to more substance in what they submit to us, because actually we have not had a tremendous amount of comment. We have had more from business, I think, than any place.

PROTECTION OF FOREIGN CONSUMERS

Mr. BINGHAM. Is it fair to say in summary that your proposed policy is based on the principle that Third World consumers of our products don't merit the same kinds of protection that American consumers of our products have?

Mrs. PETERSON. Well, you know, I don't want to make a blanket statement, but I do know from having traveled abroad, there are many things we ban in this country for completely legitimate reasons that may be very necessary in other regions.

I have Peace Corps people in my family who have described this to me very adequately. But there is an array of products for which there would be no reason to want to export them because of their severe health or safety problem. This proposed policy is designed to get at these.

Mr. BINGHAM. I have here a number of questions with regard to the procedure. The procedures seem to be quite cumbersome. But I think in the interest of time, what I would like to do is submit those questions in writing.

Mrs. PETERSON. We would be delighted to answer them.

EXPORT ADMINISTRATION ACT AUTHORITY

Mr. LAGOMARSINO. Thank you, Mr. Chairman.

I have one question. There seems to be still, or at least there was some dispute in the administration as to whether or not the Export Administration Act is the appropriate vehicle to use in this case. For example, as I recall, the Special Trade Representative says there is no basis to use it, while the Attorney General says there is. I assume from your testimony that you feel it is appropriate.

Mrs. PETERSON. We feel it is. I think there is one area we raised with the Justice Department to give us some determination in the medical area.

Mr. LAGOMARSINO. Could you offer some examples of the type of substances and products that are not permitted to be sold and the reasons?

Mrs. PETERSON. I'm sorry. The Commerce Department has also determined that we do have the authority. Excuse me.

EXAMPLES

Mr. LAGOMARSINO. Could you offer some examples of the types of substances and products that are not permitted to be sold here under one regulation or another, but that have a valid use overseas?

Mrs. PETERSON. Well, Kitty, do you want to answer this? She is our expert on this.

May I just say in relation to this, in my travel abroad, there is tremendous interest in this question. Of course, the Tris example is the one that is thrown up to me, th last time I was abroad. It came to me

in every country. How was this possible? they asked. Of course, we have taken care of that, but there are others, too. Kittty, you may know some examples.

Mr. LAGOMARSINO. You are saying on the part of other countries, they'd like to have some of these products that are banned?

Mrs. PETERSON. Mainly they want to make the determination themselves whether they want the products or not. That's why I felt so strongly about the notification part, because we don't know the cultural and social conditions of many of these countries.

Mr. LAGOMARSINO. In some cases we have been proven to be wrong.

Mrs. PETERSON. It is not a matter of being wrong. It is, in most cases, preferable for the foreign country to decide if it has the ability to do so. That's why I think it's very good for us to be able to use competent authorities in those areas.

STATEMENT OF KATHERINE GILLMAN, SENIOR STAFF MEMBER FOR INTERNATIONAL AFFAIRS, COUNCIL ON ENVIRONMENTAL QUALITY

Ms. GILLMAN. You are asking for examples of substances that are banned or significantly restricted for use in the United States that might possibly be useful in foreign countries, if they should decide they want to use these substances.

I think that pesticides might offer the broadest area of examples. DDT is often mentioned as an example of such a substance. DDT has been used in the past for malaria control. There are lots of reports nowadays that DDT is losing its effectiveness because the mosquitoes are developing resistance to it. But DDT is often held up as an example of that kind of thing.

Actually, there is a special exemption in the United States which permits use of DDT for public health purposes, but we don't have pandemic malaria in this country. So DDT is something that might indeed be of more use to foreign countries than to the United States.

Mr. LAGOMARSINO. Or a substance of that kind.

Ms. GILLMAN. That's right. You might have public health problems in tropical countries which we don't have at all here. But control of those problems might require the use of a pesticide which we would regard as too hazardous, say, over the long term to our environment to make it worthwhile to use, but other countries might still want to use it.

I don't want to specify pesticides because there are qualifications about many of them. DDT, for example, does seem to be losing its effectiveness in some cases. But pesticides might be the most likely area.

Mr. LAGOMARSINO. But between the time it lost its effectiveness and the time that it didn't, and the time it was banned here, that could be an awful lot of people saved from malaria.

Ms. GILLMAN. I might add, on the question of other countries taking an interest in the subject of export of hazardous substances, that the governing council of the U.N. environment program has three times passed resolutions asking for a degree of control over the export of hazardous substances by the exporting countries. They want to know

if they are going to get substances that are banned or significantly restricted in our country. They have said in their resolutions, they don't want the substances dumped in their countries without their approval.

Mr. LAGOMARSINO. In other words, they want to make the decision based on adequate information?

Ms. GILLMAN. Yes.

U.S. TRADE REPRESENTATIVE RECOMMENDATION

Mr. LAGOMARSINO. Have you seen the recommendation by the special trade representative for the makeup of the interagency task force?

Mr. COHEN. Yes, we have seen it.

Mr. LAGOMARSINO. As I understand, what they would recommend is representation by State, Commerce, U.S. Special Trade Representative, Council on Environmental Quality, and by the one regulatory agency having jurisdiction over the particular product in question.

Now as I understand, that varies somewhat from your recommendation.

Mr. COHEN. Yes. Our proposal would have the task force composed of the three agencies which regulate products subject to this policy. The reason for that is that we want to assure a common level of hazard, if you will, of products which are going to be subject to export controls. For example, we want to avoid subjecting a product regulated by the Consumer Product Safety Commission, which offers a substantially lower level of hazard to export controls while not subjecting ones regulated by FDA or EPA, which offers a substantially higher level.

I think that the thrust of the U.S. Trade Representative's concern in his letter is that there would be a "vote" of the task force, if you will, as to whether or not to recommend that a product be subject to export controls.

We don't envision the task force working on a majority rule basis. Since the statute provides that the State Department makes recommendations to the Commerce Department on whether or not it would enhance our foreign policy interest to subject a product to export controls, it is the State Department who basically has the only vote on the task force. The other agencies provide advice and expertise. We need to explore that recommendation with the U.S. Trade Representative, because I'm not entirely sure what their concern was.

Mr. LAGOMARSINO. I think that might be worth looking at. I think what their concern is—what's an example? FDA having a lot to say about whether a toy is banned, or something like that, with no particular expertise.

Mrs. PETERSON. We are working on that.

STATEMENT OF ROBERT HARRIS, COCHAIRMAN, INTERAGENCY WORKING GROUP ON A HAZARDOUS SUBSTANCES EXPORT POLICY

Mr. HARRIS. I might just add, there are other reasons. Some agencies offer expertise that other agencies don't have, particularly on such things as use patterns and consumer behavior. Where one agency might ban a particular substance, another agency may know something more

about the use of that chemical that would alter the other agency's conclusions about a ban.

Mr. LAGOMARSINO. Actually——

Mr. HARRIS. So it's that sort of cooperation and complementary expertise that we had in mind, in putting all these agencies together.

REGULATORY ANALYSIS

Mr. LAGOMARSINO. Now have you performed a regulatory analysis of alternative approaches related to the burdens and costs for both Government and industry, or economic impact study on the proposal?

Mrs. PETERSON. I think you should answer that. That's a legal one.

Mr. LAGOMARSINO. While you're trying to decide who's going to answer it, there was an Executive order by President Carter implementing the commitment to the elimination of unnecessary Government regulations.

Mrs. PETERSON. Well, as you notice, that is one of the principles that we looked at, that it should be as unburdensome as possible. I think in my experience with this, a lot of this has already been looked at. I think it's a matter of weighing now those few cases which are exceptional, where that would be necessary. But I'd rather the lawyer would answer it.

Mr. COHEN. As a technical legal matter, I don't believe that we are bound by law to do a strict cost-benefit analysis. We have taken a look at both the costs and the benefits of this proposal, as well as alternatives in a more informal manner than perhaps a regulatory agency would do with its regulations.

By and large we believe that from the standpoint of the Government, first of all, the cost of implementing this proposal could be done under existing resources with perhaps one minor exception—the Department of Commerce may need a couple of people.

With respect to the burden on the private sector, we do not believe that there would be any burden with respect to our notification recommendations—either the notification through the State Department or the annual notification. That is a burden that will fall on the Federal agencies. With respect to potential burdens imposed by use of the Export Administration Act, we have made it very, very clear in the report that we believe there will be a limited number of products which should be subject to export controls. I believe that Homer Moyer, who is the General Counsel of the Commerce Department, indicated at the hearing 2 month ago that he felt the economic impact would be minimal.

So while we don't have a precise dollar value, we do not think it will be great.

Mr. LAGOMARSINO. So, therefore, I guess you would answer the proposed policy would not impose a substantial export disincentive.

Mr. COHEN. That's what we believe.

Mr. LAGOMARSINO. Something I think we should keep in mind, since this very same subcommittee is working on legislation, trying to increase exports.

Mrs. PETERSON. My feeling is when we convince the world and these countries that we are concerned about them, that will increase our exports. I feel there is a very positive thing to be added to that.

Mr. LAGOMARSINO. At least they have the information.

Mrs. PETERSON. Exactly. They'll buy with confidence.

SCOPE OF POLICY

Mr. LAGOMARSINO. How many substances do you think the policy might regulate?

Mrs. PETERSON. Kitty.

Ms. GILLMAN. I am not quite sure what you mean by "might regulate." If you mean the substances that might be considered for recommendation to be placed on the commodity control list, we have a preliminary count. We don't have a complete count of them yet, but under the pesticides law, FIFRA, we believe there would be about 70 generic pesticides to be considered. Under the consumer product laws, which are administered by the Consumer Product Safety Commission, we believe there would be about 30 classes of products to be considered.

Not all of these would necessarily make it to the commodity control list. In fact, most of them wouldn't. These are simply the substances the task force would consider for inclusion on the commodity control list.

We don't have quite such a good estimate for classes or products under the Food, Drug and Cosmetic Act. That's the most difficult one to get a count on. There are quite a number of foods that have been found to be addressed or misbranded, but many of them are simply not on the shelf any more. They are not being sold any more. So it's harder to count accurately the substances banned or significantly restricted under this law. But we don't think it's going to be a very large number, maybe a couple of hundred.

Mr. LAGOMARSINO. Just one more question. As I understand the situation, even those, if they were put on the list, would be subject to export controls and validated license. Is that correct?

Ms. GILLMAN. That's right. It doesn't mean they would be banned for export. It only means they would be subject to case-by-case decision.

Mr. LAGOMARSINO. Depending on where it was going and what it was going to be used on?

Ms. GILLMAN. That's right. But we don't anticipate, as we say, that there would be a great many substances placed on the list.

Mr. HARRIS. If I can add one point to that, we don't really know how many products will end up on the commodity control list, because that will be determined by the State and Commerce Departments, with advice from the task force. I believe it will be considerably less than a hundred, without any question. And keep in mind also that what motivated us here in the very beginning, a couple of years ago, was the situation of the export of extremely hazardous products, which no one intended to continue manufacturing and exporting.

We intend the policy to address primarily those situations where manufacturers are trying to dump on unsuspecting nations products which are hazardous and where the export is contrary to our foreign policy interests. In most cases, there would be no intention of further manufacture either for export or for sale in the United States.

Mr. BINGHAM. Thank you.

Mr. Barnes.

DIFFICULTY OF THE PROBLEM

Mr. BARNES. Thank you, Mr. Chairman. The statement that you have published in the Federal Register, says: "Virtually unrestrained export is currently allowed for many substances that are banned from sale in the United States."

There seems to be general agreement that this problem—that some mechanism is needed to address it, whether it's legislative or Executive order or whatever.

Why do you think it's taken so long? I don't mean the 2 years of this particular effort. I just mean it has taken a long time for us to come to a sense this is something that should be addressed.

Mrs. PETERSON. It's really been a very, very complicated thing. Just the matter of the definition. First we agreed to the principle, we agreed on all of that. Then it was implementing the principle and spelling it out, and that's where we got into real trouble.

For example, the definition of products has been extremely difficult. Also the relationships between the various agencies, the various legal authorities, has been a very complicated area. But I want to underline the fact that something had to be done to really pull this together. So we have worked hard, and we all want to hurry and finish it up as soon as we possibly can.

We hope that in the comment period, even though we have extended it, people will be constructive, so we can pull our group together and come to a consensus. We're sorry it's this late, but it's been complicated.

STATEMENT OF ANDREW KRULWICH, GENERAL COUNSEL, CONSUMER PRODUCT SAFETY COMMISSION

Mr. KRULWICH. Mr. Congressman, one of the factors here is that it's only in the last few years that the international community and other countries have become particularly concerned with the problem, and they themselves have taken an interest in trying to address it from the other side, so that the United States isn't subject to products that are banned in those countries, as well.

I think the interest, which works to our economic interest, in the other countries toward doing something about the potential for indiscriminate dumping in Third World countries has come together at this particular time.[1]

Mr. HARRIS. Of course, Congress has not been completely inactive. I think the amendments to the Consumer Product Safety Act and FIFRA requiring notification are important steps forward.

Also, we have debated and found it difficult to educate ourselves and the American public on the long-term hazards associated with some products, particularly some of the chemicals which represent a carcinogenic hazard. There has been an even more difficult problem in bringing this problem to the attention of other countries, particularly when the effects are delayed, when the effects are not precisely known, and when the adverse effect of the import has really not been felt yet.

[1] Mr. Krulwich submitted a prepared statement, which appears in app. 5, p. 245.

So I think we have an additional problem in transmitting information from this country and having it perceived as we do by other countries, particularly Third World countries.

DESIRABILITY OF NEW LEGISLATION

Mr. BARNES. Following up on a question asked about the choice of the Export Administration Act as a mechanism or vehicle for the policy, the Federal Register statement indicates that you don't recommend any changes in existing law. What factors have you used in reaching that conclusion, and what type of evidence would you need to persuade you that there is a need for some changes in legislation?

Mr. COHEN. The particular recommendation with respect to changing laws applies, as I recall, on the section on notification. The purpose for saying or indicating that was that many of the notification provisions in the regulatory statutes are very new, and while they differ from statute to statute on how it's accomplished, we really did not have much experience in determining which is the most effective means for accomplishing notification.

So, it was the consensus of the working group that we ought to have a year or two of experience under the various notification procedures before we would make any recommendations or changes.

Mr. BARNES. There is going to be an additional 30 days for comment ending on October 13. Then what happens?

Mrs. PETERSON. Then we'll analyze——

Mr. BARNES. What is your time frame? Do you have a fairly clear sense of the next step?

Mrs. PETERSON. It depends a great deal on what comes in. I am comfortable with the proposal. But I cannot answer that until I know what comes in in the comments. It's largely for the business community that we are waiting.

Mr. BARNES. Do you anticipate an Executive order?

Mrs. PETERSON. There are a number of alternate ways to implement the policy. That is one way that is possible. Another way, of course, might be a Presidential memorandum. And another is agreement by the relevant agencies. There are at least three ways that we will have to analyze which would be the best way. We're working on that, but I can't determine that until I see what the other comments are. I felt that they felt very strongly that they needed this time. I know it's controversial and difficult, so it seemed only fair to say, all right, let's have that time. And they promised they would come with constructive help on it and I'm looking forward to that.

Mr. BARNES. I gather there has been some hesitancy on the part of the opponents of the policy to testify formally. You're not having the same experience in their interest to submit comments?

Mrs. PETERSON. They have been slow in bringing it in.

Mr. BARNES. Do you anticipate there will be some heavy lobbying to stop this policy before you make the decision, as to how it will be implemented?

Mrs. PETERSON. How can I say that there wouldn't be? I think we have considered very carefully what we are saying, and I think reasonable people will sit down with us and see the need of this. I can't read

their minds on exactly what this will be, but as long as we are fair, and as long as we have ample opportunity for them to register their feelings and make valid objections—we are bending over backwards for that. It's the delay that's bothering me, because it's holding up the whole thing, and I think it's very bad.

Mr. BARNES. As I indicated in my brief opening comments, I am concerned about the durability of the policy and that's one of the reasons that whatever happens, I'm considering some kind of legislative action.

How dependent would the process that you envision be on additional funding? Would the program be either susceptible to disruptions resulting from budget cuts or program reshuffles, changes in administration?

Mrs. PETERSON. Well, it can be subject to that, but also it depends an awful lot on the kind of public feeling and support that Congress gives us. I think the private and public sector are going to feel that this is something necessary to do. I'm hoping it can be done. I'm one for trying what we have. If it doesn't work, we'll have to try another route. I'll be the first one to come up here and ask for it. I might even support your bill.

INTERNATIONAL ACTION

Mr. BARNES. Mr. Chairman, just one other question, and that relates to the situation in the international community. Can you give this subcommittee a sense of what's happening in the OECD and the international organizations?

Mr. KRULWICH. Yes. There is substantial interest in this whole topic in the international community. The OECD has a committee on consumer policy which has made as its first priority the consideration of the export notification system that could be recommended for all the member nations. The notification system is still obviously being worked on and being considered, but it would somewhat parallel the type of program that Congress enacted for the Consumer Product Safety Commission. Under the program, the exporting nations would give notification to the importing nation of the imminent shipment of goods that had been banned or considered hazardous in the exporting country, and then it would be up to the importing country to make up its own mind on the standards to decide whether or not it wanted that product.

It is hard to predict the timing of developments in the international organizations. The task force is hoping to present a report to the OECD committee in December, and we will probably have more definite ideas of timing at that point. All of the member countries on the committee were enthusiastic in terms of making this a high priority item.

Mr. BARNES. Mr. Chairman, I've got a number of other questions, but I will submit some of them in writing.

Mrs. PETERSON. We'd be very happy to answer them.

Mr. BINGHAM. Mr. Pease.

Mr. PEASE. Thank you very much, Mr. Chairman. I apologize for having had another meeting which made me miss your formal testimony. So if I ask questions that have been covered already, I hope people will tell me.

PROCESS FOR GETTING EXPORT APPROVAL

I am interested in the process which an exporter will follow under the policy which has been suggested by the interagency working group. Let's say that I'm an exporter or a manufacturer in the United States of drugs, and I have a new drug for which approval is not affected under section 505, and I want to export it to Zaire. What process do I have to go through in order to do that?

Mr. COHEN. Our proposed policy would not affect that situation at all. It is governed by the provisions of the Food, Drug and Cosmetic Act, which provide that a new drug cannot be exported unless it's been approved for use in this country.

Mr. PEASE. What about if I have a class of food which contains a poisonous substance which exceeded the times or action level in section 406?

Mr. COHEN. Could we generalize the question, rather than apply it to a specific provision of the Food, Drug and Cosmetic Act?

Mr. PEASE. Well, sure. The point is that I have something that I manufactured that would be banned or significantly restricted in the United States, and I want to export that. What do I have to do?

Mr. COHEN. Assuming that you could export it under the existing regulatory statute, and assuming that the required notification has been effected; the question I believe you are raising is how does the Export Administration Act fit in? The exporter wouldn't have to do anything. There is no burden on the exporter immediately. It is only if the following events occur that a burden is placed on the exporter.

An interagency task force chaired by the State Department would meet to discuss whether or not the export of that product poses such an extreme hazard that in the opinion of the Secretary of State, it would hurt the foreign policy interests of the United States. If the Secretary so concludes, it would recommend to the Commerce Department that the product be placed on the commodity control list.

The Commerce Department has a whole series of procedures that it follows, including public consultation and examination of a number of factors which are explicitly detailed in the Export Administration Act.

If, after going through those procedures, it concludes that the product should be placed on the commodity control list, only then would that exporter have to apply to the Commerce Department for a validated export license so the product could be exported, and then the Commerce Department would take in a series of factors whether or not to deny or grant that license.

Is that responsive to your inquiry?

Mr. PEASE. Well, yes, it is. It's very helpful, but I want to go further than that. Let's say I have a product which is not on the commodity control list. Do I have to give notification to anyone?

As I understand it, the object of your policy is that the United States would notify foreign governments that a shipment was imminent Is that only for items on the commodity control list, or is it on other items as well?

Mr. COHEN. It is on those items where notification is now required under existing law. Specifically products subject to regulation under the Consumer Product Safety Act, the Hazardous Substances Act and the Flammable Fabric Act by the CPSC; products regulated by EPA, under FIFRA or TOSCA, and selected products regulated by FDA under the Food, Drug, and Cosmetic Act. There are no notification provisions for only a small number of product categories, however.

Mrs. PETERSON. Excuse me. Would that be something he would know he couldn't market in the United States?

Mr. PEASE. Either they could not market, or it would be restricted, yes.

Mrs. PETERSON. If he knew it were something that could not be marketed in the United States, to export it?

Mr. PEASE. Yes. That's the example I wanted to use.

Mrs. PETERSON. Knowing probably that it was hazardous?

Mr. PEASE. Knowing that it could not be marketed in the United States.

Mrs. PETERSON. And some of our businessmen would be willing to do that?

Mr. PEASE. Oh, I'm sure they would. [Laughter.]

Mrs. PETERSON. I'm sure they would, too, and that's the very thing I wish we could have is a little bit more social conscience and a little bit more cooperation on the part of our business community.

Mr. PEASE. I wish we could, too. Well, let me get back to the example. What you are saying is that under various provisions of the existing law, there are notification requirements specifically for the export of hazardous products?

Mr. COHEN. That's correct.

Mr. PEASE. OK. So there is no new notification requirement other than what is already in existing law?

Mr. COHEN. That's correct, although under the proposed policy we would be regularizing, to the extent that we could, notification, so that it routinely went to the State Department, and there was a routine minimum amount of information provided. This would let the foreign government know where to go and what it could expect with respect to hazardous products exports.

Mr. PEASE. I'm glad to hear that, and I was going to say if there were provisions for notification in five different areas of the law, FIFRA, Consumer Products Safety Commission, EPA, and so on, it would amaze me if all five were similar in terms of what the notification requirement is, who gets notified and all that sort of thing.

Mrs. PETERSON. Exactly.

Mr. PEASE. And you think that with administrative action, without changing the law, you can provide for a common notification procedure?

Mrs. PETERSON. That's exactly what we're hoping to accomplish.

Mr. PEASE. Do you think it's legal to do it?

Mrs. PETERSON. Yes.

Mr. HARRIS. As I understand it, where there are specific notification procedures required in the law, they would still have to be followed in addition to the regularized reporting system this policy proposes to set up.

Mr. PEASE. As a general matter, under the existing notification procedures, is the foreign government involved? Is the government of a foreign country to which the product is going to be exported, the entity that gets notified? And if so, is a positive response required, or is it, "If we don't hear from you in 30 days, we are going to assume it's all right"?

Mr. COHEN. Again, it differs depending on the statute, I believe, and I'd have to check. For medical devices the act requires an affirmative statement back from the foreign government that they approve the shipment. I believe the rest are simple notification and, in fact, in some circumstances, the notification does not necessarily arrive before the shipment leaves our shores. It differs from agency to agency.

Mr. HARRIS. But, the proposed policy would in effect set up another type of notification for those hazardous substances that are placed on the commodity control list. The procedures that would lead to a decision by the Commerce Department on whether to grant an export license would involve an effective notification, that is, consultation with the foreign government. Indeed, even when the export license is granted, which it may very well be in most cases, then at least what has occurred is a notification and a very close discussion with the foreign country about the hazards and reasons why that particular product was placed on the commodity control list.

Mr. PEASE. Would any of you happen to know about the notification requirement for pesticides? Whether that requires a positive response on the part of the government of the nation to which the shipment is being made?

Ms. GILLMAN. It doesn't require a positive response from the government. What is required is notification by the exporter of an unregistered pesticide to the importer. Then the exporter must get a piece of paper from the importer—the company or perhaps the government, whoever it is, that's importing it—a paper saying, "We know that this pesticide is not registered for use in the United States." Then the government of the country to which the export is being sent must also be notified. But there is no requirement of any response back from the government. The requirement under FIFRA, as amended in 1978, is for an acknowledgement from the importer, that the importer knows the pesticide is not registered for use in the United States.

Mr. PEASE. Finally, I am interested in the commodity control list. Who initiates placing of a commodity on the commodity control list?

Mr. COHEN. Under the proposed policy, this task force, chaired by the State Department, would examine each product which is banned or significantly restricted—that is a very specifically defined term in our proposal—and they would make a recommendation to the State Department which, in turn, would recommend to Commerce, which, in turn, would make a decision as to whether or not to place the product on the list.

Mr. PEASE. Then the individual exporter would be free to look at the commodity control list and if his item or commodity were not on that list, he would have no further responsibility?

Mr. COHEN. Unless the other regulatory statute prohibited the export, that's correct.

Mr. PEASE. I understand that's correct.

Mr. BINGHAM. Thank you. I would like to thank you, Mrs. Peterson, and the other members of the panel. Before you go, would you identify yourselves, once again, with your affiliation, for our benefit and also for the benefit of the the stenographer.

Mr. KRULWICH. Yes. My name is Andrew Krulwich, General Counsel of the Consumer Product Safety Commission, and the Chairman of the OECD Working Party, Consumer Product Safety.

Mr. COHEN. My name is Edward Cohen, Deputy Special Assistant to the President for Consumer Affairs, and I work on the staff of the working group.

Mrs. PETERSON. I am cochairman for the working group.

Mr. HARRIS. I am Robert Harris, a member of the Council on Environmental Quality, and cochairman of the working group.

Ms. GILLMAN. I am Katherine Gillman, staff member of the Council on Environmental Quality.

Mr. BINGHAM. Thank you very much indeed. It's a very good presentation.

We'll have to move along now to our next panel. Our next witnesses are two commentators on the draft policy, Mr. Jacob Scherr, staff attorney for the Natural Resources Defense Council, and Ms. Angela Blackwell, attorney with Public Advocates.

Welcome to you both. Would you like to begin?

Mr. SCHERR. Thank you, Mr. Chairman.

STATEMENT OF S. JACOB SCHERR, STAFF ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL

Mr. SCHERR. Thank you, Mr. Chairman. I am S. Jacob Scherr, staff attorney for the Natural Resources Defense Council. I appreciate this opportunity to present testimony to the Subcommittee on International Economic Policy and Trade concerning the administration's draft on hazardous substances export policy.

The Natural Resources Defense Council is a nonprofit, public interest environmental organization with 45,000 members in the United States and 20 foreign nations. NRDC has been actively concerned for over 4 years about U.S. exports of dangerous substances, products, and facilities. We have been involved in legal and administrative proceedings and have testified before the Congress on several occasions as to the need for effective controls over the range of U.S. hazardous exports. In June, my colleague, Faith Campbell, presented our views to this subcommittee on H.R. 6587, an important measure introduced by Congressman Michael Barnes, addressing the problem of sales abroad of products banned or restricted for use here in the United States.

On August 12, and after 2 years of work, the administration's interagency working group on a hazardous substances export policy, or HSEP, published its fifth draft report in the Federal Register for public comment. The publication of this report alone is not an insignificant accomplishment since it required the agreement of over 20 Federal agencies and offices, including some whose overriding concern with boosting U.S. trade led them in the past to discount or ignore completely severe health, environmental and foreign policy risks asso-

ciated with such exports. Their change in attitude may have been the result of a realization that the hazardous export problem will not go away, and that the United States can no longer merely disclaim any responsibility.

ONE INCIDENT

Just 2½ weeks ago, the Center for Disease Control in Atlanta reported an outbreak of mercury poisoning in Managua, Nicaragua, among workers at a chemical plant partially owned and managed by an American firm.[1] Over a third of the 152 workers at the plant showed "clinical evidence of mercury intoxication with central nervous system damage." There were pools of mercury on the floor of the plant, and workers had not been provided protective equipment nor informed of the known dangers posed by exposure to mercury.

The discovery of poisoning among the workers followed from the detection of mercury in the drinking water of Nicaragua's capital city. The American plant had been dumping mercury into Lake Managua, the city's source of water. It was estimated that some 40 tons of mercury had been discharged into water and air over the 12 years of its operation. Lake Managua is a major source of fish for residents of the city, and there is concern that consumers of this fish may suffer the same crippling syndrome as seen in Minamata, Japan, some 20 years ago. The apparent callous disregard for human health demonstrated by the plant's American owners reflects poorly upon us all and might adversely affect our Nation's relations with the people and Government of Nicaragua.

Now this incident represents just one aspect of the hazardous export problem. The working group's report focuses upon the sales abroad of banned or severely restricted products. It also discusses the dangers posed by the movement of hazardous industries overseas, the dumping abroad of U.S. toxic wastes, the mislabeling of American drugs, and the deceptive overpromotion of infant formula in developing countries.

The working group report reflects the deep concern of the American people about these practices which are inconsistent with our concepts of fairness and commitment to human rights. It reflects the outrage felt by leaders and citizens of developing countries, such as Kenya, Nigeria, Ghana, and Haiti, which are most vulnerable to hazardous exports and often lack the capability to monitor and regulate imports. It reflects emerging international norms requiring the disclosure of health and environmental risks posed by exported goods, facilities, and technology, and an opportunity for an importing nation to give its informed consent. Finally, the report reflects the limited steps our Government has taken in response to this problem during the last few years.

The working group wisely recognized that it would not be feasible nor effective to attempt to address all the diverse aspects of the hazardous export problem with a single executive branch action. The proposed policy concentrates on the export of banned or severely restricted substances, including drugs, pesticides, toxic chemicals, and consumer products.

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[1] See U.S. Department of Health and Human Services, Public Health Service, Center for Disease Control, Morbidity and Mortality Weekly Report, vol. 29, at 393 (Aug. 22, 1980).

Its most important policy recommendation is one shared with the proposed Barnes amendment, and one we strongly support; that is, the selective application of export controls under the Export Administration Act. The proposed export controls, we believe, are essential to halting sales abroad to unsuspecting foreign customers of products considered too dangerous or too little studied for use here. It would permit the U.S. Government to prohibit completely such exports, even where the importing government wanted the products, if there remained serious health or environmental risks. While urging the Administration to move ahead quickly to adopt the hazardous substances export policy, we feel five major changes should be made in the proposed export controls if they are to be effective.

UNAPPROVED PESTICIDES

First, we believe that the exception, which Mrs. Peterson mentioned earlier, regarding untested pesticides should be eliminated. According to the draft report, only those pesticides for which registration has been suspended, canceled or rejected or restricted, or those pesticides for which a residue tolerance has been revoked or rejected, would be considered for placement on the commodity control list. This loophole would permit a U.S. manufacturer to undertake the large-scale production here of an untested pesticide and to begin its distribution worldwide without even notification to EPA. It would allow a repetition of the Leptophos poisoning incident in Egypt, which in fact is relied upon by the working group as an example of the harm that can occur as a result of uncontrolled hazardous exports. Over 14 million pounds of this dangerous pesticide were exported to over 50 nations before action was first taken by EPA against the pesticide in November 1976. Given the severe hazards posed by the widespread use of an untested pesticide, the requirement of export controls should be extended to cover all pesticides which are not approved for use in the United States.

According to the working group, there are perhaps only 25 pesticides which are wholly unregistered in the United States now being manufactured for export only. It should be presumed that such pesticides will be placed upon the commodity control list. The manufacturer should have the burden of coming forward to demonstrate why such exports would not pose especially severe hazards to human health or safety or to the environment.

Also the EPA can require disclosure of information about such pesticides, including any test results or data on use patterns. Since 1978, plants manufacturing pesticides for export only must be registered with EPA, and their books and records open to inspection.

MEDICINES AND MEDICAL SUPPLIES

Second, medicines and medical supplies must be included among those products which may be subjected to export controls. The working group left open the question whether section 6(f) of the Export Administration Act prohibits the President from placing foreign policy controls on medicine and medical supplies. This section spells out the congressional intent that:

The President not impose export controls * * * on any goods or technology if he determines that the principal effect of the export of such goods or technology would be to help meet basic human needs.

The legislative history of this section confirms the underlying concern of Congress that a total embargo of exports to a foreign country, including medicines and medical supplies, might result in serious and undue human suffering.[1] Section 6(f) cannot logically be seen as a bar to placing export controls on misbranded or adulterated drugs, which now may be freely sold overseas.[2] No humanitarian purpose is served by such exports, and it is consistent with congressional intent that the President be permitted to place export controls on such drugs which may pose severe risks of injury to the health of the public abroad.

PROCEDURES

The third matter that I would like to address is the question of the procedure for placing banned substances on the commodity control list. It is our view this process, as presently proposed, must be streamlined. A distinction can be made between products which cannot be sold in the United States because they don't meet all the very detailed technical safety standards, and those products which have been affirmatively ordered off the market by U.S. regulatory agencies.

The latter decisions are not taken lightly, and must be based usually upon a determination that the product poses a severe or unreasonable risk to human health or the environment. As was the case with the banned baby pajamas treated with the cancer-causing agent Tris, there is likely to be a rush to dump the banned products overseas. There should be a strong presumption in favor of placing such products on the commodity control list, and the task force should monitor ongoing regulatory proceedings against particular products and should consider concurrently whether export controls would be required. Wherever possible, a banned product should be placed on the commodity control list at the same time the action removing it from the U.S. market becomes final.

IMPORTING COUNTRY'S CONSENT

Fourth, the State Department must afford the importing country with an opportunity for informed consent. Once a product is placed on the commodity control list, a validated license must be issued for its export by the Commerce Department after consultation with the State Department and the relevant regulatory agency. As noted by the working group report, the State Department would not recommend issuance of a license unless "it determined that the export would not be detrimental to U.S. foreign policy interests and had, after appropriate consultations, received no objections from the importing government." The HSEP should make clear the nature of such consultations. At a minimum, the State Department should confirm in writing that the

[1] See House Subcommittee on International Economic Policy and Trade, "The Export Administration Act of 1979," 96th Cong., 1st sess., 773–775 (1979).

[2] There are already export controls on unapproved drugs and unapproved or banned medical devices. Under the Federal Food, Drug and Cosmetic Act, unapproved drugs may not be exported at all, and medical devices which have been banned or not cleared for marketing in the United States may not be exported without a permit.

appropriate regulatory official in the importing government has been informed as to the export license application, has been provided information concerning the hazards posed by the product and the reasons leading to its prohibition or restriction in the United States, and has affirmatively indicated an approval of the proposed export. Otherwise, the danger remains that a half-hearted attempt will be made to consult with importing government officials and the lack of a response seen as an indication of no objection.

This is a valid concern in light of an investigation of the State Department's performance in the transmittal of notices concerning U.S. actions against particular pesticides. In July 1978 testimony to a House Government Operations Subcommittee, a GAO representative stated that: "An official at one [U.S.] embassy told us that he did not routinely forward notifications on chemicals not registered in the host country because it may adversely affect U.S. exporting." [1]

PUBLIC PARTICIPATION

Finally, there should be an opportunity for public participation in the work of the interagency task force. As a first step in the implementation of the HSEP, each regulatory agency will be required to prepare a list of those presently prohibited or severely restricted products within their jurisdiction. From this list, an interagency task force would select those products which post especially severe hazards as candidates for inclusion on the commodity control list. This process should be open to public input. The initial lists of all banned or severely restricted products should be published in the Federal Register, and the public invited to submit comments. Where the task force decides not to place a product on the commodity control list, the decision and the underlying rationale should be made public. There should also be an opportunity to petition the task force for a reconsideration.

Many American environmental and consumer organizations remain wary of the Departments of State and Commerce, which are given the major responsibilities under the HSEP. These agencies are seen as often having a concern only for the promotion of U.S. exports. The proposed HSEP will be effective only if it is vigorously implemented. While as I noted earlier my belief that there has been a change in the attitudes of these agencies, I hope that this subcommittee would monitor closely the implementation of hazardous substances export controls.

NOTIFICATION PROCEDURES

I would like to state clearly that we agree with the working group that the additional safeguard of export controls will be required on a relatively small number of banned or severely restricted products. In most cases, our Nation's international obligations would be met through improved notification procedures. No country, not even the United States, can adequately monitor the flow of imported goods and take steps to keep out dangerous products. As a matter of comity, we should expect our trade partners to inform us as to proposed exports to the

[1] House Government Operations Subcommittee. "Hearings on U.S. Export of Banned Products," 95th Cong., 2d sess., 81 (1978).

United States of products which have been banned for their domestic use.

There is already some evidence that other nations appreciate and will act upon such hazardous export notification provided by the United States.

EPA informed Ecuador that it was importing an unregistered pesticide from a U.S. firm. As a result, the Ecuadorean Government revoked its approval of the sale or use of the pesticide.

We recognize that the agencies' experience with these notification schemes is relatively limited, and we nonetheless remain concerned that sufficient attention and resources be devoted to assuring that notices are provided expeditiously to the appropriate foreign officials.

As noted by Susan King, chairperson of the Consumer Product Safety Commission, in her statement to this subcommittee in June, the CPSC immediately notified the Canadian Government of the intent of a U.S. company to export nursery lamps to Canada which could not be sold in the United States because of the excessive lead content of the paint covering them. The Canadian Government refused to permit the import of the dangerous goods. In November 1979, a U.S. firm applied to EPA for an exemption to ship PCB-contaminated animal fats to South Korea for use in the manufacture of laundry soap. EPA properly notified the South Korean Government which acted to halt the transaction.

EXPORTS OF TOXIC CHEMICAL WASTES AND HAZARDOUS INDUSTRIES

I would like to make a few comments as to two aspects of the hazardous export problem which are not covered by the proposed HSEP. The first is toxic chemical wastes. There have been already a number of reported efforts by U.S. firms to dump toxic chemical wastes in other countries, such as Sierra Leone and Haiti. There is an outstanding proposal to ship sludge from Washington, D.C., to Antigua for processing and use as fertilizer for trees. The State Department has recognized the risks to U.S. foreign policy interests posed by such deals. In March 1980, the U.S. Embassy in Haiti issued a bulletin outlining U.S. concern about hazardous waste exports to developing nations and stating that:

> The U.S. Government has undertaken to disclose information to other countries on the risks associated with the improper disposal of toxic wastes, with the same information being made public.

It is urgent that the State Department take steps to formalize this policy by placing export controls on hazardous wastes. EPA's new regulations on domestic transportation and disposal of wastes will take effect within the next two months. We agree with the working group that the State Department should make recommendations as soon as possible for the control of the export of these substances.

The problem of the movement of hazardous industries to developing countries must also be addressed. In the context of the HSEP, the working group should consider in its proposed 18-month evaluation of the HSEP whether export controls should be extended to cover the "technology" which is required to manufacture any of the products listed on the commodity control list. I agree with Representative

Miller that other remedial actions are required by Congress to discourage U.S. companies from operating dangerous, polluting factories in other countries. There are some steps that the executive branch should take. Both the Export-Import Bank and the Overseas Private Investment Corporation should fully implement Executive Order 12114, which requires the assessment of the environmental effects overseas of U.S. actions. The order specifically mentions toxic chemical hazards as triggering the need for such a review, even where the risks are limited to a single foreign nation. Both the Bank and OPIC should take great care in offering loans or insurance for American facilities overseas which produce hazardous products or dangerous emissions. They should make the host government aware of the results of any such environmental review and seek to obtain their informed consent as to the proposed facility. On the international level, the U.S. should support the inclusion of provisions in the codes of conduct now being negotiated for the transfer of technology and transnational corporations to require disclosure of known health, safety, and environmental dangers.

Ultimately, the solution to the hazardous export problem rests on the development of strong regulatory capabilities and citizen awareness in every nation. Both exporting and importing countries must recognize their shared responsibility to control international trade in dangerous goods and technology. The proposed hazardous substances export policy will reaffirm U.S. leadership on this issue, and place pressure on other industrialized nations to exercise similar restraint. With the adoption of the policy, we will come one day closer to the time when caveat emptor, "let the buyer beware," is no longer the prevailing norm in the international marketplace.

Once again, we strongly urge the administration to complete work on the final draft of the hazardous substances export policy working group report, and hope that President Carter will then act quickly to adopt a tough, humane and effective national policy on the exports of hazardous substances.

Thank you very much.

Mr. BINGHAM. Thank you very much, Mr. Scherr. We appreciate your testimony, and we will now have Ms. Blackwell. I see that you have a very extensive statement, Ms. Blackwell, and I would ask that you give us the highlights, and without objection, the entire statement will be included in the record.

STATEMENT OF ANGELA BLACKWELL, ATTORNEY, PUBLIC ADVOCATES

Ms. BLACKWELL. Thank you very much.

Good afternoon, Mr. Chairman. I am Angela Blackwell, and this is Lois Salisbury, and we are attorneys with Public Advocates, a public interest law firm based in San Francisco. We represent 17 organizations that because of their commitment to civil rights and economic justice feel compelled to unite and address this important human rights issue concerning hazardous exports to Third World countries.

These groups include black and Hispanic professional and civil rights organizations; groups which have primarily focused on inter-

national policies and human rights; organizations whose mission is to influence government policy regarding food, health, and related issues; and community-based consumer advocacy groups.

These organizations are as follows:

TransAfrica; the Government Accountability Project; the National Urban League; the Southern Africa News Collective; the Southern Africa Support Project; the Center for Development Policy; the National Women's Health Network; the Oakland Citizens Committee for Urban Renewal; the National Bar Association; the League of United Latin American Citizens; the National Lawyers Guild; the Interreligious Task Force on U.S. Food Policy; the Washington Office on Latin America; the Infant Formula Action Coalition; the National Council of La Raza; and the La Raza National Bar Association.

Not listed, but also one of the groups, is the National Medical Association.

These groups have come together to form this diverse coalition because each of them is concerned about the preservation of the health and rights of human beings throughout the world, and because each of them is concerned that the export of hazardous goods, technology, facilities and waste from this country to foreign markets threatens worldwide well-being, and is contrary to this country's stated commitment to human rights.

These organizations, from the Infant Formula Action Coalition and the National Medical Association, which have a history of international health involvement, to the Oakland Citizens Committee for Urban Renewal, a community-based organization, all feel their long history as voices for equal, fair and humane treatment for all, requires and qualifies them to speak out on this important issue.

The concern expressed by these organizations for the damage to the health and environment of foreign lands because of dangerous exports from this country has not therefore newly arisen in response to the Interagency Working Group's report on hazardous substances, but instead has been a longtime concern.

We come together at this time because we are concerned that the U.S. Government has proposed remedies that are not likely to halt the dumping of hazardous products and facilities in foreign lands.

We thoroughly reviewed the material that appeared in the Federal Register on August 12, 1980. We applaud both the important steps that are being considered by the U.S. Government in addressing this very critical problem, and the in-depth research and analysis that has gone into articulating the problem.

We cannot, however, endorse the proposal of the Interagency Working Group because it has not gone far enough. The Interagency Working Group's draft policy concludes the responsibilities of the United States regarding the export of hazardous substances would be fulfilled in most cases through notification to the importing countries that hazardous substances are coming within their border.

This approach both ignores the reality of the world and would serve to perpetuate a hypocritical export policy. This Government has repeatedly stressed a commitment to maintain and preserve human rights. That commitment has not only been expressed by the speaking out against torture and false imprisonment, but has been characterized as including the right to health, to dignity, and to self-determination.

The organizations that I represent strongly urge that any policy adopted by this Government regarding the export of hazardous substances be consistent with the following code of conduct described by President Carter in his inaugural address, and I quote:

> To be true to ourselves, we must be true to others. We will not behave in foreign places so as to violate our rules and standards here at home, for we know that the trust that our nation earns is essential to our strength.

INADEQUACY OF NOTIFICATION

Yet while having this standard as a guide for international relations, the Interagency Working Group has recommended notification as the primary way to solve the problem of hazardous exports to other countries. This approach is inadequate.

First, it must be understood that the substances for which the working group proposes notifications are those that have already been found to be hazardous, after a careful, detailed review by well-staffed agencies. It is only after this process that substances are banned domestically, either for sale or manufacture or both. That ban is imposed after other options, including notification are rejected.

In essence, the substances which the working group recommends for notification are the very ones for which notification has been determined to be insufficient to protect the American public. Therefore, the Interagency Working Group is recommending a double standard; that is, it will protect its own citizens with a total ban, but will merely notify foreign countries that hazardous substances with a "Made in U.S.A." label are coming within their borders.

Second, notification is insufficient to protect the health and well being of foreign citizens because the financial resources in many developing countries are too meager to halt the importing of hazardous substances, even after they have been notified of the danger. While these countries may wish to divert resources from other areas in order to develop the mechanisms needed to halt the dumping of dangerous imports, all of us knowledgeable in the area must conclude that mere notification necessarily imposes a financial burden on the importing country.

If this is a burden to be imposed on any country regarding hazardous exports, that burden should be upon the United States, because it is this country that has produced the products, has determined the products are not safe and has a human rights commitment which should always lead it to adopt the policy that is likely to safeguard life.

Further, the proposal of the Interagency Working Group is inadequate in that its scope does not reach far enough. Some products that have been deemed to be safe in this country are easily foreseeable as unsafe in other countries. It can be easily foreseen that the safe use of infant formula requires sanitary conditions that cannot be duplicated in many of the rural areas in Africa and Latin America. Additionally, technology, facility, and waste are among those products that pose a graver risk to life and well-being.

Accordingly, the coalition that we represent has proposed an effective and uniform solution to the problem of hazardous exports which is consistent with the country's human rights commitment.

Lois Salisbury will describe the proposals that we have put forward.

STATEMENT OF LOIS SALISBURY, ATTORNEY, PUBLIC ADVOCATES

Ms. SALISBURY. Good afternoon. For the reasons just stated by my partner, Angela Blackwell, the coalition that we represent finds it necessary to diverge from the recommendations of the Carter administration, and to put forth a separate proposal that we hope will be seriously considered by all concerned with the integrity of U.S. foreign policy regarding the dumping of hazardous goods.

Therefore this afternoon we will file with President Carter an administrative petition. This separate action is necessary because the coalition we represent believes that we must face now and completely all of the consequences of failing to take a strong and comprehensive stand on hazardous products. Any failure to face the problem squarely simply means further injury, death and greater disillusionment with our foreign policy in the Third World.

I appreciate the fact that the petition will be a part of the record, and we ask that it be so done.[1] I'd like to briefly summarize the petition and particularly the Executive order which we urge that the President seriously consider.

First of all, we describe the problem in great detail, going into considerably more length than that which is included in the Working Group's report. We have categorized the problem and feel that, in fact, all recognized categories of hazardous exports must be dealt with at this time. There is no reason which justifies delay.

Accordingly, we recognize four major areas of hazardous exports. The first certainly is commodities and substances, just as the working group recognized.

The second is technology and facilities.

The third is waste.

And the fourth is hazardous potential, such as infant formula.

Once having recognized that each of these types of exports have been a tragic source of death and harm in countries outside the United States because of our policy at this time, we urge that we do not have a double standard. Instead we propose a simple prohibition: where the United States restricts or prohibits use, consumption or exposure domestically, we should apply the same standards to our exports.

The only area where we diverge from a single standard is for products which present a hazardous potential, even though they are not banned here. For instance, while we can use infant formula relatively safely here in this country, that's not the case when you transport that product to a different environment with different economic circumstances.

[1] The 57-page petition is retained in subcommittee files.

So for exports which pose a hazardous potential, we ask that the United States assume the greater enforcement burden by responding favorably to a request for an export ban from another country, for example, a Third World country beginning to experience problems with infant formula. They could request we simply limit the export; in turn, such a request will trigger notification by the United States to other countries throughout the world, informing them of the difficulty and harm experienced abroad with products found safe in the United States.

The only exceptions to a single standard of safety rather than a double standard should be very strict. We recognize that there may be an example of a pesticide or a drug where perhaps other circumstances in another country might prompt a need for use there, where it would not be necessary for use here. In that case, both the importing country and the United States should have jurisdiction over the export of the pesticide or drug. Even then export should only be permitted when we are talking about a pesticide or a drug that is required because of extraordinary circumstances, and where we know its use presents the least harmful solution to that problem at that time. We also think that where there are safety restrictions, for instance, labeling and disclosure in this country, we should insure that equivalent restrictions will be followed in the Third World. We have proposed mechanisms which we think are fairly straightforward to accomplish that end.

We have also permitted an exception for products which pose a hazardous potential but where, perhaps through extra instructions and precautions that are not required here, the harm that is predicted could be obviated.

I leave to you the document, which goes into great detail. You will see that we have actually written an Executive order of some 10 to 12 pages in length, which details very specifically what we have proposed.

We certainly appreciate the seriousness with which this subcommittee, as well as the Carter administration, is taking this problem, and we would welcome an opportunity to work together, not only to solve it here, but to bring it to international forums, because we recognize there are no simple solutions. We are prepared to deal on an international plane, not just a domestic one.

Thank you.

[Ms. Blackwell's and Ms. Salisbury's joint prepared statement follows:]

JOINT PREPARED STATEMENT OF ANGELA BLACKWELL AND LOIS SALISBURY, ATTORNEYS, PUBLIC ADVOCATES

Good afternoon, Mr. Chairman. I am Angela Blackwell, attorney with Public Advocates, a public interest law firm based in San Francisco. I am here this afternoon representing Trans Africa; the Government Accountability Project of the Institute for Policy Studies; the Southern Africa News Collective; the National Urban League; the Southern Africa Support Project; the Center for Developmental Policy; the National Women's Health Network; the Oakland Citizens Committee for Urban Renewal; the National Bar Association; the League of United Latin American Citizens; the National Lawyers Guild; the Inter-Religious Task Force of U.S. Food Policy; the Washington Office on Latin America; the Infant Formula Action Coalition; the National Council of La Raza; and the La Raza National Bar Association.

These groups have come together to form this diverse coalition because each of them is concerned about the preservation of the health and rights of human beings throughout the world, and because each of them is concerned that the export of hazardous goods, technology, facilities and waste from this country to foreign markets threatens worldwide well being and is contrary to this country's stated commitment to human rights.

The concern expressed by these organizations for the damage to health and environment in foreign lands because of dangerous exports from this country has not newly arisen in response to the Interagency Working Group's Report on

Hazardous Substances, but instead has been a longtime concern. We come together at this time because we are concerned that the United States Government has not proposed remedies that are likely to actually halt the dumping of these products and facilities in foreign lands.

We have thoroughly reviewed the material that appeared in the Federal Register on August 12, 1980. We applaud both the important step that is being taken by the United States Government to address this very critical problem, and the in-depth research and analysis that has gone into articulating the vastness of the problem. We cannot, however, endorse the proposals of the Interagency Working Group because they do not go far enough.

The Interagency Working Group's draft policy concludes that the responsibilties of the United States regarding the export of hazardous substances would be fulfilled in most cases through notification to importing countries that hazardous substances are coming within their borders. This approach both ignores the reality of the world and would serve to perpetuate a hypocritical export policy.

This government, and particularly the Carter Administration, have repeatedly stressed a commitment to maintain and preserve human rights. That commitment has not only been expressed by speaking out against torture and false imprisonment, but has been characterized as including the right to health, the right to dignity, and the right to self determination.

President Carter, speaking in his inaugural address, stated that, "To be true to ourselves we must be true to others. We will not behave in foreign places so as to violate our rules and standards here at home, for we know that the trust that our nation earns is essential to our strength."

Yet, while having this standard as a guide for international relations, the Interagency Working Group has recommended notification as the primary way to solve the problem of the export of hazardous products to other countries. This approach in inadequate.

First, it must be understood that the substances for which the Working Group proposes notification are those that have already been found to be hazardous after careful, detailed review by well staffed agencies. It is only after this rigorous process that substances are banned domestically, either for sale or manufacture or both. That ban is imposed after other options, including notification, have been considered and rejected.

In essence, the substances for which the Working Group proposes notification are the very ones for which notification has been determined to be insufficient to protect American citizens. Therefore, the Interagency Working Group is recommending a double standard: that is, it will protect its own citizens through a total ban, but will merely notify foreign countries that hazardous

substances, with a "Made in the U.S.A." label, are coming within their borders.

Secondly, notification is insufficient to protect the health and well being of foreign citizens because many developing countries lack the resources to halt the importing of hazardous substances even after being notified of their danger. Most developing countries lack the technical or financial resources to adequately inform and protect their public. Even assuming appropriate legislation in those countries, many lack the bureaucratic agencies to monitor and enforce those laws. Even when such agencies do exist, they are usually understaffed and underfinanced. Notification in such circumstances is but a gesture with little practical consequence.

Further, proposals of the Interagency Working Group are inadequate in that their scope does not reach far enough. If the United States is going to develop a formal policy on the export of hazardous substances, it must include all hazardous exports. Therefore, technology and facilities may not be excluded and neither may waste. All of these hazardous exports should be dealt with through a uniform policy aimed at halting the flow of dangerous exports from the United States.

Additionally, some products that have been deemed to be safe in this country are easily foreseeable as unsafe in other countries. Infant formula is a classic example

of this danger. It can be easily foreseen that the safe use of infant formula requires sanitary conditions that cannot be duplicated in many of the rural areas of Africa and Latin America. All of these dangers can and should be dealt with through an Executive Order aimed at halting hazardous exports.

The Coalition that I represent, therefore, has proposed, through a separate petition which is attached to this comment and which has been filed today with President Carter, that the President issue an Executive Order that prohibits the export of all commodities, technology, facilities and waste that have either had restrictions placed on their domestic use because they are hazardous, or have been completely banned from domestic sale, manufacture or use.

Narrow exceptions to this ban are proposed. First, hazardous pesticides may be exported if they are requested in writing by the importing country, and that because of extraordinary circumstances the benefits of the pesticide outweigh the potential harm. Additionally, the agency with domestic jurisdiction over the pesticide must concur with the importing country regarding the prevailing benefits. Second, a commodity that can be easily foreseen as hazardous, may be exported if the exporter agrees to provide for the marking on each individual unit the necessary information for safe use, and the exporter, in advertising in the importing country further agrees to disclose potential

harms. Further, the importing country must concur that the warnings, labels and the advertising substantially reduce the hazardous potential. The federal agency with domestic jurisdiction over the substance must concur in the findings of the importing country.

Third, if a commodity, technology or facility may be used in this country only under restricted conditions, in order to export the commodity, technology or facility, the exporter must agree that conditions necessary for safe use in the United States are duplicated as much as possible in the importing country. Also, the importing country must agree that the exporter is in compliance with these requirements and the federal agency with domestic jurisdiction over the commodity, technology or facility concurs in the finding.

The Executive Order proposed by the petitioning organizations also includes an extensive provision for disclosure and public participation. The purpose of this section is to fully inform the domestic and the foreign public whenever an exception to an export ban is being considered. The public participation provision provides for a comment period, one public meeting, and full participation in the decision making process.

As stated in our letter[1] to President Carter introducing this petition, this nation must develop an export policy which serves our foreign relations principles and satisfies our human rights commitment. Immediate executive action is necessary to halt the export from the United States of

[1] The letter referred to follows on p. 158.

hazardous goods, drugs, pesticides, technology, facilities and waste. The issue at stake is vital. Both the United States and the international community must act responsibly. We call upon this Administration to take the lead in this effort by acting promptly to devise a United States policy that will protect foreign citizens as we have protected our domestic citizens. We also urge that the President and the Interagency Working Group join with us in seeking a uniform solution to this problem through the appropriate international bodies.

I thank you very much.

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Direct Dial Number:

September 5, 1930

President Jimmy Carter
The White House
Washington, D.C.

Re: Hazardous Exports Violate Our Foreign Policy Commitment To Human Rights

Dear President Carter:

We are a diverse coalition. We do not come together often, yet today, we write united in our commitment to the observance of international human rights. We are concerned that the United States' present policy regarding hazardous exports represents a violation of certain basic rights.

Thirty-one years ago, on December 10, 1949, the United States voted with ninety-nine other nations to adopt the Universal Declaration of Human Rights. Article 22 of that Declaration provides that everyone "is entitled to realization, through national effort and international cooperation...to the economic, social, and cultural rights indispensable for his dignity...."

In spite of this commitment, the United States has yet to develop a responsible, workable policy to control hazardous exports. While the August 12, 1980 Draft Report of the Interagency Working Group on a Hazardous Substances Export Policy recognizes that "as a nation exporting banned and significantly restricted substances, the United States has a moral obligation to recognize and assist in controlling the potential effects of these substances on the health and safety of citizens, abroad and on the world environment," the Working Group's recommendations fail to establish an export policy which would carefully prohibit and curtail hazardous goods and technology from leaving this country. Such a policy is necessary and would be consistent with your own frequent endorsements of fundamental international human rights.

On May 2, 1978, you declared:

> My administration is dedicated to supporting programs which help people meet their basic

> human needs. The United States, in partnership with international organizations and with other countries, must develop a truly international program to improve worldwide health, nutrition, and family planning. We have a long history of shared effort with other nations in the field of health, and we plan to build on the solid record we have established.
>
> The world can someday meet the basic human needs of people everywhere — if we care enough, and if we start now. I believe all Americans share my personal commitment to the goal of a world free from unnecessary disease, a world in which life is held sacred, and in which children born anywhere on Earth have the same chance to grow up to enjoy a healthy, fulfilling life.

(Presidential Statement Announcing Program to Strengthen United States Participation in Efforts To Overcome Disease and Ill Health, May 2, 1978)

In contrast to the spirit you expressed, in recent years the United States has permitted the export of hazardous pesticides banned for domestic use, such as DDT. The United States has permitted the export of hazardous medical devices which cannot be sold here, such as the Dalkon Shield. The United States has permitted the export of hazardous manufacturing facilities from which United States workers are protected, such as asbestos plants. The United States has permitted the export of goods which would pose an easily foreseeable hazard to another people, such as infant formula.

We believe that the United States' responsibility goes further than merely notifying another country that we have permitted a potential disaster — of our own making and ostensibly under our complete control -- to leave our shores. Accordingly, we petition you directly through a separate document to urge you to establish an export policy which is consistent with this country's human rights principles. We call upon you to remember and to act upon the words of your inaugural address:

> To be true to ourselves we must be true to others. We will not behave in foreign places so as to violate our rules and standards here at home, for we know that the trust which our nation earns is essential to our strength.

This nation must develop an export policy which serves our foreign relations principles and satisfies our human rights commitment. Immediate executive action is necessary to halt the export from the United States of hazardous goods, drugs, pesticides, technology, facilties and waste.

We seek an audience with you or your advisors, any time, to discuss our position. We plan to comment officially on the August 12, 1980 Draft Report of the Working Group on a Hazardous Substances Export Policy. We also hope that your administration will join with us in seeking a uniform international solution to this problem by relating our concerns to various international bodies, including the United Nations, and urging them to act.

The issue at stake is vital. Both the United States and the international community must act responsibly. We call upon you to take the lead in this effort by acting promptly to devise and implement a new United States policy.

Respectfully,

Angela Glover Blackwell

Lois Salisbury

On Behalf Of:

Center for Developmental Policies
Government Accountability Project of
the Institute for Policy Studies
Infant Formula Action Coalition (INFAC)
Inter-Religious Task Force on U.S.
Food Policy
La Raza National Bar Association
League of United Latin American Citizens (LULAC)
National Bar Association (NBA)
National Council of La Raza
National Lawyers Guild (NLG)
National Urban League
National Women's Health Network
Oakland Citizens Committee for
Urban Renewal (OCCUR)
Southern Africa News Collective (S.A.N.C.)
Southern Africa Support Project (S.A.S.P.)
Trans Africa
Washington Office on Latin America

Petitioners

NOTE.—The petition referred to is retained in subcommittee files.

Mr. BINGHAM. Thank you very much.

EXPORT ADMINISTRATION ACT AUTHORITY

Mr. Scherr, I would first like to comment on your proposal that medicines and medical supplies be included among those products that may be subjected to export controls.

You are quite right when you say that the legislative history of this section of the Export Administration Act indicates the underlying concern of Congress that a total embargo of exports to a foreign country, including medicines and medical supplies, may result in serious, undue human suffering.

We certainly did not have in mind eliminating export controls on those items. That might result in the possible export of unsafe medicines. And to me, this indicates the difficulty of applying the foreign policy control provisions of the Export Administration Act to an area which we were not really thinking about when we legislated. We were thinking about other types of controls. I would certainly agree with you that if we are talking about controls on exports of dangerous products, then certainly we don't want to exclude medicines and medical supplies.

Mr. SCHERR. I agree that the exclusion in the Export Administration Act for "medicines and supplies"' reflects a different congressional concern. The foreign policy implications of uncontrolled exports of hazardous substances were not made obvious to the U.S. Government, particularly the State Department, until early this year when there arose a number of proposals to ship American hazardous wastes to developing countries. When these proposals became public, there was a tremendous hue and cry. The State Department recognized that such exports could indeed have serious adverse effects upon our foreign policy.

The Export Administration Act does not define what "foreign policy" interests are to be protected by the imposition of export controls. I agree with the Justice Department that the Export Administration Act could be properly used to apply controls on exports of particularly hazardous products.

Mr. BINGHAM. I'm not saying it could not. I'm simply saying that this is really not what we were thinking about in drafting this provision. I think we have to be particularly careful in applying these provisions. Maybe modifications of them are in order to reflect this area of concern.

RESPONSIBILITIES OF IMPORTING AND EXPORTING COUNTRIES

Ms. Blackwell, I am somewhat troubled in your statement by what strikes me as a—this is really surprising coming from an organization with your affiliations—a somewhat patronizing attitude that papa or mama knows best, that only the U.S. Government is competent to make these decisions, and that we really can't trust the developing countries to decide what is in their interest or would protect their citizens.

I realize fully what you say, that in many cases they don't have the resources. At the same time, I do worry about that aspect of your

approach, that seems to me to leave it entirely up to the United States to decide these questions, and very little up to the importing country to decide what should be or should not be imported into that country.

Do you have a comment on that?

Ms. BLACKWELL. I am aware that it does appear that we are taking away some of the decisionmaking power of the third world countries, and that is not really the intention.

What is intended is that the United States not avoid its responsibility by saying that it's going to rely upon every country to decide for itself.

What I suggest is not that the countries don't have the capability to do it, but that it will be very expensive for them to develop that capability, and since it is the United States making profit from the export, and since the United States has already set up a system to do this sort of evaluation and has come to this conclusion to ban the products, the developing country should not have the burden of having to develop that mechanism. We do not place those decisions totally within the United States in our proposal.

What we suggest is that on items such as Tris-treated pajamas for which there would be no reason that any other country should want a cancer-causing pair of pajamas, that those decisions be made in the United States.

But in other areas regarding pesticides, the commodities that may be useful, but have a certain hazardous potential, that the burden be left with the importing country, and they make a written request for those products. There is a carefully laid-out mechanism that allows for those countries to make those decisions in areas where they are likely to have a different opinion. But where the research has already been done and the decision has been made, it is very unlikely that anyone would want something such as Tris-treated pajamas. So that decision should be made in the United States.

Mr. BINGHAM. Thank you, Ms. Blackwell.

Mr. Barnes.

Mr. BARNES. Thank you, Mr. Chairman.

LEGISLATION VERSUS EXECUTIVE ORDER

Mr. Scherr, what is your judgment about the manner in which to institute this? Would you rather see an Executive order, or do you prefer to see legislation? What manner do you think we ought to proceed in?

Mr. SCHERR. My overall preference is that the U.S. Government move forward as quickly as possible to establish procedures for placing export controls on certain hazardous substances. In this regard, it would be most effective to proceed with an Executive order in the next few months. Congress and this subcommittee should continue to monitor the consideration and implementation of such an Executive order. At a later time, a decision might be made as to whether an amendment to the Export Administration Act would be necessary to accomplish the shared objective of effective controls over exports of hazardous substances.

PUBLIC PARTICIPATION

Mr. BARNES. You're urging public participation, essentially, as I understand it, with selection of the products that are subject to regulation. Are you urging public participation there after this decision is made?

Mr. SCHERR. Our major concern regarding public participation relates to the process of selecting which products are to be placed on the commodity control list. We believe there should be full public disclosure of all candidate products, and an opportunity for public comment as to whether or not a particular product should be listed.

In regard to the issuance or denial of individual export licenses, the Export Administration Act does not call for, or, I believe, does not permit any public participation. Rather than formal public input at that stage, it is more important for concerned organizations and congressional committees to monitor generally the operation of hazardous substances export controls to assure that there are indeed consultations with importing governments and that decisions on individual export license applications are being made in a way which protects U.S. foreign policy interests.

Mr. BARNES. Thank you.

BACKGROUND OF THE COALITION

Ms. Blackwell, I have a couple of questions. I was curious how you happened to be here. You are with a public interest law firm, and presumably you serve on this council of a rather broad range of organizations that you represent here today. How did they happen to come together and review what is obviously a very complex issue and take a rather strong position on? What is the background of the coalition?

Ms. BLACKWELL. Public Advocates has a long history of representing community organizations and national organizations, and as part of our involvement with those organizations, we frequently talk about issues that are of interest that we should be involved in, in which those organizations feel they would like to speak out.

Several of the organizations and people we talked with have been very concerned about the whole problem of dumping hazardous products on third world countries.

As you recall, in November there was a whole issue of Mother Jones devoted to just that issue. Several of the groups called us and talked to us about responding to that problem, and we thought about it and thought of the appropriate way, and let other organizations know what some of the initial organizations were concerned about, and essentially ended up with this response.

Mr. BARNES. I see. Thank you.

INFANT FORMULA EXPORTS

You talk about the infant formula problem which was a real problem, but I haven't had a chance to read the details of your proposed Executive order, which I gather you appended to the petition. But how

do you handle that in the context of hazardous goods? Infant formula, in and of itself, is not hazardous, nor are lots of other goods that are routinely exported from the United States. How do you propose to handle that in this context?

Ms. SALISBURY. What we suggested, knowing that frequently the first feedback any of us would have about the hazardous potential of a product which is not a problem here would come from another country, is that any other country which has found they were having difficulty with a product which is being shipped to them could ask, as a matter of comity by the United States, that we simply place the export of that product, at least to that country, on the commodity control list. That would at least close the door to that country, and they wouldn't have to deal with it any longer.

Now that might be at least simple mechanism to control exports from this country, rather than burdening another country to have to constantly keep the product from coming in.

Once that's happened, once any country has made the request for an export ban, we then do recognize the appropriateness of notice in those circumstances and suggest the State Department take the responsibility to notify other countries. For example, if Nigeria has requested that a product no longer come to its shores, that would mean that other countries are notified of Nigeria's concerns and request for an export ban.

Beyond that, to impose a more comprehensive ban, we believe would require either a recommendation of the domestic agency which has jurisdiction over that product, or a United Nations agency. And in either case, that would require full public participation. But we think informed decisions could be made, particularly if we had the input not only of domestic groups, but of foreign countries' experience. So that a conclusion could be drawn, as I think is fairly common now, for example, that the export of infant formula is something we are all very concerned about, and wish we had better control over. We are proposing one.

Mr. BARNES. Thank you. Thank you, Mr. Chairman.

DEPO-PROVERA EXPORTS

Mr. BINGHAM. I would like to pursue that just a little bit longer. I see a petition with some references to the export or the activities of AID in relation to Depo-Provera. We're going to have some testimony on that later on this afternoon. But your position seems to criticize AID for providing support for international programs operated under the auspices of the UN or the WHO which do involve programs that make use of Depo-Provera.

Are you suggesting that Federal funds should be withheld from an international agency because we have ideas with regard to the nature of the hazards involved in a certain product which are not shared by that international agency?

Ms. SALISBURY. I'm not suggesting they be withheld. In fact, when you read the document thoroughly, you'll find we don't suggest anything specifically on that particular problem. But I'll be glad to share

with you our view of the matter, which is I don't believe we should permit the United States to finance these endeavors and certainly could restrict the use of U.S. dollars to purposes other than underwriting the expenses of Depo-Provera, because of the known risks that we believe exist, and because of the concern we have to be responsible when we spend U.S. dollars internationally. That would have to be an appropriation restriction that Congress imposes.

Mr. BINGHAM. Thank you. You are restating precisely what I said, and I'm really very much taken aback. That is the kind of imposition of U.S. views on international agency operations that we run into in the Congress frequently, and we have to fight them desperately. In many cases any effort to impose that kind of control on a contribution to an international agency would make the contribution unacceptable to the international agency, and that would simply mean we have to stop contributing to the agency.

But you confirmed my view of what you were saying.

Ms. SALISBURY. I see. Well, let me add one other thought on that, which is unfortunately with historical hindsight, a recommendation that could have dealt with the Depo-Provera situation, had an Executive order like ours been in place at the time the formula was developed. Our proposed Executive order controls the export of patents and technology and formulas and information, rather than just the product itself.

We now have a situation, as I understand it, where the formula for Depo-Provera was actually developed with U.S. technology, but the product itself is no longer being manufactured here. Had an Executive order been in place before that information was transmitted internationally, at least we would not have played quite such a sordid role in the spreading of Depo-Provera.

Mr. BINGHAM. Well, thank you very much. I think we'd better proceed with our other witnesses. I am going to ask our guests now please to cooperate. We are going to have to leave this room and go back up to 2255. We have preempted this room and interrupted the removal of the chairs from this room for a reception, and the people to do that are no longer here. So I would ask each one of you to take a chair out in the hall, and stack them as they were as best you can, along the side, so that the room will be cleared. I appreciate your cooperation. Thank you.

[Whereupon, a brief recess was taken.]

Mr. BINGHAM. The subcommittee will resume.

I want to thank the guests for their cooperation.

Our last panel of witnesses will discuss the Depo-Provera issue. We have invited and have with us Dr. Roger Rochat of the Center for Disease Control's Office of Family Planning Evaluation; Dr. Pramilla Senanayake, chief physician of the Planned Parenthood Federation; and Mr. Stephen Minkin, health policy analyst for the National Women's Health Network. In addition, we have with us at the request of our colleague from Michigan—who will be with us, I trust, shortly—Dr. Gordon Duncan of the Upjohn Co., and we will recognize the witnesses in that order, if it's agreeable.

Dr. Rochat.

STATEMENT OF DR. ROGER W. ROCHAT, REPRESENTING THE AD HOC CONSULTATIVE PANEL ON DEPOT MEDROXYPROGESTERONE ACETATE

Dr. ROCHAT. Thank you. Good afternoon. I represent the U.S. AID Ad Hoc Consultative Panel on Depot medroxyprogesterone Acetate—DMPA—which was chaired by Dr. Allan Rosenfield, director of the Center for Population and Family Health at Columbia University School of Public Health, consisting of 13 persons, including obstetricians, gynecologists, epidemiologists, veterinarians in animal research.

This Ad Hoc Panel was established at the request of Dr. Stephen Josephs, Deputy Assistant Administrator, Development Support Bureau, U.S. AID, to evaluate the use, benefits and risks of DMPA, and to advise U.S. AID on the appropriateness of providing DMPA to countries which request it.

The first meeting took place December 7 and 8, 1978. I was invited to be on the Panel because of my training as a physician and epidemiologist, and my 10 years' experience in evaluating family planning programs in the United States and various developing countries. Although I am Deputy Director of the Family Planning Evaluation Division at the Center for Disease Control, I am reporting on the findings of the Ad Hoc Panel and not representing Department of Health and Human Services or the Center for Disease Control.

I would like to submit for the record my detailed statement which contains the detailed Panel report.[1] I will summarize the key issues, some subsequent reports, and the recommendations of the Panel.

During the first meeting, the Ad Hoc Panel reviewed the results of animal toxicology studies and currently available information on the use, benefits and risks associated with the use of DMPA by humans in the United States and abroad, and reviewed the conclusions of WHO's toxicological review panel.

Based on this information, the Ad Hoc Panel, with one dissenting vote, recommended that U.S. AID make DMPA available to nations that request it.

On March 4, 1980, a special subcommittee convened to review subsequent animal studies. That subcommittee unanimously supported the Ad Hoc Panel's recommendations.

Before I review the findings on DMPA, I would like to point out that women in developing countries have repeatedly expressed their need for effective fertility control. The World Fertility Survey and contraceptive prevalence surveys show that many women have unwanted pregnancies and many desire to use contraception to postpone or prevent further childbearing.

Moreover, local experts in 60 developing countries recently estimated that about 13 million women in their countries obtained illegal abortions to terminate unwanted pregnancies. The data are shown in table 1.

These illegal procedures may be have caused nearly 70,000 women to die from bleeding or infection. These women urgently need effective means to prevent unwanted pregnancies. The current lack of acceptable, effective and safe means of fertility control causes a serious public health problem.

[1] The report appears in app. 6, p. 250.

DMPA, which is marketed by Upjohn as Depo-Provera, is one of several fertility control strategies which might reduce this health problem. DMPA is currently used in 76 developed and developing countries. Over 50 percent is sold in developed countries such as Italy, West Germany, Canada, Australia, and New Zealand. It has demonstrably high popularity in many settings. This popularity is related to its benefits, many of which are unique, and summarized in Figure 1.

It is the most effective reversible method of contraception. It is as effective as many methods of surgical contraception. It is the only available long-acting injectable contraceptive provided at 3-month intervals. Further, its effectiveness continues if the user is a few weeks late obtaining a repeat injection.

Its acceptability among some women may be related to their preference for injections, its infrequent use, and to the fact that it is not used at the time of coitus.

It can be provided by any person trained to give injections. It does not suppress lactation, and therefore facilitates successful prolonged breastfeeding which is important in lowering high rates of infant morbidity and mortality. It may reduce the incidence of iron deficiency anemia by preventing blood loss associated with menstruation.

Despite the high dose, long-term use of DMPA to treat two medical conditions, endometriosis and endometrial carcinoma, and despite its long-term use as contraception in the U.S. and elsewhere, there is no evidence that DMPA has caused the death of any woman.

DMPA has few clinical side effects, noted in figure 2. The most common complaint of a DMPA user is menstrual bleeding irregularities. These very rarely require treatment, but will lead some women to change methods. Estrogen supplement was infrequently used in the 1960's to treat these irregularities. It is almost never recommended today.

Because DMPA is a long-acting contraceptive which is stored in fat tissues, women who discontinue its use to become pregnant will require a longer time than prior oral contraceptive users to become pregnant.

However, a recent comparative study in Thailand shows that by 24 months, prior DMPA, oral contraceptive and IUD users have the same overall likelihood of becoming pregnant.

Over 90 percent of each group became pregnant.

DMPA, like oral contraceptives, causes mild changes in carbohydrate tolerance. Unlike oral contraceptives, DMPA has not been shown to be associated with thromboembolic or circulatory disease problems.

A recent study in Atlanta, Ga., shows that short-term DMPA use is not associated with any increased risk of breast cancer among American black women. See table 2.

This study was able to demonstrate no difference in relative risk of ever using DMPA for breast cancer patients who had used family planning and controls who were matched for age, race and year of clinic visit.

However, the short duration of DMPA use and the small number of cases prevented detecting a relative risk less than fourfold.

No valid evidence links DMPA with cervical diseases. DMPA is used clinically to treat endometrial cancer. There has certainly been no clinical reason to believe it causes or worsens endometrial cancer. There is no specific evidence identifying DMPA as a teratogen in humans. Furthermore, as an effective contraceptive, it will prevent the conception of many individuals with birth defects.

Clearly, these remarks about the safety of DMPA in humans are based primarily on what has been learned while the drug was available in the United States for clinical investigation or during its approved use in other countries. Rarely occurring adverse side effects can only be detected when large numbers of individuals are exposed.

Lack of approval for DMPA for use in the United States requires that extensive postmarketing surveillance take place in countries where it is approved and widely used.

The long term effect of DMPA, especially at high doses, on animals varies between animal species and appears to differ from its effect on humans. See figure 3.

For this reason, we cannot directly extrapolate DMPA effects in animals to its effect in humans. The effect of DMPA in beagle dogs is striking. Some developed inflamed uteri, a condition called pyometra, and died. Some developed an acromegalic-like condition, which was thought to be related to changes in growth hormone. Some developed vascular and renal changes. Some developed mammary nodules and cancer. Interestingly, none died from the malignancy, chiefly because of other effects of the drug.

Shortly after the ad hoc panel met, Upjohn notified the chairperson of new findings. The routine autopsies at the end of its 10-year study in rhesus monkeys showed that two of 10 monkeys given 50 times human dosage had endometrial cancer. Both of these monkeys were replacement monkeys who had received only 5 to 7 years of DMPA. None of the monkeys with 10 years of DMPA had any malignancy.

Unfortunately, we lack baseline or comparison data on the incidence of endometrial cancer in rhesus monkeys. The San Diego Zoo reports no cases in 12 animals of this same species.

Two other long-term contraceptive studies have recently reported studies in control animals. The two monkeys receiving DMPA who developed endometrial cancer had atrophied endometria, in contrast to endometrial cancer in humans, which is associated with hyperplastic endometrium.

The smaller number of monkeys involved prevents us from excluding chance as the reason the cancer occurred among treated rather than control monkeys.

On July 24, 1980, the panel's recommendations were submitted to the Agency for International Development. As a panel member I shared the recommendation that DMPA should be made available to women of all nations that request it for use as a contraceptive. Requesting nations and potential users should be fully informed about its benefits and risks. At a minimum, WHO and FDA information should be made available.

DMPA should be distributed through normal channels. We urge that USAID establish a continuing scientific advisory committee to collect and monitor data on the DMPA and other contraceptives.

We urge that special efforts be made to conduct epidemiological studies of beneficial and adverse effects of all fertility control methods, including DMPA.

Research studies in humans should focus on potential teratogenic and fetal loss effects of DMPA, on additional studies of return of fertility among prior DMPA users in different populations, and in potential carcinogenic effects in the breast, endometrium, and cervix.

Research studies in animals should continue in order to determine the causes of mammary tumors and acromegalic-like syndromes in beagles and to gain more knowledge about endometrial cancer in rhesus monkeys.

Thank you.

[The tables and figures referred to follow:]

TABLE 1

REGIONAL ESTIMATES OF LEVEL OF INDUCED ABORTIONS AND ASSOCIATED DEATHS IN IPPF REGIONS[1] (IPPF UNMET NEEDS SURVEY, 1977)

Region	Countries	Births (× 1,000)	Estimated abortions (× 1,000)	Ratio[2]	Percent illegal[3]	Estimated annual abortion deaths assuming death-to-case rate— 0.001	0.005	0.01
Africa:								
West	8	5,421	116	21.4	100	116	580	1,160
East	9	5,117	456	8.9	100	456	2,280	4,560
Middle East and North Africa	12	5,714	537	94.0	95	537	2,685	5,370
Indian Ocean	6	29,901	7,568	253.1	99	7,568	37,840	75,680
East, Southeast Asia and Oceania	6	10,064	1,778	176.1	96	1,778	8,890	17,780
Caribbean	4	389	66	169.7	80	66	330	660
Latin America	15	9,814	3,192	325.2	100	3,192	15,960	31,920
Overall	59	66,420	13,713	206.5	99	13,713	68,565	137,130

[1] Excludes Europe, United States, Canada, Australia, New Zealand, Japan, South Korea, Hong Kong, Singapore, countries with fewer than 1,000,000 population, and countries lacking IPPF affiliates.
[2] Per 1,000 live births.
[3] Median value for these countries.

Source: R. W. Rochat, D. Kramer, P. Senanayake, C. Howell: Induced abortion and health problems in developing countries, Lancet, 1980.

TABLE 2

COMPARISON OF DMPA[1] USE AMONG WOMEN WITH BREAST CANCER AND AMONG CONTROLS, GRADY MEMORIAL HOSPITAL, ATLANTA, GA., 1967–79

Category	Total	Percent DMPA use	Relative risk
Breast cancer	30	16.7	1
Controls	179	17.9	

[1] Depo-medroxyprogesterone acetate.

Source: A. R. Greenspan, R. A. Hatcher, M. Moore, M. J. Rosenberg, H. W. Ory: The association of Depo-medroxyprogesterone acetate and breast cancer. Contraception 21:563, 1980.

FIGURE 1

BENEFITS TO WOMEN USING DEPOT MEDROXYPROGESTERONE (DMPA) FOR CONTRACEPTION

Most effective reversible contraceptive (0.25 pregnancies/100 woman years.
Requires infrequent use (3 months).
Injection; a preferred route of administration.
Privacy of use: No supplies in house.
Ease and low cost of administration: Does not require clinic or physician.
Does not suppress lactation.
May decrease iron deficiency anemia.
No deaths.
No evidence of thromboembolic phenomena.

FIGURE 2

CONCERNS FOR DMPA USERS

A. HUMANS

Bleeding irregularities.
Return of fertility—over 90 percent conceive within 24 months.
Carbohydrate tolerance—similar to oral contraceptives.
Breast cancer—two studies show no risk.
Endometrial cancer.
Cervical disease—no valid evidence of association.
Abnormalities of offspring—abnormal sex ratio (Thai study).
Teratogenic potential:
No direct evidence for progestogens; weak link for exogenous hormones.
Efficacy reduces number of defects.

B. ANIMALS

1. Beagles:
Pyrometra;
Mammary nodules/cancer;
Metabolic changes;
Acromegalic-like condition;
Vascular and renal changes;
Death.
2. Monkeys (rhesus): Endometrial cancer.

FIGURE 3

SIMILARITIES AND DISSIMILARITIES IN THE RESPONSE OF BEAGLES AND HUMANS TO DMPA

A. SIMILARITIES

Prevents ovulation.
Decreases plasma cortisol.
Mild disturbance carbohydrate metabolism.

B. DISSIMILARITIES

Endometrium:
Beagle dog endometrium stimulated causing mucometra and/or pyrometra.
Human endometrium atrophies.
Growth:
Acromegalic-like condition in beagle dogs.
No such changes in humans.
Death:
High doses caused death in many beagle dogs often due to pyometra or vascular changes.
No deaths reported for humans receiving high dosages of DMPA.

Mr. BINGHAM. Thank you very much, Dr. Rochat.

I don't want to start questioning now, but I understand that you are not presenting this testimony in any way on behalf of AID.

Dr. ROCHAT. That's correct.

Mr. BINGHAM. But on behalf of the ad hoc panel.

Dr. ROCHAT. That's correct. It has been reviewed by some of the staff at the Office of Population at AID, and the letter on the last page to Dr. Allan Rosenfield from Dr. Josephs released the report for presentation in the written record here.[1]

Mr. BINGHAM. I see. Well, I am appreciative of that. Thank you very much.

Dr. Senanayake.

[1] The letter referred to is retained in subcommittee files.

STATEMENT OF DR. PRAMILLA SENANAYAKE, MEDICAL PROGRAM ADVISER, INTERNATIONAL PLANNED PARENTHOOD FEDERATION

Dr. SENANAYAKE. Good afternoon, Mr. Chairman and members of the subcommittee.

The inability of the U.S. Government to supply Depo-Provera overseas has done harm to family planning programs, and has caused suffering to many individuals. International Planned Parenthood Federation has 27 years' accumulated experience in encouraging indigenous efforts in more than 100 countries to meet family planning needs of women. It monitors Depo-Provera both directly in those family planning associations which offer it and through international consultation and study.

As IPPF's representative, I am pleased to respond to your request to testify before this subcommittee.

THE FDA DECISION

Under current U.S. law, new drugs which have not been determined to be safe and effective for use in the United States cannot be exported by the United States for distribution in any country under any circumstances. We are all familiar with the decision taken by the U.S. Federal Drug Administration in March of 1978 on the injectible contraceptive Depo-Provera.

Time does not permit me today, Mr. Chairman, to discuss the merits of that decision, but suffice it to say that international scientific opinion, including that of agencies such as the World Health Organization, have questioned the scientific background of that decision.

The United Kingdom Committee on the Safety of Medicines has also questioned the validity of some of the scientific evidence used by the FDA.

We are also aware that the FDA's decision was taken despite the recommendations of its own Advisory Committee on Obstetrics and Gynecology who, on two separate occasions, recommended the use of Depo-Provera as a contraceptive in the United States.

GENERAL CONSIDERATIONS

A number of diseases prevalent in the developing countries are rare or nonexistent in the United States. Similarly, many of the risks associated with pregnancy that women in the developing countries face are not well recognized in the more developed countries.

The maternal mortality rates in the less developed countries, particularly in Africa, range between 1 and 10 per 1,000 live births. This is a 100 to over 200 times the comparable rate for the United States.

Quite obviously, even if a drug was unsuitable for approval in the United States—and in the case of Depo-Provera there is no scientific evidence to support this—a drug could well have a favorable benefit-risk ratio in a less-developed country.

A drug that is useful against some diseases may never receive testing adequate to guarantee its use in the United States. Again, under the existing law, such a drug could not be exported from the United States for general use in other countries of the world, even if it had received approval in these countries.

In such situations, Mr. Chairman, the withholding of a drug from a country requesting it simply because of the lack of FDA licensing is tantamount to enforcement of the U.S. norm on other countries.

In the light of the above, let us look more closely at the issue of Depo-Provera.

EXPERIENCE WITH DEPO-PROVERA

The experience with Depo-Provera dates back to the early 1960's. The drug as a contraceptive has been subjected to over 6½ million women-years of use and monitoring. Its safety must be particularly emphasized as so far there has yet to be a single proven DMP-related death.

Mortality is, of course, not the only yardstick to be used when measuring safety and one does recognize that Depo-Provera is associated with some side effects, though seldom are they serious.

In fact, 77 countries around the world have approved Depo-Provera for use as a contraceptive. Since 1971, the IPPF has responded to requests for supplies of Depo-Provera from 53 different countries. In all of the recipient countries, the drug regulatory or other approving authority had cleared the drug for domestic use.

The IPPF supplies approximately half a million doses of Depo-Provera each year. Depo-Provera has also been supplied by the United Nations Fund for Population Activities and by Sweden, Belgium, and the United Kingdom, and the Canadian Government has also recently decided to provide a very substantial amount of Depo-Provera to one developing country as part of a World Bank population project.

Like all products IPPF supplies, Depo-Provera receives careful scrutiny from, in the past, the IPPF Central Medical Committee and now the IPPF International Medical Advisory Panel.

These bodies are composed of doctors directly involved in national family planning activities who have an international reputation. These bodies consult with international research organizations such as the World Health Organzation, the Center for Disease Control, the international fertility research program, and regularly review new reported evidence in contraceptive effects, both in the literature and from field experience.

Where indications of substantial new risks are found, they have been swift to act, withdrawing the contraceptive and advising the individual client.

It is widely acknowledged by health and family planning workers that there is no single contraceptive that is ideal for all individuals at all stages of their sexually active and reproductive life.

The suitability of any particular method will depend on a complex relationship of a wide range of variables. For example, social acceptability of the method, its availability, the individual's health and reproductive history, and its cost to the woman.

BENEFITS OF DEPO-PROVERA

From our own experience at IPPF, we can state that Depo-Provera has clear-cut benefits for many women, and they actively seek it. Some of these are:

1. It is a very reliable method of contraception and therefore is particularly useful for women unable to tolerate side effects of the pill and IUD, and for whom sterilization is unacceptable.
2. It is a safe method of administering a contraceptive, especially in locations which are remote and unhygienic or where there is a shortage of physicians. The first contact with a health service may then lead to the identification of other health needs and to their treatment.
3. It is culturally acceptable in many parts of the world in Southeast Asia and Africa, for example, where injections are associated with improved health and are generally the method of preference by the patients.
4. It is not coitus-related like the conventional contraceptives, nor does it require a daily activity by the user, as does the pill, and because of the ease of administration, many women find it acceptable to use Depo-Provera for long durations.
5. Many contraceptives require privacy, either during use, as with the cap or condom, or in relation to storage and supplies, as with the pill, or in monitoring, as is the case with IUD's and natural family planning. In countries especially where extended families live in crowded surroundings, a method that does not require privacy such as Depo-Provera, has distinct advantages.
6. Current evidence suggests that the use of Depo-Provera interferes less with lactation than does the pill. This would be a major advantage in the developing world, where successful and prolonged breast feeding is of critical importance in helping to lower existing high rates of infant morbidity and mortality. However, there is inadequate information presently available on the possible effects on the nursing infant of Depo-Provera in the breast milk. This area requires further study.

DEMAND FOR DEPO-PROVERA

An estimated 1½ million women worldwide now choose Depo-Provera for contraception. That number is small compared with the 65 million who use oral contraceptives and the 15 million who use IUD's, but our experience shows that the use of injectables is rising. In my testimony to the House Select Committee on Population in August 1978, I supplied evidence on this, and it is attached to this testimony, Mr. Chairman.[1]

IPPF receives frequent requests for the supply of Depo-Provera. These requests come from national family planning programs, private programs, the medical community and individuals. Some of the letters we receive are very moving. They record the misery and suffering of women in countries such as mine—I come from Sri Lanka, Mr. Chairman. These women are condemned to death and disease from repeated childbearing and its related problems. The plight of these women could be lessened by permitting the general use of Depo-Provera.

[1] Dr. Senanayake's statement is retained in subcommittee files.

68-483 O - 81 - 12

This escalation of the worldwide demand for Depo-Provera is in spite of the present USFDA regulation governing the use of DMPA as a contraceptive. Many countries still look to the United States for guidance on drug safety, efficacy and use. Even though women in developing countries demand this drug, some governments are hesitant to permit the large-scale use of the drug in their countries because of the nonapproval by the United States.

For example, the announcement of the nonapproval of Depo-Provera in the United States caused the directors of a private family planning program in one Latin American country to cancel their plans to use Depo-Provera in a rural distribution program. The drug is available in that country from retail outlets, but at a price that rural women cannot afford.

This is an example where the decision made in the United States led to the disruption of plans to provide a contraceptive to a large and quite different population in another country.

At present, the purchase of Depo-Provera is governed by the prevailing international prices. If the restrictions on the drug are removed and the drug is available on a large scale, the price would obviously be lowered. This in itself, Mr. Chairman, would enable all concerned to purchase and distribute larger amounts of Depo-Provera and thus fulfill the demand from developing countries.

Contraception and family planning, Mr. Chairman, are still controversial and sensitive subjects. However, in view of the evident facts, it is becoming more and more difficult to oppose family planning directly. Rather, opposition to family planning is now frequently disguised as opposition to the methods of family planning.

The argument becomes, "Contraception is good, but contraceptives are bad." IPPF would be the first to admit that there is no perfect contraceptive. There is no doubt. Mr. Chairman, that the means at our disposal to meet the needs of the millions of people across the world who desire to control their fertility are still inadequate. The search for the perfect contraceptive goes on.

Although unhappily the funding for research is falling, IPPF is concerned that there should be better research into existing methods and is all too aware that well-documented new information may alter its judgment at any time.

While continuing to work toward achieving the highest possible standards of contraceptive safety and acceptability, we should remember that as Dr. Fred Sai once put it, there is such a thing as statistical compassion—the good should not be made an enemy of the best simply because the best is still unattainable.

The good should be allowed, all circumstances considered. The side effects of unlimited pregnancy are well documented. The many millions of women who are suffering from it need, precisely because there is no perfect method, the greatest possible choice so they can make the best decision in the light of their own circumstances, and the care which we try to provide for them.

We are here today after all not because of the drug itself, but because of the human suffering that the lack of it has caused and will cause.

I am today making a plea, Mr. Chairman, for another look to be taken both at the FDA's refusal to license DMP, and at the regula-

tory or policy restrictions that prevent USAID from providing a drug which has not been legalized in the United States.

Mr. Chairman, Depo-Provera is safe, effective, and is needed by millions. Please help us take the shackles off. Thank you.

[The attachment to Dr. Senanayake's statement follows:]

DEPO-PROVERA

The following countries have approved Depo-Provera for contraceptive purposes or for suppression of ovulation:

AFRICA

Angola
Ethiopia
Gambia
Ghana
Kenya
Liberia
Malawi
Mauritius
Nigeria
Reunion
Somali Republic
Tanzania
Uganda
Zaire
Zambia

ESEA AND OR

Burma
Hong Kong
Malaysia
New Zealand
Papua New Guinea
Philippines
Singapore
South Korea
Thailand
Indonesia

EUROPE

Belgium
Denmark
France
Luxembourg
Malta
Netherlands
Norway
Portugal
Spain
Switzerland
United Kingdom (for specified contraceptive purposes only)
West Germany

IOR

Nepal
Pakistan
Sri Lanka
Bangladesh

MENA

Bahrain
Cyprus
Iraq
Jordan
Kuwait
Lebanon
Libya
Morocco
Muscat Oman
Qatar
Saudi Arabia
Sudan
Syria
Tunisia
United Arab Emirates
United Arab Republic (Egypt)

WHR

Antigua
Argentina (?)
Barbados
Bolivia
Chile
Colombia
Costa Rica
Curacao Aruba
Dominican Republic
El Salvador
Guatemala
Guyana
Haiti
Honduras (?)
Jamaica
Mexico
Nicaragua
Panama
Surinam
Trinidad and Tobago

OTHER

Rhodesia
South Africa

Mr. BINGHAM. Thank you very much, Dr. Senanayake. We will proceed for a few more minutes. Then we will have to break for a quorum call and a vote.

Will you start, at least, Mr. Minkin.

STATEMENT OF STEPHEN MINKIN, HEALTH POLICY ANALYST, NATIONAL WOMEN'S HEALTH NETWORK

Mr. MINKIN. Yes; thank you very much. I am Stephen Minkin, former chief of UNICEF's nutrition program in Bangladesh, where I worked closely with the Government multilateral and voluntary agencies, in designing and evaluating family planning programs. I am currently a health policy analyst with the National Women's Health Network, a public interest organization representing 118 health groups nationwide.

I am also a fellow with the Institute for Food and Development Policy.

I would like to thank Representative Bingham and the subcommittee for the opportunity to present the views of the millions of Americans concerned about the export of hazardous products, and especially Depo-Provera.

Just 1 month ago, seven network member physicians issued a joint letter to the ministries of health in more than 80 countries—mostly in Africa, Asia, and Latin America—to alert them to newly documented health risks associated with Depo-Provera hazards not previously communicated to these governments by either the manufacturer, the international population control agencies, or by the U.S. Government.

The signers of the letter, which I've attached to my statement [see attachment A], include two obstetrician-gynecologists, two pediatricians, a psychiatrist, and two family physicians, representing some of the most prestigious medical institutions in the country—Harvard Medical School and Columbia College of Physicians and Surgeons.

I would like to say that we could form an ad hoc committee with the prestigious personnel as large as the one that was formed by USAID.

DEPO-PROVERA EXPORT AND PROMOTION

The Food, Drug and Cosmetic Act categorically prohibits the exportation of drugs such as Depo-Provera which are not approved by the FDA. That is, the FDA has determined that Depo-Provera as a contraceptive is too dangerous to be on the market. Thus, when companies such as Upjohn, the manufacturer, or our own government, through the Agency for International Development—AID—promote, export and distribute Depo-Provera, these activities violate the law.

For example, did you know that Depo-Provera is used in at least three AID family planning programs in Bangladesh, Mexico and Sri Lanka? [1] Our tax dollars are used to support programs in which an unapproved drug is given to tens of thousands of women.

---

[1] See hearings before the House Select Committee on Population, August 8–10, 1978 (documents submitted by AID).

The National Women's Health Network has also secured an internal AID memorandum dated May 30, 1979, which shows how the Agency for International Development serves as a go-between in supplying massive quantities of Depo-Provera to aid recipient nations [see attachment B].

In this instance, AID is manipulating the United Nations Fund for Population Activities to purchase 600,000 doses of Depo-Provera for use in Bangladesh, and 1 million doses in Thailand.

AID, as the largest single financial contributor to UNFPA, is pushing the United Nations to use a drug worldwide that its own medical adviser in Bangladesh considered unsafe.

We have also secured a copy of an internal United Nations memorandum to the Government of Bangladesh dated August 31, 1979, which states emphatically that Depo-Provera is too hazardous to use.

I quote from that memo, which is also attached [see attachment C], for your consideration:

> Depo-Provera has generally been used in areas where followup is difficult and development of cancer resulting from this sort of drug usually takes 10 to 20 years. I know that Depo-Provera is popular and effective, but the drop-out rates are high and I don't think the small increment in fertility control which will result from use of this drug justifies the possibility that we might be responsible for an epidemic of uterine cancer in 10 to 20 years from now. Such an epidemic would be a disaster, not only for the women involved, but also for the credibility of population control programs.

I'm sure this subcommittee would agree that it would also be a disaster for the U.S. Government and American foreign policy.

President Carter's proposed executive action, as drafted by the Interagency Working Group, regrettably does not solve the problem of the circumvention of U.S. law by multinational corporations headquartered here, or by the Federal Government itself.

Depo-Provera is a classic example. Multinational corporations send distressed American businessmen to Congress to plead for lower safety standards in order to maximize profits abroad, while at the same time these American-based companies ignore the laws of this Nation by manufacturing and selling hazardous products through their overseas subsidiaries.

We are asking this subcommittee today to request that the Justice Department investigate whether the U.S. Agency for International Development, in conjunction with the Upjohn Co., has been circumventing the law in promoting, exporting, and distributing Depo-Provera.

You may be shocked to know that Upjohn admitted to the Securities and Exchange Commission in 1976 that between 1971–76, it paid over $4 million in bribes to employees of foreign governments and hospitals [see attachment D]. During this period, sales of Depo-Provera increased dramatically. We are asking this subcommittee to subpena Upjohn's records to determine whether any of these payments were made to promote Depo-Provera.

The National Women's Health Network would like to call your attention to an official document of the International Committee for

the Red Cross delegation in Thailand, which describes a compulsory program of forced Depo-Provera shots for Cambodian refugees. That's also attached [see attachment E], and I quote:

> 59 percent of women who received Depo-Provera stated that they had had no information as to the purpose of the injection * * * only 15 percent of women who received Depo-Provera were asked beforehand whether they were pregnant * * * This confirms our understanding that no medical precautions were taken before administration of Depo-Provera and of those few who were asked about their menstrual status, the information given was not acted upon.

It is accepted medical knowledge that Depo-Provera belongs to a class of drugs which causes birth defects. Yet Depo-Provera is given to pregnant women, and the manufacturer, the Upjohn Co., even promotes the drug for nursing mothers, whose infants receive large daily doses of this potent hormone. This is being done with apparently the encouragement of our own Government.

Mr. BINGHAM. Excuse me, Mr. Minkin. We'll have to interrupt you now. We'll be back in about 10 minutes.

[Whereupon a brief recess was taken.]

Mr. BINGHAM. The subcommittee will resume its session.

Will you proceed, Mr. Minkin.

Mr. MINKIN. Yes.

Mr. BINGHAM. On page 4.

Mr. MINKIN. Page 4. Thank you, Congressman Bingham.

RISKS OF DEPO-PROVERA USE

You have heard today the claim that Depo-Provera is safe and effective. There is also another claim, that the benefits of the drug outweigh the risks, especially in countries with a high maternal and infant mortality. When I served in Bangladesh with UNICEF, I was keenly aware of the real suffering faced by poverty-stricken women who desperately needed health care and a means for providing food for themselves and their children. Initially when I heard of Depo-Provera, I, too, thought it might provide promise in small, carefully administered programs. But as I studied the literature and gained access to unpublished and trade secret data, I realized that the drug was not safe.

Although many population control agencies have varied interpretations of the data on Depo-Provera, they often present opinion as if it were fact. Agencies like IPPF, WHO and AID have chosen to ignore the bulk of scientific evidence on Depo-Provera:

Breast cancer in beagle dogs tested with high and low doses, a very sensitive animal—liver cancer with low doses.

Endometrial cancer in rhesus monkeys, a cancer unheard of in this species prior to Depo-Provera testing, a very difficult animal to cause cancer in.

A marked increase in breast and cervical cancer rates in Chiang Mai, Thailand, where Depo-Provera has been most widely used.[1]

Lowered resistance to infections, including viral infections; diabetic stress; loss of hair, hyperventilation, acute depression, marked weight loss or gain, menstrual abnormalities, sterility.

[1] Confidential Draft, "Special Programme of Research, Development, and Research Training in Human Reproduction," WHO, 1980, p. 7.

Inhibition of bone growth, and possible interference with the normal development of reproductive organs in breast-fed children exposed to Depo-Provera.

It should be noted that the concentration of Depo-Provera in the breast milk is as high as that circulating in the mother's blood.

In the interest of time, I won't elaborate on all of the medical problems. Instead I'd like to counter some of Dr. Senanayake's presentation by quoting from a memo that she herself wrote on January 5, 1979 [see attachment F]:

"IPPF is, I believe, the largest supplier of contraceptives (excluding pharmaceutical industries). We do very little, however, in terms of monitoring the effects of these contraceptives on their recipients."

And for this reason, you won't find deaths caused by Depo-Provera, the mere fact that IPPF and other agencies haven't been doing even a reasonable job in monitoring the effects of their programs.

In conclusion, I would like to commend the interagency working group on its effort to insure that birth control drugs and devices bought with our tax dollars are safe and effective. But a real flaw in the proposed Presidential action is the loophole that allows drug companies like Upjohn to withhold safety test data from foreign governments and citizens in the United States and abroad.

For example, Upjohn kept it a secret for 3 years that one of its test monkeys had developed cancer,[1] and the company failed to notify foreign governments—and, to the best of our knowledge, the FDA, that abnormal curvature of the spine occurred in monkeys treated at all dosage levels.[2]

Dr. Senanayake's former boss, Dr. Fred Sai, told the Select Committee on Population during its hearings on Depo-Provera that, and I quote:

> I have no guarantee that an applicant for approval of a new drug is going to release to me in my country full documentation, including adverse findings.

On behalf of the National Women's Health Network, I'd like to thank Chairman Bingham and the subcommittee for their earnest efforts to insure that we, as Americans, are not found guilty of perpetuating a double standard of medical safety.

We leave you with these recommendations which we trust you will carefully consider:

That a special Executive memorandum be issued restraining AID from promoting or distributing FDA unapproved contraceptive drugs or devices.

That American-based multinational corporations and their subsidiaries be required to comply with U.S. law prohibiting the sale of unapproved drugs.

That the proposed Presidential action allow for the FDA to make available to foreign governments and medical personnel on request all safety test data.

Thank you. I'd be very happy to answer any questions you may have.

[The attachments referred to follow:]

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[1] Berliner, Victor. FDA Internal Report. "Review and Evaluation of Pharmacology and Toxicology Data." Mar. 3, 1979.

[2] Goldenthal, E. I. "Depo-Provera Long-Term Intramuscular Study" (draft), attachment #1, letter from Upjohn Co. vice president for research, Apr. 16, 1979.

ATTACHMENT A

National Women's Health Network

Founders
Barbara Seaman
Phyllis Chesler Ph D
Belita Cowan
Alice Wolfson
Mary Howell M D

Board of Directors
Davi Birnbaum
Kate Cook
Nina Finkelstein
JoAnne Fischer
Maureen Flannery M D
Pam Freeman
Doris Haire
Irene Hirano
Francie Hornstein
Anne Kasper
Judy Norsigian
Sandra A Salazar
Sybil Shainwald
Alice Wolfson

Executive Director
Belita Cowan

Program Director
Elayne Clift

August 8, 1980

Dear Sir or Madam,

Depo-Provera, manufactured by the Upjohn Company, is used as an injectable contraceptive in your country. As you know, Depo-Provera is not approved for use in the United States because of its health risks and hazards.

We thought you would be interested in the enclosed report: Depo-Provera, A Critical Analysis by Stephen Minkin which is the most comprehensive review of the subject written to date.

The report draws together published and unpublished studies to provide a well-documented analysis of the hazards associated with this method of contraception. Unpublished material includes animal safety test data edited out of reports sent to the United States Food and Drug Administration and The World Health Organization. The report documents how evidence of Depo-Provera's carcinogenicity remained undisclosed for the last 10 years.

Animal studies suggest that young women injected with Depo-Provera are at risk of developing endometrial cancer post menopause.

The carcinogenic effects of Depo-Provera may be related to its immunosuppressive properties. Electron-microscopic studies of dogs, monkeys, and humans show that treatment with Depo-Provera lowers resistance to viral infections. The loss of immunity is also transferred from the mother to the child via breast milk.

Depo-Provera should not be given to breast feeding women. This document clearly shows that the drug is dangerous to the health of the nursing child. For example, did you know that Depo-Provera retards osteogenesis, (bone development)? Monkeys at 50X, 10X, and even 1X the equivalent human dose developed abnormal curvature of the spine as a result of treatment with the drug.

The report also shows that Depo-Provera interferes with the normal development of the brain and reproductive organs. If women are not carefully screened for pregnancy before being injected with Depo-Provera, there is a serious danger that substantial numbers of children will be born in your country with undiagnosed cardiovascular and other birth defects.

(continued on next page)

224 Seventh Street S.E., Washington, D.C. (202) 543-9222

As medical doctors, we are deeply concerned that a drug with such poor performance on safety tests is administered to women (and to children via breast milk). We urge you and your government to carefully study the enclosed report before allowing further supplies of Depo-Provera to enter your country. Please distribute information to doctors who are using the drug, to enable them to accurately assess its risks and benefits.

Many organizations in the United States of America are concerned about the marketing of unsafe products, such as Depo-Provera, around the world. Two U.S. health organizations--The National Women's Health Network and The Institute for Food and Development Policy--have established drug information programs designed to inform government officials about the risks and benefits of drugs imported from the United States.

We are interested in your comments on this report. If you would like further information or have any questions , please write to: Stephen Minkin, The Institute for Food and Development Policy, 2588 Mission Street, San Francisco, California 94110, U.S.A.

Sincerely,

Alice Rothchild, M.D.
Harvard Medical School
Obstetrics and Gynecology

Michelle Harrison, M.D.
Family Physician
Boston, Massachusetts

Mary Howell, M.D.
Pediatrician
Watertown, Massachusetts

Robert I. Liner, M.D.
Obstetrician-Gynecologist
San Francisco, California

Maureen Flannery, M.D.
Family Physician
Whitesburg, Kentucky

Helen Rodriguez, M.D.
Director, Child & Youth Program
Columbia College of
Physicians and Surgeons
New York City

Anne Seiden, M.D.
Chair, Dept. of Psychiatry
Cook County Hospital
Chicago, Illinois

ATTACHMENT B[1]

U.S. GOVERNMENT MEMORANDUM

JUNE 7, 1979.

To: See Dist.
From: DS/POP/IO, Carl J. Hemmer.
Subject: UNFPA Support for Contraceptive Procurement.

The attached memorandum from Jim Shelton and Hal Pedersen clearly identifies an area of activity where UNFPA can provide much-needed backup for family planning programs. Pepe Donayre's statement, quoted in the memo, shows that UNFPA is well aware of the role it can and should play.

Recognizing that UNFPA field coordinators should adopt a more assertive role in identifying unmet commodity needs, AID staff can hurry the process along by following a systematic approach in bringing needs to the attention of UNFPA. The system that has worked in the past is as follows: when we learn of a commodity need by phone or cable, we (you or I) bring the matter to the attention of the backup UNFPA officer in New York. With their argeement, we notify the field to discuss the matter with the UNFPA coordinator; UNFPA does the same. At the very least, this process flags difficulties quickly and, at best, it produces a remedy for the need.

Starting from where we are, I'll be glad to work with any of you on any specific commodity need where UNFPA can play a role. Improvements on my proposed "system" are welcome.

Dist: [illegible]

U.S. GOVERNMENT MEMORANDUM

MAY 30, 1979.

DS/POP, Carl Hemmer
DS/POP, R. T. Ravenholt
From: DS/POP/R, J. D. Shelton; DS/POP/FPSD, H. A. Pedersen.
Subject: UNFPA Support of Family Planning Activities Through the Provision of Contraceptive Commodities.

The proposed UNFPA large-scale projects and country agreements you have recently circulated call for some general discussion and comment regarding UNFPA's strategy toward providing contraceptive commodites [sic]. The following quote, taken from an abstract of a presentation by Dr. Jose Donayre of the UNFPA at the recent PARER conference on vaginal contraception seems to capsulize the UNFPA position:

> The UNFPA support for contraceptive procurement is directed toward filling gaps in national programs, provision of contraceptive for programs organized by other major agencies, or in expanding the variety of methods offered.

One could argue that the UNFPA attitude toward contraceptive commodities is not as strong as one would ideally like. Even accepting this stated position as the appropriate one for the UNFPA, however, the programs delineated in the proposed projects leave much to be desired. We know that there are large gaps in AID's ability to provide commodities, particularly injectables, foaming vaginal tablets, and methods of menstrual induction. In the area of injectables, AID has received requests from Bangladesh for 600,000 doses of Depo-Provera, and from Indonesia for one million doses. While UNFPA should be complimented for providing injectables for Thailand, the decreased amount planned for 1979 raises some question since demand is unlikely to decrease. With little difficulty UNFPA could find other country settings where provision of injectables would be most welcome. Mexico is one example. Similarly, there are undoubtedly many countries where provision of other contraceptive commodities would be welcome. Philippines, for example, insists that their program is being hampered by AID's inability to provide an alternative to Noriday. Tunis voices similar reservations.

In short, we believe that UNFPA should adopt a more assertive role with respect toward contraceptive commodities in general, and in particular toward commodities that AID cannot provide.

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[1] Editor's note: These texts were transcribed by subcommittee staff from poor-quality photostatic copy submitted by Mr. Minkin.

ATTACHMENT C

UNITED NATIONS INTEROFFICE MEMORANDUM

Date: August 31, 1979.
Reference: BGD/79/PO4.

M. A. SATTAR,
Secretary, PC & FP, Ministry of Health and PC.

SIR: I would like to call your attention to the attached correspondence.

It is my personal opinion that since Depo Provera has been shown to cause cancer in two animal models (the beagle dog and the monkey), it is premature to introduce this drug for mass programs. It is, of course, possible that these animal models may not be relevant to the human, so that it would be reasonable to continue present programs while awaiting the results of the epidemiological case-control studies mentioned by Dr. Bassler. Because the drug has been in use in Thailand & elsewhere for more than 15 years, it should be possible to conduct case-control studies, but it will be difficult and will probably take several years, because the drug has generally been used in areas where follow up is difficult and development of cancer resulting from this sort of drug usually takes 10 to 20 years. I know that Depo Provera is popular and effective, but the drop out rates are high and I don't think the small increment in fertility control which will result from use of the drug justifies the possibility that we might be responsible for an epidemic of uterine cancer ten to twenty years from now. Such an epidemic would be a disaster, not only for the women involved, but also for the credibility of population control programs.

Obviously WHO doesn't feel as strongly about this—they "concluded that DMPA can continue to be used in national family planning programs". In my capacity as advisor to the Bangladesh government, I would like to have my personal opinion on the record.

UNFPA has been asked to provide 525,000 cases of Depo Provera in 1979–80 and 954,000 doses in 1981. If this large amount is to be used, an order should be placed immediately, since the manufacturers and shippers will have to make special arrangements. In the meanwhile we have enough in stock for at least the next 6 months at the present rate of consumption (12,500 vials—10 doses each).

I expect that you will want to discuss this with Antiqur Rahman Khan and others. As soon as you have made your decision, I will see that it is communicated to New York.

Sincerely,

COLIN MCCORD, M.D.,
Chief Technical Adviser MCH/FP,
UNFPA/Dacca.

ATTACHMENT D

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8

AMENDMENT TO APPLICATION OR REPORT
Filed pursuant to Section 12, 13 or 15(d) of THE SECURITIES EXCHANGE ACT of 1934

THE UPJOHN COMPANY
(Exact name of registrant as specified in charter.)

AMENDMENT NO. 1

The undersigned registrant hereby amends the following items, financial statements or exhibits or other portions of its CURRENT REPORT FOR MARCH, 1976 on Form 8-K as set forth in the four pages attached hereto:

Item 13. Other Materially Important Events.

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this amendment to be signed on its behalf by the undersigned, thereunto duly authorized.

THE UPJOHN COMPANY

By /s/ Gerard Thomas
Gerard Thomas, Vice President,
Secretary and General Counsel

July 28, 1976

Item 13. Other Materially Important Events.

In its Current Report on Form 8-K for the month of March, filed March 26, 1976, the Company disclosed that it was conducting an investigation to identify payments to employees of foreign governments and any political contributions made by the Company or any of its affiliates since January 1, 1971 and to determine whether any Company funds or assets had been improperly accounted for on the Company books during the same period. This investigation has been conducted under the supervision of the Company's General Counsel with the assistance of outside legal counsel. This Current Report describes the results of the investigation.

At the time the Company filed its Current Report for March a written questionnaire had been sent to the managers of the Company's 53 foreign affiliates, interviews had been conducted in the United States and abroad with 44 officers and employees of the Company and its subsidiaries, and certain relevant files and records of the Company had been examined. Since that time all of the Company's foreign affiliates have responded to the questionnaire, either orally or in writing, 42 additional interviews have been conducted, and a further review of Company files and records has been made.

In the initial report filed with the Securities and Exchange Commission on March 27, 1976, the Company stated that, although the investigation was still in progress, the information at that time indicated that since January 1, 1971, payments totaling $2,710,000 had been made to employees of foreign governments, or to persons who appear to have been serving as intermediaries for such employees, for the purpose of obtaining sales to government agencies or instrumentalities. Further investigation has disclosed additional payments of this type of $914,000. In addition questionable payments of $474,000 were made to numerous non-governmental hospital employees during the five-year period in one foreign country. Thus the total payments related to sales are $4,098,000. Some of these payments were not related to specific sales and the amount of some other sales can only be estimated. The aggregate of the actual and estimated sales to which payments can be related, however, is approximately $46,769,000. In addition, since 1971 payments totaling $147,579 have been made in connection with other foreign governmental actions related to the Company's foreign business. The Company has not determined the legality of the payments described in this paragraph under the applicable foreign laws. Small amounts which

were paid to minor government employees to expedite governmental services to which the foreign subsidiaries were entitled are not included in the above totals.

It has also been discovered that political contributions totaling $370 were made in two foreign countries where such contributions are legal.

Twenty-nine of the approximately 150 countries which the Company serves were involved in the payments described above. The amount of sales related to these payments is approximately one and a half percent of the Company's total worldwide sales for the years 1971 through 1975 of $3,282,553,000.

None of the Company's outside directors had any knowledge that the Company was engaged in any questionable transactions or practices until the meeting of the Board of Directors on February 17, 1976.

Certain officers and inside directors associated with international operations approved or had knowledge of payments under circumstances indicating that the payments either were, or might have been, for foreign government employees.

Some of the payments referred to above were included in the Company's consolidated United States tax return and were deducted by the Company for federal income tax purposes. The Company will file amended federal income tax returns for the years in which such payments were deducted and will pay such additional taxes as result from such amendments. The Company has been advised by the Internal Revenue Service that it is conducting an investigation for possible criminal violations or civil penalties arising under provisions of the Internal Revenue Code. It is not expected that this investigation will result in additional tax or penalities which would be material to the Company.

No fund or asset of the Company has been discovered in the course of this investigation which does not appear on the Company books. The payments described above were recorded on the books of the subsidiaries and branches involved under various accounts, which, in some instances, did not provide an adequate description of the purpose of the payment.

Since February at its regular monthly meetings, the Company's Board of Directors has been advised of the progress of the investigation.

As stated in the Company's Current Report for March, the management of the Company is of the opinion that the payments described above have not been individually, or in the aggregate, material to the Company's business or financial position considered as a whole. Although the termination of these payments may limit the ability of the Company to compete in some foreign countries, management is of the opinion that any adverse effect will not be material to the overall financial position and business of the Company.

The Company is voluntarily making this amendment to its Current Report on Form 8-K filed on March 26, 1976, under the heading "Other Materially Important Events." As indicated above, the Company does not view these matters to be material, and their disclosure herein is not an admission of materiality.

ATTACHMENT E

INTERNATIONAL COMMITTEE OF THE RED CROSS
Delegation in Thailand

924/9 Ruam Rudi 1
Bangkok.
Tel. 252-2348
251-0857

P. O. Box 11-1492

Cable address: INTERCROSS
TELEX : 82258 CICR TH

14 February, 1980.

From Dr N. J. Willmott,
Medical Co-ordinator, Kamput.

To Dr M. Duboulos,
Medical Co-ordinator,
I.C.R.C., Bangkok.

REPORT ON THE DEPO-PROVERA PROGRAMME IN KAMPUT

On 1:2:80 I reported an outline of the Depo-provera contraception programme in Kamput and recorded a meeting held with Dr Tangyoi, Director of Public Health, Chantaburi, who confirmed the authority that a programme of compulsory Depo-provera should be implemented in Kamput. Following your request for further details of the programme, I have conducted a discreet survey in which a random selection of 100 married women were interviewed.

1. It was found that 61% of married women had received Depo-provera. 74% of women interviewed had married in Kamput and of these 78% have received Depo-provera whereas only 13% of those married before arrival in Kamput have received Depo-provera. This supports our understanding that Depo-provera is given to women intending marriage in Kamput, as a pre-requisite to marriage.

2. 59% of women who recevied Depo-provera stated that they had had no information as to the purpose of the injection, which confirms that the majority of women receiving Depo-provera were given the injection on a non-informed basis.

3. 59% of those who have received Depo-provera were suffering from amennorhoea when they were given the injection, and a further 32% had irregular menstruation at the time. One of those whose menstruation was reportedly irregular at the time of receiving Depo-provera has subsequently been found to be pregnant.

4. Only 15% of women who have received Depo-provera were asked beforehand about their menstrual status or whether they were pregnant. Of the nine women who were questioned, four had amennorhoea and four had irregular menstruation. Depo-provera was still given to all of these. This confirms our understanding that no medical precautions were taken before administration of Depo-provera and of those few who were asked about their menstrual status the information given was not acted upon.

Conclusion:

1) Informed consent is not obtained for the majority of women receiving Depo-provera contraception.

2) No precautions are taken to ensure that Depo-provera is not given when women are pregnant or suffering from amennorhoea.

N. J. Willmott

N. J. WILLMOTT,
Medical Co-ordinator,
Kamput.

68-483 O - 81 - 13

ATTACHMENT F

INTERNATIONAL PLANNED PARENTHOOD FEDERATION

MEMORANDUM

To Mr B Aluvihare

Copies to See list below

From Pramilla Senanayake

Subject PSG WP - Priority Areas

Date 5 January 1979

As discussed at yesterday's PSG meeting. I give below topics which I feel could be looked at as periority areas for members of PSG.

1 Monitoring of Contraceptive Use

IPPF is I believe the largest supplier of contraceptives (excluding pharmaceutical industries). We do very little, however, in terms of monitoring the effects of these contraceptives on their recipients. The Secretary General has identified the need to monitor the contraceptives supplied by IPPF as a major activity, and I would suggest that PSG should take a leadership role in this.

2 Abortion

The medico-legal aspect of abortion (Bellagio) report would be ready in the next 4 to 8 weeks. The implamentation of the recommendations should, I feel, be a responsibility of PSG.

3 Adolescent Fertility

The Education Department, the Medical Department and the Law and Planned Parenthood Department have taken an active part in the above. The PSG would rightfully be the Group to continue these projects in a concolidated fashion.

4 Day Care Centres

The Medical Department with its contact with WHO, the Nutritionist and PPWD amongst others, have been working on this subject. PSG should be responsible for continuing this activity.

Day Care centres incorporate many priority areas for IPPF, namely, IYC, Family Planning, Women's Development, - to name but a few.

5 Primary Health Care

Alma Ata Conference NGO Primary Health Care projects are very relevant to the activities of PSG. PSG should consider this as one of its priorities.

6 Voluntary Sterilization

This subject as also been dealt with in different components by the Area Liaison Officers, Special Projects, Education Department, Law and Planned Parenthood Department, Biomedical Department, etc. The PSG would be the most relevant group to work out strategies for extending and consolidating our sterilization programme.

Mr. BINGHAM. Thank you, Mr. Minkin.

Our final witness is Dr. Gordon Duncan, manager of scientific liaison of the Upjohn Co., Dr. Duncan.

STATEMENT OF GORDON W. DUNCAN, MANAGER, SCIENTIFIC LIAISON, THE UPJOHN CO.

Mr. DUNCAN. Thank you, Mr. Chairman. I appreciate the time that you've made available for me to appear before the subcommittee. I have attached to the testimony a brief CV outlining my some 20 years of experience with contraceptive development and research, experience both at the Upjohn Co. and, within the last decade, as director of programs specifically oriented toward the introduction and adaptation of contraceptives for family planning programs and individuals abroad.

It is my understanding that this hearing focuses on Depo-Provera and issues relevant to consideration of the export of hazardous substances.

I'd like to make the first point, that it is important to note that the contraceptive formulation of Depo-Provera is not exported. This formulation is made abroad for overseas sales, and the dosage form intended for contraceptive use is not even manufactured in the United States.

The second point is that Depo-Provera itself would not appear to fall within any definition of a hazardous substance. It is to this latter point that I would like to address the remainder of my remarks.

The safety and efficacy issues associated with Depo-Provera have been reviewed in many other public forums. Extensive hearings were held in 1978 by the House Select Committee on Population. Family planning experts and health officials from many nations testified before Chairman Scheuer. There are more than 1,000 pages of the hearing report which were devoted to Depo-Provera.

If it's appropriate, Mr. Chairman, I'd like to have that part of the hearings included in the record of this subcommittee.

Mr. BINGHAM. Well, I might say on that, that would not be practical, but we will, of course, take those hearings into account.

Mr. DUNCAN. Thank you.

Mr. BINGHAM. Just in terms of saving money, those hearings are already available.

Mr. DUNCAN. All right. As I will mention later, there were two additional advisory committees of the FDA that have published extensive reports of their deliberations on Depo-Provera, and again, if appropriate, I would urge you to take these into consideration, recognizing that you may not wish to publish them in toto.

HISTORY OF FDA DECISION

In 1967, Upjohn requested that Depo-Provera be approved for long-term use as a contraceptive. In 1973, the FDA published in the Federal Register its intention to approve Depo-Provera for contraception.

Questions were then raised by the House Committee on Government Operations about the possible association between the use of Depo-Provera and the incidence of cervical cancer in the general population.

In response, the FDA convened its Obstetrics and Gynecology Advisory Committee to study the cervical cancer issue. The committee unanimously recommended approval of Depo-Provera.

It was then stated that approval would become effective in October of 1974, and in spite of this recommendation, the chairman of the House Committee on Government Operations then requested that the FDA revoke the intended approval.

FDA subsequently published a postponement of the approval due to consumer and congressional concerns, and requested further study by the combined Advisory Committees on Obstetrics and Gynecology and on Biometrics and Epidemiological Methodology.

In December of 1975, these committees again unanimously recommended that Depo-Provera be approved for contraceptive use, and although there was no further objection from the Committee on Government Operations, the FDA took no action to approve the new drug application.

In February of 1978, the House Select Committee on Population announced that it would hold a day of hearings to investigate this delay in the FDA approval of Depo-Provera.

Two days before the hearing. FDA sent Upjohn a letter stating that they found the supplemental new drug application for Depo-Provera to be nonapprovable. It should be noted that FDA has never before nor since twice rejected the recommendations of its own Advisory Committee.

In August of 1978, Upjohn requested that FDA convene a Scientific Board of Inquiry, and the FDA granted this request in July of 1979. To date, however, the board has not been selected by the FDA, nor, to the best of our knowledge, has a date been set for the board to meet.

When this board is finally convened, it will be open to the public. We look forward to the open airing of all the issues in this public scientific forum.

BENEFITS AND RISKS OF DEPO-PROVERA

Looking at the use of Depo-Provera, we should note that it was first studied clinically as a contraceptive as early as 1963, and is now administered, to update Dr. Senanayake's figures to the current year, to almost 10 million women around the world.

The unique properties associated with Depo-Provera allow a single injection to provide contraceptive efficacy for 3 months. With its high degree of efficacy and with its low incidence of side effects, Depo-Provera in all likelihood is the safest hormonal contraceptive drug available. It's approved for use as a contraceptive in some 80 countries, in Asia, Africa, Latin America, and in Europe, as you have heard from the previous speakers. It is currently approved in the United States for treatment of endometrial and kidney cancer. It is under investigation for the treatment of cancer of the breast.

It is further estimated that if it were approved for use in the United States, 5 to 9 percent of the women of childbearing age in the United States are potential users of Depo-Provera.

You have heard previous testimony about the use of Depo-Provera in programs sponsored by the IPPF. Other national and international

organizations recommend and use Depo-Provera in their family planning programs, under strict ethical, moral, and medical guidelines.

In conjunction with this use, many clinical studies have been and are now being conducted around the world by international population agencies, university groups, and physicians.

We are involved in some of these studies, because we believe our involvement in continuing studies of products is one of our responsibilities as the manufacturer of pharmaceuticals.

The Upjohn Co., further believes that a patient, with her physician, is in the best position to judge the suitability of a particular contraceptive. That decision, of course, must be fully informed. It should also be free of coercion.

We have provided materials for use by family-planning clinics and by private physicians, explaining the expected effects of Depo-Provera. In conjunction with other organizations, special printed and pictorial materials have been developed for use by illiterate women and those with limited reading ability.

FDA stated in the nonapprovable letter its conclusion that for any existing population, the risk of using Depo-Provera outweighed the benefits, but later in that same letter they noted that they recognized that the benefit-risk considerations may be different in other nations.

I draw your attention to former Commissioner Kennedy's statement:

> It follows that a decision about the appropriateness of a contraceptive drug for the United States would not necessarily apply to any other nation, let alone all.

Former Secretary Califano testified before the Senate Subcommittee on Health and Scientific Research as follows:

> A drug which has an unfavorable benefit-risk ratio in the United States and therefore is not approved for use here may, due to differences in circumstances, have a very favorable benefit-risk ratio in another country, and therefore may be entirely appropriate for use in that country.

We maintain that the benefits of Depo-Provera outweigh the risks for women in the United States as well as in other countries. Depo-Provera is a highly effective contraceptive and has several unique properties and advantages associated with it.

For example, as you have heard, Depo-Provera is particularly suitable for women who cannot tolerate the known side effects produced by estrogens or for women for whom estrogens are medically contraindicated. The so-called risks of Depo-Provera for long-term contraceptive use have been primarily theorized from animal toxicity studies. In over 15 years of clinical experience, no serious morbidity has developed with the use of Depo-Provera.

The risks in U.S. women should, of course, be assessed in controlled studies, such as the postmarketing surveillance study which was planned by Upjohn at FDA's request.

We would welcome the opportunity to market Depo-Provera in the United States, and to undertake these studies. In the meantime, however, we must not ignore the data which have shown that no deaths have been ascribed to Depo-Provera used as a contraceptive in women after more than 15 years of safe, effective and responsible experience throughout the world.

The Upjohn Co. has been extraordinarily, if not uniquely, open in its public distribution of all information about Depo-Provera. Data

were made available long ago to the World Health Organization and to a multitude of countries around the world. Within days of receipt of adverse findings in long-term monkey studies, a report was filed with the FDA investigators and health officials in many parts of the world were notified by letter and telephone.

Upjohn has also waived its right to confidentiality of information on pathology and toxicology on Depo-Provera in the files of the FDA, thus making such material available to all.

In closing, we request inclusion in the record of this hearing the detailed commentary on Depo-Provera which you have been provided, and which has been submitted in response to a recent article by Mr. Minkin, an article which was mailed to international agencies and others.[1]

We are also submitting for the record a letter written by Dr. Malcom Potts, the executive director of the international fertility research program, who also comments on this same paper.[2]

I would request that the written testimony that I provided to you be included in the record as it is somewhat more extensive.

I again thank you for this opportunity, and look forward to responding to any questions you may have. Thank you.

[Mr. Duncan's prepared statement follows:]

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[1] See apps. 7 and 8, pp. 302 and 313.
[2] See app. 9, p. 365.

PREPARED STATEMENT OF GORDON W. DUNCAN, MANAGER, SCIENTIFIC LIAISON, THE UPJOHN CO.

Thank you, Mr. Chairman, for this opportunity to appear before the Subcommittee on International Economic Policy and Trade. I have appended to this testimony a brief curriculum vitae outlining my experience, both with The Upjohn Company, and as Director of a United Nations-funded program for adapting contraceptives to family-planning programs around the world.

It is our understanding that this hearing was convened to deal with the problem of hazardous substances which are exported. If this is true, then it is important to note that the contraceptive dosage form of Depo-Provera is not exported. of August 12, 1980, which contains the working draft of the Administration export policy, notes (p. 53755) that Depo-Provera is made abroad for overseas sales. The intended dosage form for contraceptive use is not manufactured within the United States. Furthermore, Depo-Provera itself does not appear to fall within any definition of a "hazardous substance." It is an FDA-approved drug for cancer treatment in the United States.

Depo-Provera safety and efficacy issues have been reviewed in many other public forums. Extensive hearings were held in 1978 by the former House Select Committee on Population. Family planning experts and health officials from many nations testified before Chairman Scheuer. Upjohn's president, then-FDA Commissioner Kennedy, other FDA officials, and parties opposing the drug's use were all heard. There are more than 1,000 pages devoted to Depo-Provera in those Hearing Reports, and a summary of the animal safety data was included as part of that published record. If it is appropriate, I would like to include the record of those hearings as part of the deliberations of this Subcommittee on the subject of Depo-Provera.

As I will mention later, two advisory Committees of the FDA have published extensive reports of their deliberations on Depo-Provera. If appropriate, I would suggest that those reports should also be considered in your study of Depo-Provera.

In 1967, Upjohn filed a Supplement to its New Drug Application, requesting that Depo-Provera be approved for use as a long-term contraceptive. In accordance with the 1967 drug regulations long-term testing in two large animal species (the dog and the monkey) was begun approximately one year later. In 1971, sufficient clinical information in women had been gathered for evaluation of the New Drug Application and, therefore, Upjohn terminated its clinical testing in the U. S. Clinical testing of the drug continued abroad.

In 1973, FDA published in the Federal Register its intention to approve Depo-Provera for contraception. Questions were raised by the House Committee on Government Operations whether Depo-provera-treated women showed more cancer of the cervix than women included in the Third National Cancer Survey. In response, FDA convened its Obstetrics and Gynecology Advisory Committee to study the cervical cancer issue. The Committee found that, because the two studies could not be compared, there was no way to determine whether Depo-Provera promoted or impeded cervical cancer. The Advisory Committee unanimously recommended approval of Depo-Provera. Their conclusions and recommendations were published, and it was stated that approval would become effective October 15, 1974. In spite of this recommendation, the Chairman of the House Committee then requested that FDA revoke the intended approval. FDA subsequently published a postponement of the approval due to "consumer and Congressional concerns," pending further study of the safety issue by the combined Obstertrics and Gynecology Advisory Committee and the Biometrics and Epidemiological Methodology Advisory Committee. In April 1975, open hearings of the Committees were held and in December 1975, the Committees again unanimously recommended that Depo-Provera be approved for contraceptive use. Although there was no further objection from the Committee on Government Operations, FDA took no actions to approve the New Drug Application.

In February of 1978, the House Select Committee on Population announced that would hold a day of hearings to investigate the delay in FDA approval of Depo-Provera.

Two days before that hearing, FDA sent Upjohn a letter stating that they found the Supplemental New Drug Application for Depo-Provera to be non-approvable. It should be noted that FDA has never before nor since rejected the recommendations of two of its own Advisory Committees.

In August of 1978, Upjohn requested that FDA convene a Scientific Board of Inquiry, and FDA granted the request in July 1979. The next month, August of 1979, Upjohn submitted names of its nominees for one of the members of the Board (to be comprised of three scientists). To date, the Board has not been selected by FDA, a chairman has not been named, nor has a date been set for the Board to meet. When this Board is finally convened, it will consider seven issues which have been identified by the FDA. The Board's meetings will be open to the public, and a number of participants, including worldwide family planning experts, physicians, scientists, and consumer representatives will present evidence and arguments. We look forward to the open airing of all issues in this public scientific forum.

Depo Provera was first studied clinically as a contraceptive as early as 1963, and it has now been administered as a contraceptive to more than ten million women around the world. The unique properties associated with Depo-Provera allow a single injection to provide contraceptive efficacy for three months. With its high degree of efficacy and low reported incidence of side effects, Depo Provera in all likelihood is the safest hormonal contraceptive drug available. Unlike the oral contraceptives and IUD's, there has never been a report of a death ascribed to the contraceptive use of Depo-Provera.

Depo Provera is approved for use as a contraceptive in over 80 countries in Asia, Africa, Latin America, and Europe. It is approved for long-term contraceptive use in industrialized nations such as West Germany, France, Belgium, Denmark, Holland, New Zealand, and Switzerland. It is currently approved for treatment of endometrial and kidney cancer in the United States, and is under investigation for treatment of cancer

of the breast. Registration in foreign countries is an ongoing process; a new license for long-term contraceptive use was granted in France within the last two weeks.

You have heard testimony earlier from Dr. Senanyake about the use of Depo-Provera i programs sponsored by International Planned Parenthood Federation. Other national and international organizations recommend and use Depo-Provera in their family planning programs, under strict ethical, moral, and medical guidelines. In addition, local review boards comprised of knowledgeable and concerned physicians, scientists, and lay personnel review programs dealing with the use of Depo-Provera as a contraceptive by their own citizens.

Many clinical studies have been and are now being conducted around the world by international population agencies, university groups, and physicians. The Upjohn Company provides funding for some of these studies to assess, retrospectively and prospectively, the long-term safety of Depo-Provera in contraceptive users. Upjohn is funding and participating in detailed follow-up of children who were breast-fed by mothers treated with Depo-Provera. We believe this to be our responsibility as the manufacturer of pharmaceuticals. Our participation and funding have aided in the early availability of informative data and in the management of patients following initial approval of medicines.

The Upjohn Company believes that the patient, with her physician, is in the best position to judge the suitability of a particular contraceptive. That decision must be fully informed and should also be free of coercion. We have provided materials for use of family-planning clinics and private physicians explaining the expected effects of Depo-Provera. Special printed and pictorial materials have been developed in collaboration with international agencies for use by illiterate women and those with limited reading ability. Upjohn scientists have recently been in clinics in Africa and Latin America. They observed there the quality of information conveyed to patients and the adequacy of methods by which informed consent is obtained.

In FDA's letter of non-approval to Upjohn on March 7, 1978, they stated their conclusion that in the U. S. there is no definitive evidence of a significant patient population needing the drug. Studies of women given detailed patient information on potential risks revealed, however, that if Depo-Provera were approved for contraception in the U. S., between 5 and 9 percent of women of childbearing age would be potential users of the method.

FDA stated in the non-approvable letter its conclusion that, for any existing population, the risks outweigh the benefits, but later noted that they recognized that benefit/risk considerations may be different in other nations. In testimony two days later before the House Select Committee on Population, former FDA commissioner Donald Kennedy stated: "It follows that a decision about the appropriateness of a contraceptive drug for the United States would not necessarily apply to <u>any</u> other nation, let alone all." (Hearing Report, p. 311). Just a week later, former HEW Secretary Joseph Califano testified before the Senate Subcommittee on Health and Scientific Research:

> "A drug which has an unfavorablebenefit-risk ratio in the United States and therefore is not approved for use here may, due to differences in circumstances, have a very favorable benefit-risk ratio in another country, and therefore may be entirely appropriate for use in that country." (Hearing Report, p. 245).

The Upjohn Company maintains that the benefits of Depo-Provera outweigh the risks for women in the U. S., as well as in other countries. Depo-Provera is a highly effective contraceptive, having a method failure rate equal to that of oral contraceptives, but having these additional advantages: (1) the injectable route of administration prevents user failures due to lapses in the daily dosage requirements; and (2) unlike oral contraceptives, the formulation contains no estrogen. Depo-Provera is particularly suitable for women who cannot tolerate the known side effects produced by estrogens or women for whom estrogens are medically contraindicated, such as cigarette smokers. The benefit of Depo-Provera's efficacy in the U. S. is that it protects against the morbidity and mortality, as well as the social pathology associated with unwanted pregnancy and unwanted

children. This benefit is enhanced in other countries, where mortality from childbearing is far greater than in the U. S. However, we cannot and should not accept a numerical approach to avoidable deaths--even the unnecessary death of one woman is unacceptable.

The so-called "risks" of Depo-Provera long-term contraceptive use have not been identified through direct evidence from the multitude of clinical data which have been amassed. They have instead been theorized from animal toxicity studies which showed evidence of tumor formation in beagles and monkeys who were given massive doses of the drug over long periods. In over 15 years of clinical experience, no serious morbidity has developed with the use of Depo-Provera, and the tumor findings in beagles and monkeys have not been borne out in humans. Any putative risks of Depo-Provera use should, of course, be assessed against demonstrated risks of present contraceptives, including the oral contraceptives and IUDs. Risks in U. S. women should, of course, be assessed in controlled studies, such as the post-marketing surveillance study which was planned by Upjohn at FDA's request. In the meantime, we must not ignore the data which have shown that no deaths have been ascribed to Depo-Provera use as a contraceptive in women, after more than 15 years of safe, effective, and responsible experience throughout the world.

The Upjohn Company has been extraordinarily, if not uniquely open in its public distribution of all information about Depo-Provera. The president of the Company, in testimony before the House Select Committee on Population, stated that these data were made available long ago to the World Health Organization, and to a multitude of countries around the world (Hearing Report, p. 49). Within days of receipt of adverse findings in long-term monkey studies, a report was filed with FDA and investigators and health officials in many parts of the world were notified by letter and telephone. Upjohn has waived its right to confidentiality of information on pathology and toxicology in the

files at the FDA, thus making such material available to groups, including Congressional Committees, international health agencies, and consumer groups (e.g., Health Research Group).

We request inclusion in the record of this hearing the detailed commentary which we have submitted on a recent attack by Mr. Minkin, which was mailed to international agencies and others by the National Women's Health Network. We are also submitting for the record a letter written by Dr. Malcolm Potts, Executive Director of the International Fertility Research Program, in which he also comments on the same materials. He has agreed to release this private communication for your use.

I will be happy to respond to any questions.

Mr. BINGHAM. Thank you, Dr. Duncan.

In relation to your request, I would ask Mr. Minkin if he wants that article included in the record. If not, I see no purpose in including in the record the answer to it.

Mr. MINKIN. Well, I'd acutally be very pleased to have the article in the record. I haven't seen Dr. Duncan's or Malcolm Potts' reply to it. I have experienced past criticisms of my article, and I would be very happy to have the two stand side by side. I regret that the taxpayer will be burdened with so much extra printing costs.

MANUFACTURE OF DEPO-PROVERA

Mr. BINGHAM. Without objection, then, the article and the commentaries will be included.[1]

Dr. Duncan, are there other manufacturers of Depo-Provera, or is Upjohn the only one?

Mr. DUNCAN. We believe there are, or in fact know there are other manufacturers of medroxyprogesterone acetate. Depo-Provera is a trademark, but the chemical substance is manufactured by other pharmacuetical companies. I believe there are some in Italy, and also some local manufacturers who make it in less-developed countries.

Mr. BINGHAM. You don't hold a patent on it?

Mr. DUNCAN. Upjohn does hold a patent on the formulation and on the chemical, but there are countries in which this patent has not been filed or is not fileable, and it is produced in these countries.

Mr. BINGHAM. Do you license any other manufacturers for the production of it?

Mr. DUNCAN. I'm not sure of the answer of that. I know we do manufacture it ourselves in our own facilities.

Mr. BINGHAM. You manufacture the contraceptive outside of the United States?

Mr. DUNCAN. That is correct.

OTHER CONTRACEPTIVE METHODS

Mr. BINGHAM. Mr. Minkin, what is your position with regard to the suitability of other methods of contraception in developing countries? For example, the IUD and the pill.

Mr. MINKIN. I first of all think that before we can even consider the question of suitability, if I just may address the point of who is distributing these drugs and who is supervising——

Mr. BINGHAM. Please respond to my question.

Mr. MINKIN. OK. I feel the pill is totally unsuitable for lactating women, as is Depo-Provera. In some countries where there is a large percentage of lactating women, I would oppose the mass distribution of the pill. I would not oppose use of the pill in carefully controlled programs, but with this stipulation, that there be low dose pills with careful followup and supervision of the women, which could be done by paramedical personnel.

In the case of the IUD, I think the record is obvious, that in many countries, anyway, this has been a failure partially because unsterilized

[1] See apps. 7, 8, and 9.

IUD's have been utilized. But I'd say for most of the Third World, the IUD is not a suitable alternative.

In terms of condoms and diaphragms and so on, I think there is a very good scope, if we actually look at the performance, the continuation rates, and the rates in terms of how much fertility has been controlled, very often the condom does better than the pill, for instance.

And last, I would not use the method which disrupts natural fertility, which is related to breastfeeding and lactation, and that's another reason why we have seen in many aid programs, fertility actually increases with the pill.

So, in these situations I would say no mass distribution, but carefully controlled programs with well-trained personnel. That's really what is needed.

Mr. BINGHAM. What is your feeling about what should be done in countries where you have poor facilities to follow up on programs? In other words, you don't have any kind of supervision. You have people with low levels of education, poor existing medical facilities, and yet very high rates of mortality in childbirth. What is your recommended solution in situations of that kind?

Mr. MINKIN. My solution is not an easy solution. I think it's very nice for us to think we have an injection and we will inject these people and somehow reduce the maternal mortality rates. I don't believe we will reduce it that way. I think what we have to do—and there are many examples in the Third World—we have to really start supporting programs which develop the capacity of the community to serve its own health needs. All right? There is a lot of rhetoric about this, who supports this and so on, but I think that when we have top-down heavy-handed programs of contraceptive control, we are fooling ourselves into thinking we are providing benefits for people which are lasting benefits.

So I would say training to move medical care and health care closer to the hands of the people. If you are not familiar, I would like to recommend the work of Dr. David Warner, "Where There Is No Doctor," which is the title of his book, which spells out the ways that can be done.

I think it's very unfortunate that in countries such as Bangladesh and many other countries, the limited maternal child health facilities that exist have been turned into family planning facilities, and the few people who actually carry out minimal care—there's no question it was a minimal level of care—that even in these places they have been moved into population control.

I would say, in fact, the reasons for maternal mortality are not necessarily childbirth. They are malnutrition, improper supervision and screening for other types of matters, and I think we can address maternal mortality by dealing with the fundamental issues that impinge on women's lives.

RISK-BENEFIT RATIOS IN DIFFERENT COUNTRIES

Mr. BINGHAM. What is your comment on the quotation from former Secretary Califano that was included in Dr. Duncan's testimony?

Mr. MINKIN. I recall this quote and, in fact, I think it was the preceding sentence or the sentence after this where Secretary Califano

also alluder to the profit motives in this angle, and I would say that it's the notion of different risk-benefit ratios sound very foreign when we are in Washington or London or New York, or whatever; but a careful study of these matters will often show that the reported risk-benefit of a drug—and I'd like to give you a specific example, in the case of Depo-Provera—it is sometimes argued that even if Depo-Provera increased the incidence of endometrial cancer 30 times, 60 times, or 100 times in countries, the actual risk to women would be less than childbirth.

In fact, a recent analysis done by a very reputable physician who has worked in family planning for many years, has shown that a mere doubling of incidence of endometrial cancer in a country like Bangladesh would produce more deaths, many more, one-third more deaths than maternal mortality. But admittedly these are estimates, but the detail work isn't being done, so we can't say yes, it's safe and so on.

But in fact I think that the risks as you deal with them in a village level may be different from what's presumed.

Mr. BINGHAM. Well, you're arguing a factual case there, but you attack very strongly the idea of a double standard in your statement. Now I'm asking you whether it is not true that you may have a different situation in a developing country than you do in the United States, with regard to the benefit-risk ratio. Is that not correct?

Mr. MINKIN. I think we certainly do, but I think the term benefit-risk ratio masks more than it tells, and I think once we hear that term, then we say yes, it does or no, it doesn't. I think when we have carefully devised health programs with paramedical personnel, where people have greater say and responsibility for their health care, then we are talking about benefits and risks and so on in a way which is an enlightened way.

Otherwise, what we are talking about, the introduction of this technology, they're fads, they're fashions, they're profitable, but they won't solve the problem, unfortunately. The development of suitable, usable and, in the long run, beneficial programs is substantially inhibited because the funds and the momentum of health care is moving in the opposite direction.

MONITORING

Mr. BINGHAM. Dr. Senanayake, would you comment on the quotation that was attributed to you in Mr. Minkin's statement, that IPPF does very little in terms of monitoring the effects of contraceptives on the recipients?

Dr. SENANAYAKE. Yes, Mr. Chairman. That was, in fact, an internal document which was addressed by me to my superior, in documenting some of the activities we could engage in for the coming period of 6 or 12 months. It does not in any way apply to Depo-Provera, per se. It applies to all contraceptives. I was making a general case that we can do more than we are doing. It does not imply that we are doing nothing at all. Certainly we are doing quite a bit. It's a quotation taken out of context. So I'm glad you raised that issue, because it needs clearing up.

AID DEPO-PROVERA PROGRAMS

Mr. BINGHAM. Dr. Rochat, do you know anything about the allegations that AID is actually carrying on some programs with Depo-Provera? According to testimony given to us by AID earlier this year, they are not.

Dr. ROCHAT. It's my understanding that AID has not ever directly provided Depo-Provera or supplied it. It is also my understanding that Depo-Provera has been used by programs which received some of their financial support from AID.

Mr. MINKIN. Mr. Chairman, may I comment?

Mr. BINGHAM. Yes.

Mr. MINKIN. I don't have it with me, the select committee proceedings, but the submission by Dr. Ravenholt contains references to AID-supported programs in Bangladesh, Sri Lanka, and Mexico. These are described as operations, research programs, and my understanding is that AID facilities and personnel are directly involved in distributing Depo-Provera. I'm not sure who does the actual purchase, but people on the AID payroll are directly involved in the operations of these programs.

Mr. BINGHAM. Well, we will have to pursue that because we have contrary information, at least as to current programs.[1]

Mr. Barnes.

DISAGREEMENT ON DEPO-PROVERA EFFECTS

Mr. BARNES. Thank you, Mr. Chairman. I'm new to the specific issue of Depo-Provera, and I doubt very frankly that this hearing is going to give me the answer to my own question about the specifics of this drug. But I will pursue it with at least one question. Dr. Senanayake said that the side effects of Depo-Provera are "seldom serious." Mr. Minkin says they are very serious, in fact, says at one point that it is accepted medical knowledge that Depo-Provera causes birth defects. You couldn't get a much more divergent viewpoint than that and, as I say, I suspect that that will continue at the end of this hearing. But I would ask all four of the witnesses to comment on, if you would, (a) why you think this divergence of opinion exists; and (b) the specifics of the assertion.

Perhaps Dr. Rochat would like to start.

Dr. ROCHAT. Studies in humans have shown a possible twofold increase to risk of birth defects with exposure to exogenous hormones broadly grouped. Where Depo-Provera is not one of the specific agents, I believe, but progesterone is one of the drugs, in combination with estrogen, as in oral contraceptives. I don't know of any study that deals specifically with Depo-Provera in humans. Perhaps there are. I'm not familiar with them.

There are studies, as I understand it, in some animal species suggesting there might be birth defects.

Mr. BARNES. Thank you. Dr. Senanayake?

Dr. SENANAYAKE. Yes. With over 10 million women-years of use of this drug, we do not have, as far as I know, any human evidence to

[1] See app. 10. p. 370.

support the statement that there are birth defects in the offspring of women who receive this drug in the earlier stages of their pregnancy.

As I said in my own testimony, we have no evidence also of any deaths whatever attributable to this drug, and that is some of the reasons why I said the side effects are seldom serious.

To me, death is an important yardstick—not the only one, obviously, but at least with regard to the other equally reliable methods like the oral contraceptives and intrauterine device, we have deaths associated with that, and with Depo-Provera we do not.

Mr. MINKIN. Well, in part you are seeing a very good example of the fact that the supporters of Depo-Provera are capable of editing out a notion which favors basically a population control position as opposed to medical safety position. In the case of birth defects, progesterone, the class of drug that Depo-Provera belongs to, is associated with cardiovascular defects. It is very difficult to find cardiovascular defects in young infants. As you follow—and congenital cardiovascular defects. As you follow them over time, the incidence increases, so that by the age of 5, you have a fairly good idea of the kind of situation you are dealing with.

So in this case you're dealing with a situation where although they admit to giving Depo-Provera to maybe 4, 5, or 6 percent of the test population of pregnant women, they don't follow up. Maybe they don't have that capacity, but then the assumption is therefore cardiovascular defects do not occur from a very potent progestin. I think this is false.

Likewise, in the case of endometrial cancer, it is very obvious from the monkey studies that the cancers developed in older age. Endometrial cancer is a disease of menopausal women or postmenopausal women. This has been established with sequential contraceptives, this has been established with other—even where there's no association with the contraceptive.

In fact, a woman who gets Depo-Provera may not develop cancer for 10, 20, or 30 years. The crop is coming up. What is disturbing is that in Chiang Mai, Thailand, among women who have been located, who have endometrial cancer, some of those women are much younger than expected.

All right. Now we can't say whether those women have used Depo-Provera because again the studies that have been conducted have been very poor, and I think almost deliberately engineered to exclude the possibility of looking at these women. So that I would say in epidemiology there is a saying really that the more you look for something, the more you find.

I don't think we are in a situation where any supporters of the drug want to really look and see what's going on. The argument that we need millions of women to determine whether Depo-Provera is safe is very profitable and makes lots of money, but it makes very bad science.

Mr. BINGHAM. Dr. Duncan?

Mr. DUNCAN. I would like to support the statements of Dr. Senanayake on the effects on the fetus. To our knowledge, there has been no association between Depo-Provera and the incidence of fetal anomalies, either in fetuses subjected to Depo-Provera or to conceptions which have occurred as a consequence of failure of Depo-

Provera which is also perhaps associated with some exposure during the initial in utero period.

We are looking not only at those individuals, but also those that have nursed mothers who are being treated with Depo-Provera. We looked at the infants shortly after birth. We are following them again at 5 and 8 years. We will continue to follow them, and there is no evidence to date of any teratogenic effect on those infants.

Now, the literature is replete with articles on the effects of hormones on fetal development, both in animal species and in the human. I don't think any of us would propose purposely exposing a fetus to hormones. Hormones have been used for pregnancy tests in the past, and used as an attempt to salvage pregnancies. That is no longer considered good medicine in this country.

Depo-Provera is highly effective, at least as good as, if not better than, the orals. It is prescribed for use at a time when we try to minimize the exposure of the pregnant women. Women should not be pregnant when first treated with Depo-Provera following the protocols that we recommend for its use. So exposure of pregnant women should be low. We have no reported incidence of any effects of the contraceptive use of the drug, as far as inducing fetal anomalies.

STATUS OF FDA APPLICATION

Mr. BARNES. Just a followup question. You went through the background of the experience with FDA in the applications for permission to manufacture and sell Depo-Provera in the United States. You were denied twice, despite the recommendation of the advisory group. What is the status of it now? Is there a pending application?

Mr. DUNCAN. We have asked for a hearing. The request has been granted. We are expecting a public board of inquiry to be convened. As far as we are aware, the FDA has not yet named the three individuals who will be on that board, nor the chairman for the group. Nor, as I said, has a date been set.

Mr. BARNES. Thank you.

FETAL ANOMALIES

Mr. DUNCAN. May I clarify one of my previous statements on fetal anomalies? Early in the use of Provera, there were some occasions in which women were subjected to relatively large doses of Depo-Provera in early pregnancy, back in the late sixties, early seventies. Female infants of those pregnancies were observed to have some enlarged clitori; they all returned to normal within a 6-month period. We don't consider that a teratogenic effect. It is an effect on the fetus, it's one that is expected from that sort of hormonal treatment, but it did return to normal within a 6-month period of time.

Mr. MINKIN. Might I just comment on that, without getting into too much technical detail?

Mr. BARNES. Yes.

Mr. MINKIN. The fact that you had this situation in female fetuses is an indication that the drug is active throughout pregnancy. The reproductive organs of the child are being developed in the uterus and

continue to develop in the first 2 years of life, and basically this is an indication that the development of what is called an ultrastructural level, the most fundamental level, has been impaired.

This is the kind of thing that happened with DES, and this is why we are very fearful, because basically again the obvious growth form stops, because there is no more force. Eventually the hormones have been excreted out of the system. But the fact is, on the level of DNA, the changes have already occurred, and that's why it's frightening.

In adult women, you have viral particles that appear in the endometrium after a single injection of Depo-Provera. No one has seen what takes place in these infants, and that's very frightening.

Mr. BARNES. I gather you all can go back and forth for some time on this, and it is a rather technical issue that I gather is addressed in the papers that are available to the subcommittee. So rather than prolong this, I will return my time, Mr. Chairman.

Mr. BINGHAM. Mr. Wolpe?

STUDY IN THAILAND

Mr. WOLPE. Thank you. A moment ago you were describing a study in Thailand that gave cause for concern. What study was that?

Mr. MINKIN. I mentioned it in the testimony, and I would be glad to submit the study as well. We do not have the details of the study. This study is a confidential document submitted to the FDA, obtained under the Freedom of Information Act, which alludes to the fact that there had been a marked increase in the incidence of breast and cervical cancer in Chiang Mai, Thailand.

It attributes this increase to improved screening without giving any indication of how—of statistics, what kind of screening has occurred, so on and so forth. This is the first information we have had of the fact that they have been keeping counts of endometrial cancer—sorry, cervical and breast cancer in Chiang Mai, Thailand.

In effect, we are frankly alarmed to see any increase. We would like to see the denominators, baseline, and so on. The past studies in Chiang Mai, Thailand, have been primarily financed by USAID and again we doubt the credibility of them. The international fertility research program was designed to promote contraceptives in the field, and we would like to see an independent arbiter look at those statistics, and we hope this committee can obtain those statistics, so that perhaps somebody at Harvard University or elsewhere can give the committee a report on the meaning of those statistics.

Mr. WOLPE. Would any other panelist have a comment on the research that's been done in Thailand, or the general thrust of the remarks of Mr. Minkin just now?

Mr. DUNCAN. I'd just like to open them. I think WHO would be a little chagrined to learn that they were not considered to provide an objective, reputable assessment of medical health around the world. Not only do they have their own internal review committees, but they have external advisory committees, both on biological and medical phenomena and toxicologic and pathological phenomena, and also for the moral and ethics review.

Mr. Minkin did share with me what I believe was the remainder of that quote in which this information was being used as a means of exonerating the concern over Depo-Provera in its possible association with endometrial carcinoma. I want to see the data myself that he's alluding to.

Mr. WOLPE. If I could pursue that for just a moment. Let me interrupt, Dr. Duncan.

Did I hear you say, Mr. Minkin, you have not actually seen the data?

Mr. MINKIN. I have seen a confidential WHO report which clearly states there had been a marked increase in the incidence of breast and cervical cancer in Chiang Mai, Thailand. I found this shocking. I had never heard this before. I would like a full explanation as to in fact why this information has not come out before, and I would like to see the data, and I would like to see an expert panel, an independent panel, look at the data before we go to the FDA Board of Inquiry, because I think this is very interesting information.

Mr. WOLPE. Dr. Duncan, I didn't mean to interrupt you.

Mr. DUNCAN. I wanted to conclude with some difficulties I have had in handling Mr. Minkin's testimony, where it seems to come out of context or has implications ascribed to it that aren't supported by the original developers of the data. One difficulty was in the previous comment of Mr. Minkin, where he referred to the occurrence of viral particles in women treated with Depo-Provera. I don't think that's substantiated in literature.

There are some hypotheses about degenerating nuclei found in electron microscopic studies, but I think the naming of these particles as viral particles is up to Mr. Minkin.

DOCUMENTATION OF SIDE EFFECTS

Mr. WOLPE. Let me ask another—in Mr. Minkin's paper, there is a fairly bold assertion, and I would like again to track down the specific medical documentation that underlies this statement, so that we know what to go after and take a look at. There is this quotation.

> Continued use of Depo-Provera for continued birth control is unjustified and unethical. A healthy woman on Depo-Provera prematurely ages. She takes on the characteristic profile of a postmenopausal woman who is at high risk of developing endometrial carcinoma, and her uterus atrophies. She stops ovulating and she is sterile. Most women stop menstruating, but many experience excessive bleeding, some requiring D. & C.'s and hospitalization. Intermittent bleeding from the vagina commonly occurs after the first few injections. A significant portion develop abnormal glucose tolerance curves or become diabetic.

What is the specific medical documentation for that assertion?

Mr. MINKIN. Which assertion? The whole assertion? Oh, well, there's numerous sources of documentation. First of all, I would also like to explain that there were seven physicians, including gynecologists and obstericians who were in full agreement with that assertion.

Mr. WOLPE. But what is the specific data from which you got that?

Mr. MINKIN. First of all, in terms of—let's look at what happens to—well, let's look at a woman who is considered at high risk of developing endometrial carcinoma. There are certain profiles that develop. I'll give you the documentation first. This is Barron, I believe his name

is, at Columbia University, College of Physicians. You might know him. Paul Barron. It comes from a book produced by AID and others on fertility. I'll have to give you the exact name, but I certainly can say that in fact a postmenopausal woman, a woman who is sterile, who has not produced children, who is potentially diabetic or a diabetic, a woman who is overweight and so, is a woman who fits this profile.

I can certainly say—in fact, if I have a copy of the testimony, I can give you the exact reference to it.

Mr. WOLPE. "A healthy woman on Depo-Provera prematurely ages. She takes on the characteristic profie of a postmenopausal woman." I don't want the profile, I just want to know what precise scientific data underpins that assertion.

Mr. MINKIN. She loses her hair, her uterus atrophies.

Mr. WOLPE. What is the data upon which you make that assertion?

Mr. MINKIN. Well, tell me what you mean by "prematurely ages."

[Laughter.]

Mr. MINKIN. Basically——

Mr. WOLPE. I'm sorry, this is your paper.

Mr. MINKIN. In that particular situation, a woman is weaker, depressed. These are all characteristics——

Mr. BARNES. What study are you referring to?

Mr. MINKIN. Paul Barron. If I have a copy of the report, I will be very glad to give you the reference. It has to do with breast and endometrial cancer.

Mr. WOLPE. Was there a human clincal study that yielded data that would support that assertion?

Mr. MINKIN. That she prematurely ages? I don't think that there is a study that supports that assertion. I think the whole paper——

Mr. WOLPE. Then why do you make that assertion?

Mr. MINKIN. Because the whole thrust of the paper supports that assertion.

Mr. WOLPE. That's your paper.

Mr. MINKIN. Based on another 90 or 60 or 70 references, depending on—the paper is based on an accumulation of medical knowledge, all right? And then I am summarizing that knowledge, yes.

Mr. WOLPE. That's fine. I simply want to understand the basis from which you make the assertions. You are not arguing, are you, that you are the medical expert in the sense that you are summarizing medical data?

Mr. MINKIN. I am summarizing scientific data.

Mr. WOLPE. You are not arguing this as a matter from your own first-hand knowledge? You do have scientic expertise that you're bringing to bear yourself?

Mr. MINKIN. I disagree with that. I have years of research on this subject, and on the basis of that, I have come to these conclusions, based on, in this case, 110 footnotes.

Mr. WOLPE. Fine. It is precisely the data, the medical data, that underlies that assertion I am seeking, so we could then look at that data and see if, in fact, there is some relationship between the study that has been performed and the conclusion that the use of this drug would tend to produce premature aging.

Mr. MINKIN. All right. I would suggest a careful reading of the paper, anywhere where there is a specific documentation to a scientific

article, there is a footnote. Anywhere there is a statement being made by the author, it should be made very clear to the reader that in fact this statement was a conclusion that's been made in a way in which any scientist who's putting together a summary would do. So, basically, yes, I'm saying if you look at that, if there's no footnote there, it is obvious to the reader that in fact——

Mr. WOLPE. That's your interpretation?

Mr. MINKIN. Yes.

Mr. BINGHAM. Would the gentleman yield?

There is a fact of a footnote at the bottom of the page. No. 108. It refers to an article by someone named Parvine.

Mr. MINKIN. Yes; that's a very good point. That refers to the fact that most women stop menstruating and experience excessive bleeding, some requiring D. & C.'s. There's an article by Parvine, Choudhry, and others; it's in the medical journal Lancet; it's referred to above, and it is a very thorough study by a group of physicians who in fact are now disillusioned with Depo-Provera in Bangladesh.

Mr. WOLPE. Let me ask, if I may, Mr. Chairman—may I reclaim my time?

Are the other panelists aware of any human clinical studies that would support that particular conclusion?

Dr. ROCHAT. No.

Mr. DUNCAN. No.

Dr. ROCHAT. And I would add, if I may, with respect to the article by Parvine, that it's not a controlled study, and the amazing thing is that it was published, in my opinion.

I'd like to comment also on the request for information from Thailand, that we had a Thai physician on our ad hoc consultative panel, Dr. S. Koetsawong from the faculty of medicine at Bangkok who did present data on studies from Thailand which looked like very good scientific studies. I don't recall all the particular ones, and none of them dealt with the particular issue that Mr. Minkin brought up now.

WITHHOLDING OF INFORMATION BY UPJOHN

Mr. WOLPE. Let me turn to another question, if I may, very briefly. There have been some rather strong allegations with respect to the availability of data. There have been assertions in the course of this paper that Upjohn has withheld data, manipulated data, that somehow you've had to resort to Freedom of Information requests in order to get material.

My understanding based on the Scheuer testimony and on other things that have come my way is that indeed all the material has been made available by Upjohn. Indeed it was even made available to Dr. Well's health research group.

I'd be interested in knowing from the other panelists—first, Mr. Minkin, on what basis do you substantiate an intention to conceal data?

Mr. MINKIN. I think it's very interesting, we have the Congressional Record, the Population Committee hearings, and nonetheless the assertion that was made at the time of those hearings was that the only medical evidence against Depo-Provera was development of mammary carcinomas. During that period of time there were palpable lesions.

Mr. WOLPE. I'm sorry. I would like just a specific response to the question.

Mr. MINKIN. It is that Upjohn was concealing the cancer in one monkey, at the same time they were telling the public that there were no cancers in any animal, other than the beagle dog. That's the information that's documented, and the documentation is enclosed. It comes from Victor Berliner from the Food and Drug Administration, internal memo, accessible only through the Freedom of Information Act, and not available to foreign governments or to citizens in this country or in any other way.

Mr. WOLPE. I'm going to come to that in just a moment and provide Dr. Duncan an opportunity to respond to that. Are there any other instances of concealment?

Mr. MINKIN. Yes.

Mr. WOLPE. OK, what are they?

Mr. MINKIN. There was a cystal polypoid—cystal polypoid growth in the endometrium of a monkey who was later identified to have viral particles throughout the body by U.S. Army pathologists. That particular finding is an indication of the development of endometrial cancer in about 15 percent of postmenopausal women, according to very eminent British obstetricians and gynecologists. It's all documented here. That information was not given to the world. The most recent information has to do with curvature of spines in monkeys at all treatment doses on Depo-Provera. Control animals did not develop abnormal curvature of the spine, treated monkeys in the 50-time, the 10-time, and the 1-time dose category did develop abnormal growth curvature of the spine, and I think it's very serious when a drug is known to inhibit bone growth, and it shows it produces abnormal curvature of the spine, to give it to breastfeeding women or to women around the world. And that has been concealed. I haven't read a single Upjohn statement to that effect.

Mr. WOLPE. Dr. Duncan.

Mr. DUNCAN. That's obviously a very serious allegation, and one that we have felt strongly about responding to, and I appreciate this opportunity.

The monkey studies were done by an independent, third party contractor located outside of the Upjohn Co. This adds a degree of objectivity to the study. It also means we have information only when they provide it to us, and this was under a scheduled protocol. The particular statement that Mr. Minkin is referring to was provided to us in the final pathology report at the termination of the 10-year study. There was no communication from that research organization to us at any time prior to that regarding that observation that they claim was made 2 years earlier.

They themselves had dismissed that observation, as we found in subsequent discussion with them, at the time because they thought it was a normal observance of no consequence. They were not even sure it was repeated at subsequent observations of that same monkey. It became important only at time of sacrifice when that monkey was identified to have the cervical—excuse me, the uterine cancer.

But I repeat, we were not aware of that information prior to that time. The report was immediately filed with the FDA, even before the

report was final, and the information was immediately sent by telephone and by letter to principal investigators around the world, and we can document that, and I feel very strongly about that accusation.

Let me also add during this period of time I was not with the Upjohn Co. I was one of the recipients of the distribution of this information with an organization at that time, and I can personally attest we were provided all of the information that we either wanted or that Upjohn even felt sometimes was necessary for us to know, where we didn't even make a request.

Let me further go on about the accusation that Depo-Provera inhibits bone growth. Again, I don't know where the basis for such a statement would arise. There is an effect of Provera in an acromegalic individual, where it may lower growth hormone levels in that animal—excuse me, in that subject, but in all normal individuals Depo-Provera has a favorable effect on the calcium deposition in the bone and on the absorption of the calcium.

Mr. WOLPE. Would the other panelists care to respond to the accessibility of Upjohn's information?

Dr. ROCHAT. Certainly as a representative of the ad hoc panel, we were informed—when was the finding made available to you, Gordon?

Mr. DUNCAN. I don't know the exact dates, because I wasn't there at the time.

Dr. ROCHAT. Our panel met December 7 and 8, 1978, and within 2 weeks, William Hubbard, Jr., M.D. president of Upjohn Pharmaceuticals, telephoned Dr. Rosenfield to inform him, as soon as he was aware of the findings.

Mr. DUNCAN. The first letter went out around the first of the year, and a more detailed letter went out in April, just as rapidly as we could.

Dr. ROCHAT. I know that Upjohn made available to the ad hoc panel several boxes of both published and unpublished data on Depo-Provera to review. So we were as well informed as we were capable of informing ourselves from the data available to us.

Mr. WOLPE. I thank you for that. Did you want to make a statement?

Dr. SENANAYAKE. We don't normally request information from pharmaceutical agencies, but on the few occasions we have, we have had no problems getting it from Upjohn. And I have also been at the receiving end of the mailing list. Thank you.

Mr. WOLPE. OK. I thank you.

Mr. BINGHAM. It's been a long afternoon, ladies and gentlemen. Thank you very much for your testimony. The subcommittee stands adjourned.

[Whereupon, at 6:10 p.m., the subcommittee adjourned, to reconvene at the call of the Chair.]

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APPENDIX 1

96TH CONGRESS
2D SESSION

H. R. 6587

To amend the Export Administration Act of 1979 to restrict the export of goods which have been found to be hazardous to the public health.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 25, 1980

Mr. BARNES introduced the following bill; which was referred to the Committee on Foreign Affairs

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A BILL

To amend the Export Administration Act of 1979 to restrict the export of goods which have been found to be hazardous to the public health.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That the Congress finds that—
4 (1) certain goods, the sale of which has been pro-
5 hibited or restricted under the laws of the United
6 States for reasons relating to the public health and
7 safety or the health and safety of the individual con-
8 sumer, have been exported for sale or distribution in

1 foreign countries where such goods have not been sub-
2 ject to prohibition or restriction;
3 (2) certain goods, which might be subjected to
4 prohibition or restriction under the laws of the United
5 States, but because of such expectation have not been
6 submitted for licensing or approval, have been exported
7 for sale or distribution in foreign countries;
8 (3) the sale or distribution of such goods in foreign
9 countries has often resulted in injury to the public
10 health and safety, or the health and safety of individual
11 consumers; and
12 (4) except in such cases as the use of such goods
13 may outweigh the risks and damages to the health and
14 safety of the general public or individual consumers,
15 the export of such goods from the United States is in-
16 jurious to the foreign policy of the United States and
17 to the reputation and credibility of the United States as
18 a responsible and moral partner in the community of
19 nations.
20 SEC. 2. Section 6 of the Export Administration Act of
21 1979 (Public Law 96–72; 50 U.S.C. 2405) is amended by
22 adding at the end thereof the following new subsection:
23 "(l) EXPORT OF HAZARDOUS GOODS.—(1) Unless the
24 conditions set forth in paragraph (3) are met, no good the
25 sale of which is regulated under any of the laws set forth in

1 paragraph (6) may be exported unless the sale of that good in
2 the United States is permitted under that law.
3 "(2) Unless the conditions set forth in paragraph (3) are
4 met, no good may be exported if the sale of that good in the
5 United States is subject to registration, licensing, or use re-
6 quirements or similar restrictions which are imposed under
7 any of the laws set forth in paragraph (6).
8 "(3) The Secretary may issue a validated license or a
9 qualified general license permitting an export prohibited by
10 paragraph (1) or (2) to a country if, in addition to any other
11 requirements for the export of such good imposed under any
12 other provision of law, the Secretary and the head of the
13 agency regulating the sale of such good in the United States
14 under any of the laws set forth in paragraph (6) concur, on
15 the basis of documentation submitted by the applicant for
16 such license and any other appropriate factors—
17 "(A)(i) that the government of such country has
18 requested that such good be exported,
19 "(ii) that the applicant has fully informed such
20 government and the consignee of any restrictions on
21 the sale of such good in the United States and of the
22 possible hazards posed by the good to the public health
23 (or safety) or to the environment, and
24 "(iii) that the potential benefits of the intended
25 use of the good outweigh those possible hazards; or

1 "(B) in the case of a good described in paragraph
2 (2), that the sale of the good in that country would be
3 subject to requirements or restrictions comparable to
4 those referred to in paragraph (2).
5 "(4) Notwithstanding the provisions of paragraph (3), no
6 good may be exported which does not contain all warnings,
7 instructions for use, or any other information required under
8 any of the laws set forth in paragraph (6) to be included in
9 the packaging of such good for sale or with respect to which
10 the Secretary determines that such warnings, instructions, or
11 other information is likely to be ineffective in the country to
12 which the good would be exported on account of a lack of
13 adequate translation or illustration or any marketing or dis-
14 tribution practice in that country.
15 "(5) No good may be exported for the purpose of using
16 that good in the manufacture of another good the export of
17 which is prohibited by this subsection.
18 "(6) The laws referred to in paragraphs (1), (2), and (4)
19 are the Toxic Substances Control Act, the Federal Food,
20 Drug, and Cosmetic Act, the Federal Hazardous Substances
21 Act, the Fair Packaging and Labeling Act, the Poison Pre-
22 vention Packaging Act, the Flammable Fabrics Act, the
23 Consumer Product Safety Act, the Federal Caustic Poison
24 Act, the Federal Insecticide, Fungicide, and Rodenticide Act,
25 the Controlled Substances Act, the Lead-Based Paint Poi-

1 soning Prevention Act, and any other law designated by the
2 Secretary, the major purpose of which is to protect public
3 health and safety from the hazards of drugs, medicines, medi-
4 cal devices, including contraceptives; pesticides; carcinogens;
5 toxic substances; contaminated foods; and similar hazards to
6 health and safety.

7 "(7) No law enacted after the date of the enactment of
8 this subsection shall supersede this subsection unless it does
9 so in specific terms, referring to this Act and declaring that
10 the new law supersedes the provisions of this subsection.".

APPENDIX 2

STATEMENT OF PUBLIC CITIZEN HEALTH RESEARCH GROUP

June 5, 1980

The Health Research Group commends Congressman Bingham, chairman of the Subcommittee, for his recognition that exports of hazardous substances (such as dangerous drugs, pesticides, food additives, consumer products, and medical devices) need to be restrained and in many cases stopped. These exports, though they may aid the U.S. balance of trade and contribute to corporate profits, often poison our relations with recipient nations and always endanger the lives and health of the citizens of those nations.

This Subcommittee has before it two proposals concerning exports of hazardous substances. The first, H.R. 6587, introduced by Rep. Michael Barnes of Maryland, would take several significant steps toward controlling these exports, though the bill needs strengthening in the areas of disclosure to the public of information about hazardous exports and public participation in the decision whether to license such products for export. The second proposal, the Carter Administration's draft executive order, by contrast, is structured in so lax a fashion that in all likelihood the export of hazardous substances would continue virtually unabated in all but rare circumstances, and the U.S. and foreign public would continue to be denied the facts about dangerous exports.

I. Comments on the Barnes Bill, H.R. 6587

Under the Barnes bill, products banned, disapproved, or restricted for use in the U.S. could not be exported without a license. An export license would be issued only if the Secretary of Commerce and the head of the agency with jurisdiction over the product concurred that several conditions are met: (1) The government of the importing country requests the product after receiving full information about the hazards of the product and any restrictions on its sale in the U.S. (2) The potential benefits of the intended use of the product outweigh the possible hazards. (3) If the sale of the product is restricted in the U.S., its sale in the importing country would be subject to comparable restrictions. (4) The product's labelling at a minimum meets U.S. labelling requirements--but export may still be prohibited if the labelling "is likely to be ineffective in the

[importing] country . . . on account of a lack of adequate translation or illustration or any marketing or distribution practice in that country." (5) The product is not intended for use in producing another hazardous product abroad.

This proposal would construct a generally sensible system requiring an assessment of the likely practical effect on the health and safety of people in the importing country if a hazardous product were used in that country. If properly designed and administered, such a system would potentially remedy the most serious consequence of the existing laissez-faire regime: that decisions about international trade in hazardous products are made on the basis of narrow commercial considerations rather than a thorough analysis of effects on public health and the environment.

There are two major flaws in the Barnes proposal, however, that would hinder the government's ability to carry out the contemplated program in an impartial fashion. First, nowhere in the proposal is there any provision for public disclosure in the U.S. or in the importing country of information about proposed, or even licensed, exports of hazardous products. Second, there is no provision for public participation in agency determinations concerning export licenses.

Unless the public is made aware of a company's intention or practice of exporting hazardous products and given an opportunity to bring its views and expertise to bear on the question, agencies will be denied the benefits of informed public analysis of the likely environmental and health effects of the hazardous exports. Concerned citizens of the foreign countries in question, as well as U.S. citizens knowledgeable about environmental and public health conditions in such countries, would be shut out of the process. The absence of public input is certain to bias the agency's decision-making process in favor of allowing export, since the primary submitters of information to the agency will be industry interests favoring export. Moreover, the unavailability of information underlying decisions to permit export will preclude the public from effectively scrutinizing these decisions.

Unless these flaws are corrected, the Barnes proposal, for all its good intentions, is unlikely in practice to result in adequate reform of present industry practices.

II. Comments on the Carter Administration's Draft Executive Order

The Carter Administration's draft policy[1] is certain to have

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1 The present proposal is the fourth draft of the government's Ad Hoc Working Group on Hazardous Substances Export Policy. The Working Group was convened in 1978 by Esther Peterson, Special Assistant to the President for Consumer Affairs, and includes representatives from about 20 departments and agencies in the Executive Branch.

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little or no effect in controlling hazardous exports. The proposal is deficient in three major respects: (1) It would set up a cumbersome and restrictive procedure for determining which hazardous substances would be subject to effective export controls. (2) The proposal would permit continuation of American industry's exercise of undue influence over foreign governments in order to dump hazardous substances overseas. (3) The public, U.S. and foreign, would continue to be kept in the dark about the facts of hazardous exports.

A. Determination of Products to Be Controlled

Rather than presuming that hazardous substances banned, disapproved, or restricted in the U.S. are likely to be equally dangerous when shipped abroad, this proposal sets out an elaborate scheme for determining which of these substances constitute "severe hazards." Only "severe hazards" would be candidates for the withholding of export licenses.

The agency with jurisdiction over each hazardous substance that was banned, disapproved, or restricted for use in the U.S. would have to make a separate determination, based on six factors set out in the proposal,[2] that for the particular country to which export of the substance in question is proposed, that substance would constitute a "severe hazard." The expenditure of agency resources in making these hundreds of individualized determinations would be tremendous. The opportunities for industry lawyers to delay these determinations, while exports continued unabated, would be manifold. Such a system is unlikely to result in any significant restraint on hazardous exports in the near future.

Moreover, the proposal unaccountably exempts from the possibility of export controls "hazardous production facilities and United States financial assistance for such facilities," and "substances that are not inherently unsafe but may prove hazardous in certain circumstances of use"--even if such facilities or substances have been totally banned in the U.S.

B. Vulnerability of the System to Industry Pressure on Foreign Governments

Under the proposal, even if an agency determines that a particular substance is a "severe hazard" for a particular country, that

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2 The six factors specified in the draft Executive Order are: (a) the type and extent of the potential detrimental effect; (b) the likelihood of the effect; (c) the permanence or irreversibility of the effect; (d) the importing country's ability to avoid or mitigate the effect; (e) the number of people likely to be detrimentally affected; and (f) the availability of other products or methods that would serve the same purposes as the substance proposed to be exported.

determination would be entirely nullified if the foreign country is notified of the determination and requests that hazardous substance anyway. Likewise, if a substance is unapproved in the U.S. because of of a lack of safety or effectiveness information submitted to the U.S. government, it could receive export approval merely upon receipt of a request by the foreign government.[3]

Widespread bribery of foreign government officials by representatives of U.S. corporations and other methods of undue influence by industry to obtain export contracts have been amply documented. Moreover, it is well established that most foreign governments lack the resources to make the careful, product-by-product scrutiny of industry claims of safety and effectiveness that is (or should be) carried out in the U.S. These loopholes automatically granting export permits upon request by a foreign government for any reason or no reason will subject the export control system to large-scale abuse, will make previous agency determinations about product hazards nothing more than a waste of time and agency resources, and will unnecessarily endanger the lives and health of residents of foreign nations.

C. Failure to Require Disclosure of Export Information to the Public and to Provide for Public Participation in Agency Decisionmaking

Like the Barnes bill, the Carter Administration's draft Executive Order fails to include provisions for public disclosure of information about proposed, or even licensed, exports of hazardous substances. Nor does the draft policy provide the U.S. and foreign public an opportunity to balance industry claims by contributing informed analysis and commentary to the agency charged with making export determinations. Like the Barnes bill, the Carter draft policy's omission of public input is certain to bias the agency's decision-making process in favor of allowing export, since the agency will be receiving most of its information from industry interests favoring export. Moreover, the lack of information about the reasons for agency decisions will prevent public scrutiny of those decisions, rendering the agency essentially unaccountable for its actions.

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3 There are two exceptions mentioned in the proposal: export licenses would be denied despite the importing country's request if the agency determines export would pose "severe hazards" to people or the environment outside the importing country, or if export would be "inconsistent with the foreign policy objectives of the United States."

Another exception unmentioned in the proposed Executive Order is that under present law unapproved new drugs may not be exported. This is necessary, as Dr. Theodore Cooper, Assistant Secretary for Health in the Ford Administration put it in testimony to Congress on drug legislation, to avoid "subjecting foreign citizens to health risks from hazardous or fraudulent drugs not permitted in this country," and to preserve "control of domestic marketing of such drugs." It should be made clear that this policy would continue under the proposed Executive Order.

III. Suggestions for Strengthening the Proposals

These flaws in the two proposals before this Subcommittee can be corrected by restructuring the export control system in two simple ways: (1) place the burden of persuasion that export of a hazardous substance should be allowed upon the manufacturer of the substance; and (2) allow the U.S. and foreign public an opportunity to participate in all such decisions.

A. Presumption of Equivalent Treatment for Both Domestic Use and Export

If any hazardous substance is banned, disapproved, or restricted in the United States, the immediate presumption should be that that substance should be treated equivalently for purposes of export. U.S. agencies will have conducted extensive proceedings, usually with opportunity for participation by both industry and the public, before the decision to ban or restrict these products for domestic use. It would be a waste of time and resources to require further procedures before controlling their use for export purposes.

Similarly, if a hazardous substance has not received approval in the U.S. because of lack of safety or effectiveness data, or failure to submit such data to the U.S. government, the same presumption--that approval for export is unwarranted--should apply, in the absence of a clear showing that the hazardous substance has no uses in the U.S.

Hazardous production facilities should be treated in similar fashion.

If a company or foreign country nevertheless wishes for an exception to these general rules, it would be free to petition the agency, adducing any special circumstances rendering use of the product more beneficial in the foreign country than it is in the U.S. The agency could then determine whether export is warranted, on the basis, for example, of the six factors (see note 2 above) set out in the Administration proposal. (This process would permit an inquiry into whether the company had exercised undue influence over the foreign government.) After State Department concurrence, the Secretary of Commerce could grant an export license.

B. Disclosure of Information and Public Participation

Whenever a company or foreign government petitions for an exception to the general rule against export of hazardous substances, the American public should be notified through announcements in the Federal Register and by other appropriate means. Citizens of the foreign country should also be made aware of the export petition, through notices in foreign media. A mechanism should be set up whereby the U.S. and foreign public would have access to enough

information (excluding genuine trade secret information about manufacturing processes, formulas, etc.) about the proposed export to make informed comments about its environmental and health effects. The agency with jurisdiction over the hazardous substance in question would then have the benefit of a complete record on which to base its ultimate decision.

C. Conclusion

In summary, no hazardous substance should be licensed for export unless:

- the company or foreign nation petitions the agency with jurisdiction over the hazardous substance, adducing valid reasons why treatment of the substance for export purposes should be different from its treatment for domestic use;

- substantial information is released to the public about the nature and circumstances of the proposed export;

- the U.S. and foreign public has notice of, and the opportunity to participate in, the proceeding;

- the agency gives a reasoned basis for its decision; and

- the State Department concludes that export is in the foreign policy interest of the U.S.

Unless these steps are taken to strengthen the export control proposals, they are unlikely to have significant effects on the export of hazardous substances.

Sincerely,

Robert B Leflar
Staff Attorney

Benjamin Gordon
Staff Economist

Sidney M. Wolfe, M.D.
Director

APPENDIX 3

STATEMENT OF PUBLIC CITIZEN HEALTH RESEARCH GROUP

September 19, 1980

I. SUMMARY

The Health Research Group strongly objects to the Carter Administration's proposal to give continued legitimacy to virtually all hazardous exports by U.S. companies to foreign nations. In the face of evidence, acknowledged by the Administration, of abuses in the export of dangerous pesticides, drugs, medical devices and consumer products and of hazardous factories, the Carter Administration is persisting in a course that is certain to destroy or endanger the health of large numbers of foreign and American citizens, and cause serious damage to the environment.

The Carter Administration's Interagency Working Group on a Hazardous Substances Export Policy[1] correctly concluded that "[u]ncontrolled export of hazardous substances . . .tends to damage our relations with foreign countries," and that "the problem of hazardous substances exports is likely to increase over the next several years."[2] The Carter Administration's contemplated response to this assault by the U.S. on world-wide public health and the environment, however, appears dangerously inadequate: while giving the appearance of controlling hazardous exports, the proposed policy would actually legitimize their continuance in virtually all cases. The policy would:

--exclude broad classes of hazardous products and production facilities from the possibility of export controls;

--set up a cumbersome and delay-prone mechanism for attempting to control all other categories of hazardous exports;

--permit the notoriously export-minded Commerce Department[3] (without even requiring referral to the agency with scientific expertise about product hazards) to decide on applications to export goods presenting "especially severe hazards";

--fail to provide specifically for monitoring of hazardous exports for compliance with the law; and

--exclude the public from information about and routine participation in the hazardous export-licensing process.

We call on the Carter Administration to recognize that substances hazardous to Americans are hazardous to all. As Ralph Nader stated in his July 10, 1978 letter to President Carter, "There is a compelling need for a major statement by the U.S. government regarding the double standards that are observed by U.S. corporations here and in exporting abroad." We urge the Administration to institute an export control program (such as that suggested in Part III of these comments) based on these five principles:

(1) If a hazardous substance or production facility is banned, disapproved, or restricted in the United States, the presumption will be that it will be treated equivalently for export purposes.

(2) Exporters may apply for exceptions to this general rule only by demonstrating, before the Commerce Department and the agency with primary domestic jurisdiction over the substance in question, valid special circumstances rendering use of the substance or facility substantially more beneficial in the foreign country than it is in the U.S.

(3) The U.S. and foreign public will have adequate advance notice of all agency proceedings, the opportunity to participate fully in them, and access to substantial information about the proposed export.

(4) The agencies must give a reasoned basis for their recommendations and decisions.

(5) The State Department must concur that export is in the foreign policy interest of the nation.

Only if all five conditions were met should the Commerce Department be authorized to issue an export license for a hazardous substance or factory.

II. FLAWS IN THE CARTER ADMINISTRATION DRAFT REPORT

A. Exclusion of Some Hazardous Exports from All Controls

The Carter Administration is considering, without justification, the exclusion of several critical categories of hazardous export from all new export restrictions: hazardous production facilities; products such as infant formula that may be safe in the United States but are demonstrably dangerous in conditions prevalent overseas; and possibly, dangerous or ineffective drugs and medical devices.

1. Hazardous production facilities: The Carter Administration proposal would not require foreign governments to be notified that a U.S. firm's planned construction of production facilities abroad would involve serious occupational health and safety or environmental dangers. Nor would the proposal offer the possibility that exports of such facilities could be restricted. Unconscionably, the draft report would even permit federal support for the export of hazardous factories, through such agencies as the Export-Import Bank and the Overseas Private Investment Corporation.

The exclusion of hazardous production facilities from export restrictions undercuts the entire rationale of a conscientious hazardous export control policy. As Rep. David Obey (D-Wisc.) has forcefully stated:

> Simply put, the problem is that as we learn more and more about the health hazards which certain manufacturing processes pose for workers and the general public, there is apparently a growing trend toward moving such manufacturing to countries where knowledge of the health hazards is limited or where concern about worker and public health is secondary to economic development goals. The result is that citizens of foreign countries sacrifice their health, U.S. workers lose their jobs and ethical businessmen who go to the expense of implementing needed safeguards are undercut by those who knowingly poison foreign workers and their communities in order to gain competitive advantage.[4]

As Rep. Obey pointed out, the roster of hazardous production activities carried on by U.S. firms in developing countries is an alarming one. U.S.-owned plants producing asbestos textiles and friction products, arsenic and refined copper from primary smelters, mercury, primary refined zinc, other minerals, pesticides, benzidine dyes, vinyl chloride, other chemicals, and steel have killed and injured large numbers of people and severely damaged the environment in numerous countries in Asia, Latin America, Africa and Europe.[5]

The Interagency Working Group's draft report questions the legal basis for controlling exports of hazardous production facilities.[6] There is no legal foundation, however, for the Working Group's hesitation. The same statute upon which the Working Group relies to support the imposition of export controls over hazardous substances, the Export Administration Act, also authorizes controls over hazardous production facilities. Under this legislation, items potentially subject to export controls include virtually all "goods" and "technologies."[7] A "good" is defined as "any article, material, supply or manufactured product, including inspection and test equipment, and excluding technical data." "Technology" is defined as "the information and knowhow that can be used to design, produce, manufacture, utilize, or reconstruct goods, including computer software and technical data, but not the goods themselves."[8] These two terms taken together easily provide sufficient scope for the imposition of controls over exports of hazardous production facilities.

2. Failure to control products presenting special hazards overseas: The Carter Administration proposal would rule out export controls and even notification to foreign governments about product hazards for "products that are not restricted for use in the United States, but [are] subject to unsafe circumstances of consumption abroad."[9] Through this glaring omission, the Administration proposes that the United States wash its hands of all responsibility for harm caused by products that we know will be dangerous when used in conditions prevalent in the importing country--while refusing even to inform the importing country of the impending hazard.

A typical example of this category of hazardous product is infant formula, mass marketed by American and other firms in Third World countries where use of impure water, excessive dilution of the product because of consumer families' poverty, and other entirely foreseeable practices inevitably render the product a serious public health hazard. Under this Carter Administration proposal, infant formula manufacturers could continue pushing their product on unsuspecting Third World health care providers and consumers without hindrance.

3. Drugs and medical devices: Much of the impetus for controlling exports of hazardous substances has come from reports of serious abuses in the marketing of drugs and medical devices abroad by U.S. firms.[10] Now the Pharmaceutical Manufacturers Association, however, is contending that no new controls[11] on exports of drugs or medical devices are legally permissible,[12] and the Interagency Working Group has asked the Justice Department for a legal opinion on the question.[13]

It is clear that the Export Administration Act of 1979 gave the President the authority to restrict the export of drugs and medical devices for reasons of foreign policy, in addition to the FDA's previously granted authority to restrict such exports for reasons of public health and safety. The 1979 Act authorizes the President to "prohibit or curtail the exportation of any goods, technology, or other information. . .to the extent necessary to further significantly the foreign policy of the United States or to fulfill its declared international obligations."[14] As an April 11, 1980 memorandum from Deputy Assistant Attorney General Leon Ulman to Esther Peterson pointed out, the Report of the House Foreign Affairs Committee placed "emphasis on the range of purposes that foreign policy controls may serve," which "suggests strongly that controls on exports of hazardous substances are included. The Conference Report provides further support in its statement that this authority 'encompasses the full range of U.S. foreign policy goals.'"[15]

The Export Administration Act of 1979 does contain an exception for "medicine or medical supplies" to its general authorization of export controls for foreign policy reasons.[16] Explaining the exception, the Act states: "It is the intent of Congress that the President not impose export controls under this section on any goods or technology if he determines that the principal effect of the export of such goods or technology would be to help meet basic human needs."[17]

This explicit statement of Congressional intent makes clear beyond peradventure that drug and device exports are excluded from consideration for export controls only if the President makes a specific determination that "basic human needs" would be met by the export in question--hardly the case when the substance to be shipped is a dangerous or ineffective drug or medical device. Particularly since the Interagency Working Group has found that the uncontrolled export of hazardous substances, including medical products, "tends to damage our relations with foreign countries,"[18] this exception for "medicine or medical supplies" should be narrowly construed. We suggest that it be read to encompass drugs and medical devices that have been approved for general marketing in the United States, to be exported for use only for such purposes and under such conditions as are sanctioned in the U.S., unless the exporter can demonstrate in public proceedings before the FDA that an unapproved use is substantially more beneficial in the foreign country than it is in the United States.

B. Ineffective Controls over Other Hazardous Substances

The Carter Administration proposal is unlikely to bring about any significant reduction in exports of even those hazardous substances that the policy ostensibly covers. The policy relies almost entirely on mere notification of foreign governments that hazards exist. For "relatively few" products there would be a possibility of actual export controls, but the determination of which products would be subject to controls would be a lengthy and cumbersome process. Even after an extremely hazardous product came under export controls, potential exporters could still receive an export license from the Department of Commerce after proceedings from which the public would apparently be excluded and to which the agency with scientific expertise in the field might not even be asked to contribute.

1. Inadequacy of mere notification of hazards: The Carter Administration's tool for controlling the great majority of hazardous exports under the proposed policy would be notification of foreign governments that particular products pose specified hazards. This reliance on mere notification is virtually certain to prove ineffective, with the result that foreign (and in some cases American) citizens will continue to be injured and environmental destruction will proceed unchecked. The reasons for the notification approach's inadequacy are evident.

First, the hazardous substances at issue are precisely those for which "notification" has been determined after careful review to be insufficient to protect the American public. These products are by definition so dangerous that banning or severe restrictions are necessary; labelling, consumer information, and the like have been found an inadequate approach. Second, as the Assistant Secretary for Health in the Ford Administration, Dr. Theodore Cooper, recognized in the context of unapproved drug exports:

> Many countries are in the process of building their own FDA-type activity, but don't have it at this time. We are very concerned that drugs determined to be unsafe in this country may be exported to a country whose health agency may now lack the necessary information and experience to make an informed and wise judgment on such an issue. . . . Furthermore, control of domestic marketing of such drugs would be undermined because they could still be legally produced domestically.[19]

Similar considerations apply to the export of other hazardous products. Countries lacking regulatory institutions with the necessary scientific background and experience will find it difficult or impossible to make effective use of product hazard notifications received from the U.S. Moreover, widespread bribery of foreign government officials by representatives of U.S. corporations and other methods of undue influence by industry to obtain export contracts have been amply documented;[20] such practices could completely nullify any effect that notifications of product hazards might otherwise have. Finally, and of critical importance, there is no reason to believe that such notifications would ever reach those most likely to sustain injuries from the hazardous exports--the foreign citizens themselves.

2. Inadequacy of proposed export control procedures; rejection of public participation: Rather than presuming that hazardous substances banned, disapproved, or restricted in the U.S. are likely to be equally dangerous when shipped abroad, the Carter Administration proposal sets out an elaborate scheme for determining which "relatively few"[21] of these substances would be included on the Commodity Control List. The proposal then delineates a procedure whereby exporters of even these products with an especially severe level of hazard could obtain export licenses nevertheless, free from public scrutiny of the process.

In essence, under this proposal a federal interagency task force would select from among all banned, disapproved, and restricted substances a group of products whose export would pose "especially severe hazards. . .to human health or safety or to the environment."[22] From among these extremely dangerous products, the State Department (subject to the concurrence of the Commerce Department) would pick out "those relatively few" substances as to which export controls would further U.S. foreign policy or fulfill U.S. international obligations. After the President made a series of further determinations required by the Export Administration Act, this short list of extremely hazardous products would be added to the Commodity Control List of goods that cannot be legally exported without a license. Unless extended by the President, export controls instituted for foreign policy reasons would expire one year after their imposition.

Even for this very limited class of extremely hazardous substances, firms could obtain export licenses from the Commerce Department. While the Commerce Department could entertain objections to the export application from the State Department, the Carter Administration proposal does not even require the Commerce Department to refer the application to the agency with scientific expertise concerning the product in question, despite a provision in the statute authorizing such referrals.[23]

Nor is there any requirement in the Carter Administration proposal for disclosure to the U.S. and foreign public of information about applications to export hazardous substances or production facilities, or for public participation in the determination of whether such applications should be granted or denied. Thus the Commerce Department, which already tends to consider the promotion of exports as part of its mission, would be denied the benefits of informed public analysis of the likely environmental and health effects of the hazardous exports. Concerned citizens of the foreign countries in question, as well as U.S. citizens knowledgeable about environmental and public health conditions in such countries, would be shut out of the process. The absence of public input is certain to bias the agency's decision-making process in favor of allowing export, since the primary submitters of information to the Commerce Department will be industry interests favoring export. Moreover, the unavailability of information underlying decisions to permit export will preclude the public from effectively scrutinizing these decisions, rendering the agency essentially unaccountable for its actions.

Finally, there is no provision in the Administration proposal for effective oversight of the export and marketing of hazardous products. It is firmly established that some drug companies, such as Warner-Lambert, have promoted drugs (e.g., chloramphenicol) in Latin America and Europe for a wide range of conditions for which the drugs are clearly contraindicated in the U.S.[24] U.S. meat and poultry firms have recently been reported to have falsified export certificates, potentially endangering foreign consumers.[25] Yet there is nothing in the Carter Administration proposal that would prevent such abuses in the future.

III. SUGGESTIONS FOR STRENGTHENING THE EXPORT CONTROL PROPOSAL

These flaws in the Carter Administration proposal can be corrected by restructuring the export control system in two simple ways consistent with the Export Administration Act: (1) place the burden of persuasion that export of a hazardous substance or production facility should be allowed upon the manufacturer; and (2) allow the U.S. and foreign public an opportunity to participate fully in all proceedings in which hazardous exports are being considered.

We note that this approach, which we have repeatedly advocated in comments on earlier drafts of this policy, corresponds to the two "guiding principles" upon which government control of exports should be based, in the view of the Hon. Anwar Fazal, president of the International Organization of Consumers Unions. Testifying before the House Subcommittee on International Economic Policy and Trade on June 5, 1980, Mr. Fazal stated:

> There should be no distinction between domestic and foreign consumers unless there are exceptional reasons for doing otherwise (and there will be exceptional circumstances).
>
> The process for determining these exceptional circumstances should involve a procedure whereby (a) the onus for proving the exceptional case should be with the manufacturers and/or the foreign government concerned, and (b) there is adequate disclosure of information to public citizen groups both in the home and foreign countries.[26]

A. Presumption of Equivalent Treatment for Both Domestic Use and Export

If any hazardous substance is banned, disapproved, or restricted in the United States, the immediate presumption should be that that substance should be treated equivalently for purposes of export. The President should make the Commodity Control List determinations required by the Export Administration Act[27] in the light of this presumption. U.S. agencies will have conducted extensive proceedings, usually with opportunity for participation by both industry and the public, before the decision to ban or restrict these products for domestic use. It would be a waste of time and resources to require further procedures before controlling the products' use for export purposes.

Similarly, if a hazardous substance has not received approval in the U.S. because of a lack of safety or effectiveness data, or failure to submit such data to the U.S. government, the same presumption--that approval for export is unwarranted--should apply, in the absence of a clear showing that the hazardous substance has no uses in the United States and that its use would be beneficial in the foreign country in question.

Hazardous production facilities--i.e., those unable to meet U.S. health, safety, or environmental standards--should be treated in similar fashion.

If a company or foreign country nevertheless wishes for an exception to these general rules, it would be free to apply to the Commerce Department pursuant to the statutory procedure,[28] adducing any special circumstances rendering use of the product more beneficial in the foreign country than it is in the U.S. Conversely, any person could petition the Commerce Department to place on the Commodity Control List any substance or hazardous production facility--including any product, such as infant formula, which may be safe in the U.S. but hazardous when used in circumstances prevailing abroad.

After 30 days, the Secretary of Commerce would refer the application or petition to the agency primarily responsible for domestically regulating the hazardous substance or facility in question. That agency, after obtaining public comment as suggested below, would recommend approval, approval with conditions,or denial of the application or petition. After the State Department submitted its recommendation, the Secretary of Commerce would make a final ruling.

B. Disclosure of Information and Public Participation

Immediately upon receipt of an application for an export license for a hazardous substance or hazardous production facility (or a petition to place an item on the Commodity Control List), the Secretary of Commerce should notify the American public through announcements in the Federal Register and by other appropriate means. With the State Department's assistance and through notices prominently placed in foreign media, the Secretary of Commerce should also see to it that both the government and the citizens of the foreign country are notified of the export application and are fully apprised

of the nature and scope of the hazards associated with the substance or production facility. A mechanism should be instituted whereby the foreign government and the U.S. and foreign public would have access to enough information about the proposed export to make informed judgments about its environmental and health effects. Among the information disclosed should be included copies of all labelling and promotional material to be distributed in the importing country, so that a judgment can be made about its accuracy.

The agency with primary domestic responsibility for the substance or facility to be exported would expeditiously set a public comment period, with informal hearings where appropriate, to gather views and information (in addition to that already compiled by the agency) to employ in formulating its recommendation. That recommendation, which should provide a detailed rationale and must be available to the public, should be given great weight by the Secretary of Commerce in ruling on the application or petition. The Secretary would then have the benefit of a complete record on which to base the ultimate decision. Whether the Secretary grants or denies the application or petition, or grants it subject to conditions, there should be published a full statement of the Secretary's reasons for the decision.

C. Reporting and Enforcement

Finally, exporters of hazardous substances and facilities should be required to submit to the State Department, for transmission to the Commerce Department and the agency with primary domestic jurisdiction, copies of all labelling and promotional materials distributed in the importing country, and full descriptions of marketing practices. If it is brought to the attention of the Commerce Department that the marketing or promotional practices of the exporting firm do not meet the conditions upon which export approval was granted, the Secretary of Commerce should revoke the export license.

In addition, the President should direct each agency with jurisdiction over hazardous products to step up efforts to ensure that procedures governing hazardous exports are not circumvented by exporting firms.

Unless all these steps are taken to strengthen the Administration's export control proposals, hazardous exports are likely to continue virtually unabated.

Respectfully submitted,

Robert B Leflar
Staff Attorney

Benjamin Gordon
Staff Economist

Sidney M. Wolfe, M.D.
Director

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FOOTNOTES

1 The Working Group was convened in 1978 by Esther Peterson, Special Assistant to the President for Consumer Affairs, and includes representatives from over twenty departments and agencies in the Executive Branch.

2 Interagency Working Group on a Hazardous Substances Export Policy: Draft Report, 45 Fed. Reg. 53754, 53756 (August 12, 1980).

3 With the advice of the State Department.

4 124 Cong. Rec. E3559 (daily ed. June 29, 1978).

5 See, e.g., Castleman, The Export of Hazardous Factories to Developing Nations, reproduced in 124 Cong. Rec. E3559-67 (daily ed. June 29, 1978)(remarks of Rep. Obey).

6 45 Fed. Reg. 53764 (August 12, 1980).

7 50 U.S.C.A. App. §§ 2403(b) & 2405(a) (West Supp. 1980).

8 50 U.S.C.A. App. § 2415(3) & (4) (West Supp. 1980).

9 45 Fed. Reg. 53764 (August 12, 1980).

10 See, e.g., 45 Fed. Reg. 53755-56 (August 12, 1980); Dowie et al., The Corporate Crime of the Century, Mother Jones 23-49 (Nov. 1979). See also Drug Safety Amendments of 1976: Hearings on H.R. 11617 and H.R. 12391 Before the Subcomm. on Health and the Environment, Comm. on Interstate and Foreign Commerce, 94th Cong., 2d Sess. 273-74 (1976) (statement of Asst. Sec'y for Health Theodore Cooper, M.D.); Medical Device Amendments, 1973: Hearings on S. 2368, S. 1446, and S. 1337 Before the Subcomm. on Health, Comm. on Labor and Public Welfare, 93rd Cong., 1st Sess. 442-43 (1973) (statement of Joel J. Nobel, M.D.).

11 At present, certain adulterated and misbranded drugs and antibiotics can be exported without restriction by the U.S. 21 U.S.C. § 381(d)(1)(1976). Experimental drugs can be exported upon request of the foreign government. 21 C.F.R. § 312.1(a)(2)(1980)(proviso). Unapproved new drugs may not be exported, 21 U.S.C. § 355(a)(1976), although a bill passed by the Senate (S.1045) would permit such exports if the approval of the foreign government is obtained and FDA determines that the export would not be contrary to public health and safety.

(footnote continued)

Since most medical devices will not be subject to premarket testing requirements or performance standards even in the U.S. for at least two years, see 21 U.S.C. §§ 351(f)(2)(B), 360d & 360e (1976), there are virtually no restrictions at present on export of the great majority of medical devices. Experimental medical devices, however, must obtain foreign government approval and an FDA determination that export "is not contrary to public health and safety" before export approval is granted. 21 U.S.C. § 381(d)(2)(B)(1976); 21 C.F.R. § 812.18(b)(1980).

These rules on exports of potentially hazardous drugs and medical devices are clearly far too lax. The proposed policy should be revised to strengthen them (see Part III of these comments).

12 PMA Comments on Export Policy, PMA Newsletter, Sept. 15, 1980, at 4.

13 45 Fed. Reg. 53760 n. 10 (August 12, 1980).

14 50 U.S.C.A. App. § 2405(a) (West Supp. 1980).

15 45 Fed. Reg. 53768 (August 12, 1980), quoting H.R. Conf. Rep. No. 96-482, 96th Cong., 1st Sess. 43(1979).

16 50 U.S.C.A. App. § 2405(f)(West Supp. 1980).

17 Id.

18 45 Fed. Reg. 53754 (August 12, 1980). See also id. 53760 ("If the United States does not exercise special vigilance over the export of some banned or significantly restricted products which are particularly hazardous, our economic and diplomatic ties with other countries could be jeopardized.").

19 Drug Safety Amendments of 1976: Hearings on H.R. 11617 and H.R. 12391 Before the Subcomm. on Health and the Environment, Comm. on Interstate and Foreign Commerce, 94th Cong., 2d Sess. 273-74(1976).

20 See, e.g., id. at 309-10 (statement of Dr. Wolfe and Ms. Johnson)(admissions to the SEC by drug manufacturers G.D. Searle, Abbott Laboratories, Pfizer, and Warner Lambert that they had bribed foreign officials to procure drug sales).

21 45 Fed. Reg. 53761 (August 12, 1980).

22 Id. at 53760.

23 50 U.S.C.A. App. § 2409 (d)&(e) (West Supp. 1980).

24 Competitive Problems in the Drug Industry: Hearings Before the Subcomm. on Monopoly, Senate Select Comm. on Small Business, Part 32, 94th Cong., 2d Sess. 15359-83 (1976) (statements of Sen. Beall, Dr. Silverman, and Dr. Lee); 45 Fed. Reg. 53755 (August 12, 1980).

25 OIG [Dep't of Agriculture Office of Inspector General] Investigating Export Certificate Falsification on U.S. Products, Food Chemical News, Sept. 15, 1980, at 41-42.

26 Mr. Fazal's testimony is reprinted in IOCU Newsletter No. 91, June 30, 1980, at 3-4.

27 50 U.S.C.A. App. § 2405 (West Supp. 1980).

28 50 U.S.C.A. App. § 2409 (West Supp. 1980).

APPENDIX 4

LETTER DATED JULY 18, 1980, FROM EDWARD COHEN, ENCLOSING RESPONSES BY THE INTERAGENCY WORKING GROUP TO ADDITIONAL QUESTIONS SUBMITTED IN WRITING BY REPRESENTATIVE ROBERT J. LAGOMARSINO

THE WHITE HOUSE,
Washington, July 18, 1980.

Hon. JONATHAN B. BINGHAM,
Chairman, Subcommittee on Economic Policy and Trade, Foreign Affairs Committee, House of Representatives, Washington, D.C.

DEAR CONGRESSMAN BINGHAM: Enclosed please find the responses of the Interagency Working Group to the questions sent to us by Congressman Lagomarsino. I hope that you will find them responsive.

During the hearing, the question was raised as to the export status of the drug, Depo-Provera. I would like to further refine our response.

Under the Federal Food, Drug and Cosmetic Act, new drugs which are unapproved by the Food and Drug Administration may not be exported. Approved drugs may only be exported with labeling for the approved indications. Depo-Provera has been approved for adjunctive therapy and palliative treatment of inoperable, recurrent, and metastic endometrial carcinoma or renal carcinoma. Therefore, it can be exported only for those indications. It may not be exported with labeling for other indications.

If I can be of further assistance, please let me know.

Sincerely,

EDWARD B. COHEN,
Deputy Director,
Office of Consumer Affairs.

Enclosures.

RESPONSE TO QUESTIONS FROM CONGRESSMAN LAGOMARSINO

Question 1. It is unclear to me that this legislation will actually do what it is intended to do. Can it really prevent, for example, exports of grain containing foreign matter, animal wastes or other harmful contaminants that might not fit into one of the categories covered by this legislation?

Answer 1. The Barnes bill could prevent exports of grain containing foreign matter or animal wastes, since such contaminated food products may not be sold in the United States (the sale of adulterated food is prohibited under the Food, Drug and Cosmetic Act). The coverage of the Barnes bill is widely inclusive; it essentially would control the export of any product which could not be sold in the U.S. because of health and safety reasons. The only harmful products which would escape coverage would be ones which are not regulated domestically.

Question 2. If you maintain that a country is incapable of making its own decision, is that because you believe it does not have sufficient information on which to base a decision or that even with enough information, you do not believe it would make the "right" decision?

Answer 2. The Working Group has not suggested that a country is incapable of making its own decision. Rather, we believe that if the appropriate official of a foreign government is provided with basic information about a substance which is destined for that country (e.g. the name of the substance to be exported, a concise summary of the domestic agency's regulatory actions, and a summary of the potential risks to human health or safety or to the environment that are the grounds for the agency's action), then that government will be in a better position to make an informed decision about the importance of the product.

Question 3. What has changed since 1978 when the Administration said the Export Administration Act was not applicable to exports of hazardous substances when it now says that Act would apply?

Answer 3. In the attached December 14, 1978 letter[1] sent to Congressman Rosenthal, then Secretary Kreps sought to clarify the misconception that the Export Administration (the Act) could not be used to prevent the export of banned products. The Secretary reported that the General Counsel and the Department of Justice had concluded that "statutory authority *does* exist under the Export Administration Act to regulate or prohibit export of domestically banned products where such control is necessary to further significantly the foreign policy of the United States." The Department of Justice has reached a similar conclusion in a memorandum dated April 11, 1980 (attached) regarding the EAA of 1979.[2] Foreign policy controls can be applied to the export of hazardous substances as long as the requirements of § 6 of the Act are met.

Question 4. Why is it necessary to rely on the Export Administration Act at all? Aren't the other laws dealing with individual substances sufficient to control exports of hazardous substances? For that matter, isn't there a question of jurisdiction by other committees which have an interest in this issue?

Answer 4. The Working Group believes that there are likely to be some limited circumstances—not addressed by other laws which establish general regulatory framework for categories of substances—where export of a specific substance may result in harm to our relations with other countries by the unrestrained export of those substances. It is for this purpose, i.e. "further(ing) significantly the foreign policy of the United States or fulfill(ing) its declared international obligations" (Sec. 6(a)(1)), that the authority of the Act would be invoked.

There is only a very limited category of substances for which existing statutes provide for the ban of the export of hazardous substances (i.e. unapproved new drugs, unapproved biological products, and meat and poultry failing to meet U.S. quality standards).[3] For many other categories of hazardous substances (e.g. unapproved foods, cosmetics, medical devices and investigational drugs, adulterated or misbranded drugs and antibiotics, non-complying electronic products, pesticides whose registrations have been cancelled or suspended for most uses, pesticides not registered in the United States, certain regulated chemical substances, and banned or non-complying consumer products, fabrics, garments, and certain toxic, flammable, or corrosive hazardous products) existing statutory authority does not authorize an export ban.

With respect to the committee jurisdictional question, we defer to the Congress on this issue.

Question 5. The Justice Department view of the criteria which the Administration must consider for imposing foreign policy controls under the Export Administration Act is that the criteria are not binding. Does that mean the Administration would not consider those criteria? What importance would the Administration give to those criteria in exports of hazardous substances?

Answer 5. The legislative history of the Act supports the Justice Department's view that the § 6(b) criteria to be considered in assessing foreign policy controls are non-binding. However, as the Justice Department pointed out these criteria have to be considered. In any given case some of the criteria will be more relevant than others and one or more of the criteria may be irrelevant to a given decision. They must, however, be considered in each case. These criteria are of obvious importance since they must be considered whenever foreign policy controls are suggested and the President in his reports to Congress must refer to his conclusions with respect to the § 6(b) criteria.

Question 6. Each of the laws already passed governing exports of hazardous substances has specific provisions restricting exports. Can an executive order, like the one the Administration's Task Force is considering, override the very specific export laws drawn by Congress? Would not each of these laws have to be amended before the executive order could become effective? In the case of a contradiction between the law and the executive order, which should take precedence?

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[1] Letter referred to appears on p. 242.

[2] The Department of Justice memorandum referred to appears in the Federal Register of Aug. 12, 1980, vol. 45, No. 157, p. 53768.

[3] For some categories of substances (i.e. chemical substances, consumer products, fabric-type products, and household chemicals) an export can be banned if there is a risk to the health or environment within the United States.

Answer 6. An executive order cannot override a federal statute and if an executive order or other executive document implementing the recommendations of the Working Group is ultimately issued, it will be consistent with existing law.

Any such order or document would be based on authority vested in the President by the Constitution or by authority delegated by Congress and would provide for effective and responsible implementation of the Export Administration Act and the other regulatory statutes insofar as they relate to the export of hazardous substances.

Question 7. Mr. Harris, your statement describes pretty well why you believe H.R. 6587 is not necessary, but why does the Administration believe it is not desirable?

Answer 7. Accompanying my prepared statement to the Committee was a statement of the Administration describing what we believe to be the deficiencies of H.R. 6587. For your information, I am enclosing a copy of our analysis.[1]

Question 8. In last week's hearings, an example was given of an export to Iraq of grain seeds, treated with a fungicide. The seeds were used for baking rather than planting. How could that incident have been prevented under legislation or an executive order like the ones described here today? The problem apparently resulted from improper use by the recipient country by not following directions on the label. It certainly does not appear to be a result of some malicious intent on the part of the exporter.

Answer 8. The Congressman has noted that there were serious problems when seed grain treated with fungicide was used in Iraq for baking rather than planting. As written, the Barnes bill covers any good which is "subject to registration." Since all fungicides are subject to registration, the Barnes bill would impose export controls. Under this proposal, export could thus be prohibited if the U.S. had reason to believe that the product would be used improperly (e.g. labels ignored) in the importing country. Export could also be permitted to countries where no such difficulties were expected.

Under the principles agreed to by the Working Group, the incident of the seed grains probably would not have been prevented, though certain similar incidents might be. The Working Group framework would not subject all pesticides and fungicides to export controls categorically. The only pesticides which would be considered for controls would be pesticides for which most major uses have been cancelled or suspended or which are significantly restricted as to circumstances of use in the United States. There are certain acutely toxic pesticides, for example, which may only be used by a certified applicator, wearing certain specified clothing, under specified conditions.

Under procedures outlined by the Working Group, if the U.S. had reason to believe that such use instructions are not being followed abroad and that serious damage to health and thus, U.S. foreign relations is occurring, such products could be placed under export controls. If controlled, the State Department would then consult with the foreign government before shipments were allowed, alerting them to the danger, and a reasonable decision could be made as to whether the danger could be averted and whether export should be permitted.

LETTER DATED DECEMBER 14, 1978, TO HON. BENJAMIN S. ROSENTHAL FROM THE SECRETARY OF COMMERCE

HON. BENJAMIN S. ROSENTHAL,
Chairman, Commerce, Consumer and Monetary Affairs Subcommittee, Committee on Government Operations, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Thank you for your letter of October 26, 1978, forwarding copies of House Report No. 95–1686 on "Export of Products Banned by U.S. Regulatory Agencies". We appreciate the opportunity to comment on the report.

The Department's interest in the policy issues involved has intensified during recent months because of several factors: (1) Congressional action on a part of the overall problem through S. 2796, which amended several statutes administered by the Consumer Product Safety Commission, (2) intensive work on approaches to a national policy by the working group on "Hazardous Substances Export Policy", chaired by Esther Peterson, Special Assistant to the President for Consumer Affairs, and (3) the opportunity to review House Report No. 95–1686.

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[1] The analysis appears on p. 66.

At the time of your hearings, this Department focused on (1) our statutory authority to control the exportation of products banned in the U.S., and (2) the feasibility of the Bureau of the Census developing statistical data on such exports.

We have reviewed the report carefully, especially as it relates to the role of the Department of Commerce. We should like to clarify one issue and correct the apparent misimpression in numbered paragraph 25 at page 5 of the report, that the Department does not have statutory authority under the Export Administration Act to prevent the export of banned products. The General Counsel has reviewed the statute and, after consultation with the Department of Justice, has concluded that statutory authority *does* exist under the Export Administration Act to regulate or prohibit export of domestically banned products where such control is necessary to further significantly the foreign policy of the United States.

To invoke this statutory authority, however, the Department of Commerce must determine, after consultation with the Department of State, such control is necessary to further U.S. foreign policy. As a matter of practice, we have customarily deferred to the State Department on this foreign policy judgment. Should the Administration, through State, determine that our foreign policy objectives would be served by such controls, statutory authority presently exists under the Export Administration Act to impose those controls.

Second, the Bureau of the Census is considering ways of obtaining reliable statistical data on such exports. However, because of the current reporting procedures discussed before the Subcommittee, what can now be obtained through Census data is quite limited. The Department's recommendations for possible changes in this area will depend in large part upon the scope, and specificity, of recommendations ultimately made by the working group on a national policy. Thus, for example, a sufficiently small, well defined, universe of reportable products subject to the policy could conceivably be collected by Census.

Work of the Esther Peterson working group is continuing. The following are the issues that we believe must be resolved by that group:

1. Definition of products and substances covered by such a policy. In our view, a uniform policy will be most effective if targeted specifically on truly significant hazards. Your Subcommittee focused on "banned products." Whatever our ultimate definition of products covers, it is essential, however, for the definition to be a clear and precise one. Only with the universe of products or substances carefully described can we make informed decisions about what measures a uniform policy should appropriately include.

2. A uniform notification policy should be agreed upon. Notification, which should be the focus of our energies in the short term, is now implemented in a variety of inconsistent ways. A notification policy should be designed to cover those exports that are particularly hazardous; at the same time, it should be targeted enough to be useful and practical to those countries receiving notice. It should also be designed to eliminate unnecessary paperwork and to minimize burdens on exporters. As the President stated in his signing statement on S. 2796:

"I am concerned that the shipment-by-shipment notification required by this bill will impose unnecessary burdens on American exporters and my Administration will work with Congress to attempt to reduce these burdens. U.S. policy governing the export of hazardous products has been proliferating on a piecemeal basis. A number of statutes applicable to differing types of products address the export issue in different ways."

We will work to implement the President's guidance.

3. We must fully consider how various policy options might be implemented. We must determine, for example, what agency(ies) will implement the policy; what resources will be required, both in terms of costs and personnel; how can effective enforcement be achieved; what will be the private sector costs and burdens; what will be the impact on other important national policies; and can the policy be easily and effectively implemented from the perspective of foreign countries?

The Department will continue its efforts to make important contributions to the work of the task force, and we hope to have task force decisions soon. We are also appreciative of the valuable work your Subcommittee has done on this important subject.

Sincerely,

JUANITA M. KREPS,
Secretary of Commerce.

APPENDIX 5

STATEMENT OF ANDREW S. KRULWICH, GENERAL COUNSEL, CONSUMER PRODUCT SAFETY COMMISSION

MR. CHAIRMAN, THE CONSUMER PRODUCT SAFETY COMMISSION WELCOMES THIS OPPORTUNITY TO SUBMIT THIS STATEMENT TO THE SUBCOMMITTEE CONCERNING THE EXPORT OF PRODUCTS DEEMED TOO HAZARDOUS TO BE SOLD IN THIS COUNTRY. CPSC IS PLEASED THAT REPRESENTATIVE BARNES AND THE SUBCOMMITTEE HAVE CONTINUED TO FOCUS ATTENTION ON THIS IMPORTANT SUBJECT.

WHEN CPSC CHAIRMAN SUSAN KING TESTIFIED AT THE PREVIOUS HEARING HELD BY THE SUBCOMMITTEE, THE INTERAGENCY POLICY ON HAZARDOUS SUBSTANCES WAS NEARING FINALIZATION. A REVISED FIFTH DRAFT HAS NOW BEEN PUBLISHED FOR AGENCY AND PUBLIC COMMENT. IF ALL GOES WELL WE WILL HAVE A FINAL INTERAGENCY EXPORT POLICY BY THE END OF THE YEAR. AS YOU KNOW, CPSC HAS BEEN AN ACTIVE PARTICIPANT IN THE INTERAGENCY WORKING GROUP THAT HAS SPENT MANY MONTHS DEVELOPING AN ADMINISTRATION EXPORT POLICY. IN ADDITION CPSC CONTINUES TO PARTICIPATE AS A REPRESENTATIVE OF THE UNITED STATES IN THE ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD). THE COMMISSION STRONGLY SUPPORTS THE DEVELOPMENT OF A UNIFORM EXPORT POLICY, AND WE SPECIFICALLY SUPPORT THE REVISED FIFTH DRAFT.

THE PROBLEM BEFORE US IS AN IMPORANT ONE BECAUSE IT HAS MAJOR IMPACT ON OUR ECONOMIC AND POLITICAL RELATIONS WITH OTHER NATIONS. THERE IS NO QUESTION THAT FOR THE UNITED STATES TO EXPORT SERIOUSLY DEFECTIVE OR DANGEROUS PRODUCTS TO UNSUSPECTING AND OFTEN UNDERDEVELOPED COUNTRIES IS BAD

FOREIGN POLICY. IT IS INCONSISTENT WITH THIS COUNTRY'S COMMITMENT TO THE PROTECTION OF HUMAN LIFE.

MOREOVER, THE "DUMPING" OF SUCH GOODS IS ALSO BAD ECONOMIC POLICY. THE SHIPMENT OF DANGEROUS GOODS BEARING THE LABEL OF AN AMERICAN COMPANY CAN ONLY SERVE TO UNDERMINE FOREIGN CONFIDENCE IN THE QUALITY AND INTEGRITY OF AMERICAN PRODUCTS. THE LABEL "MADE IN THE USA" IS TOO IMPORTANT TO BE JEOPARDIZED IN THIS FASHION.

ADDITIONALLY, DUMPING CAN ALSO HAVE AN ADVERSE IMPACT HERE AT HOME. IF MANUFACTURERS BELIEVE THAT A READY MARKET EXISTS ABROAD FOR DESIGN OR QUALITY CONTROL FAILURES, IT MAY REDUCE THE INCENTIVE TO INSURE SAFETY IN THE DOMESTIC MARKETPLACE. CERTAINLY THE U.S. CONSUMER LOSES IN SUCH A SITUATION, AS DOES THE DOMESTIC MANUFACTURER OF THE SAFE PRODUCT WHO HAS NOT CUT CORNERS.

THE PROBLEM, HOWEVER, IS COMPLEX. PRODUCTS MAY POSE VARYING DEGREES OF RISKS; PRODUCTS MAY RESULT IN VARYING BENEFITS AT HOME AND ABROAD. DIFFERENT COUNTRIES HAVE DIFFERENT NEEDS AND DIFFERING CONCERNS. THE PROBLEM POSED BY THE EXPORT OF HAZARDOUS SUBSTANCES WARRANTS A FLEXIBLE AND WORKABLE APPROACH, AND THE INTERAGENCY WORKING GROUP'S POLICY PROVIDES SUCH AN APPROACH. THE POLICY HAS TWO IMPORTANT FEATURES IN THIS REGARD.

1. THE POLICY PROVIDES A GRADUATED SERIES OF RESPONSES DEPENDING ON THE SEVERITY OF THE PROBLEM POSED BY THE HAZARDOUS GOODS, AND THE INTERESTS OF THE UNITED STATES AND THE IMPORT-

ING NATION. IN SOME CIRCUMSTANCES THE HARM MAY BE SO GREAT AND THE FOREIGN POLICY INTERESTS OF THE U.S. SO COMPELLING THAT A BAN ON EXPORTATION MAY BE APPROPRIATE.

2. THE POLICY RECOGNIZES THE NEED FOR INTERAGENCY COOPERATION TO INSURE COMPREHENSIVE CONSIDERATION OF THE COMPETING INTERESTS AND VIEWPOINTS PERTINENT TO THE DECISION WHETHER TO CONTROL THE EXPORTATION OF HAZARDOUS GOODS.

CPSC BELIEVES THAT THE APPROACH CONTAINED IN THE POLICY IS A RESPONSIBLE WAY OF DEALING WITH A DIFFICULT PROBLEM THAT AFFECTS INTERNATIONAL HEALTH, INTERNATIONAL COMMERCE AND INTERNATIONAL RELATIONS. I STRONGLY URGE THAT ANY LEGISLATION PROPOSED IN THIS AREA CLOSELY TRACK THE APPROACH OF THE INTERAGENCY POLICY. AS THE PRODUCT OF THE THINKING OF THE DISPARATE AGENCIES INVOLVED WITH THE EXPORT POLICY ISSUES, IT REPRESENTS A COMPREHENSIVE AND CONSISTENT APPROACH TO THE PROBLEM OF THE EXPORT OF HAZARDOUS SUBSTANCES.

A KEY ELEMENT OF THE INTERAGENCY POLICY IS THE DISCLOSURE TO IMPORTING NATIONS OF THE IMMINENT SHIPMENT OF GOODS THAT MAY NOT BE DISTRIBUTED IN THE DOMESTIC COMMERCE OF THE UNITED STATES. THE PURPOSE OF SUCH EXPORT NOTIFICATION IS TO PROVIDE THE IMPORTING NATIONS WITH SUFFICIENT INFORMATION ABOUT THE GOODS TO BE SHIPPED, THE HAZARD POSED AND THE U.S.'S RESTRICTION ON DOMESTIC DISTRIBUTION SO THAT AN

INFORMED DECISION MAY BE MADE WHETHER TO ACCEPT ENTRY OF THE GOODS. THE UNITED STATES WOULD BE SIMPLY PROVIDING INFORMATION; THE DECISION WHETHER TO ACCEPT THE GOODS WOULD BE LEFT SOLELY WITH THE IMPORTING NATIONS. THE EXPORT NOTIFICATION PROCEDURES SET OUT IN THE DRAFT POLICY CLOSELY PARALLEL THE NOTIFICATION SYSTEM CPSC HAS UTILIZED FOR THE PAST TWO YEARS.

EXPORT NOTIFICATION HAS BEEN AN IMPORTANT TOPIC UNDER CONSIDERATION BY THE OECD. AS CHAIRMAN OF THE WORKING PARTY ON PRODUCT SAFETY, I AM PLEASED TO SAY THAT THE COMMITTEE ON CONSUMER POLICY IS MAKING STEADY PROGRESS IN ITS CONSIDERATION OF AN EXPORT NOTIFICATION PROCEDURE THAT COULD BE ADOPTED BY ALL THE OECD MEMBERS. UNDER THE PROCEDURE EACH OF THE OECD'S 24 MEMBER COUNTRIES WOULD PROVIDE NOTICE OF THE IMMINENT SHIPMENT OF GOODS THAT MAY NOT BE DISTRIBUTED IN THE EXPORTING NATION. THIS WOULD COVER GOODS THAT ARE BANNED, DO NOT MEET SAFETY STANDARDS OR ARE SUBJECT TO RECALL. THE COMMITTEE WILL BE CONSIDERING THE DETAILS OF SUCH A NOTIFICATION SYSTEM AT ITS DECEMBER MEETING.

THE OECD IS NOT ALONE AMONG INTERNATIONAL ORGANIZATIONS CONSIDERING EXPORT ISSUES. VARIOUS UN ORGANIZATIONS INCLUDING THE U.N. ENVIRONMENT PROGRAM AND THE ECOSOC COMMISSION ON TRANSNATIONAL CORPORATIONS ARE ACTIVE IN THIS AREA.

INDEED EXPORT CONTROLS AND THE SHARING OF INFORMATION CONCERNING UNSAFE GOODS HAVE BEEN THE SUBJECT OF A 1979 UN RESOLUTION. THE UNITED STATES, AS A WORLD ECONOMIC LEADER, CAN PROVIDE, THROUGH THE ADOPTION OF A U.S. EXPORT POLICY, SUBSTANTIAL ENCOURAGEMENT TO THESE INTERNATIONAL EFFORTS. A U.S. EXPORT POLICY WOULD ALLEVIATE, IF NOT ELIMINATE, THE FEARS OF SOME NATIONS THAT EXPORT NOTIFICATION WOULD PUT THEIR DOMESTIC COMPANIES AT A COMPETITIVE DISADVANTAGE.

THE INTERAGENCY POLICY IS A PROGRESSIVE, BALANCED APPROACH FOR DEALING WITH A DIFFICULT AND IMPORTANT PROBLEM. WE LOOK FORWARD TO THE CONCLUSION OF PUBLIC COMMENT ON THE REVISED FIFTH DRAFT AND THE ISSUANCE OF A U.S. EXPORT POLICY THIS YEAR.

APPENDIX 6

Report to U.S. Agency for International Development of the Ad Hoc Consultative Panel on Depot Medroxyprogesterone Acetate, July 1980

Chairperson
Allan Rosenfield, M.D.
Center for Population and
Family Health
College of Physicians and Surgeons
Columbia University
New York, New York

Guiseppe Benagiano, M.D.
Special Programme of Research,
Development and Research Training
in Human Reproduction
World Health Organization
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Rebecca Cook
Georgetown University Law Center
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William Hansel, Ph.D.
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Dwight Janerich, M.D.
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James Shelton, M.D.
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REPORT TO USAID OF THE AD HOC CONSULTATIVE PANEL ON DEPOT MEDROXYPROGESTERONE ACETATE

New York City, December 7-8, 1978

I. Summary Statement

An Ad Hoc Consultative Panel on Depot Medroxyprogesterone Acetate (DMPA) has reviewed the results of animal toxicology studies and currently available information on the use, benefits and risks of DMPA in humans in the U.S. and abroad. In addition, it has reviewed the conclusions of the World Health Organization (WHO) Toxicological Review Panel. Based on these reviews and the information available to it, the Ad Hoc Consultative Panel (with one dissenting vote) recommends that the United States Agency for International Development (USAID) make DMPA available to nations which request it.

II. Introduction

At the request of USAID, an Ad Hoc Consultative Panel on DMPA was formed to review a variety of issues relating to DMPA and its possible provision in the international programs of USAID, despi : the present U.S. Food and Drug Administration (FDA) ruling. The Panel met for two days (December 7-8, 1978) in New York and included members who had expertise in the fields of obstetrics and gynecology, animal physiology and toxicology, epidemiology, pathology, law and health policy. The deliberations of the Panel are presented herein.

DMPA has been used both for clinical gynecologic and contraceptive purposes since the early 1960s.[1] At the present time it is approved in the U.S. for the treatment of endometrial cancer, but not for use as a contraceptive. It is, however, approved for contraception in 76 developed and developing countries and has been demonstrated to have unusual popularity as a contraceptive method in many settings.[2]

Initial experience with this drug was gained through its use for treatment of two conditions, one benign (endometriosis) and one malignant (endometrial carcinoma). In both instances high dosages of the drug were used for long periods of time.[3] In some instances these dosages were as much as 50 to 75 times the dosage currently recommended for contraceptive use, and treatment at these high dosages was maintained in some instances for several years. Thus, in addition to animal toxicologic studies there was the unusual opportunity to have available high dose human data to review. However, it must be added that no systematic studies have been published which specifically reported on long-term follow up of these women.

The review of this drug by the FDA has taken place over a long period of time and has been unusual in many regards. In 1967, a new drug application (NDA) for approval of DMPA as a contraceptive was filed by the Upjohn Company.[4] In 1973, following a favorable recommendation of its Advisory Committee on Obstetrics and Gynecology, the FDA announced its intention to give qualified approval for contraceptive use for those women who: 1) refused or were unable to accept the responsibility demanded by other contraceptive methods; 2) were incapable or unwilling to tolerate the side effects of conventional oral contraception; 3) had repeated

failures with other contraceptive methods.[5] Because of concern about reversibility, it was recommended that it be used only for women who had completed their childbearing. The FDA further recommended that women be informed of the possible risk of breast cancer.

In September, 1974 the FDA announced in the Federal Register its proposed final form of approval, which was to take effect from October 15, 1974.[6] Letters to this effect were sent to physicians throughout the country. At approximately the same time, however, a House Subcommittee on Intergovernmental Relations held hearings which resulted in a letter from the chairman of that committee to the Secretary of HEW, who then stayed the approval of the drug.[7] Among the issues raised by the subcommittee were concerns about potential carcinogenic effects on cervix and breast. In 1975, the FDA convened a joint meeting of its Advisory Committees on Ob/Gyn and on Biometric and Epidemiological Methodology. These committees, in turn, jointly constituted a subcommittee task force which, after open hearings, subsequently recommended that the FDA approve DMPA with the earlier limitations. After continued review, however, the FDA made a decision in March, 1978, to deny approval of the Upjohn application for the following five reasons:[8]

1. Safety questions, raised by studies in dogs showing an increased incidence of mammary tumors associated with the drug, have not been resolved;
2. A number of safer alternative methods of contraception are available in this country, and no clear evidence has been submitted to show that a significant patient population in need of the drug exists in the U.S.A.;

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3. Irregular bleeding disturbances caused by the drug may necessitate administration of estrogen, imposing an added risk factor and decreasing the benefits of a progestogen-only contraceptive;
4. Exposure of the fetus to DMPA, if the drug fails and pregnancy occurs, poses a risk of congenital malformations, a risk potentially enhanced by the prolonged action of the drug;
5. Serious reservations about the ability of the postmarketing study for breast and cervical carcinoma, proposed by the Upjohn Company, to yield meaningful data.

This decision has been appealed by the Upjohn Company and the FDA announced in July, 1979, that this appeal will be heard by an FDA-appointed Board of Inquiry.[9]

USAID, as part of its program of population and family planning assistance in developing countries, provides contraceptive commodities. At present, the methods provided include oral contraceptives, IUDs, condoms and vaginal methods. Recently, the agency has received requests for DMPA from a number of countries, since local purchase in bulk is very costly.[10] USAID policy, however, has prohibited it from providing other countries with drugs which are not approved by the FDA for use in the U.S. Because this is a policy of the agency and not a legal regulation, and also because of reviews of the Drug Act which are currently taking place in Congress,[11] USAID requested that this Panel be constituted. Its task is to review the risks and benefits of DMPA, to advise USAID on appropriate action the agency can take in response to requests for DMPA from developing countries, and to recommend additional studies, ongoing monitoring and postmarketing evaluation which should be undertaken, if indeed the agency does provide the drug. The

following report will discuss the benefits of DMPA, review various actual and hypothetical side effects and complications, and make a series of recommendations.

III. Benefits

DMPA has certain benefits not possessed by any other contraceptive. It has a higher use effectiveness than any other reversible method[12] and is the only available long-acting injectable contraceptive which is highly effective and can be provided at three-month intervals.[13] Further, its effectiveness continues even if the user is a few weeks late in obtaining a repeat injection.[14]

It is a uniquely acceptable method for some women because of the preference for injection over other approaches to contraception. It is not used in relation to coitus, requires infrequent administration, is provided outside the home and requires no supplies to be left around the home, thus giving the user a high degree of privacy. Further, it can be administered by any person who normally gives injections in a health care system and does not require a clinical setting for administration.[15]

DMPA does not suppress lactation and thus, in comparison to oral contraception, has been considered for use among postpartum women.[16] This would be a major advantage in the developing world, where successful and prolonged breastfeeding is of critical importance in helping to lower existing high rates of infant morbidity and mortality. However, there is inadequate information presently available on possible effects on the nursing infant of the DMPA in the breast milk; this is an area requiring further study.

Among women in whom iron deficiency anemias are common, the development

of oligomenorrhea and secondary amenorrhea following use of DMPA may help to decrease the incidence of this problem.

Based on information available to the Ad Hoc Panel at the time of its meeting, there appear to be few, if any, contraindications to the use of DMPA,other than pregnancy. Because it is administered periodically by injection and has few potentially harmful metabolic side effects,[17] DMPA may be the preferred method for several groups of women who desire effective, reversible contraception, but who have special medical needs which contraindicate the use of other methods, and for whom sterilization is not legal or desired. The Panel did not agree with the FDA that there is not a significant population of potential users for this method in the United States; it felt that no data were available which would allow one to draw such a conclusion.

Although, as with the pill and the IUD, different DMPA continuation rates have been reported in different studies, even within similar cultural settings, [18] the Panel felt there were no physiological reasons to explain this. Rather, it was felt that differences in patient education, preparation and understanding of the potential side effects, as well as different physician responses to these effects, probably explain most of these differences. As with all contraceptive methods, clear and understandable consumer education and information is essential to method choice, effective and safe use, and, where possible, consumer identification of contraindications. Other causes of the continuation rate variations might include age and parity differences, as well as differences in availability and price of subsequent injections.

IV Metabolic Effects

As judged by laboratory findings, DMPA appears to have a mild effect on carbohydrate tolerance in women,although this effect is apparently less severe than that caused by oral contraceptives.[19] In a relatively small percentage of women using DMPA, weight gain occurs, which occasionally can be significant.[20] Data also suggest a possible effect on the adrenal glands, with a resultant decline in cortisol levels, although this has not been shown to be of clinical significance.[21] Studies have not identified any effect of DMPA on liver function or lipid metabolism.[22]

The effect of DMPA on blood pressure in unclear. While the number of users is probably still too small, there is no evidence of thrombo-embolic phenomena or other circulatory diseases, as are seen with estrogen-containing oral contraceptives in the United States and Britain.[23] The Panel urged further monitoring of this aspect since, if the lack of cardiovascular effects is confirmed, DMPA will have an important advantage over estrogen-containing oral contraceptives.

In contrast to oral contraception, DMPA does not appear to produce a decrease in either the quality or quantity of milk in lactating women.[24] To the contrary, the data suggest that it stimulates an increase in the quantity of milk. The effects of DMPA and its metabolites on the growth and development of the nursing infant, however, are still unknown.

V. Menstrual Side Effects

Among minor side effects, the most significant relate to menstrual irregularities. During the first six to twelve months, the most common irregularities are spotting, staining and bleeding. Later, as many as 40 to 60% of women become amenorrheic. Heavy bleeding requiring estrogen

therapy is rare, and almost never is severe enough to require operative procedures such as dilatation and curettage.[25] During the 1960s, estrogens in low dosages were occasionally used to treat spotting and staining [26] but the results were equivocal and this therapy is no longer recommended by most physicians. If amenorrhea is not acceptable to a woman, cyclical estrogens may be used to cause monthly withdrawal bleeding. However, this is not recommended. Menstrual irregularities virtually never necessitate the use of estrogen. The Panel, therefore, felt that the FDA's concern about the potential administration of estrogen to women using DMPA could not be substantiated by available reports and experience. Further package labelling for physicians could caution against the supplemental use of estrogens.

VI Return of Fertility

One injection of DMPA provides reliable contraception for a period of three months, with continuation of contraceptive effect for a varying period thereafter. While this is an advantage for the woman who may be late for her next scheduled injection, this does lead to a delay in the return of fertility for some women. Thus, there appears to be a delay in the percentage of women who become pregnant after terminating DMPA use, when compared to women discontinuing use of other reliable contraceptive agents such as the pill or the IUD. However, available data suggest that by 24 months, over 90% of DMPA users who have discontinued use in order to become pregnant have indeed conceived.

The following table compares a series of 756 DMPA users with 437 oral contraceptive users in Thailand.[27] The women in both groups had discontinued

use in order to become pregnant. The mean gravidity of the DMPA users was 1.5, roughly double that of oral contraceptive users, suggesting more of the DMPA users had proven their fertility prior to beginning contraception. The mean time for establishment of pregnancy after the discontinuation was 5.1 months for DMPA users, as compared to only 2.5 months for pill users. The table demonstrates that there is a delay in return of fertility, with substantial differences at 6 and 12 months. By 24 months, however, there was no significant difference.

	Prior DMPA Users	Prior O.C. Users
Number	756	437
Mean Age	24.5	22.3
Mean Gravidity	1.5	0.7
Proven Pregnancy		
6 months*	53%	75%
12 months	75%	85%
24 months	92%	94%
Mean months	5.5 months	2.5 months

(Source: T. Pardthaisong, 1978)

* Months after stopping contraceptions; contraception was considered stopped after last cycle of O.C. was taken or 3 months after last injection.

Another analysis of data from this same population in Thailand found that the proportions of women who had become pregnant were almost identical at 12, 18, and 24 months among women who had discontinued DMPA and those who had an IUD removed in order to conceive.[28]

Because of these data and other studies from the U.S with similar findings,[29] Panel concluded that, while there is a delay in the return of fertility the vast majority of women desiring a pregnancy were able to conceive within a two-year period of time. Thus, concerns about irreversibility, or chemical sterilization, do not appear to be substantiated.

The same Thai study did suggest an abnormal sex ratio (more males

than normally expected) among children born to prior DMPA users, but the number of infants was small and this may have been a chance finding.[30] However, this finding should be assessed in additional studies.

VII. Teratogenic Potential

Laboratory experiments have shown that exposure in utero to very large doses of DMPA can have a virilizing effect on rat and rabbit fetuses, but this is not so in humans.[31]

Several epidemiologic studies suggest that prenatal exposure to exogenous sex hormones may rarely produce various types of congenital abnormalities in a developing fetus.[32] However, there is very little information on the possible effects of progesterone alone.[33] Nonetheless, the possibility of an effect is of concern, since some women starting to use DMPA may have an unrecognized early pregnancy and women stopping DMPA may conceive before DMPA is completely cleared. Because of the depot or long-term action of DMPA, this could possibly be of concern even beyond the three months of contraceptive effectiveness. Information about such conceptions and their outcome should be collected, perhaps in an international registry, as an extremely large series would be necessary to refute or prove this possible relationship, as discussed below.

A review of the evidence in recent studies concerning the possible teratogenic effects of exogenous sex hormones showed that, although all of the available studies have methodologic deficiencies, the data suggest an association between prenatal exposure to these hormones and a variety of congenital abnormalities, especially cardiac defects, with a relative risk probably in the range of two-fold.

Since effective contraception prevents both normal and abnormal pregnancies, it can be shown that even if a two-fold increase in con-

genital defects were associated with prenatal exposure to DMPA widespread use of the drug would result in a net decrease in the number of anomalies. Because of this, only a very small number of fetuses would be exposed to the two-fold increased risk associated with maternal use of the drug.

The Panel felt that continued surveillance was essential to evaluate potential teratogenic effects, but stated that no human data was available to suggest that DMPA increases the risk over that which may be associated with other hormonal contraceptives.

VIII. Carcinogenic Potential - Cervix

There is no strong evidence linking DMPA with cervical disease.[34] Furthermore, it is virtually impossible to conduct a good scientific study to persuasively identify a relationship between the use of any hormone and cervical cancer, unless the increased risk is at least four-fold. The major reason for this is that the risk of cervical cancer is strongly associated with sexual behavior variables, which are difficult to control. Many past studies, including those reported to the FDA by the House Subcommittee in 1974, have been confounded by failure to deal with these difficult-to-measure, but critical sexual variables. The development of invasive cervical cancer lags 5 or more years after the development of presumed cancer precursors, which can be detected by pelvic examination and Pap smear.[35]

It appears that any effect of hormones on cervical cancer incidence, if present, is unlikely to affect the risk of cervical cancer to a degree

which can be measured with current medical and epidemiologic evaluation techniques Pathologists differ significantly in their interpretation of cervical biopsies, so that it is nearly impossible to conduct comparative studies in the large populations required to detect differences of less than a four-fold magnitude in relative risk.

The Panel felt that there was no evidence presently available to suggest a relationship between the development of either cervical cancer or its precursors and the use of DMPA; thus there is no contraindication of its use for this reason. Given the long delay in human carcinogenicity, however, continued data collection was recommended.

IX. Carcinogenic Potential - Endometrium

In December, 1978, several weeks after the Ad Hoc Panel had adjourned, it became known that the required 10-year studies of DMPA in monkeys had been completed, and the preliminary results of the autopsies contained the surprising finding that two of the monkeys which had been receiving 50 times the human dose had endometrial cancer.[36] No other neoplasia were found. The Chairperson of the Panel, after consultation with Panel members, arranged for a special toxicology committe to consider this information and the reports of consultant toxicologists (to the Upjohn Company) who reviewed the microscopic specimens of all the test monkeys. (See Appendix I for the Toxicology Committee's full deliberations.) In brief, the Committee concluded that the meaning of the finding of endometrial cancer in two of the monkeys subjected to extremely high doses of DMPA for many years is far from clear, for the following reasons:

1. There is no baseline information on the incidence or natural history of endometrial cancer in monkeys.

2. There is a substantial body of literature which shows that progestogens do not promote endometrial cancer in women. In fact, there is some preliminary evidence that they may even be protective.

3. DMPA does not cause hyperplasia in either monkeys or women; it causes atrophy. Hyperplasis is the state believed to be favorable for the development of endometrial cancer in women.

4. There is considerable doubt among toxicologists and pathologists that it is valid to extrapolate from the experience of animals given extremely high doses.

5. There is no evidence, in the few and preliminary data available, of an increase of endometrial cancer among long-term users of DMPA.

Weighing these factors against the considerable benefits of DMPA, the Commmittee was unanimous in supporting the original recommendation of the Ad Hoc Panel that DMPA should be made available to developing countries, upon request, as a part of its assistance program, provided that careful study of the possible health effects of DMPA continues. Thus, the Committee was in agreement with the WHO's Toxicology Review Panel.

X Carcinogenic Potential - Breast

Of great concern to the Panel were data from toxicologic studies of DMPA in beagle dogs, in which the treated animals have manifested more mammary gland tumors than control animals, and some of the tumors have become malignant.[37] Data from a series of studies were

reviewed in which varying dosages, ranging from the human contraceptive dose to 25 times this dose, were used over a varying period of years.[38]

Because of the complexity of the issues involving the beagle dog and its relevance to humans, much time was spent discussing both similarities and differences in the beagle dog response to the exogenous sex hormones, particularly progestones. In both beagle dogs and humans, progesterone prevents the LH surge, prevents ovulation, decreases plasma cortisol, and causes a mild disturbance of carbohydrate metabolism.[39]. Beagle dogs and humans, however, differ in their response to progestogens three important ways:

1. The beagle dog endometrium is stimulated by DMPA, producing dilated secretory glands, leading to a condition of mucometra and/or pyometra (the latter, in some cases, causing death).[40] In the human, on the other hand, there is an initial stimulatory effect, followed by a quiescent stage, leading to atrophy of the endometrium.[41]
2. With higher doses an acromegalic-like condition is seen in the beagle dog which becomes conspicious in many of the animals tested.[42] At the present time it appears that this may be related to a stimulatory effect on growth hormone, although the data on this particular point are not yet conclusive. In the human no acromegalic changes are seen.[43]
3. Finally, many beagle dogs that were treated with high doses of DMPA, many of whom developed mammary gland tumors, died from causes other than breast cancer (usually pyometra).[44] No deaths in humans receiving high dosages of DMPA have been reported.

Studies comparing beagle dog responsiveness to DMPA with that of other test animals and humans show significant species differences in the metabolism and progesterone receptor responses.[45] In all the reported studies, mammary gland nodules developed in almost all treated beagle dogs that lived beyond the first few years of treatment. In 2 of 16 animals receiving high doses of DMPA, mammary gland tumors metastasized to other parts of the body.[46] In animals which were hysterectomized in order to prevent death from pyometra, and then received high doses of DMPA, widespread vascular changes were noted, with increases in platelets and many had massive thromboses.[47] Serious renal changes were observed with early deposition of PAS-positive material, together with some instances of amyloidosis and diabetic glomerular changes.[48] These effects have not been seen in the human. In other studies, using lower doses of DMPA, liver adenomas were found in the beagle dog, together with an increase in gallbladder stones.[49] Progesterone itself, at physiologic dose levels, produced no such changes in these particular experiments.

There is little doubt that C-21 steroid derivaties with progestational activity, including progesterone itself, produces a series of toxic manifestations in the beagle dog. All progestogens, including 19-NOR derivatives, also produce mammary changes in beagles, if given in high enough doses. A probable explanation of differences between progestogens in tumorogenic potential relates to the wide variation in relative affinities of synthetic progestogens for the progesterone and estrogen receptors of various species.* There have been problems

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For this reason, the Committee on Safety of Medicines in the United Kingdom no longer requires beagle dog studies for contraceptive drugs.50

however, for technical reasons, in the ability to precisely measure progestogen receptors in the normal human breast.

Finally, since the Ad Hoc Panel meetings, new information bearing on this subject has come to light. (See Appendix II for summaries of relevant information released in the year following the Panel meetings). Most importantly, data from nine years of prospective study of thousands of contraceptive users in Britain found absolutely no excess of breast cancer among women using contraceptives containing progestogens closely related to DMPA.[51]

As mentioned earlier, the various committees that have reviewed the effects of DMPA in the human had available to them the unique opportunity to review human data in which DMPA had been used for long periods of time at much higher doses than the contraceptive dose. With some fifteen years of experience, there have been no known fatalities related to DMPA administration in the human, nor any of the endometrial, acromegalic, vascular or mammary gland changes shown to occur in the beagle dog.

After reviewing animal as well as human data, the Toxicology Review Panel of WHO, which met in September, 1978, and whose report was available to the Panel in draft form, concluded that:

> Considerable reservations must be expressed over the relevance of the findings in the beagle dog to the possible toxicity of long-acting progestogens in humans. Significant differences in the response to progestogen treatment between dogs and women have demonstrated. . . . There is evidence that the healthy beagle dog's breasts contain a reservoir of microscopic neoplasms which may grow and occasionally become malignant in response to prolonged over-stimulation by progestogens, especially by those compounds particularly active in the canine species. Progesterone treatment stimulates progesterone receptors in the

> breasts of the dog, but not in the rat nor in the human. The available evidence suggests that all investigated progestogens, including progesterone itself, are able to promote mammary tumors in the beagle dog. For these reasons the beagle dog does not appear to be an appropriate animal model for the evaluation of carcinogenic risks associated with progestogens.[52]

In addition to work on beagle dogs, studies have also been carried out in rodents and monkeys. The WHO Toxicology Panel reviewed these in depth. Included were several very high dose studies in both mice and rats, with doses up to 200 times the recommended human contraceptive dose. Results indicated no change in mortality rates and there was a similar incidence of neoplasms in both treated and untreated animals. In particular, no mammary cancer was observed. Growth hormone release was stimulated by DMPA, but there was no effect on prolactin. Benign hepatoma was seen rarely in test animals. The relevance of the rodent results to the human is difficult to assess in the absence of detailed comparate pharmacokinetic and pharmacodynamic data.

Studies on monkeys show no demonstrable differences between controlled groups and monkeys treated with low, middle or high doses of DMPA, in the development of mammary nodules, except for one study in which mammary nodules were noted in some of the animals receiving the middle but not the high dose.[53] These nodules were benign, with dilated ducts and alveoli, together with a slight proliferation of epithelial cells and connective tissue, but no indication of neoplasia.

XI. Monitoring and Research

While there has been an extensive literature published on the use of DMPA for both clinical and contraceptive uses in the United States and abroad,there is need for continued and additional data on the short- and long-term risks and benefits of DMPA in humans. In order to be able to more accurately continue to evaluate and assess risk/benefit, and to resolve

any continued uncertainties and doubts, there is a need to support both the organization of appropriate surveillance systems and the development of carefully focused research studies. Many of the steps to be suggested below are relevant to other contraceptive methods, as well, and should also strengthen the capacity for conducting risk/benefit analyses both in the United States and other countries when DMPA is used as a contraceptive.

A. Surveillance: Routine surveillance or reporting systems, such as those existing in the United States and Britain, are the source of much of the present epidemiologic information on the risks and benefits of contraceptives. Although these systems are costly, require a degree of technical expertise, and cannot easily be established, they are important if countries are going to be able to effectively monitor the use of agents such as hormonal contraceptives. Such systems might include the following:

1. Brief case reports of untoward and unusual illness among women in this reproductive years. Even if initially incomplete, such reporting, especially if followed up routinely, will improve reporting completeness, generate hypotheses for study, and allow for epidemiological assessment of potential and actual complications related to the use of DMPA and other contraceptive methods.
2. Periodic cross-sectional surveys of health care providers may reveal unusual or dramatic complications of an old or newly introduced contraceptive method like DMPA.
3. Formal registries, perhaps first organized on a limited geographic basis, also lay the foundation for further study. Since the issue of neoplastic disease has been

raised with the use of hormone contraceptives, cancer registries should be considered. This should be recognized as a long-term investment in disease control yielding potential benefits beyond the issues addressed by the Panel.

B. Research Studies

1. In order to gather additional information relating to the potential teratogenic effects of DMPA (either when injected during an unrecognized pregnancy, or when conception occurs before DMPA is cleared from the woman's system), as well as to gain information on the potential risk to child development arising among infants exposed to DMPA and its metabolites in the mother's milk, prospective and retrospective studies are required to assess spontaneous fetal loss, stillbirth, birth weight, congenital abnormalities, sex ratio, early growth and development, and other pertinent measures of morbidity in infancy and childhood. Suitable non-exposed controls, matched on relevant reproductive characteristics, will be necessary.

2. While the data from Thailand on return of fertility following discontinuation of DMPA was felt by the Panel to be reassuring, differences in proven fertility of the two groups of women studied shows the need for continued assessment of this issue, especially regarding use of DMPA in women with unproven fertility and/or irregular menstrual cycles. In addition, there is a need for detailed workup of those women unable to become pregnant after discontinuing DMPA.

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Further, one study noted a rather high male-female ratio among births to women conceiving after DMPA use and further evaluation of this finding is required.

3. Attempts to assess the possibility of malignant changes in the cervix related to hormonal preparations were felt by the Panel to be extraordinarily difficult for technical reasons, if only a small increased risk is involved. The problems described earlier in this report are thought to be significant; continued follow-up and observation are recommended, but no new controlled studies are proposed at this particular time because of the difficulties and costs.
4. The Toxicology Committee which reviewed the information on endometrial cancer and DMPA emphasized the need for further and more intensive investigation of this issue. Several studies are already planned by the World Health Organization and by the International Fertility Research Program. These will be carried out in areas where DMPA has been established as a popular method of contraception for years. It was suggested that a variety of research approaches be utilized, including: registries of pathology where unusual types of tumor would be noticed; case control studies in areas where use is common; and cohort studies (perhaps based on an initial cross-sectional study of a population that could be followed).
5. The potential for development of breast cancer in humans remains one that requires continued follow-up because the latent period between exposure and appearance of cancer may be long

in the human. It is urgent that observational case control studies begin now. Clinical studies to assess the metabolic effects on DMPA in humans should be continued both here and abroad. In addition, studies should be continued on the beagle dog, until explanations of the causes of the mammary tumors, as well as the acromegalic-like syndrome, are available.

XII. Conclusions

Based on the testimony and discussion of Panel members with expertise in various areas of concern related to DMPA use, on review of the extensive bibliography on the subject, and on review of WHO materials (most particularly the findings of the Toxicology Review Panel of the WHO Special Program of Research in Human Reproduction), the Ad Hoc Consultative Panel on DMPA has drawn the following conclusions:

1. DMPA has been used rather widely for clinical gynecologic uses (for endometriosis and endometrial carcinoma) at doses significantly higher than that recommended for contraception, and as yet the Committee knows of no reports of significant adverse effects.
2. DMPA is the only widely available long-acting injectable contraceptive and has a higher use effectiveness than any other reversible contraceptive method, particularly since it has no relation to coitus, requires infrequent administration, and is provided outside the home.
3. Metabolic Effects: While laboratory findings suggest a mild effect on carbohydrate tolerance and a mild adrenal suppressive effect, these are probably less than similar effects caused

oral contraceptives. There appears to be no circulatory system effect, although it would be premature to make definitive statements in this regard at the present time.

4. Menstrual Effects: Menstrual side effects are the most important complaints related to the use of DMPA. Initially, there is irregular spotting, staining or bleeding, while later amenorrhea develops in as many as 60% of women. A review of the literature suggests that use of estrogens in the treatment of the spotting and staining are ineffective and are no longer recommended for this reason. FDA's concern that estrogen will be prescribed frequently to DMPA users users does not seem to the Panel to be justified in fact.

5. Return of Fertility: Data were presented from Thailand, in which a series of women who discontinued use of DMPA in order to become pregnant was compared to a similar group of women who discontinued use of oral contraceptives and IUDs for the same reason. These data suggest that, while the return of fertility was delayed in the previous DMPA users, by 24 months there was no significant difference in pregnancy rates between women who discontinue DMPA use in order to become pregnant and prior pill or IUD users. The mean gravidity in DMPA users, however, was slightly higher than that of the oral contraceptives users, suggesting that more of the DMPA users had proven their fertility prior to contraception.

6. Teratogenic Effects: There is suggestive evidence that a two-fold risk of certain congenital anomalies is associated with prenatal exposure to some exogenous sex hormones. With DMPA there is concern that a woman with an unrecognized early pregnancy may receive an injection of DMPA, or that conception may occur before the effects of DMPA have cleared from the woman's system. The weight of available epidemiologic data suggest that there may indeed be a small association between prenatal exposure to all exogenous hormones and a variety of congenital defects, with a relative risk, perhaps in the range of two-fold. However, because data have not been found specifically identifying DMPA as a causative teratogen, it is impossible to state that it poses a greater or lesser risk than other hormones. Further, the teratogenic risk, if it exists at all, is small, and the risk of pregnancy is also very small, thus making this potential risk an extraordinarily rare one. The Panel recommended continued evaluation, but did not feel that the available data suggest DMPA should be held off the market because of this possible risk.

7. Cancer - Cervix : There had been some concern that DMPA might produce premalignant changes in the cervix. However, review of the available data suggest that there is no demonstrable effect on cervical disease. Further, studies to identify a small increase in risk (less than four-fold) were deemed to

be extraordinarily difficult for a variety of technical reasons, including differences in pathologists' interpretation of cervical biopsies, together with the need to control for a range of sexual behavior factors, for which information is difficult to obtain.

8. Cancer - Endometrium: The Committee of experts, which reviewed the data on cancer of the endometrium associated with DMPA among monkeys, concluded that, while continued studies are imperative, the data available at this time do not warrant discontinuing use of DMPA for this reason. The full Ad Hoc Panel reviewed the Committee's report (Appendix I) and was in agreement with the Committee's conclusions.

9. Cancer - Breast: Of great concern to the Panel was the development of breast nodules, some of which have been malignant, in beagle dogs subjected to varying doses of DMPA. Assigning a different order of magnitude to the possibility of an association between DMPA and breast cancer from that assigned to non-threatening risks, the Panel spent a great deal of time reviewing this particular issue and felt that, while studies must continue to assess the meaning of beagle dog data, there are significant differences between the beagle dog and the human in the response to progestogens and in the histology of the mammary gland. These differences include a different response of the endometrium, which is stimulated in the beagle dog and which atrophies in the human; the development of acromegalic changes

in the beagle dog and no similar changes in the human; the latent neoplastic foci in the beagle mammary gland, which do not exist in the human; and death of beagle dogs due to pyometra, secondary to the hyperstimulation of the endometrium, which, again, does not occur in the human. The Panel concluded that while studies should continue, the evidence suggests that the response in humans is different and that the beagle dog data are not sufficient reason to withold DMPA.

XIII. Recommendations

1. After a review of the various materials and information described earlier, and after as thorough as possible an assessment of the risks versus benefits of DMPA use in humans, the Panel recommended that USAID make DMPA available to those nations that request it for use as a contraceptive. One Panel member, Dr. William Hansel, does not concur with this final recommendation. (The majority of Panel members also felt that this drug was appropriate for use in the United States as a general contraceptive agent but this was beyond the purview of issues the Panel was asked to address).
2. This recommendation holds even if the FDA does not change its present stance at the time of its hearing in response to the Upjohn Company's request, unless new or additional adverse data or information become available.
3. USAID should inform nations to which it provides financial and commodity assistance of the availability of DMPA, but should take care to avoid influencing the choice of DMPA within a

country's program. It should not promote DMPA as a contraceptive method, as long as the drug is not approved for contraceptive use in the United States by the FDA.

4. USAID should provide as much information as possible about the risks, benefits and use effectiveness of DMPA as a contraceptive, to enable other nations to assess, in light of their own health needs, whether DMPA should be used in their respective countries. This recommendation may be minimally satisfied by providing information obtained for this purpose from both the FDA and the WHO.
5. If DMPA is provided this should be done through the normal channels through which USAID provides such commodities, including direct bilateral distribution and distribution through intermediaries. The Panel did not feel that there should be any special distribution channel for this drug that would be different from AID's procedures with other such commodities.
6. The Panel did not feel that USAID should place restrictions on use of this drug, feeling instead that this was the role of the requesting nation, which, after its own review, should make such decisions.
7. As with other forms of contraception, consumer information and education on DMPA should be an integral part of programs providing contraception. The methods of providing this information should be decided within each country according to its own practices, but the Agency should recommend that consumers

be as fully informed as possible about the benefits, risks and side effects of all forms of contraception and provide contraceptives only where such consumer safeguards are in place.

8. A series of recommendations are included in the body of the report concerning the establishment of appropriate surveillance and monitoring procedures, together with suggestions as to the types of research studies that should be undertaken. The Panel did not feel that these could be conditions for provision of the drug, but, rather, that AID should be prepared to support such activities upon request and should encourage surveillance, monitoring and research studies wherever appropriate. It should also work in close collaboration with WHO,(which is involved in developing and conducting a number of the types of studies listed in the body of the report), and also with the UNFPA, IPPF and other donor agencies.

9. If USAID does elect to distribute DMPA,despite the present FDA ruling, this should not be seen as a precedent for the more general provision of other drugs not approved by the FDA. If exceptions are deemed of importance in the future, careful review of all related issues should first be carried out, through the mechanism of an expert and ad hoc panel.

10. In order to monitor, on an on-going basis, data on DMPA, as well as data on other contraceptives, the Panel recommends the establishment by USAID of a continuing Scientific Advisory Committee.

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APPENDIX I—REPORT OF THE TOXICOLOGY COMMITTEE

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I. INTRODUCTION

In December, 1978, at the request of the U.S. Agency for International Development, an Ad Hoc Consultative Panel on Depo Medroxyprogesterone Acetate (DMPA) was convened in New York. After review of animal toxicology studies and available information on the use, benefits and risks of DMPA, the Panel was prepared to recommend, unanimously, that USAID make this drug available, as part of its assistance program, to those countries which, after reviewing the available information, wish to use it.

Prior to finalizing the Panel's report, however, information was received indicating that endometrial carcinoma had developed in two test monkeys which had been receiving 50x the therapeutic dose of DMPA A research firm under contract to the Upjohn Pharmaceutical Company, at the end of required ten-year studies, had carried out routine postmortem examinations on animals which had been receiving 1x, 10x, and 50x the therapeutic dose, as well as a group of controls. Two of the 10 monkeys receiving the highest dose were found to have endometrial carcinoma, while none of the seven control animals had this disease, nor did any of the 20 monkeys receiving other doses. (A number of animals in the study died from various causes before completion of the 10-year study period. None of them had endometrial disease).

As a result of the monkey data, the Panel agreed to table its report until more information was available, so as to be better able to interpret the findings. The Upjohn Company sent the monkey's endometrial slides to a number of leading human and veterinary pathologists for their interpretation.

With the reports sumbitted by these pathologists to Upjohn, and after telephone conversation with Panel members, the Panel chairperson organized a special, one-day committee meeting to review the data and make recommendations to the Panel for its final report. A group of experts was recruited for this meeting from a variety of relevant fields, including obstetrics and gynecology, gynecologic pathology, veterinary pathology and reproductive physiology. Committee members trained in these fields all had experience with endometrial disease in either primates or humans. In addition, other Committee members had experience in cancer epidemiology, international public health programs, and one was a lawyer with experience in ethics. (See Appendix for a list of Committee members.) The Committee reviewed materials provided by Upjohn, including the outside pathologists' assesments of the microscopic specimens. Committee members also reviewed the draft of the Ad Hoc Panel's original report, a summary of relevant literature published during the year since that report was written, and materials provided by the World Health Organization (WHO).

In October 1979, the WHO's Toxicology Review Panel issued its final appraisal of the DMPA monkey study. After reviewing all the data the Panel concluded "that the adenocarcinoma in these two monkeys were the result of massive overdosage. The Panel felt that the current and planned WHO studies of the health effects of DMPA should continue, and that there is no reason to recommend discontinuation of the use of DMPA in national family planning programmes."[1]

2. PATHOLOGIST'S REVIEW

Dr. Ralph M. Richart, Director of Obstetric and Gynecologic Pathology at the Sloane Hospital for Women, reviewed the reports submitted to the Upjohn Company by five consulting pathologists who examined the histological sections taken from the monkeys in the study of DMPA. The pathologists were Drs. Arthur T. Hertig, Ralph Heywood, John M. Morris, D. L. Moyer, and Marion G. Valerio. Dr. Richart's report to the panel follows:

> There was uniform agreement among the consultants that in the majority of the monkeys the endometrium was atropic with a pseudo-decidual transformation of the endometrial stroma similar to the alterations commonly seen in women receiving DEPOPROVERA at contraceptive doses. They also agreed that the neoplasms noted in two of the high-dose monkeys were endometrial adenocarcinomas and that one was metastatic. Although there were some variations in the histological description of the two cancers, particularly with regard to differentiation, there was no greater variability than would be expected based on past experience, and the differences were not thought to be significant. Because of the small number of animals in the study, the relative paucity of data regarding the occurrence of endometrial carcinoma in older monkeys and the lack of accompanying endometrial hyperplasia, it was difficult for the reviewers to make a determination as to the possible relationship of the endometrial cancers to the administration of DMPA."

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3. COMMITTEE'S DELIBERATIONS

The Committee members stressed the difficulty of interpreting the information because so little is known about endometrial disease in monkeys: Few institutions keep monkeys for such prolonged periods of time (10 years in the Upjohn study). There is no information on the baseline incidence of endometrial cancer in monkeys.

However, it does appear to be uncommon. For example, the San Diego zoo performs autopsies on all animals. Of 46 female macaque monkeys examined, none had endometrial abnormalities.[2] However, the zoo's Director of Research, Dr. Kurt Benirschke, who gave the Committee this information, cautioned that there is great variation among the many species of macaques, and there were less than a dozen rhesus monkeys (the species of macaque used in the DMPA test) in their sample. The Armed Forces Institute of Pathology does not have any cases of uterine cancer in its collection of primate neoplasia. On the other hand, Committee members said that they knew of two cases of uterine abnormality in monkeys, neither of which had been administered hormones. Dr. E.S. Gerard of the Upjohn Company provided the Committee with information on these cases:

> At this time we are aware of three long-term monkey studies that have been completed. These are our own Depo-Provera study, a Population Council study utilizing the Tatum T intrauterine device, and a Wyeth study utilizing their marketed contraceptive steroids. The Population Council study had one control animal with endometrial adenocarcinoma in situ and the Wyeth study had one control animal with atypical adenomatous hyperplasia which is considered to be a premalignant lesion. Thus, each of the three studies has abnormalities of the endometrium: in a treated group in our study and in the control groups in the other two studies.

Dr. Bardin of the Population Council pointed out that the endometrial cancer in this control monkey would probably not have been detected on routine autopsy. The endometria of animals in their experiment were especially carefully scrutinized because it was an IUD study.

Dr. Gerard noted that there are a number of long-term trials underway on the effects of contraceptive steroids on monkeys. Perhaps when these are completed they will provide more information on endometrial lesions in monkeys.

It was suggested by the Committee that the monkeys' endometrial cancer could have arisen by any of three routes: through hormonal action of the DMPA; through some nonhormonal, toxic action of the DMPA; and independently of the DMPA, by chance.

If the hormonal action of the DMPA caused the cancers, then they are unusual in several ways: (1) They were associated with the superficial layers of the endometrium; whereas in women, cancer usually arises from deeper layers of the endometrium. (2) Endometrial cancer in women is usually associated with hyperplasia, such as that caused by estrogen. There was no evidence of hyperplasia among the DMPA treated monkeys. (3) The endometria of the monkeys treated with DMPA were atrophied, a condition which has been thought to decrease the risk of carcinoma developing. In short, the theory that the hormonal action of DMPA caused the endometrial cancer in the test monkeys is contrary to what is known of the natural history of endometrial cancer in women.

Additional evidence against the hormonal action of DMPA having caused the endometrial cancer is found in a variety of clinical and epidemiologic studies. Excess estrogen is known to increase a woman's

risk of developing endometrial cancer. There is evidence that progestogens neutralize this effect. For example, while use of estrogens by postmenopausal women increases the rate at which they develop endometrial cancer, use of a combination of estrogen and a progestogen does not increase the rate of disease.[3] Similarly, while use of sequential oral contraceptives (which emphasized estrogenic action) may have increased the risk of this disease among young women, use of oral contraceptives (which contain estrogen and a progestogen in each pill) does not have this effect.[4] In fact, there is new evidence from a case control study which suggests that women who use combined oral contraceptives may even have less risk of endometrial cancer than do women who do not take oral contraceptives -- in other words these preliminary data suggest that progestogens may even protect against endometrial cancer.[5] Finally, DMPA and other progesterones have been used clinically to slow the growth of advanced endometrial cancer in women. While none of these findings rule out the possibility that DMPA may have caused the cancer found in the monkeys, they do call into question the meaning of that finding.

There is, of course, the possibility that the hormonal action of DMPA may increase the risk of endometrial cancer in monkeys through some unknown route. There is no way of knowing, with so few data, if this is the case. If it is, is this finding applicable to women? Some pathologists believe that DMPA, at very high doses, may affect tissues in the monkey endometrium which are known to react differently from those in women.[6]

It is also possible that the massive doses of DMPA may have affected the monkeys in the 50x group through some nonhormonal action -- i.e. as a toxin. The Committee members thought that this seemed unlikely because there was no evidence of a dose response: there was no higher mortality rate among

the monkeys receiving DMPA than among the control monkeys, nor any increase in mortality with increasing dosage. Neither was cancer found in sites other than in the uterus. However, these observations must remain speculative, because of the very small number of monkeys in the experiment.

Finally, the possibility that the two cases of endometrial cancer in the 50x group arose by chance cannot be ruled out. Using Fisher's exact test, the probability that the results of the monkey test could have occurred by chance ranged from one chance in three (P=0.33), to one chance in four (P=0.28), depending on whether only the monkeys left at the end of the trial or all monkeys ever in the trial were included In addition, exploration with a variety of statistical techniques showed that these data lack both significance and power, even if margins of error (both Types 1 and 2) much larger than usual are allowed. For example even with an alpha as high as .30 (rather than the traditional .05), .80 power was not achieved unless the relative risk associated with DMPA use was assumed to be at least 6.6. In addition, even if four cases of endometrial cancer had been found among the monkeys in the 50x group (rather than the two cases which actually occured), and the alpha level was set at .10, power did not reach .80 even assuming a relative risk with DMPA use of 10.

Several members of the Committee questioned the usefulness of testing contraceptives with massive doses. Dr. C. Wayne Bardin, Director of the Center for Biomedical Research at The Population Council, reported on the effects of very high doses of hormones, such as those used in the monkey experiments. His report can be summarized as follows:

> One of the problems associated with current toxicologic studies for contraceptives is that steroids must be tested at 1-, 10-, and 50-fold the human dose. While this might be a reasonable approach for a chemical

carcinogen, it is not necessarily valid for hormones. The reason for this relates to the fact that there is not absolute specificity between various steroid hormones and their respective receptors. For example, a given progestin will bind to the progesterone receptor with high affinity ($Kd=10^{-9}$). Progestins also bind to glucocorticoid, mineralocorticoid and androgen receptors with decreasing affinities. Thus, at physiological concentrations progestins bind to progestin receptors and produce progestational responses in organs that have these receptors. At slightly greater than physiological concentrations, progestins are also glucocorticoids by means of their interaction with the glucocorticoid receptors. At still greater concentrations progestins bind to the mineralocorticoid and androgen receptors. Over the enormous dose range tested in toxicologic studies, progestins would be bound to all of these hormone receptors and would exert many effects not related to the progestational activity seen at physiological concentrations of the hormone. (Almost certainly, many of the pathologic effects of MPA in the beagle dog related to their effects on other than progestin receptors).

Because progestins can interact with multiple hormone receptors when greater than physiological concentrations are present in the blood, unique and unexpected effects can be seen. One example of this is the interaction of progestins with the androgen receptor in kidney and prostate. MPA produces a moderate androgenic effect on the kidney, but only a slight androgenic effect on prostate. When administered in the presence of an androgen, MPA potentiates androgen action on the kidney but not on the prostate. This potentiating effect was unexpected and is still unexplained. Another progestin, cyproterone acetate, has no effect on kidney or prostate when administered alone. However, when administered with a low dose of testosterone it potentiates androgen action on the kidney but not on the prostate. When cyproterone acetate is administered with a large dose of testosterone, it inhibits androgen action both on the kidney and on the prostate. Many other progestins exert similar effects as described for MPA and cyproterone acetate. Thus, when progestins interact with the androgen receptor they may mimic, potentiate, or inhibit androgen action. Progestins are known to produce analogous effects when they interact with the glucocorticoid and mineralocorticoid receptors. It should be emphasized again that these unusual effects are seen when high doses of progestin are given, such as those that are present in animals treated with 50 times the human dose.

> In conclusion, it is important to realize that these considerations on hormone action have been appreciated only in the last several years -- after the pattern of testing contraceptive steroids was well established. In view of these recent observations and conclusions, it is reasonable to reconsider whether contraceptive steroids should be tested at 50- and even at 10-fold greater doses.

In addition to trying to interpret the monkey data and assess their applicability to humans, the Committee considered the experience of women who have used this method of contraception. In response to the endometrial cancer finding at the conclusion of the monkey trial, Drs. Edwin McDaniel and Malcolm Potts have made an effort to determine whether there was an increase in endometrial cancer among women in Chiang Mai and Lumpoon provinces in Thailand, where DMPA has been used by more than 86,000 women since it was introduced in 1965.[7]

McDaniel and Potts report that a search of the records of all seven hospitals operating in these areas produced evidence of 39 cases of proven or presumptive endometrial cancer in 1974-1978. During these years, they note, ". . . there has been a steadily increasing patient load for diseases of all kinds." However, there was no clear increase in the number of cases of endometrial cancer seen each year, as Table I shows.

Table I. Proven and Presumptive Cases of Endometrial Cancer Reported in Chiang Mai and Lumpoon Providences, Thailand, by Year of Diagnosis.

	Diagnoses		
Year	Proven	Presumptive	Total
1974	3	0	3
1975	8	1	9
1976	6	6	12
1977	7	3	10
1978	3	2	5
Total	27	12	39

Source: McDaniel and Potts

Of the 27 women with proven endometrial cancer, 16 came from Chiang Mai or Lumpoon province, where they could have received DMPA. Of these 16, four were too old to have received DMPA (63-84 years old at diagnosis), one had never been married, and two could not be located at the time of the report. Of the remaining nine women, none had ever used DMPA. Because the numbers are so small, the time too short, and the conditions of the study far from satisfactory, these findings cannot be construed as proof that DMPA does not cause endometrial cancer. Nevertheless, the authors note, the lack of a substantial increase in endometrial cancer -- in an area where hundreds of women are known to have used DMPA continuously for 10-13 years and many thousands for shorter periods -- ". . . is a reassuring preliminary observation."

The Committee members emphasized the need for further and more intensive investigation on this issue. Several studies are already planned by the World Health Organization and the International Fertility Research Program. These will be carried out in areas where DMPA has been established as a popular method of contraception for years. It was suggested that a variety of research approaches be utilized, including: registries of pathology where unusual types of tumor would be noticed; case control studies in areas where use is common; and cohort studies (perhaps based on an initial cross-sectional study of a population that could be followed).

4. CONCLUSION

The assembled experts concluded that the meaning of the finding of endometrial cancer in two of the monkeys subjected to extremely high doses of DMPA for many years is far from clear, for the following reasons:

There is no baseline information on the incidence or natural history of endometrial cancer in monkeys.

There is a substantial body of literature which shows that progestogens do not promote endometrial cancer in women. In fact there is some preliminary evidence that they may even be protective.

DMPA does not cause hyperplasia in either monkeys or women; it causes atrophy. Hyperplasia is the state believed to be favorable for the development of endometrial cancer in women.

There is considerable doubt among toxicologists and pathologists that it is valid to extrapolate from the experience of animals given extremely high doses.

There is no evidence, in the few and preliminary data available, of an increase of endometrial cancer among long-term users of DMPA.

Weighing these factors against the considerable benefits of DMPA, the Committee was unanimous in supporting the original recommendation of the Ad Hoc Panel that DMPA should be made available to developing countries, upon request, as a part of its assistance program, provided that careful study of the possible health effects of DMPA continues. Thus, the Committee was in agreement with the WHO's Toxicology Review Panel.

It should be added that both this Committee and the original Ad Hoc Panel found no reason to support the FDA's decision not to approve use of DMPA as a contraceptive in the United States.

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Appendix 2:

FROM: James D. Shelton, USAID

SUBJECT: Relevant information regarding the safety of Depo-Provera (DMPA) which has accrued during the last year, 1979.

Since the December 1978, meeting of AID's advisory panel on Depo-Provera, a notable number of important findings on the various safety considerations of Depo-Provera have become available. The most well-known of these was probably the finding of adenocarcinoma of the endometrium among two of the rhesus monkeys given 50 times the human dose of DMPA. The implications of this animal evidence for the human is as yet unclear. Some of the evidence described below, however, bears heavily on the endometrial cancer issue as well as other important issues and offers a good deal of encouragement. I think the information cited below is fairly complete, but would welcome information regarding data I may have omitted. Copies of cited studies are available on request.

I. Breast Cancer

A. Human Data

1. Investigators at Emory University in collaboration with the Center for Disease Control have conducted a case-control study of breast cancer among contraceptive users.[1] From 1969 to 1978, over 11,000 women received DMPA. The study showed a relative risk of 1.0 (i.e., no increased risk vis a vis other contraceptive users). While the study was limited to 30 cases of breast cancer (because of the low incidence of breast cancer in this contracepting population), the authors calculated they would have had an 80% chance of detecting a three-fold risk and a 95% chance of detecting a four-fold risk.

2. Results regarding breast cancer and oral contraceptive users were published from the highly regarded "Oxford" study.[2] Breast cancers diagnosed over the decade from 1968 to 1977 were included. While the study looked at all oral contraceptive users, information was broken out on preparations containing chlormadinone acetate or megestrol acetate since these progestins belong to the same class of progestin as DMPA (17α-hydroxy progesterone derivatives and the whole group has been particularly implicated as a cause of breast tumors in beagles. The British investigators found 30 cases of breast cancer among users of these preparations and 30 cases among controls. Thus, there was no increased risk and the relative risk was again 1.0.

3. Results on breast cancer became available from a 10-year double-blind prospective study of postmenopausal women receiving conjugated estrogens and cyclic oral medroxyprogesterone acetate (MPA) seven days in each month.[3] Other evidence has indicated that the oral MPA, if anything, gives higher blood levels than the injectable DMPA.[4] Although the sample size in the prospective study was relatively small, it showed a statistically significant lower indidence of breast cancer among women receiving the estrogen with MPA.

B. Animal Data

Published articles from Upjohn[5] and Schering[6] report a marked stimulatory effect on growth hormone when DMPA is administered to beagle dogs. This effect is known not to occur in humans. The data suggest that the profound effects of DMPA on the beagle mammary gland is a

species-specific effect related to its important effects on the dog's pituitary gland. Additionally, the British Committee on Safety of Drugs (equivalent to our FDA) has abandoned the beagle dog as a model for making judgments of the impact of contraceptive steroids on human beings.[7]

II. Endometrial Cancer

A. Human Data

1. McDaniel and Potts [8] have investigated confirmed cases of endometrial cancer hospitalized at the McCormick Hospital in Chiang Mai, Thailand. Between 1965 and 1979, the McCormick Hospital program provided Depo-Provera to over 86,000 users. Of the 16 cases of endometrial cander from Chiang Mai and Lumpoon provinces, four were 63 years old or older. Nine of the remaining women were successfully followed-up and another had never married or borne children. None of the women followed-up had ever used DMPA or oral contraceptives. Furthermore, there has been no increase in hospital admissions for endometrial cancer over time, although there has been a steady increase in hospital admissions for other reasons. This negative result is, of course, not conclusive regarding DMPA use and endometrial cancer, but it certainly allays fears of any marked increase in risk.

2. A number of studies have reported that, whereas postmenopausal estrogens may induce endometrial cancer, addition of a cylic progestin (usually MPA) nullifies this risk and may in fact provide protection.[3,9-12] This apparently occurs because MPA and other progestins suppress the endometrium whereas estrogens stimulate it.[10-15] One study of cyclic oral contraceptives and endometrial cancer also

showed no increased risk.[16]

B. Animal Data

The significance of the rhesus monkey findings remains elusive. WHO's expert toxicology panel has twice discounted the relevance of the monkey information although it appears true that endometrial adenocarcinoma is very rare in the rhesus monkey. The report of the advisory subpanel elaborates on this issue (Appendix 1).

III. Metabolic Effects

A. Blood Clotting

British investigators report fewer abnormalities of blood coagulation among Depo-Provera users than among oral contraceptive users.[17]

B. Lipid Effects

Swedish researchers report markedly decreased effects of MPA on High Density Lipoprotein (HDL) and other lipid parameters associated with atherosclerosis. MPA might, therefore, be expected to have less theoretical effect on atheroschlerosis than other progestins.[18]

C Sex Hormone Binding Globulin (SHBG)

SHBG is a carrier blood protein which binds estrogens, progestins, and androgens. Steroid hormones which are bound to SHBG are generally not available for biologic activity. It has been known that the usual synthetic progestins (19-nor testosterone derivatives) bind strongly to SHBG whereas MPA does not.[19-20] Thus, these 19-nor synthetic progestins, by displacing estrogens and testosterone from SHBG, could contribute to the side effects attributed to these hormones. In addition to this theoretical advantage of MPA, British investigators in a recent study report that the 19-nor derivatives actually decrease SHBG while a progestin belonging to the MPA class

(megestrol acetate) slightly increases it. [21]

D. Vaginitis

An Egyptian study reports a decreased incidence of positive culture or smear for monilial (yeast) infection following use of DMPA. [22]

E. Blood Pressure

Careful blood pressure measurements before and after DMPA showed a small and statistically non-significant decrease.[23] Blood pressure measurements before and after any treatment should generally be evaluated with caution, however.

IV. Effect on Breat Milk and Child Growth

Some previous studies of the effect of DMPA on lactation have shown an increase. Others have reported no change. A recent study from Bangladesh goes beyond the usual breast milk measurements and actually looks at child growth among users of various methods of contraception.[24] Cross-sectionally, the average weight for height was remarkably similar for infants-whose mothers used DMPA, oral contraceptives, sterilization, and no method. The caloric content of the breast milk was also remarkably similar. The DMPA group's weight/height percent improved significantly more than the non-hormonal group, but the authors caution that "socio-economic and other factors may have somewhat favored the injectable group."

Summary and Conclusion

Aside from the information regarding the endometrial cancer in rhesus monkeys, all of the latest information is favorable to Depo-Provera. The human epidemiologic studies, while not conclusive, are strongly reassuring. The metabolic data support other previous work which collectively shows a superiority over oral contraceptives in a number of metabolic areas. This is not surprising since Depo-Provera contains only a single progestin rather than a progestin plus an estrogen and that single progestin is chemically more similar to the natural progestin (progesterone) than the 19-nor testosterone progestin generally found in oral contraceptives.

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APPENDIX 7

"Depo-Provera—A Critical Analysis,"[1] by Stephen Minkin

Introduction

Currently Depo-Provera is being used as a contraceptive in more than 82 countries. An estimated five million women have been injected with the drug in the course of the last 15 years. (1) In the United States, Depo-Provera is indicated for "adjunctive therapy and palliative treatment of inoperable, recurrent and metastatic endometrial carcinoma." (2) It is not approved by the Food and Drug Administration (FDA) for use as a contraceptive. Many physicians, however, disagree with the FDA and continue to prescribe it as one.

This report presents documentation showing that doctors, family planning professionals and patients do not have access to the information necessary for making a scientific assessment of Depo-Provera. The report also suggests that the manufacturer withheld data from the public concerning the adverse effects of the drug. Much of the information that follows comes from proprietary 'trade secret' documents not available to the public or the medical community. Other data were supplied by the Food and Drug Administration under the Freedom of Information Act or from published sources.

Background

Depo-Provera (DP) is a long-acting injectable contraceptive manufactured by the Upjohn Company. Depending on the dose, DP makes women infertile for three to six months or longer. Depo-Provera, the trade name for medroxyprogesterone acetate, acts on the hypothalamus-pituitary axis to suppress ovulation. It interferes with the normal pattern of hormonal changes usually associated with the menstrual cycle. Principally, it inhibits the surge of luteinizing hormone (LH) which precedes ovulation. It has also been suggested that when the drug is injected, the initial blood levels of DP are high enough to "produce a shock" to the hypothalamus, disrupting the menstrual cycle for three months or longer. (3)

Depo-Provera also acts on the ovaries and the endometrium (4)—the uterine lining—as well as the mammaries, the clitoris, the blood and other glands and tissues. (5)

The Food and Drug Administration rejected Upjohn's application to approve DP as a contraceptive on the grounds that "studies in beagle dogs have shown an increased incidence of mammary carcinoma." (6) Hence, the benefits did not outweigh the risks.

In rejecting Upjohn's request, the FDA took the extraordinary step of informing the company that the assessment of the risks of DP was not necessarily applicable to other countries: (7)

> We recognize that the benefit/risk considerations may be different in other nations, where alternative methods of contraception may be less available or less acceptable and where the physician/patient ratio is lower. Our evaluation of your supplement was based only upon benefit/risk considerations in the U.S. (8)

The reference to other countries appears to be a response to pressure by Congress and international population control agencies, including the U.S. Agency for International Development (AID) and the International Planned Parenthood Federation. The Drug Regulation Reform Act before Congress would allow U.S. drug companies to export directly to other

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countries drugs not approved by the FDA. According to former HEW Secretary Joseph Califano,

> This export policy will give due respect to the health decisions of foreign countries, while fulfilling America's obligation not to dump dangerous drugs overseas. It will also encourage drug manufacturing in the United States, and thereby increase jobs and ease our balance of payments problems. (9)

Depo-Provera has had an important role in the development of key provisions of this bill. An informal survey of several legislative assistants and FDA officials revealed that DP was the only drug known to fall within the category—"Required by other countries but not approved by the FDA."

Upjohn Company's animal studies were designed to meet the FDA requirement that long-term animal safety tests be carried out and assessed before a drug is marketed. Because the test results are "proprietary," they are exempt from public disclosure under the Freedom of Information Act. Former FDA Commissioner Donald Kennedy said that this type of information is "protected trade secret data which are releasable only subject to criminal penalty." (10) According to Upjohn Company president William N. Hubbard Jr., the drug firm has,

> ...made all these data available long since to the World Health Organization and to a multitude of countries all over the world. Any authority that has made an inquiry we have released data to. Dr. Kennedy is precisely correct insofar as the law is concerned; as a matter of the real world, these data are no secret and are very widely held. (11)

Dr. Hubbard was asked if he is "prepared to support provisions in the Drug Reform Act that would provide for the release of such data as a matter of law?" Dr. Hubbard replied, "No." He explained, "It's question of whether one does it himself out of a sense of responsibility or has it done to him for reasons which may or may not be useful."(12)

One promoter of Depo-Provera, however, disagreed. Dr. Fred Sai, former Secretary of Health in Ghana, and former Deputy Director of the International Planned Parenthood Federation responded as follows:

> I think we have a small problem here. I have no guarantee that an applicant for approval of a new drug is going to release to me in my country the full documentation, including adverse findings. However, if the Food and Drug Administration is permitted to release the documentation, I would be happier. It would be full documentation including adverse findings.(13)

During the last 12 years, Upjohn withheld many incriminating findings from animal safety tests. As a result, the company was able to manipulate the flow of information regarding the alleged benefits and risks of the drug. The restricted access to safety test data thereby increased the desirability of Depo-Provera in the minds of many physicians and family planning professionals. The uncritical support of population control agencies, concerned more with controlling fertility than safety, strengthened the company's promotional campaign.

The Animal Safety Studies

In 1968, Upjohn initiated seven-year beagle and ten-year monkey studies to assess the safety of Depo-Provera as an injectable contraceptive. Thirty-six dogs were divided into three treatment categories. Sixteen were injected with 25 times the equivalent of a human dose. (14) The dosage used was roughly equivalent to 150mg Depo-Provera given every 90 days to a 60kg woman. Four dogs received 1X the equivalent human dose and 16 controls were injected with the same volume of saline. Similarly, two groups of 16 monkeys were placed in 50X and 10X categories, four monkeys in the 1X and 16 as controls. (15) A second dog study was undertaken in 1972 with a significantly modified protocol. (16)

In the last 12 years, millions of women and breast-fed children have already been exposed to Depo-Provera. If the present trend continues, tens of millions more will be exposed in the next decade. Public testimony before the Select Committee on Population (a joint committee of the House and Senate), and a review of the family planning literature, suggest that the medical community is poorly informed about the harmful effects of the drug.

As late as 1978, leading experts on Depo-Provera were in agreement that

> by far the most controversial issue involves the question of the relevance to humans of the development in beagle dogs of breast tumors secondary to DMPA (Depo-Provera) administration. There is much in the literature concerning susceptibility of this species of animal to such tumors and there is significant evidence to suggest that beagle dog toxicology studies are not predictive of mammary tumors in women. (17)

Until December 1978, doctors using DP as a contraceptive were led to believe that the only serious adverse effects of the drug had been the malignant breast tumors in beagles. The following statement in the medical journal *Fertility and Contraception* expresses the opinion of numerous physicians who are using the drug despite its non-approved status:

> Despite worldwide publicity, the only valid scientific objections to the substance (Depo-Provera) are those pertaining to carcinoma of the breasts in beagles. The particular type of neoplasm produced is almost unknown in humans and it is time an unbiased group examines the evidence objectively. (18)

The following results of the animal studies are not generally known:

Monkeys

• "Curvature of the spine with or without leg muscle atrophy was noted in 1 monkey in the 1X group, 2 monkeys in the 10X group, and 6 monkeys in the 50X group." (19) This condition was not reported in any of the controls. Depo-Provera inhibits the secretion of growth hormones. (20) It has been used to retard bone growth in the treatment of acromegaly. (21)

• "Statistical decreases in liver and ovary weights at the 10X and 50X human dosage levels, and adrenal weights at 50X human dosage level, and uterus weights at the 10X human dosage levels were considered compound related." (22)

• "There was a drug related, but not a dose related increase in mammary nodular hyperplasia in monkeys treated with Depo-Provera." (23)

• "Other drug and dose related microscopic signs of chronic exposure to Depo-Provera were found in the urogenital tract, liver and endocrine organs." (24)

• At two years, high dose monkeys had three times the mortality of controls (3:1). The dead DP treated animals were replaced with live ones in the 85th week of the study. Four controls were sacrificed for no apparent reason. (25)

Dogs

• Malignant tumors and other breast pathologies occurred in conjunction with endometrial disease. (26) An independent study, on low doses of DP, reported that some of the mammary tumors in beagles were similar to those found in women. (27)

• The cause of deaths in three of the dogs was also ascribed to "drug induced diabetes," since glucosuria was found in all three dogs. Hyperglycemia was found in two of the dogs. (28) Upjohn admits that in women DP "treatment in contraceptive doses appears to produce diabetic stress..."(29)

• The adrenals of many dogs in both treatment groups were atrophied. (30)

• Most organs were autolized (destroyed) before they were examined by pathologists. (31) Independent studies found tumors of the liver, gallstones and gallbladder cysts in dogs treated with low doses of Depo-Provera. (32)

• Within three and one-half years all dogs in the high dose group and half in the low, died from the action of the drug on the uterus. The two survivors in the low dose group were saved by hysterectomies. All the controls survived to the end of the seven year study, except four sacrificed in the second year, and one that died from bite wounds. (33)

Endometrial Carcinoma

It has been suggested that the most aggravated symptom in the dogs, pyometra or inflammation of the endometrium, does not occur in monkeys or humans. Pyometra is seen in "malignant states of the uterus" in women. (34) It is also one of the best recognized forms of chronic endometritis. A growing body of experimental and clinical evidence suggests that long-term administration of Depo-Provera may result in chronic and malignant forms of uterine disease in women as well as animals.

Two decades ago it was established that progesterone is a "promoter of chemical carcinogens." (35) In 1971, investigators reported that immature and adult monkeys treated with Depo-Provera exhibited increased susceptibiltiy to virally induced cancers. Animal experiments documented how "the administration of progesterone or its synthetic analogues resulted in increased susceptibility to tumors caused by Rous sarcoma virus as well as by many chemical carginogens."(36)

Electron microscopic studies have elucidated Depo-Provera's "profound influence on human endometrial glandular cells." (37) Perhaps the most profound changes occur in the nucleus. After a single injection, suspected viral particles or viral influences appear in the nucleolus. (38) The presence of fibrillar nuclear inclusions "has not been reported in normal endometrial glands or in endometrial glands under the influence of oral contraceptives or intrauterine devices." (39) Their presence "in endometrial tissue under the influence of medroxyprogesterone suggests the possibility of an alteration of cellular function at the nuclear level." (40) Cancer would develop if, as a result of long-term exposure, a few of these cells produced permanently altered progeny. (41)

At the end of the ten year study all the surviving monkeys were sacrificed. Two monkeys in the high dose category were found to have endometrial carcinomas which reportedly spread throughout the reproductive tract. In one, the cancer was also found in the lungs. (42) In addition, one pathologist, Dr. John Morris of Yale University, described "an adenofibroma possibly malignant" in another monkey. (43) Dr. Ralph Heywood of the Huntington Research Centre in England, however, diagnosed this finding as a benign polypoid mass. (44) All surviving monkeys in the 10X and 50X groups reportedly suffered from chronic endometritis. (45)

Experts all over the world expressed surprise at these unexpected findings. No doubt they were unaware that Upjohn withheld evidence of precancerous lesions discovered early in the study. Monkey #8112 in the 50X group, for example, died in 1969 after 12 months of treatment. Published pathological reports show that "no significant lesions were found in the monkey."(46) The appendix of an unpublished document, however, indicates that "sessile polypoid endometrial thickening" was found. (47) Furthermore, independent pathologists found "numerous intramuscular viral inclusion bodies in the bone marrow and adrenal

glands of this monkey." (48)

The appearance of endometrial polyps is by no means insignificant. In 1968, Novak reported that previously benign endometrial polyps can degenerate into adenocarcinomas. Novak and Peterson pointed out that polyps are associated with malignancy in over 15 percent of most post menopausal cases, the majority being adenocarcinomas of the adjacent endometrium. (49) The simultaneous appearance of viral inclusion bodies in the monkey with pre-cancerous lesions and in women after a single injection of DP is cause for concern. It suggests that DP, an immunosuppressive drug, can increase susceptibility to virus and possibly viral carcinogens.

Upjohn failed to release early evidence of serious uterine disease in monkey #9060. Dr. V. Berliner from the FDA Bureau of Drugs twice emphasizes this point in a memo dated May 11, 1979:

> Monkey 9060 that at necropsy was found to have the uterine carcinoma was reported to have a palpable uterine enlargement for the last 2½ years of the study. This upsets the claim by the sponsor that endometrial tumors were not found before the final sacrifice. We have *not* as yet received reports for the histology of all monkeys that died during the test.
>
> The presence of a palpable uterine enlargement in monkey 9060 found already in the 7th year that later was found to be a carcinoma militates against the claim that these cancers appeared only in the 10th year of treatment. (50)

Before the surviving monkeys were sacrificed, Dr. Hubbard stated the *fact* that insofar as the metabolism of progesterone and Depo-Provera is concerned "rodents and primates more nearly resemble humans than do beagle dogs." (51) The company president *argued*, however, that "in the last analysis no accumulation of animal experience can substitute for direct observations in humans." (52) In his *opinion* "The only clinical evidence yet to be accumulated is that which can come only with a large number of patients receiving the drug for general use over very extended periods of time." (53) More recently, D. I. Weisblat, vice president for research, *argued* that "the appearance of these carcinomas in the high dose group is not judged to be relevant to the human experience....We continue to *believe* that Depo-Provera, when used at the recommended dosage for contraception, is safe and effective." (54)

While there is little or no room for disagreement about the above-mentioned *facts*, one must recognize that millions of dollars in risk-capital and unrealized profits are tied to these *opinions*. The monkey studies were an embarrassment to the company. Experiments on millions of women over extended periods of time may tell us nothing about the incidence of disease, but will no doubt increase the company's cash flow.

There are obvious similarities in the way cancers develop in monkeys and humans. In both species "an extremely long latent period" usually occurs between the introduction of a carcinogen and the first appearance of tumors. (55) The length of the latent period corresponds with the life-span of the species, and is therefore shorter in monkeys than in humans. (56)

The incidence of spontaneous malignant tumors is very rare in monkeys. Only 70 cases were reported in the many thousands of monkeys used in experiments between 1947 and 1973. No uterine cancers were reported in rhesus monkeys during this period. (57) The cancers in the Upjohn experiments occurred in monkeys first treated with Depo-Provera ten years earlier. In human terms, they occurred around the age of menopause.

The claim that the two cancers resulted from the high treatment schedule is unfounded. It is just as likely that the cancers reflected individual differences between the monkeys, including differences in age. Only nine out of 16 (50X) monkeys survived to the end of the ten-year study. (The figure excludes animals arbitrarily added to the study in the 85th week.) Likewise, only seven out of 16 (10X) and two out of four (1X) animals survived. Abnormalities and precancerous lesions were diagnosed in the endometria of all surviving animals in the 10X and 50X groups. (58) This suggests that had any of these monkeys or the non-survivors lived longer, they would have had a higher risk of developing cancer than the controls.

In a recent collaborative effort, Mc Daniel, the World Health Organization (WHO), and Upjohn found no cancerous lesions in 22 Thai women who were continuously on DP for eight to 13 years. (59) In women, diseases of the endometrium do not usually occur until after menopause. (60) This was obvious in the case of the proven association between endometrial carcinoma and sequential contraceptives. (61) In both humans and monkeys evidence suggests that tumors would not appear for 20 years or more in women who initiated DP treatment at the age of 20. Thirty years would be required for those first injected at 16. Therefore, it would be ludicrous to suggest that the Mc Daniel-WHO-Upjohn study shows that DP is not carcinogenic.

It is unlikely that a systematic epidemiological surveillance of the relationship between Depo-Provera and endometrial cancer will ever be carried out. The diagnosis of chronic endometritis and endometrial carcinoma is often missed in women and requires special procedures. These would be time consuming and costly for the already hard pressed health services in the third world. Even in Europe and North America systematic follow-up of women treated with Depo-Provera for more than 20 years would be nearly impossible. In many African, Asian and Latin American countries, where per capita expenditure on health services is less than a few dollars annually, an epidemic of endometrial cancer would never be discovered.

Mortality, Diabetes and Immunity

The animal studies indicate that there are more immediate difficulties for women on Depo-Provera than the prospect of developing cancer in 20 or 30 years. In animals, life expectancy was shortened and resistance to infection lowered. Diabetes and degenerative conditions of the pancreas, liver, adrenals, the uterus and ovaries were some of the consequences of the treatment with Depo-Provera.

The disastrous effect of Depo-Provera on the uterus in the first beagle study masked a number of life-threatening and degenerative conditions. In the second dog study, animals were hysterectomized prior to treatment. Nonetheless, mortality remained high. "There was a 30 percent mortality of high dose DP dogs by the end of the fourth year compared to 100 percent of the dose in the first study." (62) Depo-Provera treated dogs showed evidence of "glomerulonephrosis, vascular degeneration and lower host resistance [to infection]. These changes may be evidence of altered carbohydrate metabolism which has resulted because of increased secretion of growth hormones."(63)

Although the anti-insulin effects of Depo-Provera are not mediated by increased growth hormones, it is clear that the drug interferes with carbohydrate metabolism in women. Spellacy *et al* found abnormal glucose tolerance curves on 15 percent of the women treated with the contraceptive. (64) Upjohn officials admit that "Depo-Provera treatment in contraceptive doses appears to produce diabetic stress which seems partly related to the weight gain it produces. The effect seems most pronounced in the previously untreated overt diabetic." (65) Surely then, this presents a serious health hazard for women living in countries where facilities for the treatment of diabetes are unavailable.

The appearance of viral particles in human endometrial tissue at contraceptive doses follows numerous animal studies on the immunosuppressive effects of the drug. Depo-Provera inhibits the production and alters the distribution of antibodies. In dogs and rabbits, skin-allograph-rejection time was retarded and "circulation lymphocytes were decreased and lymphopoiesis in the lymph nodes and spleen was suppressed." (66) In the Upjohn study, treated dogs suffered "lowered host resistance to infection." (67) This may explain why, early in the study, mortality in the high dose monkeys was greater than in controls.

The immunosuppressive effect, while making women more vulnerable to infection, seems also to promote malignancy. This interpretation received unintended support from William N. Hubbard, Jr., president of Upjohn Company, in testimony before the Select Committee on Population. Dr. Hubbard quoted verbatim from an article entitled *The Beagle Dog and Contraceptive Steroids*:

> ...for certain progestogens such as medroxyprogesterone acetate (Depo-Provera) and negestrol, but not norethisterone or norgestrel, have glucocorticoid activity, and so may suppress immunological mechanisms which naturally restrain the development of microscopic neoplasms in the breasts of beagles. (68)

The FDA failed to appreciate the possible significance of numerous pathological findings in the Depo-Provera treated animals. For example, subsequent to the death of all the 16 dogs, the agency agreed to Upjohn's request for a second dog study. This protocol called for the addition of new groups of dogs treated with natural progesterone, and for hysterectomizing all the dogs before the start of the study.

Reportedly, the hysterectomies were carried out to enable the animals to live long enough to study the drug's effect on the mammary glands.* Two dogs in the high dose group were found to have mammary gland adenocarcinomas, and a drug induced proliferation of breast nodules was common among treated dogs. (69)

In 1971, Depo-Provera and another progestational contraceptive, chlormadinone acetate, were withdrawn from clinical use because they produced tumors in dogs. The FDA, however, had second thoughts regarding DP, and planned to reintroduce the drug in 1973, albeit for a "special population." The reasons behind this apparent inconsistency were explained to an international symposium by an agency pharmacologist responsible for evaluating the drugs:

> A different stand was taken by the agency (from chlormadinone acetate) with the injectable preparation medroxyprogesterone acetate. Even though this compound too is implicated by its action in beagles as being potentially carcinogenic, the uniqueness of this preparation and its high efficiency as a contraceptive provides it with a risk-benefit ratio which permits its use in the US all but for a very special population. Although the criteria for patient selection will make its use very limited in the US, these criteria may have more widespread applicability in other countries.† (70)

The addition of progesterone treated dogs only replicated previous findings. These were summarized by Hill and Dumas in 1973: "Generally speaking, those compounds which are structurally related to progesterone enhanced the development of mammary gland neoplasia and diabetes in beagle dogs." (71) This aspect of the study, however, gained undeserved notoriety as a demonstration of the unsuitability of the "Beagle model" in Depo-Provera testing.

Upjohn sources classified "the beagle studies as a 'waste of time' because the dogs are too susceptible to progesterone to be useful test subjects." (72) Dr.

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* A request by the author under the Freedom of Information Act failed to produce any documentation of the FDA's basis for this decision.

† The FDA withheld approval following unconfirmed findings suggesting that DP increased the risk of cervical cancer in women.

Hubbard told the Congressional Select Committee on Population "that mammary carcinoma developed in dogs given high doses of MPA (medroxyprogesterone acetate) or progesterone. (73) The Upjohn president missed mentioning that it took less Depo-Provera to produce the tumors than it did progesterone. Progesterone treated dogs receiving *1140mg every week* were compared with DP treated dogs injected with only *690mg every 90 days*. (74) According to standard biological assays Depo-Provera "is the most potent synthetic progestin available." (75) The data indicate that it takes far less Depo-Provera to produce cancerous lesions than any progestin used in contraception.

Two independent studies in New York State suggest that had the details of the first dog study been available to the scientific community, the second protocol could have been designed to yield more useful information. These investigations indicate that the dog findings are not esoteric and that even the administration of dosages far below FDA requirements produced mammary, uterine and liver tumors, as well as gallstones.

The study by Fowler *et al* found that DP administered at "all levels that suppressed ovulation resulted in mammary gland hyperplasia and neoplasia as well as cystic endometrial hyperplasia and mucometra." (76) The researchers noted that "some of the tumors found were similar to those found in women." (77) Fowler also found evidence of chromosomal abnormalities in the nuclei of endometrial cells taken from beagle bitches: "The nuclei had unusual, dispersed heterochromatin which differed from involuted control glands." (78)

Hansel *et al* reported that "the proliferative lesions in both mammary gland and liver induced by these relative low doses of MPA are clearly a matter of concern." (79) The adenomas found in the livers of dogs are of particular importance since in some respects they resemble liver damage now being reported with increasing frequency in young women on long-term oral contraceptives. (80) Likewise, the findings on gallstones and gallbladder cysts were "remarkable in view of increased incidence of gallstones reported in patients on oral contraceptives." (81)

Action of the Drug on Children

Depo-Provera, like other progestogens, is associated with an increased risk of congenital malformation in children exposed to the drug *in utero*. It differs from non-injectable contraceptives in that it continues to act on the fetus for several months or longer, when taken during pregnancy. In a study in Thailand by McDaniel, using the high dose six months' regimen of DP, two percent of the treated women were pregnant at the time of injection and another two percent became pregnant while on the drug. (82) A series of studies suggests that there are reasonable scientific grounds for suspecting "that exogenous female hormones, medroxyprogesterone included, may be harmful to the fetus." (83) Depo-Provera seems to increase the risk of congenital heart defects and other abnormalities in children.(84) The appearance of enlarged clitorises in newborn females (85) suggests that DP given in early pregnancy affects development through parturition and into the neo-natal period.

Breast-feeding mothers from the poorer classes are the target population for the use of Depo-Provera in most countries. Depo-Provera is promoted as suitable for lactating women and post-partum mothers. (86) There is evidence indicating that DP, unlike oral contraceptives, does not inhibit lactation. (87) Studies in Egypt, Sri Lanka and Bangladesh indicate that the supply of milk was reduced. In Bangladesh, for example, Parveen *et al* reported:

> 1020 accepters were breast-feeding at the time of their first injection. 147 of them reported a decrease in lactation, 37 an increase; the rest reported no change. In some mothers, lactation may have been drawing to a natural close, but in all cases the ages of the youngest child was less than 18 months, and 11 babies were under 6 months. In 20 cases, milk production declined sharply soon after the first dose of D.M.P.A. (D.P.) One healthy mother had her milk production completely cease within 20 days of injection, when her child was only 40 days old, and another with a 5-month-old child reported a substantial decrease during the first week after D.M.P.A. (88)

Depo-Provera is found in substantially higher concentrations in breast milk than are steroids from oral contraceptives. In 1972, *The Journal of The American Medical Association* warned that "it is neither wise nor advisable to prescribe oral contraceptives to nursing mothers. This is because the steroids' components...are excreted into the milk." (89) Following injection, Depo-Provera is released into the blood and transferred to the breast milk for 90 days or longer. The ratio of concentration between the maternal plasma and the breast milk is approximately 1:1; there is as much Depo-Provera per volume of milk as there is circulating in the mother's blood. (90) Every suck by the breast-fed child contains an orally active dose of Depo-Provera. The nursing child consumes between 600-800ml of milk containing a steady dose of 1-2 micrograms of the synthetic hormone daily.

Breast milk provides effective protection against diarrhea and cholera. Jelliffe and Jelliffe attributed the relatively low incidence of diarrhea infections among breast-fed babies in slums and poor rural areas to the passive immunity transferred in the milk. They note that such infants survive and grow despite the inevitable "ingestion of environmental microbacteria from dust, dirty hands and other sources." (91)

The administration of Depo-Provera to lactating mothers can harm infants by interfering with immunoglobins in the breast milk. The high concentration and glucocorticoid action of the drug in the milk may interfere with the production of

antibodies protecting the infant from diarrhea and cholera. (92) B-lymphocytes isolated from the milk of poor Pakistani women were found to produce specific antibodies against *E. coli* and *V. cholera*. Glucocorticoids interfere with the development and distribution of lymphocytes. (93) Oral contraceptives containing lower levels of steroids have been found to reduce a number of specific antibodies in the breast milk. (94)

A maternal and child health specialist at the World Health Organization (WHO) suggested that the risks of Depo-Provera exposure in breast-feeding children are unknown:

> As regards the possible long term consequences for the nursing child, no answer will, of course, be available before children born in the International Year of the Child are approaching parenthood themselves. (95)

The newborn infant's capacity to metabolize and eliminate drugs is poorly developed. Depo-Provera is stored in the fat tissue. Its toxicity is enhanced by its high concentration in the breast milk, long-term action, and its re-administration every 90 days. (96) As in adults, the hypothalamus, pituitary and reproductive organs are the most likely organs to be adversely affected by DP. Studies in nursing mice have shown that Depo-Provera significantly delays the reproductive development of females. (97)

Infantile production of sex steroids is necessary for the normal organization and structural development of the sexual organs. Previously it was believed that gonads were inactive from the middle of pregnancy until puberty. It is now known that the pituitary stimulates the metabolism of hormones by the ovaries and testes during the first two years after birth. (98) In females, substantial ovarian activity and growth occur during infancy. Estrogenic changes of the vagina and endometrium result from estradol production by the ovaries. The ovaries in turn are stimulated by luteinizing hormone (LH) and follicle stimulating hormone. (FSH). LH stimulation appears particularly important because normal sexual development "requires a certain sustained LH stimulation to activate the aromatization of ovarian steroids." (99) Normal development of the testes also seems to depend on the stimulation by LH during infancy.

In women, Depo-Provera prevents the surge of LH that normally precedes ovulation. This suppression of LH production is described as its primary contraceptive effect. DP acts on the hypothalamus and higher centers in the brain. It "may produce a 'shock' to the hypothalamus within 24 hours of administration, with the resultant effect for three to four months." (100) A child whose lactating mother is on DP could receive four such shocks a year.

The ovaries and testes go through a period of "quiescence" from the age of two until the onset of puberty. Any abnormalities resulting from the incidental exposure of children to Depo-Provera may not become apparent for 15-20 years or more. The experience with DES demonstrates that interference by synthetic sex hormones at critical phases of development produces cancer and structural abnormalities of the sex organs.

Investigators believe that Depo-Provera shocks the growth centers in the hypothalamus as well. Lawrence and Kirsteins comment:

> The role of hypothalamic growth hormone releasing factor in the regulation of growth hormone production and release in animals is established and in all likelihood pertains for man as well. Thus, it is possible that MPA (DP) directly affects this hypothalamic center or indirectly affects it via suppression of gonadotrophin releasing substance and in some fashion extends the hypothalamic centers responsible for the secretion of growth hormone releasing substance as well. (101)

This may partially explain the alarming findings of *abnormal spinal curvature in monkeys at all dose levels*. DP's effect on growth can be particularly disastrous for the breast-feeding child. To continue carelessly administering it to millions of lactating mothers would be callous and cruel.

The third world market for Depo-Provera would be dramatically reduced if it were no longer promoted as safe for breast-feeding women. Upjohn officials admit that "it is not known whether children who receive some of the compound in breast milk will develop cancer or be predisposed to it or some other problem later in life." (102) Putting their lack of knowledge aside, however, they state that "Depo-Provera does not interfere with lactation; therefore it can continue until the child is able to survive on a normal diet." (103)

Many population control experts also have turned their ignorance into exaggerated claims that Depo-Provera is safe during lactation. The officials and experts, unlike millions of vulnerable children, are protected by the fact that physiological effects in infancy have not been studied. Furthermore, genital malformations and carcinomas in Depo-Provera babies could not be detected for decades.

Conclusions

The proposed Drug Regulation Reform Act contains two sections which are germane to the Depo-Provera controversy. The 1978 version of the bill, introduced by Senators Kennedy, Javits and others, allows public access to safety test data while experiments are in progress. As a result of objections raised by pharmaceutical industry lobbyists, the senators proposed a weaker version in 1979. The current Kennedy-Javits bill allows public access to summaries of tests prepared by the drug companies themselves. The experience with Depo-Provera suggests editing by drug companies is often misleading. On the other hand, public scrutiny should enable a widely constituted forum to evaluate the safety of drugs before they are marketed.

At present, drugs must be approved for use in the United States before they are legally exported to

other countries. The export provision of the proposed Drug Reform Act allows manufacturers to respond to requests from foreign governments for unapproved drugs. Under the new law, the FDA has to evaluate these drugs using less rigorous criteria than those applying at home. Drugs found acceptable under this procedure, however, must be labeled "not approved for use in the USA."

There is considerable scope for the United States to pressure aid recipient nations to utilize long-acting contraceptives as a precondition for food and development assistance. The fact that the FDA almost approved DP in 1973, because of "the uniqueness of the preparation and efficiency as a contraceptive," shows that the criteria for approval may be based on Malthusian ideology, rather than an informed sense of how the drug could be used and abused elsewhere. Doctors from Bangladesh writing in the medical journal *Lancet* expressed their fear of widespread abuse of Depo-Provera. Parveen *et al* warned: "If governments, perhaps under pressure from international agencies adopt a 'speed and number' approach to family planning, the result is likely to be havoc." (104)

This year three "scientific judges" constituting a FDA Board of Inquiry must decide whether Depo-Provera should be marketed as a contraceptive in the United States. If the board votes for approval, the United States Agency for International Development (AID) will attempt to export the drug on a vast scale. Past experience has shown that as many as 90 percent of the recruits to AID-sponsored contraceptive inundation campaigns are lactating mothers. (105)

Apparently the health and safety of women and children have a lower priority in AID and many other international organizations than does population control. Even after the cancers were discovered in monkeys, AID, WHO, and International Planned Parenthood continued to pressure the FDA to approve the drug. The WHO toxicology review panel, for instance, "expressed reservations about the relevance of the findings of endometrial cancer in monkeys to women using DMPA (Depo-Provera)." (106) The panel also reaffirmed its conclusion "that there were no toxicological reasons for discontinuing the use of Depo-Provera in current and planned WHO studies or family planning programmes." (107) The official position of these agencies on Depo-Provera is not necessarily scientific nor well informed. It clearly reflects the political orientation, the male dominance and, perhaps, the undue influence of the pharmaceutical industry at the policymaking levels.

The continued use of Depo-Provera for birth-control is unjustified and unethical. A healthy woman on Depo-Provera prematurely ages. She takes on the characteristic profile of a post-menopausal woman who is at high risk of developing endometrial carcinoma. Her uterus atrophies, she stops ovulating and is sterile. Most women stop menstruating, but many experience excessive bleeding, some requiring D&Cs and hospitalization. (108) Intermittent bleeding from the vagina commonly occurs after the first few injections. A significant proportion develops abnormal glucose tolerance curves or becomes diabetic.

The animal studies strongly suggest that the incidence of endometrial cancer will be higher with Depo-Provera than with oral contraceptives. Does the fact the two surviving monkeys developed cancer mean that two women in 100, or 1,000, or 10,000 or 100,000 will develop the disease? Obviously the answer will depend on the age of women, length of treatment, dietary, environmental and possibly genetic factors. The cancers may not develop for 20 to 30 years after the initial exposure. It is unlikely that the relationship between Depo-Provera and cancer will ever be studied in the countries where it is widely used. The estimation of risks decades later will provide little comfort to women dying of uterine disease.

For many women the chance of surviving until menopause will be decreased by the use of Depo-Provera. The presence of viral particles in the endometrium is *proof* of the immunosuppressive effect in women at contraceptive doses. The alteration of immune response increases the vulnerability of women to serious illness particularly in countries where mortality from infectious diseases remains high.

In 40 Egyptian women on Depo-Provera liver function tests showed "a significant decrease in the prothrombin activity" and a significant impairment of hepatic excretion. (109) The exact mechanism whereby liver function is weakened by Depo-Provera is not known. The livers of DP treated monkeys were atrophied, however, and liver disfunction as well as liver cell adenomas were reported in dogs at relatively low doses of Depo-Provera. (110)

Depo-Provera inhibits bone growth. It produced skeletal abnormalities in monkeys in *all* treatment groups. The drug should be withdrawn from family planning programs on these grounds alone. Furthermore, treatment with Depo-Provera resulted in the degeneration of the adrenals and produced lesions in the urogenital tract, gallbladder and the endocrine glands.

Finally, all arguments about the suitability of Depo-Provera during lactation collapse when child growth and development are taken into consideration. Daily microgram doses of the contraceptive are carried in the breast milk for three months or longer after injection. Does the harm caused by the drug pass from the mother to her nursing infant? Does Depo-Provera damage the hypothalamus and higher centers in the brain? Does it retard bone growth or produce skeletal abnormalities? Does it lower resistance to infection and interfere with the normal development of the sexual organs during infancy, causing a threat of cancer later in life? The promoters of the drug have not asked these questions, yet they claim Depo-Provera is safe. Do you believe them? Would you give this contraceptive to your child, to any child, or to tens of millions of women and children? ■

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APPENDIX 8

Commentary on Depo-Provera, Submitted by the Upjohn Co.

INTRODUCTION

For some time now, a number of "consumerist" groups (e.g., National Women's Health Network, Institute for Food and Development Policy) have been challenging the use of Depo-Provera as a contraceptive. While the concern of such groups is primarily social and political, they raise medical and scientific issues in support of their arguments. A recent example is "Depo-Provera: A Critical Analysis," written by Mr. Stephen Minkin. The National Women's Health Network distributed this paper, printed with the letterhead of the Institute for Food and Development Policy. The paper has not been published in a reputable medical or scientific journal and therefore has not received scientific peer review.

The Upjohn Company has been aware of drafts of Mr. Minkin's paper for some time--and aware of the misleading interpretations of data it may suggest to the uninformed, uncritical reader. Communications such as this letter and paper, which contain many inaccuracies and unsubstantiated allegations, use faulty scientific arguments in an attempt to legitimize predetermined social and political points of view. Mr. Minkin's statements that his paper has been written with use of information from "trade secret" documents is false, since these materials have been widely disseminated and are available to the medical and scientific community, as well as to the public at large.

The letter and paper raise issues which have been considered many times before, both by the U.S. Food and Drug Administration (FDA), the U.S. Congress, the World Health Organization (WHO) and by health ministries around the world. All the selected data referred to have been available for years to the FDA, other health agencies and, in most cases, to the public. Further, these selected data represent only a small nonrepresentative part of the many volumes of data which have been submitted to regulatory agencies. The data have been previously reviewed by independent experts whose qualifications as competent scientists are well established.

Nevertheless, we will (1) review the full range of evidence of Depo-Provera's safety and efficacy as a long-acting injectable contraceptive; and (2) put into perspective the biased allegations made by Mr. Minkin.

CLINICAL PERSPECTIVE

Medroxyprogesterone acetate (MPA), the active ingredient affording the contraceptive effectiveness to Depo-Provera, is prescribed for a variety of therapeutic indications. MPA is a synthetic progestogen designed to mimic in many respects the naturally occurring progesterone produced in abundance by the body during the luteal phase of the menstrual cycle and in pregnancy. The effects of MPA on the body reported to occur during clinical use or during toxicity studies include those encountered at physiologic as well as pharmacologic doses of progesterone. Thus, a detailed knowledge of the endocrinology of reproduction in both humans and animals is essential for the proper interpretation of events observed when MPA is administered.

First studied clinically as a contraceptive as early as 1963, Depo-Provera has now been administered as a contraceptive to more than 10 million women around the world. With its high degree of efficacy and low reported incidence of side effects, Depo-Provera is probably the safest hormonal contraceptive drug available. The rate of contraceptive failures among Depo-Provera users is extremely low. The women who receive Depo-Provera for contraception report an incidence of side effects comparable in numbers to reports for oral contraceptives (OC's). However, Depo-Provera's side effects are less serious; unlike OC's, there has never been a death reported which was ascribed to the contraceptive use of Depo-Provera.

Unique properties associated with Depo-Provera allow a single injection to provide contraceptive efficacy for 3 months. This method of contraception is particularly suitable for women who for various reasons do not accept the responsibility demanded by dosage schedules of contraceptive methods such as the pill. Depo-Provera is an optional method for women who cannot tolerate the estrogenic side effects associated with OC's or the pain and bleeding associated with

intrauterine devices (IUD's), or who wish to avoid demonstrated life threatening complications. Depo-Provera does not suppress lactation, which is important in those developing countries where infant survival is dependent on breast-feeding. It also has little, if any, effect on suppression of vitamin levels or mineral metabolism, important in many developing countries where nutrition is marginal. Excessive menstrual flow is common with IUD's, resulting in iron deficiency anemia. Iron deficiency anemia has not been a problem with Depo-Provera, even in cases where menstrual irregularity occurs. The amenorrhea associated with Depo-Provera prevents this anemia. The method is easily administered by paramedical personnel, in contrast to the IUD which requires a physician or highly skilled paramedical personnel for insertion. This is important in locales where such personnel are scarce.

Thorough study by competent investigators has shown the drug to be at least as safe and efficacious as the OC's. Most serious adverse reactions from OC's have generally been attributed to the estrogen component. Depo-Provera contains no estrogen, nor has it been shown to be metabolized to estrogen as are other currently available progestogens. Adverse effects such as suppression of adrenal and pituitary function have not been encountered clinically. There has been no demonstrable increase in breast, cervical, or endometrial pathology; and although there has been a slight delay in return to fertility reported after discontinuation of therapy, fertility rates are the same as those for OC's, IUD's, and diaphragms 18 months after discontinuation of treatment.

No increase in the frequency of anomalies occurs among infants born after discontinuation of Depo-Provera contraception, nor has there been an increase in the rate of spontaneous abortion following Depo-Provera use. No anomalies have been reported among infants born as a result of conceptions occurring during the use of Depo-Provera.

A potential disadvantage of Depo-Provera is the inability to withdraw the drug promptly in the event of a serious adverse reaction. In actual clinical experience, however, this has not presented a problem. Other disadvantages include disturbed menstrual patterns, possible slight delay in return to fertility upon discontinuation, and the impracticality of self-administration. The latter also may be considered an advantage, because required regular visits to medical personnel can result in better monitoring of a woman's overall health status.

Depo-Provera is presently approved for use as a contraceptive in over 80 countries, including such scientifically advanced countries as West Germany, France, Belgium, Denmark, Holland, New Zealand, and Switzerland. In the U.S., where a hearing on the registration of Depo-Provera's use as a contraceptive is still pending, it has been estimated that 5-9% of the women of childbearing age are potential users of Depo-Provera. It is currently approved for treatment of endometrial and renal carcinoma in the U.S.

Depo-Provera is recommended and utilized by a number of national and international organizations particularly concerned with the availability of safe and effective contraceptives in developing countries (e.g., WHO, IPPF, and FPIA). These organizations are sensitive to the special needs of women in developing countries. Their programs and selection of contraceptive methods not only conform to their own strict ethical, moral and medical guidelines, but are also subject to thorough review by advisory boards comprised of internationally recognized experts in the fields of family planning, medicine, and ethics. In addition, local review boards comprised of equally knowledgeable and concerned physicians, scientists, and lay personnel review programs dealing with the use of contraceptives by their own citizens.

Mr. S. Minkin's paper ("Depo-Provera, a Critical Analysis," distributed by the Institute for Food and Development Policy and the National Women's Health Network) attempts to paint a bleak picture of Depo-Provera's utility as a contraceptive, based largely on alleged toxicities Mr. Minkin claims to have discovered in Depo-Provera animal data. The effects he points to are typically overstated. Unwarranted conclusions are drawn from a series of unrelated observations. The pattern that emerges from his paper is one of attempting to take advantage of readers' ignorance--(1) he assumes ignorance on the part of scientific readers about the details of published data and interpretations of other scientists who Mr. Minkin quotes improperly; and (2) he assumes ignorance on the part of nonscientific readers about the proper interpretation of technical vocabulary, even the most innocuous of which he inaccurately links to easily understood and highly feared language such as "cancer" and "precancerous."

None of the alleged toxicities have been observed in clinical use of Depo-Provera for contraception. It is not appropriate to extrapolate, as Mr. Minkin does, from animal toxicity data to the contraceptive use of Depo-Provera in humans. We do know a great deal about the effects of Depo-Provera in women, from over 15 years of safe, effective and responsible experience throughout the world.

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CONCERNS ABOUT THE AVAILABILITY OF INFORMATION AND DATA

Mr. Minkin states that "During the last 12 years, Upjohn withheld many incriminating findings from animal safety tests" (Minkin, p. 2, col. 1). This is not true. The record will show that Upjohn has always submitted interim reports on the animal tests to the FDA as they were received from the testing laboratory. In addition, many of these reports were voluntarily made available to WHO and to other interested parties.

As stated by Upjohn's president, Dr. William N. Hubbard, Jr., when testifying before the Select Committee on Population of the U.S. House of Representatives (Select Comm. Hearing Report No. 12, 1978, p. 49):

> "We have made all these data available long since to the World Health Organization and to a multitude of countries all over the world. Any authority that has made inquiry we have released these data to."

As a matter of fact, the animal safety data available at that time were published in the Hearing Report of the abovementioned Committee, and were available to the public, published by the U.S. Government Printing Office.

Mr. Minkin's allegations that Upjohn manipulated the flow of information to enhance the desirability of the drug are totally unfounded. As Dr. Malcolm Potts of the International Fertility Research Program, has written "I do not find the inuendoes of Upjohn withholding information very convincing. I think the rapidity with which they made the monkey information available is a mark of their integrity" (Potts, 1980).

Specific allegations made by Mr. Minkin about suppression of findings by Upjohn for two monkeys in the 50x-dose group of the 10-year

toxicology study are completely unfounded. The Upjohn Company released to the FDA in complete and verbatim form every report that the company received from the contract laboratory conducting the study. The contract laboratory had responsibility for thoroughly investigating any preliminary findings discovered in the examination of animals who died or were sacrificed during the study, as well as for reporting any and all findings to the FDA via The Upjohn Company. Cumulative reports from the contract laboratory reached Upjohn on a yearly basis throughout the study's 10 years. The independent contract laboratory conducted all examinations of monkey tissue, gross and microscopic, that were contained in these reports.

In the case of Monkey #8112, which died approximately 12 months after the start of the study, mention was made in the next yearly report (Year 2) of an endometrial thickening discovered on microscopic examination of animal tissue after death. Subsequent reports summarizing the previous years' findings and adding the new developments noted that Monkey #8112 showed "no significant lesions" upon microscopic examination (e.g., see Select Comm. Hearing Report No. 12, 1978, p. 609). This type of observation was apparently considered by the contract laboratory scientists to be nonserious, of a type that frequently spontaneously occurs in monkeys during cycling, and/or probably had been present prior to the start of the study led them to the action that the statement "no significant lesions" was a fair and accurate interpretation of their data. Certainly, in 1969 when the data were interpreted, there was no reason to be suspicious of such a finding. At that time, there was little concern from any source that steroidal contraceptives might be associated with endometrial pathology in monkeys.

Mr. Minkin also refers to the data generated by an independent reading of microscopic slides by a pathologist at the Armed Forces Institute of Pathology (AFIP) (Weisblat, Attachment 6). This laboratory asked

for the cooperation of Upjohn and others in gathering monkey toxicology data from a wide variety of hormonal contraceptive studies. In 1974, AFIP received blocks of tissue from all monkeys who died or were sacrificed during the first 5 years of Upjohn's study, including tissue blocks from Monkey #8112. The AFIP cut their own slides from the tissue blocks and read them for their own purposes. No report of their findings was made to The Upjohn Company until February of 1979, when Upjohn specifically requested a report from AFIP. Upjohn's request was made as soon as the monkey endometrial carcinoma was first reported.

The AFIP pathologist reported nothing in the endometrium of Monkey #8112; they did, however, note viral particles in the bone marrow and adrenal gland. Their report states that "latent herpes virus infection was the most likely consideration" (Weisblat, Attachment 6, p. 5) in interpreting the particles. The presence of latent herpes virus in many species is not at all uncommon.

One of the two monkeys found to have endometrial carcinoma at the end of the 10-year study was Monkey #9060. The cancer had metastasized to the lungs. Mr. Minkin again suggests that Upjohn suppressed data because of a mention in the final report of a palpable uterine enlargement found 2-1/2 years earlier in Monkey #9060. Upjohn first became aware of the enlargement in reading the final report. As specifically stated in that report: "A possible uterine enlargement was noted for replacement Monkey #9060 at the 50x human dosage level the last 2-1/2 years of the study. This was not noted in prior reports; condition was considered to be related to endometriosis as seen in a number of other older monkeys in this laboratory, and was not considered to be related to compound at that time." (Carlson, 1979, p. 16) The scientist who belatedly reported the enlargement noticed it on one palpation of the monkey's uterus and then found no evidence of it in subsequent examinations. Therefore, the single

unreplicable observation was not entered into the yearly report. Not until Monkey #9060 was found to have endometrial cancer at the end of the study did the single, earlier observation take on importance to the contract laboratory. This may be an unfortunate error in judgment on the laboratory's part, but it cannot be called Upjohn-perpetrated suppression of relevant data.

Mr. Minkin buttresses his allegations of data suppression by Upjohn with references to reports which were appended to a letter from Dr. D.I. Weisblat, dated April 16, 1979. The letter was sent to various international health agencies, including WHO, IPPF, and others. Dr. Weisblat, Vice President for Pharmaceutical Research and Development at Upjohn, sent the letter to disclose to all interested groups the results of the monkey studies as soon as they had been received at Upjohn.

A pattern emerges from Mr. Minkin's paper. The pattern takes advantage of (1) experts' changes of interpretation through the years, (2) the normal controversy among scientists about appropriate interpretation of data, (3) scientists' use of speculation to stimulate further testing of hypotheses; and even (4) the lack of familiarity with scientific terminology to be expected among nonscientist readers.

An example of abusing nonscientists' unfamiliarity with scientific terms and procedures appears on page 3, column 1 of Mr. Minkin's paper. He defines "autolyzed" for the reader as "destroyed," within the allegation that "most organs were autolized [sic] (destroyed) before they were examined by pathologists." In fact, the autolysis of tissue in toxicology studies does occasionally occur. When an animal dies and is not immediately discovered, some tissues can begin rapid disintegration within a matter of a few hours. When this happens, the autolyzed tissues cannot be accurately analyzed at necropsy or in tissue sections. The most typical circumstances that lead to this

condition involve animals that die at night, lying undiscovered until the next morning. In the Upjohn dog toxicology study to which Mr. Minkin's quote refers, no mentions of autolysis appear. The 10-year monkey data do show autolysis of some tissues, but it occurred primarily among control group monkeys.

Mr. Minkin states his belief that, based on Hearing Reports of the Select Committee on Population and a selective review of the family planning literature, the medical community is poorly informed about what he calls harmful effects of the drug. Indeed, the Hearing Reports of only four days' testimony comprise 1,025 pages of information on the benefits and risks of Depo-Provera, printed by the U.S. Government and available to the public. The medical and scientific bibliography on the human contraceptive use of Depo-Provera includes over 300 references, and articles appear in medical and scientific journals to inform the medical community.

METABOLIC EFFECTS

Immunosuppression

Adverse effects such as suppression of adrenal and pituitary function have not been encountered clinically among Depo-Provera users. Drs. Schwallie and Mohberg (1977) have summarized the conclusions from studies of the effects of Depo-Provera on pituitary/adrenal function:

> "The fact that medroxyprogesterone acetate, given in large doses, is known to have glucocorticoid properties (Camanni et al., 1963) also caused concern about the effect of long term usage on the pituitary-adrenal axis. Several investigators (Briggs and Briggs, 1972; Schwallie, 1974; Jones et al., 1974; Moorehouse, unpublished data; Vermeulen and Thiery, 1974) have studied the effects of the drug on plasma hydrocortisone and the response of the pituitary and adrenal glands to ACTH and metyrapone stimulation tests in women under treatment for up to 18 months. Results of the plasma hydrocortisone measurements varied. Some investigators found a depression of hydrocortisone, while others found no change from control values. All investigators found a normal response to ACTH stimulation, with slight blunting of the response to oral metyrapone stimulation. No signs or symptoms of adrenal insufficiency have been detected clinically" (underlining added).

There is little evidence in women to suggest that Depo-Provera is an immunosuppressant at contraceptive doses. Animal studies cited by Mr. Minkin (Turcotte et al., 1968) used large doses of Depo-Provera--up to 30 milligram per kilogram daily. Interest in the use of MPA as an immunosuppressant has not continued, suggesting that any immunosuppressant effect is so weak as to render it clinically ineffective in both animals and humans.

Mr. Minkin's choice of immunosuppression as a hypothetical explanation for increases in breast tumors among beagle dogs (see his paper, p. 5)

is only one of many possible explanations--and actually not the explanation favored by Dr. Briggs (1977), the source Mr. Minkin uses for support of his theory. Dr. Briggs favored potent progestogen-stimulated mammary growth in the beagle as a primary mechanism. This effect occurs in both MPA-treated and untreated dogs, due to the natural presence of progesterone. Dr. Briggs goes on to say:

> "It seems likely that the beagle bitch is an unusual animal which contains a reservoir of microscopic breast neoplasms. On prolonged exposure to massive doses of those progestogens which are particularly potent in the canine species, these neoplasms are stimulated and become palpable mixed mammary tumors. Continued stimulation may induce transformations in a few of these tumors. <u>There is no evidence that a similar mechanism occurs in women</u> and the beagle is a totally inappropriate model for the chronic toxicological testing of contraceptive steroids." (underlining added)

Mr. Minkin also suggests immunosuppression as an explanation for deaths among the high dose (50x human dose) group in the long term monkey toxicology study (Minkin, p. 5, col. 1). See page 27 of this discussion for more on the beagle dog.

The point that Mr. Minkin emphasizes in his argument for an immunosuppressive effect is "the presence of viral particles in the endometrium" (Minkin, p. 8, col. 2). He refers to a study by Dr. Roberts et al. (1975) designed to investigate the effects of Depo-Provera on the ultrastructure of the human endometrium over time. Among the findings of the study, the authors reported the transient occurrence of a previously undescribed fibrillar nuclear inclusion. The inclusion was noted at 10 days post treatment and also occurred "but much less frequently in the specimens 20 days after injection and even more infrequently in the specimens 85 days after injection" (p. 814). The authors offer some speculation about these structures but

warn "...however, a cause-and-effect relationship between medroxy-progesterone's contraceptive effect and the presence of this structure cannot be established or excluded by this investigation" (pp. 817-818). In terms of overall conclusions about the long term effects of Depo-Provera on the human endometrium, Dr. Roberts et al. remark: "Ultrastructurally, medroxyprogesterone's effect does not appear cumulative over nine months when administered 150 mg every 90 days" (p. 818).

Whether the nuclear inclusions represent viral particles is certainly open to question. The temporary nature of these inclusions, however, suggests strongly they are not viral particles. It is not at all unusual for ultrastructural or microscopic observations to have no explanation as to cause. It is Mr. Minkin (pp. 5 and 8) who names these nuclear inclusions as "virus particles," whereas the scientists, Dr. Roberts et al., are justifiably cautious about including such a label in their remarks.

Bone Metabolism

It is unclear exactly what was the nature or the source of the skeletal abnormalities reported in the monkey toxicology study. However, we do have information from two different sources about the effects of Depo-Provera on human bone metabolism.

Many abnormalities in bone metabolism are detectable by visual observation during physical examination. Radiologic examination can detect even more subtle bone structural abnormalities, such as osteoporosis (a disease typically associated with the elderly).

Among the thousands of women who were studied during controlled clinical evaluation of Depo-Provera for contraception, no cases of spinal curvature were ever reported. In addition, at least one study

specifically evaluated the effects of Depo-Provera on bone density in 12 normal women (Upjohn NDA 12-541, Amendment 9, Vol. 2, 2e [I.V.] 75). After receiving 150 milligrams every 3 months of Depo-Provera for 16-44 months, their radiographic profiles indicated no evidence of osteoporosis. If Depo-Provera were suspected to contribute to osteoporosis, then the opposite result would be anticipated.

Other studies on specific aspects of calcium absorption and metabolism reinforce the idea that Depo-Provera has, if anything, a positive effect on bone. In studies of elderly patients both with and without osteoporosis, the following results have been reported:

(1) oral doses of MPA appear to increase the ability of bone to incorporate calcium and to decrease urinary calcium excretion (Molinis et al., 1970);
(2) MPA increases the intestinal absorption of calcium (Tonelli et al., 1970).

Mr. Minkin's conjecture about possible skeletal effects on humans treated with Depo-Provera for contraception is an unwarranted conclusion.

Effects on Liver

Five cases of benign liver tumor have been reported in women who used Depo-Provera for contraception (Nissen et al., 1977). Three of these women received concomitant estrogen. These may be coincidental to the use of the contraceptive (Rinehart and Felt, 1977).

An extensive review of the incidence of liver tumors indicates that over 100 cases of benign liver tumors in women using oral contraceptives were reported between 1972 and 1977 (Rinehart and Felt, 1977). Suspicion has focused on estrogens--not progestogens--as the primary responsible agent. The annual incidence of all types of benign liver

tumors in U.S. women, including those reported in women using contraceptives, has been estimated at 1 case in 200,000. Other reports indicate that the rate may be as low as 1 case in 2,500,000 women in an eastern U.S. urban area (Rinehart and Felt, 1977).

In terms of liver function, oral contraceptives cause changes in certain excretory functions and enzyme concentrations. Limited studies with the oral contraceptives show that the changes in these functions and concentrations revert to normal when the medication is discontinued (Anonymous, Population Reports Series A, Number 2, 1975).

Data on the effects of progestogens, including Depo-Provera, on liver function are conflicting. Mr. Minkin cites one study that found an alteration in two of eight liver function tests (Saleh and Abd-El-Hay, 1977). There was no significant change found in SGPT and SGOT and a significant decrease in prothrombin and bromosulphalein retention. On the other hand, he failed to note that Dr. El-Mahgoub et al. (1972b) studied liver function (including albumin/globulin ratio and bromosulphalein tests) in women using Depo-Provera for contraception and found no significant changes. In studies conducted by Upjohn, a single bromosulphalein retention test was performed on 74 patients who had been using Depo-Provera as a contraceptive for 12 or more months. There was no significant difference in retention from controls receiving no therapy or having IUDs in place (Upjohn NDA 12-541, Amendment 6, Vol 1, 20).

Carbohydrate Metabolism

Depo-Provera may have some effect on carbohydrate metabolism, but this has not been clearly established. Several publications report that Depo-Provera raises glucose levels in the blood; while a nearly equal number report the opposite effect (see Rinehart and Winter, 1975).

In one study, daily oral doses of 15-20 mg of MPA given for 6 to 18 months to diabetic patients resulted in effective treatment of serious retinal complications associated with diabetes (diabetic retinopathy). Left untreated, diabetic retinopathy can lead to permanent blindness. In these same patients, treatment with MPA had no adverse effect on the control of their diabetes (Canadell et al., 1972).

Because diabetics and pre-diabetics face higher risks during pregnancy than normal women, their need for effective contraception is great. If a woman with diabetes does not have her disease under control or if she does not have ready access to medical treatment for diabetes, pregnancy is an even greater risk. Her pregnancies should be very carefully planned and monitored. Likewise, medical supervision of contraceptive use is especially important for the diabetic woman. For this reason, physician information about use of steroidal contraceptives includes special discussions about the advisability of prescription for diabetic or pre-diabetic women.

In addition, Upjohn, as long ago as 1973, clearly publicized its position with respect to Depo-Provera and diabetes:

> "The development of clinical diabetes has been rare enough that it has not become a problem in the extensive use of the method to date. However, as with the orals, screening for diabetes is advisable prior to initiation of treatment. Extra care should be taken with women with a strong family history of diabetes or with a prediabetic history such as the delivery of a large infant. It would appear inadvisable to use this method in the known diabetic patient, unless other methods are not feasible" (Vecchio, 1973, p. 194).

No contraceptive method, including Depo-Provera, is likely to prove appropriate for every woman.

EFFECTS ON THE CHILD

Levels of MPA in Breast Milk

MPA and/or its metabolites are known to be excreted in human breast milk, prompting concern among some "consumerist" groups about possible effects on nursing infants. Much of the concern centers on questions of future reproductive ability of the infants, improperly linked to early animal studies demonstrating that it is possible to produce modifications of sexual behavior and sterility in rats and mice by giving large doses of some steroidal hormones. To produce such effects, the hormones must be given to the newborn animal during the critical period for development of hypothalamic control of reproductive function, that is, during the first few days after birth. In humans, however, this critical period occurs before birth while the fetus is in the uterus (Yen and Jaffe, 1978), so fears that lactation may have an effect on human infants' later sexual development appear unfounded.

Based upon estimates of Depo-Provera levels in human breast milk and known nutritional requirements for infants, it is possible to calculate the average dose of Depo-Provera and/or its metabolites which an infant would receive via breast milk. This calculated mean value is 0.2 micrograms per kilogram body weight per day immediately after the injection, decreasing to less than 0.08 micrograms per kilogram per day at the end of the 90 day dosing interval. For comparative purposes, a baby being fed formula based on cow's milk is receiving average daily doses of natural progesterone at levels from 1.5-6.0 micrograms per kilogram per day (calculated from data presented by Bulman, 1979).

The amount of Depo-Provera present in the breast milk, however, is not a measure of the amount that a baby can actually absorb into its

bloodstream through its digestive system. Again, estimates can be made for the infant, based on measured adult blood levels of MPA from gas chromatography/mass spectrometry data published by Drs. Phillipou and Frith (1980). In that study, adult women were given very large oral doses of MPA for cancer treatment--approximately 400,000 times as much MPA as an infant receives through breast milk per day. The measured blood levels ranged from 4 to 16 nanograms per milliliter MPA, with a median of 11 nanograms per milliliter. Assuming a high average total blood volume of 5000 milliliters and a maximum absorption rate of 16 nanograms per milliliter, we can conservatively estimate that only one part in 5000 of the oral dose actually enters the woman's bloodstream. Following this analogy through to the infant, the measureable amount in a baby's bloodstream would be at or below trace levels.

Of course, no final conclusions can yet be drawn about the effects of Depo-Provera in breast milk on the lifetime development of nursed infants, because the drug has not been in use for a long enough time. However, researchers have been and are continuing to monitor the development of children who received Depo-Provera during lactation.

For example, Dr. Zanartu et al. (1976) found no adverse effects on the nursing infants of 406 mothers who were receiving Depo-Provera for contraception (150 mg every 3 months or 250-300 mg every 6 months). Dr. Karim et al. (1971) examined 100 nursing infants of mothers receiving Depo-Provera for contraception. Their examinations detected no physical, mental or radiologic abnormalities. Infants in both studies were followed for up to more than 18 months.

In current studies, children who received MPA and/or its metabolites through breast milk during infancy are being reexamined now that they have reached ages of 4-12 years. Data on both physical and mental development are being gathered on the children. Interim medical

histories are being taken for mothers and children in both Depo-Provera-treated and control groups.

Mr. Minkin's accusation (p. 7, col 2) that "Depo-Provera's effect on growth can be particularly disastrous for the breast-feeding child," is totally speculative. There is no factual material cited by him to back up this claim (see section on Miscellaneous Effects on Growth and Development, p 23). No adverse effects have been observed in ongoing clinical studies of children who have been nursed by mothers who received Dp for contraception. He then implies that the drug is being administered without proper care, and goes on to make the gratuitous statement that those administering the drug would be "callous and cruel." A remark of this nature, unsupported by any facts, is only argumentative and inflammatory.

Milk Volume and Duration of Lactation

The questions of the effect of Depo-Provera on the duration of lactation and the volume of milk have been studied by several scientists; the majority of reports indicate no adverse or enhancement effect of Depo-Provera on lactation. Several studies report an increase in the duration of lactation with Depo-Provera given for contraception (e.g., Guiloff et al., 1974; Zanartu et al., 1976). Others report increases in milk volume due to Depo-Provera injections (Karim et al. 1971; Koetsawang et al., 1972). A recent study from Bangladesh (Huber et al., 1979) documents that Depo-Provera did not decrease milk volume. This can be compared with an earlier study from the same country (Parveen et al., 1977) which has been selected by Mr. Minkin to support his argument for reduction of milk volume. Huber further found that infants nursing mothers treated with Depo-Provera had improved weight/height ratios over control infants. He cautioned, however, it was not possible to conclusively ascribe this benefit to the use of Depo-Provera.

The quantity of breast milk and the duration of lactation are influenced by multiple factors. It is probable that the conflicting reports of the effects of Depo-Provera on lactation reflect these influences.

A steroidal contraceptive that does not reduce lactation is needed for two reasons:

(1) A highly effective method should be available to a mother who needs to breast-feed her infant; and

(2) Lactation is not necessarily an effective suppressant of ovulation and cannot, therefore, be depended upon as an effective contraceptive method. Pregnancy while the mother is still breast-feeding will inhibit lactation and may jeopardize the nutrition of the nursed infant, especially in situations where alternate forms of infant feeding are not available or feasible.

Large numbers of women worldwide breast-feed their infants. While the proportion doing so may be greater in developing countries, the quality and quantity of breast milk are of concern to mothers and their physicians worldwide.

Birth Defects

There has been no evidence to suggest that Depo-Provera used for contraception increases the incidence of congenital anomalies, according to the accumulation of all clinical data, or even according to Dr. Moghissi, whom Minkin (p. 6) has incorrectly cited as having testified that enlarged clitorises appeared in babies born to Depo-Provera-treated females. Moghissi testified that: "Infants born from treated pregnancies did not show an increased incidence of congenital anomalies" (Select Comm. Hearing Report No. 12, 1978, p. 347). Further, Moghissi began his discussion of Depo-Provera and congenital anomalies by stating:

> "The assertion that 'MPA like other progestogenic and estrogenic hormones is associated with a risk of congenital malformations in infants exposed to the drug during pregnancy' is not supported by experimental or clinical observations" (Select Comm. Hearing Report No. 12, 1978, p 346).

Some progestogens, when given in early pregnancy, can cause masculinization (clitoral enlargement) of the external genitalia of the newborn (human) female (see e.g., Wilkins et al., 1958). Many of these cases occurred in the late 1950's and early 1960's when large doses of progestogens were given as therapy in pregnancy salvage and were primarily associated with the 19-nor progestogen derivatives, which are commonly contained in OC's. The few infants who reportedly received Depo-Provera in utero returned to normal within 6 months of age. This anomaly occurs extremely rarely among infants born to women accidentally treated with Depo-Provera during pregnancy because:

(1) The dose for contraception is smaller than that used for threatened abortion;

(2) Depo-Provera is an extremely effective contraceptive, so the chance of any pregnancy occurring while a women is treated with Depo-Provera is remote; and

(3) The first dose of Depo-Provera is properly administered during or immediately following a woman's menstrual period to insure her freedom from pregnancy.

Those studies which do report cases of congenital anomalies associated with progestogens are frequently difficult to interpret because of procedural problems in the data collection or small numbers of subjects (Rinehart and Winter, 1975; Shapiro, Select Comm. Hearing Report No. 12, 1978, pp. 431-437). In one study where these problems are minimal, there was reported a non-significant increase in the cardiac malformation rate in the fetus when the pregnant woman was exposed to progestogen only (Heinonen et al., 1977).

Researchers who have evaluated the intellectual and personality development of children whose mothers received progestogens during pregnancy report no adverse affects even from large doses used for pregnancy salvage. For example, a study by Drs. Reinisch and Karow (1977) examined 71 children (aged 4-21 at testing) who had received synthetic progestins in utero. Their siblings (aged 5-17) acted as controls. Drs. Reinisch and Karow concluded that the groups did not differ in I.Q. and that progestin-exposed children were characterized by the tests as more independent, sensitive, self-assured, individualistic, and self-sufficient.

Other children exposed to Depo-Provera in utero took part in a long-term follow-up study at Children's Hospital in Buffalo, N.Y. (Ehrhardt et al., 1977; Meyer-Bahlburg et al., 1977). This was a double-blind study involving comprehensive psychological examination covering a variety of sex-dimorphic behavior. Children's mean age at time of testing was 11 years; the studies included 15 girls and 13 boys in the experimental groups. No significant differences were found for boys, and girls showed a slight effect on only two variables: The girls exposed in utero to Depo-Provera were slightly more likely to prefer feminine clothes styles and slightly less likely to rate themselves as tomboys.

Miscellaneous Effects on Growth and Development

A. Accusations were made by Mr. Minkin about the effects of Depo-Provera on the release of growth hormone and curvature of the spine (Minkin, p. 7). If there were any basis for these accusations, the effects would be readily detectable in routine physical examination of women's posture. No reports have been received by The Upjohn Company of Depo-Provera causing skeletal or bone-growth abnormalities.

Physicians are fully aware of the need to evaluate the health and body growth of all the children they treat. Children born to women treated during pregnancy for threatened abortion or children born after a rare contraceptive failure are especially closely monitored. Major congenital skeletal defects present would be detectable upon routine physical examination at birth. Patients are examined for any unusual changes in the spine and limbs on subsequent examinations, and any questionable findings would be further evaluated by radiography. There have been no reports of skeletal or bone growth abnormalities from either clinical practice or from research specifically designed to look at physical effects of progestogen exposure in utero (Reinisch and Karow, 1977; Ehrhardt et al., 1977; Meyer-Bahlburg et al., 1977).

Furthermore, several studies have evaluated children who received breast milk from mothers treated with contraceptive doses of Depo-Provera. None of the studies showed any differences between Depo-Provera-treated and untreated children (Zanartu et al., 1976; Karim et al., 1971; Koetsawang et al., 1972, p. 84).

As for the women treated with Depo-Provera for contraception, at least two studies have specifically looked for influences on the release of growth hormone in the adult female (Spellacy et al., 1972; Briggs and Briggs, 1972). Neither study showed any relationship between treatment with Depo-Provera at contraceptive doses and the release of growth hormone. The one study selected by Minkin (p 7, col. 2) to support his theory of suppression of growth hormone in humans (Lawrence and Kirsteins, 1970) used dosages many times greater than those received by women for contraceptive treatment.

B. There are at least three points of a scientific nature that must be understood in order to put into perspective Mr. Minkin's

accusation that "the administration of Depo-Provera to lactating mothers can harm infants by interfering with immunoglobins in the breast milk" (p. 6, col. 2).

(1) There are high concentrations of progesterone present in the fetus and placenta during pregnancy (Jaffe, 1967). The newborn infant has blood levels of progesterone from the mother present at birth far higher than any amount of Depo-Provera that could be transmitted through breast milk.

(2) Infants who are breast-fed receive, in an early lactational secretion called the colostrum, substances thought to help protect the newborn against infections until their own immune system gains competence. The administration of Depo-Provera for post-partum contraception is commonly delayed for 6 weeks. By this time, lactation is well established, and there has been ample opportunity for the colostrum to be passed to the child.

(3) When researchers examined the effect of injected progestogens on the immunologic powers of breast milk, no effect was found (El-Mahgoub et al., 1972a). The immunoelectrophoretic pattern of the breast milk in 60 lactating women who received Depo-Provera for contraception was compared to matched untreated women. There were no appreciable differences between treatment groups in the pattern of specific immunoglobins IgA, IgG or IgM. There were a few cases of increased levels of IgG and IgM. Data, such as those reported by Dr. El-Mahgoub et al., must be given more weight than an unsubstantiated hypothesis put forth by Mr. Minkin.

C. Mr. Minkin also implies that Depo-Provera transmitted through breast milk may "interfere with the development and distribution of lymphocytes" in the infant (p. 7, col. 1). He cites Dr. Papaioannou (1974, p. 262) as a source for this hypothesis:

> "Endogenous or exogenous corticoids profoundly affect lymphoid tissues and lymphocytes in many ways, and they may influence immune responses primarily through these properties."

Here Mr. Minkin has again improperly used scientific material. Dr. Papaioannou's quote immediately continues with an explanation that this effect may not pertain to the human:

> "Marked differences exist among species in these responses. Two broad categories of species have been distinguished with respect to their sensitivity to these agents: the steroid sensitive species consists of mice, rats, hamsters, and rabbits, and the steroid resistant species is composed of guinea pigs, monkeys, and humans" (Papaioannou, 1974, p. 262).

Based on this evidence, there would appear to be no scientific basis to give credence to Mr. Minkin's hypothesis that Depo-Provera effects the development and distribution of lymphocytes.

D. Finally, Mr. Minkin implies that Depo-Provera, because of its similarity to one of the components in an estrogen-progestogen oral contraceptive, mimics the effect of that OC in lowering levels of specific antibodies in breast milk (Minkin, p. 7, col. 1). The data which Mr. Minkin references do not support an hypothesis that either the progestogen or the estrogen in OC's alter milk protein composition. The data appear in an editorial format, without the support of statistical analysis (Ramadan et al., 1972), and do not present a reliable difference between OC's and control groups concerning breakdown of milk protein components.

LONG-TERM TOXICOLOGY -- THE DOG

Review of Design and Major Findings

The FDA guidelines for the safety evaluation of steroidal contraceptives, introduced in 1967, include the requirement that one long-term (7-year) evaluation of dogs treated with doses of drug approximately equivalent to 10 times (10x) and 25x the intended human dose be started before a drug can be approved. Dosing schedules must also mimic the intended schedule for humans.

There were two 7-year dog toxicity studies undertaken to evaluate Depo-Provera's safety. In the first study, 4 dogs were treated with the 1x dose and 16 dogs each were included in the 25x and control groups. There was a high mortality rate among the high dose (25x) group, due to pyometra. The dog uterus frequently responds to treatment with any progestogen--including endogenous progesterone--by developing this condition (Briggs, 1977). The dog's extreme sensitivity to all progestogens as well as the specific structural characteristics of its uterus are thought to be contributing factors to its susceptibility to pyometra.

Although the death rate problem effectively interrupted the long-term safety evaluation of Depo-Provera on the dog, the final results of the study did show a dose-related effect in the occurrence of benign breast tumors (mammary lobular hyperplasia and mixed mammary tumors). In addition, two dogs in the 25x group were found to have cancer of the breast (metastatic mammary adenocarcinoma) (Select Comm. Hearing Report No. 12, 1978, p. 596).

A second study was undertaken with modifications in design. All dogs were hysterectomized at the beginning of the study to improve the beagles' chances for 7-year survival. This change was made so that

any Depo-Provera toxicity on all other organ systems could be evaluated. Three additional groups were added: Depo-Provera at 10x the human dose and progesterone at 1x and 25x the level of progesterone naturally found in the dog during its progesterone-producing phase of estrus (the luteal phase). By adding these groups, the second study could examine and attempt to separate the dog's response to progestogens in general from its specific response to Depo-Provera.

The progesterone groups received drug on a weekly schedule, instead of the 84-90 day schedule for Depo-Provera. This was done because the absorption rates of the two progestogens differ. Weekly doses of progesterone were necessary to maintain more constant blood levels, to more closely parallel the levels produced by the slow release action of Depo-Provera.

As with the first, the second study is being conducted by an independent contract laboratory. The final report has not yet been received by The Upjohn Company. The survival data Mr. Minkin reports appear in the 4-year interim report (Longenecker, 1978). These data show an 85% survival among control dogs (17/20) and a 70% survival for the 25x Depo-Provera group (14/20). These percentages are not significantly different. Only 20% of the 25x progesterone group were alive at the end of 4 years. The incidence and histologic types of breast abnormalities (mammary dysplasia) found in both Depo-Provera and progesterone-treated groups were very similar (Select Comm. Hearing Report No. 12, 1978, p. 611; Frank et al., 1979).

Mammary Toxicity and the Beagle Model

Among the concerns that have arisen about FDA's dog toxicology guidelines is a long-standing controversy about the appropriateness of using the dog for toxicity studies of steroidal contraceptives. Following a meeting in London in February, 1979, held by the Committee on

the Safety of Medicines (CSM) of the United Kingdom which was attended by representatives of 14 countries together with a number of scientific experts, the CSM issued a statement which reads as follows (Dept. of Health and Social Security, U.K., 1979, p. 2):

> "1. Because of differences between the beagle bitch and the human female in the sensitivity to and the metabolism of progestogens, positive carcinogenicity studies in the beagle bitch can no longer be considered as indicative of significant hazards to women; and
>
> 2. The beagle bitch should no longer be a mandatory species for the long term testing of progestogens/contraceptive steroids."

Numerous investigators have questioned the suitability of the female beagle dog as a model for predicting mammary dysplasia in the human female for the following reasons:

(1) the beagle dog is highly susceptible to mammary malignancy;
(2) the dog is far more sensitive to progesterone analogs than to testosterone analogs;
(3) there are differences between the dog and human in metabolism of progestogens; and
(4) other than the ferret, the dog is the only known species in which considerable mammary lobular-alveolar growth can be produced by progesterone or its analogs alone. Other species require a pituitary or placental factor in addition to progesterone.

This issue has been discussed both in the scientific literature (e.g., Hill and Dumas, 1974; Briggs, 1977; El Etreby et al., 1979) as well as in other public forums (e.g., Select Comm. Hearing Report No. 12, 1978, p. 58-61; 65-67). Various agencies and regulatory bodies have periodically reviewed the scientific evidence and have drawn their own conclusions. For example, a statement by the WHO Toxicology Review Panel issued on September 19, 1978, reads: "The beagle dog does not

appear to be an appropriate animal model for the evaluation of carcinogenic risks associated with progestogens and the panel recommends that an alternative, more appropriate species be identified for the assessment of the chronic toxicology of progestogens."

As long ago as 1973, a U.S. FDA scientist expressed reservations about the suitability of the beagle dog to evaluate the tumorigenicity of hormonal contraceptives (Berliner, 1974, p. 252).

There have been several studies which describe the mammary tumors in progestogen-treated bitches. Recent information suggests that nodules are also caused by the 19-nor progestogens, the progestogen used in most of the currently marketed oral contraceptives. Another study reports findings from 1x and 25x normal dose levels of MPA and of progesterone, given to dogs for a period of 4 years (Frank et al., 1979). They report no difference in the incidence or histologic types of mammary dysplasia between MPA and progesterone-treated beagles, suggesting that Depo-Provera did not produce unique toxic effects.

Since one purpose of the long-term toxicity studies is to predict potential toxic effects in women, it should be noted that by 1977, worldwide use of Depo-Provera for contraception totaled more than 6 million women-years of experience (Select Comm. Hearing Report No. 12, 1978, p. 281). No hint of an increased frequency of breast tumors or cancer has emerged from this experience.

All mammary tumors that developed during Depo-Provera clinical trials for contraception were reported fully to the FDA in the New Drug Application and supplemental documents. Drs. Schwallie and Mohberg (1977) have summarized the data as follows:

> "During the course of investigations conducted under the U.S. IND, involving 11,631 women studied for a total of 17,408 woman-years (longest time on therapy was 99 months), 24 women were reported to

> have either developed mammary nodules or had an enlargement of previously existing nodules. Five of these women had carcinoma. One woman undoubtedly had the disease prior to entering the study. Three of the 5 women received concomitant estrogen therapy. The remaining woman received only 4 injections of the drug."

In one of the studies outside the U.S. IND, breast examinations were performed on 1,270 women who had received 1 to 25 consecutive Depo-Provera injections and on 257 untreated control women. Breast nodules were found in 8 (0.6%) of the 1,270 treated women and in 3 (1.2%) of the 257 untreated controls. None of the nodules was malignant (McDaniel and Parathaisong, 1973).

Other scientists specifically reporting negative results of breast examinations in Depo-Provera users include Jeppsson (1972); Mishell et al. (1973); Rubio (1973); and Zanartu et al. (1973). More recently, Dr. Ghali et al. (1975) reported that none of 206 women completing 11,683 women-months of Depo-Provera contraceptive treatment had breast nodules or palpable breast pathology.

Liver and Gallbladder Toxicity in Dogs

It is difficult to speculate on the significance of reported liver and gallbladder toxicity in the Depo-Provera dog studies. Dr. Hansel et al. (1977) reported that MPA-treated dogs showed more liver and gallbladder toxicity than did control or even progesterone-treated dogs. On the other hand, Drs. Goyings and Sokolowski (1975) specifically searched for gallbladder abnormalities in dogs treated with MPA, but concluded that their data showed no evidence of abnormality.

In the first dog toxicity study, there was a high incidence of both liver and gallbladder pathology that appears to be equally distributed across all groups tested--high-dose, low-dose, as well as control (Select Comm. Hearing Report No. 12, 1978, pp. 598-602). Data from the second dog toxicology study have not been reported because the laboratory has not yet provided its final report to The Upjohn Company.

LONG-TERM TOXICOLOGY -- THE MONKEY

Review of Design and Major Findings

The guidelines for long-term safety and toxicity testing also require that a 10-year study in monkeys be started before a drug can be approved. The required dose levels are established at 10x and 50x the anticipated human dose, administered via the intended route (therefore, for Depo-Provera, by injection). A 10-year rhesus monkey study was conducted for The Upjohn Company by an outside testing laboratory. Female monkeys received Depo-Provera intramuscularly at 3, 30 and 150 milligrams per kilogram (1x, 10x and 50x the dose recommended for contraception in humans) every 84 to 90 days. Control monkeys received injections of sterile water on the same schedule. At the beginning of the study, there were 4 monkeys in the 1x group and 16 monkeys in each of the other groups. Seven monkeys were added to the study in its early phases: 2 to the control group and 5 to the 50x group. These additions were made because four of the monkeys were removed as TB suspects, 2 each in the control and 50x groups. Three other monkeys died. An interim sacrifice of 4 control monkeys occurred at the end of the second year of the study. These monkeys served simultaneously as controls for a second study which had a protocol requiring the sacrifice.

Normal Histological Findings

Surviving at the end of the 10 years of treatment were 7 of the 18 control monkeys, 2 of 4 monkeys in the 1x group, 7 of 16 in the 10x group, and 12 of 21 monkeys in the 50x dose group. The findings at the end of the study were those expected of a potent progestogen. Ovarian atrophy and decidual transformation of endometrial stroma were noted, with atrophy of glandular epithelium and decreased uterine weight. These effects were noted for all 10x and 50x monkeys. Small

benign hyperplastic mammary nodules were found in the control, 1x, and 10x groups, but not in the 50x dose group. A statistically significant decrease in liver and ovary weights occurred in the 10x and 50x groups, in adrenal weight in the 50x group, and in uterine weight in the 10x group. These weight decreases were considered compound related. "A curvature of the spine was noted for one, two and six monkeys at the 1x, 10x and 50x human dosage levels, respectively, at least at one examination" (Carlson, 1979, p. 3).

Microscopic examinations at the end of the study revealed endometrial carcinomas in two 50x monkeys (#8275 and #9060). In one of these animals, the carcinoma had metastasized to the lung. Three other monkeys, two in the 50x group and one in the control group, developed benign tumors.

As previously mentioned, the 10x and 50x monkeys' endometria all showed expected effects from large doses of progestogen therapy--specifically, decidual transformation of endometrial stroma with atrophy of glandular epithelium. This response was morphologically similar to the decidua of pregnancy. The cervix in the high dose (50x) monkeys exhibited diffuse cystic mucinous hyperplasia of the cervical glands. These findings are attributable to the long-term high dose administration of MPA.

Such changes might be termed "abnormalities" (Minkin, p. 4, col. 2) by those unfamiliar with the terminology, but scientists do not designate these as "precancerous" lesions. They are in fact the expected and predictable findings directly related to the desired action of the drug.

Abnormal Histological Findings

It was completely unexpected to find two animals with adenocarcinoma of the endometrium in the 10-year monkey study. Two of the 12

surviving animals in the 50x dose group were found at autopsy to have adenocarcinoma of the endometrium. Both of these tumors are considered to be malignant. In one animal the tumor had metastasized to the lung.

Upon learning of the carcinomas, The Upjohn Company immediately notified the FDA. Because the contract laboratory had not yet completed their final report, the FDA was sent a draft copy of the findings. In addition, investigators and health officials in many parts of the world were notified by letter and telephone.

The reason for the concern was that out of all the possibilities which one might consider in a long-term toxicology study with Depo-Provera, adenocarcinoma of the endometrium would be considered one of the least likely. Depo-Provera is approved for the palliative treatment of human endometrial carcinoma and has been extensively used over the past several years for this purpose. Further, Depo-Provera has been shown to be capable of treating early adenocarcinoma in-situ of the uterus in some instances (e.g., Steiner et al., 1965). All interested parties were alerted and at the same time, independent consultants were called upon to give expert opinion on the interpretation of tissue samples.

Published reports of spontaneous tumors in nonhuman primates have been infrequent, and, in the past, the incidence of tumors in these animals has been considered to be very low (Chesney, 1972; Kent and Pickering, 1958; Newberne and Robinson, 1960; Ruch, 1959), but a more recent report showed that they are not as rare as was generally thought (McClure, 1975). Reports state the overall tumor incidence in rhesus monkeys to be 3.8%; and for malignant tumors, 2.7% (from the Yerkes Primate Research Center, Atlanta, Ga., McClure, 1975). At the Sukhumi monkey colony, U.S.S.R., tumor incidence among monkeys over the age of 9 years was 9% reported between the years of 1927 and 1953

(Ruch, 1959). However, these figures may be unusually low because the female reproductive tract was not routinely examined at necropsy until 1951. Dr. Lapin (1973) reviewed the literature on malignant tumors in monkeys and concluded:

> "Thus it follows that the opinion that tumors occur rarely in monkeys is wrong. We have studied the incidence of tumors in certain monkey species at the 'sensitive age' (i.e., > 10 years old), and preliminary calculations suggest that the frequency of tumors in monkeys is very much the same as the frequency of tumor diseases in man."

Age is an important factor in the occurrence of tumors in monkeys (Jungherr, 1963; Lapin, 1973). The exact age of the monkeys when they were caught, imported, and entered into the Depo-Provera study was not known. However, they were mature (presumably menstruating), therefore by the end of the 10-year study they would have been at least 12 to 14 years old.

Five consulting pathologists prepared independent reports concerning the uteri from all monkeys in the study. There was general agreement that the tumors were adenocarcinoma of the endometrium. Huntingdon Research Center, England, concluded that the tumors were caused by massive doses of Depo-Provera administered for prolonged periods of time to an atrophied endometrium (Weisblat, 1979, Attachments 4 and 5). On the other hand, the pathologist from the New England Primate Center, Massachusetts, agreed that the tumors were carcinoma, but did not believe that they were the result of Depo-Provera administration. Instead, his classification was that they were spontaneously occurring endometrial adenocarcinoma (Hertig, 1979). The University of Southern California Medical Center described the material as moderately to poorly differentiated adenocarcinoma of the endometrium. No comment was made about cause (Weisblat, 1979, Attachment 7). The Yale University School of Medicine pathologist suggested that the monkey endometrial tumors might be a new type, possibly "arising from decidua,

which obviously an epithelial tumor should not do" (Weisblat, 1979, Attachment 2, p. 1). An independent veterinary pathologist from Maryland also agreed with the general classification of the tumors as adenocarcinoma, but believed that the cells or origin of this tumor were most likely those of the plaque forming epithelial cells of the endometrium (Weisblat, 1979, Attachment 9). She further stated that "If this should be the case, then this tumor probably would not have a histogenically similar carcinoma in women since this epithelial proliferation does not occur in the gravid human uterus" (Weisblat, 1979, Attachment 9, p. 6). Although the pathologists disagreed about possible cause of the tumors, none expressed concern that the findings might have implications for human use of Depo-Provera.

Additional Microscopic Findings

An AFIP pathologist found viral particles in the bone marrow and adrenal gland of one monkey from the 50x group. This monkey, #8112, died approximately one year into the study (Weisblat, 1979). The pathologist stated that "latent herpes virus infection was the most likely consideration" in attempting to identify the virus.

In addition, two monkeys were identified as having a "polypoid mass" (Weisblat, 1979, p. 10) or "polypoid thickening" (Wazeter, 1970, Monkey Study Appendix II). Mr. Minkin speculates from these reports that endometrial polyps in women could evolve into malignancy. In fact, however, the use of the word "polypoid" in pathologists' very precise terminology carries a different meaning than their use of the word "polyp." "Polypoid" means that the observations were not polyps, but in some way could be said to resemble polyps. To further put Mr. Minkin's conjecture into proper perspective, it should also be noted that in later summary comments about the polypoid observation, Dr. Wazeter stated that the animal in question (Monkey #8112) showed "no significant lesions" during microscopic evaluation (Select Comm. Hearing Report No. 12, 1978, p. 609).

DEPO-PROVERA'S MECHANISM OF ACTION

Depo-Provera is the injectable form of medroxyprogesterone acetate, a synthetic progestogen whose structure is very similar to that of natural progesterone. It has pure progestational action, i.e., it does not act like an estrogen. Like progesterone, MPA acts to suppress the pituitary hormones that cause the release of the mature egg (ovulation). This action occurs, in part, through interaction with the hypothalamus. During the normal menstrual cycle progesterone levels rise following ovulation and prevent further ovulation. If pregnancy occurs, progesterone from the corpus luteum in the ovary and from the placenta continue to inhibit ovarian follicle growth. Intramuscular administration of MPA in an aqueous suspension, the drug form of Depo-Provera, results in slow release from the injection site. The effect of release is extended over several months, comparable to the long-term exposure to progesterone during pregnancy. It is this action which affords Depo-Provera its principal contraceptive action.

MPA, like progesterone, also acts on the lining of the endometrium. During the menstrual cycle progesterone acts on the proliferative phase of the endometrium, after estrogen has already stimulated it to grow. Progesterone changes the proliferative endometrium into the secretory phase, in which the lining is suitable for implantation of the embryo. The effect of progesterone, then, is to convert the estrogen-stimulated endometrium to the more quiescent form. Continued administration of progestogen prevents the regrowth of the endometrium.

The action of steroid hormones and synthetic analogs on the tissue of the reproductive tract is determined by the ability of the compounds to bind to the specific estrogen and progesterone protein receptors (binding sites) in the target tissues. Estrogen causes an increase in the number of specific receptor sites for estrogen, progesterone, and

androgenic steroids. Progesterone, on the other hand, produces an overall decrease in binding sites for these steroids. In general, the synthetic steroids, like MPA, have the same effect on the specific binding sites as their natural precursors.

In practice, estrogen treatment increases the number of endometrial estrogen and progesterone receptors resulting in growth of the endometrial lining. Progestogen treatment, in contrast, decreases the number of both estrogen and progesterone receptors. This results in inhibition of endometrial growth.

Protective Effect of Progestogens in Women

This interaction between the two steroid hormones is used therapeutically to control the abnormal growth of the endometrium. Numerous scientists have reported that administration of progestogen will convert a histologic pattern of hyperplasia into one of secretory endometrium (e.g., reviews by Ober and Labay, 1972; Huggins and Giuntoli, 1979; Whitehead et al., 1977; and Greenblatt and Stoddard, 1978).

The well-documented ability of progestogens to reverse hyperplasia has for years been applied to palliative treatment of endometrial carcinoma with large progestogen doses. Progestogens as the sole therapy eliminate in situ endometrial cancer in about 60% of cases and invasive cancer in 30%. Progestogens as sole therapy also induce considerable histologic transformations in 50% of persistent invasive cancers (Bonte et al., 1978). There is usually a clinical response when tumors have been demonstrated to contain estrogen and progesterone receptor levels (Martin et al., 1979; Janne et al., 1979).

Anderson (1[illegible]2) detailed the histologic changes in patients given Depo-Provera as palliative treatment for endometrial adenocarcinoma.

In two patients, "neoplasms seemed to be replaced by endometrial hyperplasia, and, with continued therapy, atrophy of the neoplasm as well as the remainder of the endometrium occurred with marked decidual reaction of the stroma, typical of the progestin effect."

These experiences in clinical treatment of the endometrium, coupled with the understanding of MPA's mechanism of action gained from laboratory studies, give considerable confidence about Depo-Provera's continued use for the palliative treatment of endometrial carcinoma. These clinical data aid in evaluating the importance of the adenocarcinoma occurrence in the monkey toxicity study, making its relevance to human use of Depo-Provera doubtful. The studies in no way support Mr. Minkin's allegations that a woman treated with Depo-Provera will age prematurely because her endometrium is atrophied (Minkin, p. 8, col. 1).

Effects on the Hypothalamic-Pituitary Axis

The lack of an effect of Depo-Provera on the hypothalamic-pituitary axis is demonstrated by the fact that lutenizing hormone (LH) blood levels are unchanged by the drug, which in turn indicates normal tonic release of gonadotropin-releasing hormone (GnRH) from the hypothalamus and LH from the pituitary (Mishell et al., 1970). In another study, Dr. Goldzieher et al., (1970), found that LH and follicle stimulating hormone (FSH) levels did not differ from values in untreated controls except for elimination of the preovulatory peak of both hormones. During the preovulatory peak, levels of both hormones are depressed, as evidence of the efficacy of the desired protective effect against pregnancy. The presence of ovarian follicles in all stages of development on ovarian biopsy (El Mahgoub et al., 1972b) is indirect evidence of adequate GnRH from the hypothalamus and FSH from the pituitary. Further evidence for the integrity of the hypothalamic-pituitary-ovarian axis is the ability to induce ovulation in the Depo-Provera-induced anovulatory ovary by the sequential use of fertility drugs (e.g., clomiphene citrate and human chorionic gonadotropin; Zanartu, 1968).

Despite the wealth of information about the minimal disruption of hormonal balance due to Depo-Provera, Mr. Minkin (p. 1, col. 2) hypothesizes a "shock to the hypothalamus." This is no longer a widely held view. See Drs. Schwallie and Assenzo (1974) for a thorough review of the literature on Depo-Provera's effect on pituitary and ovarian function.

BENEFIT-TO-RISK JUDGMENTS

Mr. Minkin begins his discussion of the risk-benefit ratio of Depo-Provera by noting that when the FDA sent its nonapproval letter to Upjohn, they took the "extraordinary step" of informing Upjohn that the "assessment of the risks of Depo-Provera was not necessarily applicable to other countries." (Minkin, p. 1, col. 2). This is hardly to be considered "extraordinary."

Dr. Fred T. Sai, former IPPF official and health minister in Ghana, in testimony before the House Select Committee on Population, stated:

> "Now, when you have this kind of a reality and you have a situation where you have mortality related to mere childbirth being at least a hundredfold the mortality rate related to childbirth in this country [U.S.] -- and in some instances, 200-fold to 500-fold -- then you have a distinctively different situation which calls for certain measures" (Select Comm. Hearing Report No. 12, 1978, p. 5).

Former HEW Secretary Joseph Califano, in testimony one week later before Senator Kennedy's Subcommittee on Health stated:

> "A drug which has an unfavorable benefit-risk ratio in the United States and therefore is <u>not</u> approved for use here may, due to differences in circumstances, have a very favorable benefit-risk ratio in another country, and therefore may be entirely appropriate for use in that country" (Senate Subcommittee on Health and Scientific Research Hearing Report, March 17, 1978, p. 245).

Although Mr. Minkin conjectures that "Depo-Provera has had an important role in the development of key provisions in [the Drug Regulation Reform Act]" (p. 2, col. 1), it in fact does not fall within the scope of the bill because the drug is manufactured overseas in countries where it is licensed for use as a contraceptive. The contraceptive dosage form is not exported from the U.S. The Drug

Regulation Reform Act would only allow manufacture of the drug within the U.S., but Mr. Minkin fails to mention the critical restrictions contained within the proposed Act which would allow export of a nonapproved drug from the U.S. only if the recipient country's authorities formally indicated to FDA that they did not object to the importation. The U.S. FDA could also refuse to allow export of any drug if the Secretary judged that it presented a public health problem. The provisions are entirely consistent with the 1976 medical device export provisions (see Testimony of former FDA Commissioner Dr. Donald Kennedy before House Select Committee, Hearing Report No. 12, 1978, p. 313).

As explained by Dr. Kennedy in his testimony:

> "A drug is approved in this country on the basis of a judgment by FDA and its advisory committees that the benefits it offers for a particular patient population outweigh the risks. Among the factors that might legitimately make that decision a different one for different nations are: the demographic structure of the population (if the risk is a side effect that takes many years to develop, it will be of less concern in a population with a relatively shorter life-expectancy); the availability of alternatives (a safe alternative may be available to citizens of one country but not to another); the nature of the health care system (in a nation with many doctors, other kinds of medical intervention that demand physician consultation may be feasible); and social customs (religious beliefs or traditions in one country may invalidate options available in another). Nations may differ from one another in any or all of these respects. It follows that a decision about the appropriateness of a contraceptive drug for the United States would not necessarily apply to <u>any</u> other nation, let alone all" (Select Comm. Hearing Report No. 12, 1978, pp. 310-311).

In the case of contraceptive agents, the basic observation must be made that in <u>developed</u> countries, approximately 25 women die as a result of each 100,000 pregnancies. In developing countries, the

average mortality as a result of childbearing approximates 500 per 100,000 pregnancies.

By contrast, the oral contraceptives and IUD's are estimated to have mortalities associated with their use ranging from 1 to 4 per 100,000 users. In the case of Depo-Provera use as a long-term contraceptive, no death has ever been reported from the method itself. Legal abortions have about the same overall mortality rates a OC's, while illegal abortions are estimated to result in a minimum of 100 mortalities per 100,000 abortions (Tietze, 1977).

The characterization of Depo-Provera as "potentially high risk" has stemmed from animal toxicity studies. Use in women has to date shown little serious morbidity with Depo-Provera and has not borne out the breast findings in the beagle dog model (Nash, 1973; Vecchio, 1976) or the endometrial tumors in high-dose monkeys (McDaniel and Potts, 1979). The risks of Depo-Provera in U.S. women should, of course, be assessed in controlled studies, such as the post-marketing study planned by The Upjohn Company at the FDA's request (Testimony of Dr. William N. Hubbard, Jr. before House Select Committee on Population, Hearing Report No. 12, 1978, pp. 298-99). In the meantime, data amassed in the rest of the world should not be ignored.

Experience in industrialized countries has not substantiated allegations that Depo-Provera is a "high-risk" drug. Neither have the two largest studies reported to date. Rall et al. described 19,875 women with a total of 220,530 women-months of use. No malignancies of cervix or breast and no thromboembolic episodes were reported (Rall et al., 1977). Dr. E. B. McDaniel has commented on his experience in Thailand:

> "...in the 12-year-old Chiang Mai programme, as of 30 June 1977, there had been a total of 69,316 women who had received one or more injections (some up to 48 consecutive injections) of Depo-Provera

> for a total group experience of 146,508 women years, without a single death" (McDaniel, 1978).

Mr. Minkin has grossly overstated the "risks" of Depo-Provera use by scientifically unwarranted extrapolation of the observations made in animal studies to potential similar risks for women. The relationships are highly theoretical and have been demonstrated only in stressed laboratory animals. As many scientific authorities agree, it is not possible to extrapolate from any single animal species to human experience (see, generally, Finkel and Berliner, 1973; Rinehart and Felt, 1977; Briggs 1977). None of these alleged toxicities have been observed in clinical use of Depo-Provera for contraception. We do know a great deal about the safety of Depo-Provera in women from over 15 years of safe, effective, and responsible experience throughout the world.

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APPENDIX 9

Letter Dated August 12, 1980, to Bob Curtis, Planned Parenthood Coordinator, World Neighbors, From Malcolm Potts, Executive Director, International Fertility Research Program

Bob Curtis
Planned Parenthood Coordinator
World Neighbors
5116 North Portland Avenue
Oklahoma City, OK 73112

Dear Bob:

Thank you for enclosing the paper by Steven Minkin, which I had not seen.

I think there is a lot to be learned from Minkin's paper. Perhaps the most important thing to be gained relates to his statement of evidence and his overstatement of conclusions. Clearly, contraception is a matter we all get excited over and in the increasing polarization of use which is taking place I think those of us that favor the use of Depo-Provera should be careful not to overstate our case in the same way that Minkin overstates his disapproval.

I have seen a draft paper by Goldzieher and Benagiano (Benagiano is from the program for Research in Human Reproduction, WHO and Joe Goldzieher is from Southwest Foundation, San Antonio) that reviews all the long acting steroid injectable contraceptives and that answers a great many of the points in the Minkin paper.

I will now work through the paper, making some scientific and political comments.

Page 1: There is nothing "extraordinary" about suggesting that the risks/benefits of contraceptive use will be different in other countries when maternal mortality around the world varies up to 100-fold.

I have seen the suggestion that MPA produces "shock" to the hypothalamus but I do not know of any evidence for this.

I find the Califano comments on giving his backing to the decision of foreign countries (Page 2) while not dumping dangerous drugs overseas a perfectly reasonable, thoughtful statement.

I do not find the inuendoes of Upjohn withholding information very convincing. I think the rapidity with which they made the monkey information available is a mark of their integrity.

In general, I find that Depo-Provera has less physiologic effects than the pill but there are more questions over its possible effects in the development of cancer then in the case of oral contraceptives. It is a swings and roundabouts situation; would you rather your wife run the proven risk of thrombosis now or

the possible risk of cancer in 20 years? I do not mean to be flippant but if we accept, as I do, that all new therapies carry with them a certain risk then perhaps it is not unfair to encapsulate the problem in this way.

I do not find Minkin's statements on the nonmalignant effects of MPA convincing. With the 6,000,000 women that have used Depo-Provera and 1,000,000 currently using it, if there was a demonstrable consequence of effects on growth hormones then gross changes such as "curvature of the spine" and "leg muscle atrophy" would surely have been seen. Many of the changes that take place in the reproductive system are rather like those which occur during pregnancy and lactation, and I do not see anything threatening about ovarian inactivity. Indeed, the evidence is that repeated menstruation may carry with it certain dangers.

I was not aware that at two years the treated monkeys had a higher mortality than controls but I was aware that at ten years the controls have a higher mortality then the treated monkeys. When you are dealing with 16 animals I think these kind of conclusions are rather stupid.

As I read the literature, in particular, Goldzieher's article, the metabolic changes and possible diabetic changes are much less with Depo-Provera than with oral contraceptives. Further, there is no significant change in blood coagulation of fibrinolytic systems (American Journal of Obstetrics and Gynecology, 107, 1147 and 106, 187)

Statements in the conclusion such as "a healthy women on Depo-Provera prematurely ages . . . for many women the chances of surviving until the menopause will be decreased with the use of Depo-Provera . . . a significant proportion develop abnormal glucose tolerance curves or become diabetic" are not justified by the available evidence.

In relation to cancer, we have a different picture. It is impossible to prove safety or danger in advance of long-term use. Probably it is only case-control retrospective studies that will produce the most useful evidence. Minkin's conclusion (Page 4), "it is unlikely that a systematic epidemiological surveillance of the relationship between Depo-Provera and endometrial cancer will ever be carried out", is probably true.

While I do not think it is reasonable to criticize people because they are not doctors and make comments on medical matters, I think there are one or two things that creep into the paper which are just not clinically reasonable. One of them is the comment about pyometra being seen in "malignant states of the uterus". Obviously, that is true, but it is not the explanation of what is happening in dogs and monkeys, nor it is the most common explanation of the disease in women. It is a case of the author looking around for anything which sounds bad.

The information I had from Upjohn was that the endometrial cancer in the monkeys had not spread elsewhere. Minkin says it spread to the lungs but quotes an unpublished report. I do not know who is right.

Minkin makes a number of points about the electromicroscopy of the endometrium of Depo-Provera users. At one point he quotes "numerous intramuscular viral inclusion bodies in the bone marrow and adrenal glands of this monkey". I do not know what this means and it does not make sense. It could be intranuclear. I have looked at the original paper (his reference 37) on the electromicroscopy of the endometrium; this was part of the subject of my PhD and I am probably better informed then most people in this area. I have to confess that I have not seen this paper before and it is an interesting one. As with many cases of studies with the electromicroscope it is not at all clear what is happening. Certainly, something that is morphologically dramatic is occurring to the nucleus. I do not think it is reasonable to conclude that the strange inclusions are viruses. They certainly do not look like virus particles to me. The road is full of microscopic observations which nobody can interpret. These are pieces of information that a biologist stores away until he comes across something else that may make the picture clearer. Looking at this paper it occurs to me that IFRP might attempt to get some biopsy material from DMPA users for electromicroscopy after several years of use. The original study was just a single 90-day injection. The rather extended passage in Minkin's paper about this subject is an effort to bring together a tenuous collection of facts in the most pessimistic way possible. What is interesting and reprehensible in the writing is that by the time he comes to summarize his conclusions he writes a sentence that says "the presence of virus particles in the endometrium is proof of the immunosuppressive effect in women at contraceptive doses." (The emphasis is the author's). This is a total misrepresentation. The original observers using electron microscopes say "the possibility that the nuclear inclusion represents viral particles or viral influence remains a strong consideration". Minkin has taken this suggestion and then put it together with a series of not very substantiated observations to do with immunosuppression and made his own proof.

There are a number of inuendos that people's judgement is influenced by their financial interest in Depo-Provera (eg, bottom of page 4) where the words "argued, opinion, and facts" are all italicized. As I understand the situation, the patents on Depo-Provera have already run out. If we assume that the directors of Upjohn are making sensible decisions in relation to their shareholders (which is a supposition that both Minkin and I might agree on) then I think that Upjohn is bloody stupid to continue any interest in Depo-Provera at all! I think the chances of them making a significant profit out of this particular compound are slight. I believe, and I suspect that Upjohn would also agree, that the future of injections is going to be with other compounds or with things like the encapsulated microsphere. The fact that Upjohn is still putting a considerable amount of money into the support for research has, I think, become a point of honor rather than a matter of crude financial return. I would hasten to add that I am not a naive friend of the pharmaceutical industry and only the other day I was criticizing the Schering Company for permitting their so-called steroid pregnancy test to remain on the market as long as it did.

Minkin refers, although he does not give a reference, to the recent paper that Ed McDaniel and I published concerning the follow up of cancer cases in the North of Thailand. It was not a WHO/Upjohn/McDaniel study, it was an intelligent attempt to use existing information. I agree with Minkin that "it would be ludicrous to suggest that the McDaniel study shows that the Depo-Provera study is not carcinogenic." In fact, the study does not suggest this. All it says is that no cases of cancer were found in Depo-Provera users. This is reassuring. The main purpose of the study was that if a high proportion of cancers had been associated with Depo-Provera then we would have known we had a disaster on our hands and would have had to do something about it. Ed McDaniel has been an enthusiast but has been academically careful to present his data within the limitations that surround any study.

The statements on mortality seem to be contrived and the evidence concerning diabetes is much less powerful in the case of Depo than in the case of the pill. There is some evidence from the Royal College study on oral contraceptives that there is a change in patterns of infection and some effects on immunosuppression.

On page 6, it is pointed out that higher doses of progesterone were given to beagle dogs and monkeys. Certainly, many artifical progestins are more active than natural compounds when measured by such things as response of the rodent uterus to injections, which is a standard biological test. I honestly do not know what the situation is here but it could be checked up on and I would doubt if a noncomparable regimen had been deliberately choosen.

I think there are important questions to be asked about breast-feeding. It is certainly true that some of loading dose comes across in the milk. So far there is no evidence of any abnormal effect but it does not prevent one from taking a somewhat cautious attitude. I think we need more well thought out guidelines to give to lactating women about steroidal contraceptives and this is certainly an area where IFRP wants to do further work.

Clearly, we have to be cautious in reviewing the effect of any drug on the next generation. For a series of reasons which I do not find clinically convincing but nevertheless occurred, DMPA was given to women with threatened and habitual abortion and there was no evidence that when the drug was deliberately used in pregnancy that it had an adverse effect. But again, Goldzieher and Benagiano have done a second paper on the effect of contraceptives on children. Some of the long-term effects on the nervous system or on the reproductive system certainly represent questions which should be asked, but they also relate to other steroids. There are reasons for caution but not for condemnation of the drug.

The concluding pages take a number of extreme attitudes. In passing, I am always amused when I see Senator Kennedy's name associated with drug regulation reform acts, for, as an English medical journal recently pointed out, he was illicitly importing non-FDA registered drugs for the treatment of his son's

bone cancer. Minkin has a desire to misinterpret every statment that is made about anything. He says that when the FDA came near to approving DMPA in 1973 it was because of the "uniqueness of the preparation" and its "efficacy as a contraceptive," interpreting that as a possible approval "based on Malthusian ideology!" Does he only want the FDA to approve ineffective contraceptives? If that was the case then he and his colleagues would find all sorts of reasons for interpreting statements as being some kind of abuse and exploitation of women.

I know that Minkin lived in Bangladesh, but it seems to me that he must have had his eyes closed most of the time to suggest that the "health and safety of women and children have a lower priority in AID and many other international organization than does population control". I enclose a little story that I have just written about something that happened to the safety and health of one woman because she stopped using Depo-Provera.

I do agree with Minkin on one thing and that is the last question of his last sentence. Yes, I would give Depo-Provera to tens of millions of people. I acknowledge that in giving an intuitive answer there is always a possibility that a horrible scientific and clinical mistake may be made. But that is the nature of decision making in relation to the use of drugs and I do not hear anyone telling me that they do not want to work toward improving contraceptive services around the world. I do not think that the Depo-Provera debate is a "politically oriented," male "dominant" issue. I know of two exceptionally intelligent well-informed women who use Depo-Provera in the United States: one previously worked in Bangladesh and is married to a doctor; the other one works with a family planning organization that I am sure Minkin would interpret as having a "Malthusian ideology."

All best wishes,

Sincerely,

Malcolm Potts /KKL

Malcolm Potts, MB, BChir, PhD
Executive Director

MP/sdr044

cc: Sharon Camp
Ed McDaniel
Joe Goldziehier

APPENDIX 10

STATEMENT OF THE CHEMICAL MANUFACTURERS ASSOCIATION

The U. S. chemical industry is pleased to respond to the Subcommittee's request for comments on H.R. 6587 which would amend the Export Administration Act of 1979 to restrict the export of goods which have been found to be hazardous to public health. The U. S. chemical industry shares the concern for public health and safety that caused the introduction of this legislation. This includes consideration for the health and safety of the residents of other countries to which we export a wide variety of our products.

However, we believe that H. R. 6587 creates regulatory and administrative procedures that are unnecessary. A small number of instances where substances restricted for U. S. sale have been exported is not an adequate basis for such restrictive legislation. We therefore do not support the enactment of H. R. 6587.

H. R. 6587 provides that unless a validated license is issued under complex and stringent conditions, products regulated or restricted in the United States may not be exported. This includes products regulated or subject to registration, licensing or use requirements or similar restrictions under 11 existing environmental and health laws. The Secretary of Commerce may issue a validated license or a qualified general license permitting an export of such products if the Secretary and the head of the agency regulating the product concur that such a license should be issued. This could be done only if the government of the country receiving the product requests it, the U. S. exporter has informed that government of all applicable restrictions and hazards, and the benefits outweigh the risks. Also, restrictions in the receiving country must be comparable to those in the United States.

The bill further provides that products may not be exported which do not contain all warnings and other information required under the variety of environmental and health laws referred to above, and that no product may be exported for the manufacture of another product, the export of which would be prohibited.

The impact of H. R. 6587 on the U. S. chemical industry is troubling in many respects. First, Congress has already enacted two major federal regulatory programs which restrict the export of U. S. chemicals. Section 17 of the Federal Insecticide, Fungicide, and Rodenticide Act regulates the export of registered, as well as unregistered, pesticides manufactured in the United States. Section 12 of the Toxic Substances Control Act provides the Administration with broad authority over the export of chemicals found under this Act to be hazardous. In view of such a broad-based congressional program for the regulation of the exports of the U. S. chemical industry, there is no need for another law.

Indeed, the most serious problem in this legislation is the open-endedness with regard to the future. Regulations are still issuing for some of the laws referred to in Section 2 (6). The Toxic Substances Control Act is one of the most important of these. It is entirely likely that long lists of products may be put under restrictions under this law even though they may not have a proven negative effect on public health and environment. Nonetheless, these products would, under H. R. 6587, be subjected to export restrictions.

H. R. 6587 does not, of course, put an outright ban on the export of all products restricted in the United States. The licensing procedure called for in Section 2 (3) however, presents a severe and unnecessary disadvantage for chemical exporters.

Also, in Section 2 (5) of the bill, there is authorization for an export ban on products already cleared for use in the United States by virtue of the fact that such products may be used as raw materials, intermediates or components of a banned product manufactured abroad. This interrelationship of chemical products would lead to an impossibly complex determination resulting in an export ban on hundreds of products, effectively reducing U. S. chemical exports by billions of dollars only to benefit foreign competitors.

The Secretary of Commerce is given discretionary authority to issue an export license if he and the head of the appropriate regulatory agency restricting the sale concur on the basis of the information supplied by the exporter. The exporter must show that the foreign government itself has requested that the product be exported; that he has fully informed the government and his customer of any U. S. restrictions on the product and the possible hazards posed by the product to the public health or environment; and that the potential benefits of the intended use of the product outweigh possible hazards.

Also, products subject to registration, licensing or use requirements must be subject to similar restrictions in the receiving country.

The Secretary's power to issue an export license is highly discretionary, meaning that even if all the conditions and requirements for export are met, a license might still be withheld. Obtaining approval from one Cabinet office is difficult enough; obtaining two such approvals might well be impossible. Even if such approvals are granted, valuable time and sales would be lost. Moreover, some export sales may not be attempted due to anticipation of delays and failure to achieve approvals. To get foreign governments to request export of such products means that a private business overseas will have to get permission before entering into transactions with U. S. companies. The U. S. exporter and agencies of the government may be required, as a condition of export, to reveal a great deal of confidential business information to foreign governments, including trade secrets, with no controls over how such information may be used and protected.

More importantly, because of the extensive U. S. effort within various international regulatory organizations, there is no need for a cumbersome and time-consuming domestic program such as proposed in H. R. 6587 which will merely be duplicative. For instance, the United States participates in the following international organizations which are presently establishing or already have established international controls over the import and export of chemical products: (1) Organization for Economic Cooperation and Development; (2) World Health Organization; (3) Food and Agricultural Organization; (4) Codex Alimentarius Commission; (5) United Nations Environment Programme; and (6) The Tri-Partite Pesticide Agreement between the United States, U.K. and Canada. Such organizations are establishing and/or have established, through multilateral negotiations, what possible chemical hazards exist and what measures can be effectively taken by the international community to regulate the hazards. The policy of H. R. 6587 to duplicate such programs and have the United States unilaterally decide what is hazardous for the rest of the world is not in keeping with sound international policy. The United States should not decide what chemicals other countries may use.

Moreover, with regard to the exporter being able to determine possible hazards overseas, it is instructive to review the Environmental Protection Agency's position as to having even it make such determinations. EPA Deputy Administrator Barbara Blum in her February 14, 1980 memorandum to the White House, objected to any requirement that EPA perform a risk assessment of the product and its possible adverse effects on the importing country. She points out that EPA is "not in a position to undertake evaluations of user or regulatory technologies abroad." She says that such risk assessments would require extensive data and expertise on the social and cultural conditions and regulatory capabilities in other countries that the EPA cannot obtain. We would agree with the EPA in this regard.

H. R. 6587 would permit the U. S. government to license an export if it determines that the foreign government has a regulatory scheme similar to that of the United States. Such an alternative is not, however, a means of resolving the problem. The difficulties noted by EPA will likely be surpassed only by the difficulty of trying to establish that a regulatory scheme under a form of government different from that of the United States is in fact similar. Such a requirement demonstrates again the bureaucratic inefficiency of the proposal.

H. R. 6587 envisions a new and complicated export license process which will assure a steady erosion of U.S. chemical exports. Total U. S. chemical exports were $17.3 billion in 1979, creating a chemical trade surplus of $9.8 billion. This large balance of trade will not continue if legislation like H. R. 6587 is enacted. It is critically important to help pay for imported oil and to reduce the overall U. S. trade balance deficit of $37 billion.

Congress would be creating a powerful export disincentive because the administrative burden alone would be enough to curtail severely the export of U. S. chemical products.

President Carter and a number of others in the Administration have stressed that we must eliminate export disincentives. It's true, of course, that we must not do this at the expense of health and safety of individuals either in the United States or abroad. However, this objective can be met more reasonably than by subjecting chemical exports to the very great administrative burden proposed in this legislation.

The proposed legislation seeks to eliminate the export of U. S. products which are available from manufacturing plants located overseas. If U. S. laws and regulations further restrict exports, increased production of these products abroad, and the loss of U. S. jobs are certain to result. Of the 10 largest chemical companies in the world, only three are U. S. firms. It seems clear that any reasonable economic analysis would result in this Subcommittee's rejecting the broad and vague wording in this legislation.

We are not in a position to comment in great detail on the Administration's proposed hazardous substances export policy because we have had its new draft for only a short period of time. In a matter of such importance, we believe that consultations between government and industry are very important. We hope that there will be a sharing of views and information as the Administration continues to refine its policy.

The export of tris-treated sleepwear is often given by proponents as the best example of the need for new legislation or administrative action. A new control system, it is said, would eliminate that and similar instances where hazardous products are sold to customers abroad who do not know of the hazard involved.

It seems clear that consideration by the Congress of H. R. 6587 and by the Administration of a proposed executive order have not fully considered the restrictive nature of the Toxic Substances Control Act and other environmental and health laws. These laws already include provisions regulating exports. When these provisions are understood, it will be apparent that there is no "gap" to fill and that a new layer of regulation would be totally unnecessary.

We believe that the legal authority of EPA to regulate the export of chemicals and pesticides is more than adequate. A new law is not necessary. H. R. 6587 would impose rigid procedures for the granting of export licenses with no real flexibility. Interpretation would then have to come through the courts rather than through administrative proceedings.

The chemical industry is sensitive to its responsibilities for the health and safety of the public. Great strides have been made in cleaning up the water and air and in testing new products for potential hazards. We would not recommend against this legislation if its provisions provided a reasonable solution to a still undefined problem.

APPENDIX 11

STATEMENT OF THE NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

June 20, 1980

The National Agricultural Chemicals Association (NACA) submits the following statement to the International Economic Policy and Trade Subcommittee of the Foreign Affairs Committee on H.R. 6587 which would amend the Export Administration Act of 1979 to restrict the export of goods which have been found to be hazardous to the public health. NACA is a nonprofit trade association representing manufacturers and formulators who produce and sell virtually all of the pest control chemicals used for agricultural production in the United States. A significant volume of the agricultural chemicals produced in this country are exported, to virtually every nation in the world.

The pesticide industry supports the position of the Chemical Manufacturers Association which opposes enactment of H.R. 6587. While we also share the concern of this Subcommittee for the public health and safety, we firmly believe that the exporting of pesticides and other chemical substances are already fully regulated under Section 17 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, and Section 12 of the Toxic Substances Control Act (TSCA), respectively. Our member companies are concerned that outdated reports and unsubstantiated claims against pesticides are being used to justify the placing of further restrictions on pesticide shipments to foreign purchasers who want, and need, these products for public health control and national food production in their countries.

The U.S. Congress should be fully informed about the facts concerning the exporting of pesticides, and the substantial harm which will result to the U.S. export program if the United States takes unilateral action to curtail overseas shipments. A highly competitive situation exists between U.S. manufacturers and foreign manufacturers. Therefore, any additional licensing procedures would definitely present a severe and unnecessary disadvantage to U.S. pesticide exporters. Unnecessary delays can result in the loss of business, or failure to meet the emergency that exists in the importing country. Notwithstanding these considerations, we are also concerned that all of the cited examples occurred before existing regulatory controls were established and that no recent situation has been identified.

Regulatory action against pesticides has become an emotional and political matter without the support of confirmed scientific facts. As a result, many chemical uses have been voluntarily withdrawn by companies without a final determination on the actual effect upon public health and safety. Nevertheless, the pesticide industry supports international efforts to fully review the use of pesticides in the world environment, and believes that unilateral U.S. action in any form is improper.

For these reasons, NACA opposes enactment of H.R. 6587, and any other proposal, such as the Administration's proposed export policy, which fails to define the problem, if in fact one exists at all. Our statement to the Office of Consumer Affairs more fully outlines our position and is attached as part of this statement.

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NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION
THE MADISON BUILDING
1155 Fifteenth Street, N.W., Washington, D. C. 20005
202 • 296-1585 Cable: NAGRCHEM

Dr. Jack D. Early
President

June 13, 1980

Mr. Ed Cohen
Deputy Director
Office of Consumer Affairs
Room 495
Old Executive Office Building
Washington, D. C. 20500

Dear Mr. Cohen:

The National Agricultural Chemicals Association (NACA) appreciates the opportunity to make a statement concerning the January 7, 1980 draft Report and the May 23, 1980 Memorandum of the Ad Hoc Working Group on a Hazardous Substances Export Policy (HSEP).

NACA is a nonprofit trade association representing manufacturers and formulators who produce and sell virtually all of the pest control chemicals used for agricultural production in the United States. Upwards of 40 percent of the agricultural chemicals produced in this country are exported, to virtually every nation in the world.

For reasons summarized below, NACA is obliged to express unqualified opposition to the present Administration proposal, or any proposal, to superimpose additional export controls on those existing under present law. This position is based upon considerations of adequate existing controls, economic disincentives and questionable legal authority. Therefore, we cannot comment on the specific provisions of the draft policy, and we want to make it clear that the agricultural pesticide industry does not sanction the approach suggested in the draft policy.

Adequate Existing Controls

Exports of pesticides and other chemical substances are already fully regulated under Section 17 of FIFRA and under Section 12 of TSCA, respectively. These statutes provide for adequate notification to foreign purchasers and importing countries about the regulatory status and hazardous properties of chemicals. The 1978 FIFRA amendments established a very specific mechanism

for exporter accountability, to which the industry has been responsive, even though implementing regulations have not been finalized.

Not only are pesticides closely regulated in the U.S., extensive laws and regulations are in place in many foreign countries. Similarly, international review bodies have been in existence for many years and have been effective in monitoring and evaluating the use of pesticides throughout the world. The World Health Organization (WHO) and the Food Agricultural Organization (FAO), for example, provide monitoring of pesticide residues, surveillance of pesticide use, and investigation of any potential adverse effects resulting from pesticide use. Also, many foreign countries are represented on the Codex Committee on Pesticide Residues where safety and residues attending the use of most of the important pesticides are thoroughly reviewed. The list of pesticides under review includes products that have been banned in the U.S., but which still have essential uses in other parts of the world. U.S. law requires EPA involvement with certain of these international forums. For example, EPA must notify all OECD member nations of any domestic pesticide suspension or cancellation. Finally, the State Department AID program precludes use of toxic or hazardous products in foreign projects subsidized by U.S. funds.

More importantly, no major incidents have been identified to justify the imposition of additional controls on pesticide exports. The three examples cited in the HSEP draft are out of date and off point. The Leptophos incident occurred over eight years ago when the EPA regulations and the state of the art of testing for neurotoxicological effects were in their early stages of development. The "case" against DDT has now been shown to have been based upon incomplete, incorrect and anecdotal information. Indeed, there is not now, nor was there ever, any demographic evidence that DDT is carcinogenic in humans. Furthermore, the little inferential evidence that exists is derived from effects of very large doses in mice. What is more, recent research has altered earlier assumptions by refuting the persistence, biomagnification and adverse environmental effects of DDT. The WHO estimates on the number of pesticide poisonings each year were prepared in 1972 on data from the 1960's, and have no basis for extrapolation under the present regulatory scheme.

Economic Disincentives

Last February the President made a statement to the effect that trade disincentives were placing American industry at a severe disadvantage and giving a relative advantage to foreign exporters.

We agree with this statement. We also construe the HSEP export policy proposal as typifying the kinds of disincentives of which the President spoke.

The range of substances contemplated by current law is broad and diverse, as are the hazards and problems associated with their sale and use. As a result, Congress quite properly developed differing regulatory and export policies to meet the problems posed by these goods. Imposition of a new, blanket policy on top of existing laws and regulations constitutes a potentially sweeping and harmful change in national policy.

Certain of our more specific concerns in this area are summarized below:

1. An inventory of chemicals is tantamount to a blacklist with customers, and results in all the attendant downside effects.

2. Embroiling chemical exports in another layer of red tape will further complicate the now serious logistical problems involved in transferring pesticides from point of origin to point of use. Foreign language requirements, letters of credit deadlines, cargo space and warehousing needs contribute to this problem.

3. Pesticide sales to meet agricultural demands are highly seasonal, and shipments cannot be delayed. In other non-agricultural cases, such as a malaria or typhus outbreak, shipments are on a crisis basis. Timing is critical and bureaucratic delays in approving export could result in extensive crop losses, or human illness. As a result, foreign purchasers will turn to sources outside the U.S. who are more than willing to capture the business.

4. Existing law provides domestic manufacturers with a modicum of protection from government disclosure of their data to foreign manufacturers. The HSEP draft would undercut this protection and set the stage for piracy of American data by foreign producers who are in direct competition with American producers. We do not oppose data disclosure, provided restraint is exercised by the U.S. Government and some control can be maintained by the owner of the data.

For these reasons, the HSEP draft is in conflict with U.S. interests and will harm the international trade program.

Questionable Legal Authority

There are strong reservations within government and the private sector that the Export Administration Act (EAA) does not authorize regulation of hazardous exports. We are aware of two opinions from the Justice Department on the old EAA and its 1979 revision which state that the foreign policy language is broad enough to encompass the proposed action. However, in one of these opinions the Justice Department enters a significant caveat about existing laws:

> "Certain statutes presently impose conditions on the export of hazardous substances (e.g., the Toxic Substances Control Act), requiring notice to the recipient nation of product risks. It may be that these statutes foreclose Presidential discretion to take some actions, for example, banning a product that a statute allows to be exported if notice is given." (Opinion dated April 11, 1980 from Leon Ulman to Esther Peterson.)

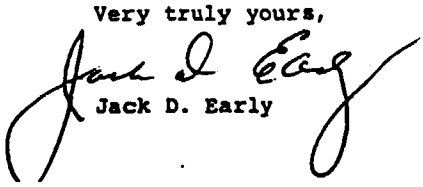
Moreover, neither act has been used for the purpose of regulating export of hazardous substances, and, indeed, the latest amendment was designed by Congress to reduce the amount of discretion of the Commerce Department and the President in withholding export licenses. The language of the statute appears rather to support the notion that the EAA is intended to be used as a punitive device, against countries like South Africa.

Conclusion

For the foregoing reasons, NACA must oppose the HSEP proposal. We are willing to meet with you at any time, however, to provide details concerning our position.

We seriously urge you to reconsider the HSEP proposal and the adverse implications on U.S. trade for which the President would be made responsible. This policy will jeopardize the availability of various essential vector control insecticides abroad, and it quite simply reflects an emotional attitude that neglects many considerations of balance or relative values. Existing pesticide controls are adequate and have not resulted in any present-day incident to justify a change in policy. U.S. interests would be better served by considering the public health and agricultural needs of literally millions of people in lesser developed countries.

Very truly yours,



Jack D. Early

JDE:etb

APPENDIX 12

LETTER DATED JULY 8, 1980, FROM LAWRENCE W. BIERLEIN, ATTORNEY, WASHINGTON, D.C.

Mr. Vic Johnson
House Foreign Affairs Committee
House of Representatives
Washington, DC 20515

Dear Mr. Johnson:

I have recently reviewed H.R. 6587, a bill "To amend the Export Administration Act of 1979 to restrict the export of goods which have been found hazardous to the public health." As drafted, the scope of coverage of the bill is extremely broad and, I believe, broader than intended by the drafters.

The list of statutes in Sec. 2(6) is all-inclusive. Most of those statutes do not involve registration or licensing but, rather, limitations on packaging and labeling for every consumer product, including cosmetics and pharmaceuticals. Aerosol cans, for example, are required to be labeled with a warning that the user should not puncture or incinerate the can.

Sec. 2(2) of the bill covers goods that are subject to registration, licensing, "or use requirements or similar restrictions." As we discussed, the precautionary label to not incinerate or puncture the aerosol can would bring this statute into play, requiring a license to export the can or a finding that the receiving country imposed "requirements or restrictions comparable" to those imposed in the U.S.

Among other things, an export license would require a request from the receiving country that the product be exported to them. In any country where the U.S. product would compete with the products of that country, there is a natural political and economic incentive on that part of the receiving country to withhold a request for the U.S. goods, or to delay such a request indefinitely. An economic disruption in U.S. exports through the provision of a handy nontariff barrier to trade certainly was not the intent of the drafters of H.R. 6587, but this result is inescapable.

The alternative to licensing for some products is a U.S. finding that the receiving country restricts products in a similar fashion. By the wording of this paragraph, such restrictions would have to be legally imposed by a third party and could not be voluntarily self-imposed by the manufacturer. In other words, a manufacturer who chose to give the warning against puncture and incineration on the can in the language of the receiving country would not satisfy this requirement. The restriction would have to be imposed on him by the receiving country.

In short, the bill as drafted as a minimum has the following shortcomings:

1. It is unduly broad, covering far more U.S. requirements than are necessary.

2. It is unduly vague, leaving the reader to guess what "use requirements or similar restrictions" may be, or what "comparable" foreign requirements or restrictions are.

3. The requirement that the foreign government request that the product be exported provides a natural opening for nontariff barriers to U.S. trade which would be difficult if not impossible to surmount.

4. The breadth of coverage will require the establishment of yet another bureaucracy to administer the statute, without necessarily achieving the basic expressed goal of curtailing the "dumping" of dangerous goods overseas.

Please let me know if you have any questions on my letter.

Very truly yours,

Lawrence W. Bierlein

APPENDIX 13

LETTER DATED SEPTEMBER 18, 1980, FROM MARK SILBERGELD, DIRECTOR, AND SHARON L. NELSON, LEGISLATIVE COUNSEL, CONSUMERS UNION

Honorable Jonathan B. Bingham, Chairman
Subcommittee on International Economic Policy
and Trade
House Annex # 1
Room 707
Washington, D.C. 20515

Dear Mr. Chairman:

As part of our effort to further a federal policy that will control the export of hazardous substances that have been banned or restricted in the United States, we have outlined below for the Subcommittee's record our comments on the Fifth Draft Report of the Interagency Working Group on a Hazardous Substances Export Policy.

The fundamental problem with the Working Group's proposal is that it does not presume what is unsafe for American consumers to be equally unsafe for foreign consumers. Consumers Union believes that such a presumption is essential for a responsible and effective U.S. policy on the export of hazardous products. The Working Group's policy relies upon hazard notification under existing laws that do not consistently require affirmative acknowledgement of warnings. It does little to insure that importing nations will give informed consent to the receipt of hazardous goods produced by U.S. manufacturers who cannot sell those goods at home. Furthermore, as H.R. 6587, now before your subcommittee, provides, the burden of overcoming the presumption that hazardous products are not exportable should fall on the U.S. exporters, rather than on the importing nations or the U.S. government.

Hazard Notification

The Working Group concluded that "in most circumstances the international responsibilities of the United States could be met by an effective hazard notification system." Their report states that this can best be accomplished by means of the notification procedures already in effect under existing laws, but recommends greater uniformity among agencies in their

notice requirements. A further recommendation is that notification be centralized, with the State Department taking responsibility for informing foreign governments of impending hazardous exports. This scheme would allow the export of banned and restricted products after the State Department had notified the importing country of the risks associated with the products.

Mere notification of the sort envisioned by the Working Group is not adequate to protect foreign consumers of American-made hazardous products. U.S. export policy should require informed consent of, not mere acquiescence by, an importing country. Under existing laws, hazard notification is not always required in advance of shipment, but only at the time the goods are shipped. Furthermore, a response from the foreign government would be necessary, according to the Working Group proposal, only if it is required under current regulatory schemes.

We believe U.S. export policy should require that hazard notification be followed by an affirmative response to the effect that the importing country has received a notice of the fact and risks of non-conformity of the goods with U.S. regulations and, nevertheless, desires to permit import. Such warnings should be issued prior to the shipment of hazardous products, in order to insure that the importing nation has had an opportunity to consider the potential consequences of allowing such an import.*

Although the exporter should bear the burden of notification, the federal government should assure that the notice is adequate. To meet both of these objectives with a minimum of delay in the proposed transaction, we recommend the following procedure in place of the one proposed by the Fifth Draft.

The exporter should be responsible for (a) identifying the respects in which the product intended for export does not meet applicable domestic regulations, (b) determining that the State Department considers the notice to be adequate,** (c) providing notice to the importing nation and (d) providing the State

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* Repeat advance notice, where multiple shipments or subsequent, identical transactions are involved, should not be required, however, if the consenting foreign government indicates that it contemplates such transactions by the exporter.

** The Department may, in turn, rely upon the appropriate regulatory agency in making this determination.

Department with a copy of this notice. The State Department should be responsible for (a) coordinating federal agency response to importer inquiries regarding the adequacy of notices intended to be sent to proposed importing governments, (b) receiving the foreign nation's formal response to request for approval, (c) notifying the exporter of that response and the Department's action regarding export approval or denial.

This procedure will reduce delay in transmitting requests for approval to intended importing governments by permitting the exporter to send them directly, rather than through the State Department, while keeping the Department informed of all requests. This expedition should be especially significant where the form of notice regarding a particular product already has been approved in a previous transaction and all that is required to initiate the export approval process is notice to the intended importing government. At the same time, the provision for State Department receipt of the official notification of action on the request would permit the Department to hold up export in any instance where notice is deemed to be inadequate. By permitting the notification and State Department approval processes to proceed simultaneously, there is the potential for substantial time savings in non-routine transactions.

We also believe that the ability of exporters to develop quickly approvable notices could be assisted substantially by State Department development and publication of guidelines as to what information is expected to be included in notices. In this respect, we note that the information that the Fifth Draft would require exporters to submit is incomplete. In addition to the items the Draft specifies to be submitted,* exporters should be required to submit a statement of the specific ways in which the product does not meet the U.S. regulatory standards and the risks associated with the nonconformance with U.S. standards.

This information is essential when the product that is "banned" cannot be sold in the U.S., not for the reason that no product of its kind can be sold here but, rather, because the proposed export version of the product will not comply with an applicable design or performance standard or labeling requirement or a portion thereof. Mere notification to the foreign government regarding the general standard not met will not permit an assessment of the risk to foreign consumers if the article for export deviates from a standard or labeling requirement only in some respects, especially where the standard is designed to avert multiple risks.

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* The Draft calls for submittal of (a) the name of the hazardous substance to be exported, (b) a concise summary of the agency regulations regarding the substance (including the statutory authority for such actions and a timetable for any future actions that are planned), and (c) a concise summary of the potential risks to human health or safety or the environment that are the grounds for the regulatory actions.

Export Controls

The Fifth Draft Report notes that there is a small number of particularly hazardous products for which notification is insufficient. For these substances, foreign policy export controls under the Export Administration Act are proposed. Extremely hazardous products, to be placed on a commodity control list by the Departments of State and Commerce after consultation with an interagency task force, could not be exported without the State Department's issuance of a validated export license.

After an exporter applied for an export license, the State Department would inform the foreign country of the nature and quantity of the product to be exported, the U.S. regulatory action prohibiting or restricting its domestic use, and the potential risks involved. As is the case with less hazardous products, a product could be exported if no objections were received from the foreign country. However, there is a large area of U.S. discretion as to the export of controlled commodities. If the proposed export were found to be detrimental to U.S. foreign policy, the U.S. would prohibit export even though a foreign government might want the goods.

This section of the Working Group report does, as we recommend, rest on a presumption against exporting hazardous goods. However, export is not, but should be, required to depend upon the foreign government's affirmative consent. Mere failure to object should not be assumed to constitute approval by a foreign country.

We support the approach suggested by the Working Group for evaluation of export license applications. They advocate a cost-benefit analysis, but specify that it need not necessarily be a rigorous, quantitative analysis. This would allow the evaluation to take into account the social, economic, and environmental conditions in specific foreign markets which may be significantly different from those in the U.S. and which, consequently, may justify the sale of a product which is banned or restricted in the U.S. It also would avoid any "numbers game" usage of benefit/cost techniques where facts are not quantifiable or data are unknown or unreliable.

When a domestic regulatory agency has banned or restricted a product, there will ordinarily be a lag time before a decision is made regarding its placement on the commodity control list. The presumption should be that such products will be placed on the commodity control list and, therefore, exports should be banned until a formal decision is reached. The interagency task force which will create the commodity control list should be required to monitor closely federal

regulatory activities, so that the export control decision can be made as soon as possible after, if not simultaneously with, the domestic regulatory actions.

Scope of Export Controls

The Fifth Draft Report excludes from consideration for export controls two classes of products which should be subject to controls: unregistered pesticides and medicines.

The Working Group concluded that pesticides for which registration had never been sought - of which there are approximately 25 currently being manufactured solely for export - would not be considered for export controls since there would be no readily available health and safety test data drawn from agency proceedings. However, pesticides for which a tolerance has been denied or revoked would be candidates for export controls because data from regulatory proceedings would be available.

The Working Group points out, correctly, that a pesticide may be unregistered only because there is no need for the substance in this country, not necessarily because it poses unreasonable risks. Nevertheless, that is not necessarily the case. The presumption should be against the export of such unregistered pesticides. The presumption that what we don't know can't hurt the rest of the world would be highly irresponsible. If a private company wishes to export such an unregistered pesticide, it should bear the burden of coming forward with evidence on the substance's effect on human health and the environment.

Public Participation

The only provision for public participation made by the Working Group is that comments will be accepted by the Commerce Department on proposed regulations governing its consideration of export license applications. There should be much greater opportunity for public comment and participation in the control of hazardous exports, not only in determining which products are to be placed on the commodity control list, but also in the evaluations of individual export licenses. Public participation is the only way to insure that the decision-making bodies will receive all of the information - both favorable and unfavorable to exports - necessary for a balanced decision. Furthermore, the bases of the State and Commerce Departments' decisions regarding the commodity control list and individual export licenses should be available to the public, so that such decisions can be the subject of review.

Labeling of Hazardous Exports

The Working Group calls for simplified and more understandable labeling of hazardous exports. However, its suggestion that regulatory agencies might want to consider more stringent labeling requirements does not go far enough. All hazardous exports should be required to contain labels to the effect that the products are not permitted to be sold in the U.S. or that they do not meet the requirements for sale in the U.S. This will enable foreign consumers and private organizations to identify differences in the degree of protection afforded American and foreign consumers. Hazard warnings and instructions for safe and proper use of products should be aimed at the individual foreign consumer. They should be in a readily understandable language, use common words, and should be designed with a cognizance of the level of literacy in the importing country.

Annual Summary

The Working Group's suggestion that the U.S. publish each year a summary of the proposed and final regulatory actions taken by domestic federal agencies is excellent. Such a report would be a way of informing all countries regarding implementation of U.S. hazardous substances export policy. Furthermore, it would help importing countries to find information more easily and to get U.S. assistance, if they desire it, in evaluating the risks of various products. The inclusion of OSHA standards and similar regulations that might be of interest to foreign countries is also encouraged.

The Working Group declares that, in its own dealings in hazardous exports, the United States government should maintain the highest standards of good judgment and scrupulous care for the health and welfare of foreign citizens and their environment. Government assessment of its own export programs should include consideration of the hazards of products, such as infant formula or birth control devices, which may be quite safe in the U.S. but would be potentially hazardous in non-sterile conditions. The annual report would also be a good place to include warnings to foreign governments of problems that have been encountered in the use of such products. Although the U.S. may not prohibit all export of a product such as infant formula, the U.S. can adopt a policy which maximizes the information available to importing countries, so they can initiate their own controls.

International Efforts

Finally, we agree with the Working Group's emphasis on U.S. participation in international activities to control the use of hazardous substances. No U.S. policy on hazardous products can be truly successful until there is a common international effort to deal with these problems.

We hope these comments are of use to you and to the Subcommittee in evaluating the Fifth Draft Report. Please let us know if we can be of further assistance.

Sincerely,

Mark Silbergeld
Director

Sharon L. Nelson
Legislative Counsel
Washington Office

cc: Representative Michael D. Barnes
Esther Peterson

APPENDIX 14

Letter Dated September 26, 1980, From Leonard Marks, Jr., Executive Vice President, Castle & Cooke, Inc.

Honorable Jonathan Bingham, Chairman
Subcommittee on International
Economic Policy & Trade
Committee on Foreign Affairs
U.S. House of Representatives
Washington, D.C.

Dear Mr. Chairman:

On September 9, 1980, your Committee received the testimony of Ms. Angela Glover Blackwell representing Public Advocates, Inc. of San Francisco, California. Ms. Blackwell's testimony was made in reference to "Immediate Executive Action to Halt the Export from the United States of Hazardous Goods, Drugs, Pesticides, Technology, Facilities and Waste." In the course of her testimony, specifically in the discussion on pages 28 through 30, Ms. Blackwell made reference to alleged actions by Castle & Cooke, Inc. to support her position. Because of this reference, and because the allegations are both inaccurate and not supportable in fact, I would, on behalf of Castle & Cooke, Inc. like to take this opportunity to comment on the statement and respectfully request that this letter be made part of the Committee's record.

Castle & Cooke, Inc. is primarily engaged in the world-wide production, processing, distribution and marketing of high-quality food products. Overseas food production facilities are located in the Latin American countries of Brazil, Colombia, Costa Rica, Ecuador, Honduras, Nicaragua and Surinam, as well as Puerto Rico, and the Asian nations of the Philippines, Thailand and South Korea. Our primary food products produced abroad are bananas, and pineapples plus some citrus and coconuts as well as seafood.

In her testimony, Ms. Blackwell made the sweeping statement, unsupported by data, that DBCP (1-2 Dibromo-3-Chloropropane) "has been used indiscriminately in third world countries" (page 28) and that "workers in the fields labor without any protection" (page 30). While I can speak only for Castle & Cooke, Inc., I wish to assure the Committee that Castle & Cooke, Inc. recognizes the potential hazards involved in the use of

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pesticides in agricultural production and that all practical measures are taken, wherever our crops are grown, to insure judicious use and application only where necessary. To this end, Castle & Cooke, Inc. has adopted a corporate policy (attached hereto as Exhibit I) which reflects its continuing commitment to provide a safe working environment for its employees.

At Page 30 of her testimony, Ms. Blackwell stated that after the November, 1979 ban, "large plantations such as those of Castle & Cook (sic), one of the largest foreign corporate landholders in Central America, simply purchased its DBCP through a local importer to buffer themselves from American regulations."

It should be noted that much of the acreage Castle & Cooke, Inc. uses for agricultural production is land which is owned by nationals of the host country in which that land is located and food products are purchased through grower agreements; for example, 100% of the Company's banana production in Nicaragua comes from independent growers. As to the question of local purchases of DBCP to "buffer itself from American regulations", after the Environmental Protection Agency banned the use of the product in the United States, Castle & Cooke, Inc. cancelled existing purchase contracts and has not purchased DBCP from any source since that time. Existing inventory was utilized with final application in early 1980. Since then DBCP has not been used on any bananas produced on Company owned land. Furthermore, all nationals producing bananas under purchase contract to Castle & Cooke were informed that Castle & Cooke would no longer supply the chemical nor buy bananas treated with it. It is Castle & Cooke's corporate policy that we will not use nor purchase product treated with any pesticide which is not specifically registered for that use by the U.S. Environmental Protection Agency.

The 1979 EPA suspension of the use of DBCP on many products, including bananas, specifically permitted its continued use on pineapple under conditions of specified and stringent worker protection. Castle & Cooke, Inc. continues to use DBCP in Hawaii and Honduras under this restricted use permit. The product is not used in the Philippines or in Thailand.

Ms. Blackwell also stated (page 30) that "... (DBCP) remains on the bananas, coffee, tea and pineapples, that eventually find their way to the dining tables in the United States". Castle & Cooke does not grow nor does it import coffee or tea; but more importantly the implication that a hazardous residue exists in the food imports is untrue. For example, during the 1979 Environmental Protection Agency's suspension hearings, considerable testimony was offered to prove that no detectable DBCP residues occurred in Hawaiian pineapples (Pineapple Growers of Hawaii, Exhibits 3 and 5).

Mr. Chairman, Castle & Cooke, Inc. recognizes the critical importance of the issue now before your Committee. We trust that this statement will be called to the attention of your colleagues to correct any misimpression and to aid in the Committee's work by providing a more factual basis from which the Committee can develop its legislative recommendations. Moreover, we believe it is critically important to correct such widely distributed and quoted sources as the Congressional Record. Our experience has been that unless there is prompt and clear correction of factual errors, gross exaggerations and/or misrepresentations, the misinformation is given an aura of respectability and credibility and then broadly used to discredit the free enterprise system in general and this Company in particular.

Thank you.

Sincerely,

Leonard Marks Jr.

Leonard Marks Jr.
Executive Vice President

EXHIBIT I

CASTLE & COOKE, INC.

TOXIC AND HAZARDOUS SUBSTANCES POLICY

FORWARD

Insecticides, herbicides, fungicides, nematocides are an indispensable part of commercial agricultural protection throughout the world. Chemicals and other materials or substances are also an indispensable part of agricultural production in manufacturing operations. Although many of these substances may be hazardous or toxic to man and animals if treated in a negligent manner, they can be safely used if all precautions are observed and all uses are conducted in compliance with instructions accompanying the product. All hazardous materials in standard product applications have been approved by government and regulatory agencies for general or specific use according to such instructions.

I.

TOXIC AND HAZARDOUS SUBSTANCES POLICY

It is the policy of the Company to provide to its employees a place of employment which is free from recognized hazards which are likely to cause serious or fatal physical injury from toxic or hazardous substances, by:

(1) Complying with all requirements of law,

(2) Following all manufacturers instructions with respect to the use, application and disposal of the same,

(3) Exercising prudent and reasonable care in safety and health matters related to toxic substances; each employee has the duty to comply with the safety and health laws which are applicable to his actions and conduct on the job.

II.

Materials, chemicals, equipment, pesticides and our agricultural and manufacturing practices are reviewed and analyzed in the conduct of our operations to determine whether there may be any resulting toxic or hazardous effects upon our employees and their work environment.

Selection for use and determination of the manner of use is made only after careful consideration and assessment of the risks assumed by the Company and its employees, and whether the substance or article can be safely used without injury to our employees in their work environment.

Standards and procedures are established and followed for handling and use of each toxic or hazardous substance which may subject any employee to any risk of fatal or serious injury. Employees involved are trained, advised and supervised with respect to the proper handling, use, storage, application, and dispoal of the same, and provided with appropriate safety equipment to prevent any risk of fatal or serious injury. Employees are instructed to comply with rules issued by the Company with respect to the safe handling and use of such substances.

The Company routinely monitors the results and effectiveness of its programs for the safe handling and use of toxic and hazardous substances to determine compliance with this policy.

The Company regularly reviews and compiles information published by government regulatory agencies, health organizations, and manufacturers of toxic and hazardous substances to insure that its assessments, determinations, and programs are based on reliable, up-to-date information, data, and analyses, and comply with all requirements of law.

The efforts of the Company under this policy are guided and coordinated by a committee composed of representatives from the medical, agricultural, production divisions, purchasing, research, law, personnel, safety, quality control, and regulatory-compliance staffs of the Company.

APPENDIX 15

LETTER DATED SEPTEMBER 19, 1980, FROM FRANCES E. NEELY, LEGISLATIVE SECRETARY, FRIENDS COMMITTEE ON NATIONAL LEGISLATION

Rep. Jonathan Bingham
Chairman, House Foreign Affairs Subcommittee
on International Economic Policy and Trade
707 House Office Building, Annex 1
Washington, D.C. 20515

Dear Rep. Bingham:

The Friends Committee on National Legislation applauds your subcommittee's interest in developing a national policy on the export of hazardous substances.

We support the recommendation of the Interagency Working Group for continued U.S. participation in international efforts and for increased activity by the UNEP Committee on Toxic Chemicals and the WHO International Program on Chemical Safety.

We share the Group's concern that U.S. economic development programs and other official activities "maintain scrupulous care for the health and welfare of foreign citizens and their environment." We regret that the Group's proposals covering private commercial shipments are much less forthright. Could they have been unduly influenced by economic considerations?

We do not believe that perfecting and standardizing notification procedures will enable the United States to meet its international responsibilities "in most circumstances." Those responsibilities are heavy because the substances under consideration either can't be used in the United States, or their use in this country is "significantly restricted."

It is begging the issue to imply that potential dangers will be mitigated if more health-and-safety-technical-assistance is targeted to countries that are increasing importation and use of chemicals.

Requiring export licenses for a "relatively few" substances which are "particularly hazardous" would create many difficulties. It would involve U.S. officials in numerous unilateral definitional exercises and judgments which they have no right to make, such as "the number of people potentially affected by the hazard" and the "benefits" to be gained by the export.

Ralph Rudd
Clerk, General Committee
Ralph Rose
Clerk, Executive Committee
E. Raymond Wilson
Executive Sec. Emeritus
Edward F. Snyder
Executive Secretary
Frances E. Neely
Legislative Secretary
Don Reeves
Legislative Secretary
George I. Bliss
Field Secretary
Nick Block
Administrative Secretary
Evelyn W. Bradshaw
Administrative Assistant

We Americans know from experience how difficult it is to assess dangers, how farcical is the concept of "informed choice", how carelessly our society handles chemicals, despite U.S. technical prowess, and what human agony and environmental damage can result. Those who live in the Washington metropolitan area are still haunted by the Hopewell, Virginia, disaster--where workers in a plant producing Kepone (largely for export) suffered serious health impairments, the James River was desecrated, and watermen lost part of their livelihoods.

Is it possible that the Interagency Group was inhibited by tying its recommendations to existing legislation, including the President's authority to restrict exports for foreign policy reasons? The Export Administration Act is not an appropriate vehicle.

Rep. Barnes' bill is stronger, but it is also tied to the Export Administration Act.

The Friends Committee urges this Subcommittee to draft comprehensive humanitarian-oriented legislation which would prohibit:

*Exporting substances whose use is banned in the United States
*Exporting hazardous wastes, and
*Exporting hazardous production facilities or providing direct or indirect financial assistance for those facilities through such institutions as the Export-Import Bank and the Overseas Private Investment Corporation

The legislation should also prohibit:

*Exporting substances whose use is "significantly restricted" in the United States, unless or until such export is approved by a representative committee from the UNEP, the WHO and the ILO.
*Production of hazardous substances for "export only" should be ended, unless and until that production has been approved by the same committee from the UNEP, the WHO and the ILO.

We appreciate the opportunity to comment on the Interagency Draft Report. Would you please include this letter in the printed record of your hearings.

Thank you.

Sincerely,

Frances E. Neely

FEN/gpj

APPENDIX 16

LETTER DATED SEPTEMBER 17, 1980, FROM J. M. GILL, SENIOR VICE PRESIDENT, ETHYL CORP.

The Honorable Jonathan B. Bingham
Chairman, Subcommittee on International
Economic Policy and Trade
United States House of Representatives
707 House Office Building, Annex No. 1
Washington, D.C. 20515

Dear Mr. Bingham:

The Administration's proposed Hazardous Substance Export Policy (HSEP) that was presented by Mrs. Peterson and Dr. Harris at the September 9, 1980 hearing raises questions of serious concern to us. We have prepared some comments about our concern and opposition to the proposed HSEP. They have been forwarded to the Interagency Working Group.

It is our understanding that the Subcommittee record from the September 9th hearing is open for comments until the 19th of September; therefore, we respectfully request that the copy of our comments to the Interagency Working Group which accompanies this letter be entered on the record. The comments basically oppose the proposed policy, but indicate that we could support certain regularization in notification procedures subject to the stipulations outlined in our comments.

Thank you for the opportunity the Subcommittee has provided to the public for commenting on a proposed Administration policy that is most important to the domestic chemical industry and that we consider a potentially significant export disincentive.

Sincerely,

J. M. Gill

J. M. Gill
Senior Vice President

Enclosure

Interagency Working Group on a
Hazardous Substances Export Policy,
c/o Esther Peterson, Special Assistant
to the President for Consumer Affairs
495 Old Executive Office Building
Washington, D.C. 20500

Dear Mrs. Peterson:

Pursuant to the draft report published in the Federal Register (45FR 53754) of August 12, 1980 welcoming comments on the report, Ethyl Corporation submits herewith comments which we urge you to consider prior to the preparation of a final report. Ethyl's position is basically one of support for certain notification procedural changes, and opposition to the imposition of any futher export controls on certain substances.

Ethyl support the establishment of a more uniform notification process if a notification is now required by current statute prior to the exportation of certain substances and, providing that:

-- the required notification is consistent with the applicable notification statute;

-- the notification procedure does not delay export transactions;

-- the Administration considers the economic impact on domestic industries of any new notification procedures;

-- any documents or information furnished to foreign governments pursuant to any new notification procedures do not include "business confidential" data protected by statute and that the consent of the manufacturer be obtained before any such data is provided to a foreign government;

-- the Annual Summary in Section V.B.(2) is restricted to final regulatory actions and does not include prospective regulatory actions as outlined in Section V.B.(2)(b) or the additional information outlined in Section V.B.(2)(c); and

— proposed notification procedures, including the forms to be utilized and the expected contents of annual summaries, are published for public comment.

Ethyl opposes any proposal to impose new export controls on certain substances pursuant to provisions in the Export Administration Act of 1979 (EAA). Reasons for opposing the imposition of new export controls include the following items and concerns.

1) We do not believe that it was the intent of Congress nor does any provision in the EAA specifically authorize the actions proposed by the draft report concerning the imposition of new export controls on certain substances.

2) Even if it may be determined that legal authority exists to impose export controls under the EAA, we do not believe the ramifications and impact of the applicability to other countries has been considered. Clearly this could be potentially quite harmful to U.S. trade policy.

3) The report does not contain the regulatory analysis and economic impact study required by Executive Order 12044.

4) If other alternatives to the proposed policy were considered, a description of those alternatives is not provided in the draft report.

5) The proposed policy would be a new export disincentive and one that is basically unilateral on the part of the U.S. There is no indication what international cooperation is promised or even expected.

6) Recommendations concerning new labeling requirements and legislation that may be required to impose such requirements conflict with current international efforts to establish an acceptable international code.

7) Requiring validated export licenses for certain substances would delay exports and no doubt cause domestic industries to lose sales. Any alternatives should be something less stringent than shipment-by-shipment validated export licenses.

8) The proposed policy does not definitively identify the substances that agencies will have under their jurisdiction. The scope is potentially too broad to make a meaningful analysis for the purpose of comments. Until a list of the current substances to which the proposed policy would apply is published for public comment, constructive comments cannot be effectively made.

9) The proposed policy does not provide procedures concerning how new substances could be added to the list to which the policy is intended to apply.

10) No specific appeal procedure appears evident for the public to protest an item that is to be placed on the Commodity Control List.

We firmly believe that adequate statutes governing exports of hazardous substances and export notification requirements currently provided for in these statutes already exist to maintain full foreign confidence in American-made products. Further regulations are not required. An alternative would be an appropriate communication from the Administration to applicable agencies that charges them with following current regulations and statutes.

Ethyl Corporation respectfully requests that you not issue new policies or an executive order that requires new regulations to be issued that would impose the export control procedures outlined in the draft report.

Sincerely,

J. M. Gill

J. M. Gill
Senior Vice President

APPENDIX 17

Letter Dated June 9, 1980, From David N. Bull, Oxfam, Oxford, England

Congressman Jonathan B. Bingham (D-NY)
Chairman
Sub Committee on International Economic Policy & Trade
Room 707 HOB Annex No. 1
U.S. House of Representative
Washington DC 20515
USA.

9th June, 1980.

Dear Congressman Bingham,

I am writing to you in connection with your discussions concerning the export of potentially hazardous products. Oxfam is an international voluntary, non-governmental organisation concerned with poverty and development in the developing countries. As such we take a particular interest in the fields of health and agriculture, which constitute a major part of the 1,000 plus projects in 76 countries; to which Oxfam contributes funds totalling $15 million a year.

Our work with the poor, particularly in the fields of health and agriculture, have led us to be concerned about the impact of western goods and technologies on the very poor. In this context we have recently begun to carry out research on the effects of western exports, particularly of medicines and pesticides. This is a complex field involving many interrelated issues. The potential harm resulting from chemicals considered so dangerous as to require legal restriction or prohibition in the country of origin is one of the most important of these issues. Others include the effects of high-priced branded drugs on the allocation of developing countries' scarce health resources, and health and food problems associated with resistance to pesticides.

The export of goods to developing countries, which have been banned or restricted in the country of origin, puts at risk the health and livelihood of poor people. We therefore welcome the attempt to regulate such exports. While our research is as yet still in its early stages and our knowledge of U.S. law is far from complete, it is our belief that the provisions proposed in the bill put forward by Congressman Barnes are a sensible and balanced attempt to alleviate an important problem. Whilst the regulation of the export of banned or restricted goods is unlikely to remove all the problems associated with the sale and use of drugs and pesticides in developing countries, such regulation does represent a moderate and necessary step in this direction.

Oxfam's concern is with the health and well-being of the poor in developing countries. Many of these countries do not have legislation to protect their citizens from the effects of hazardous goods, neither do they have the expertise or ability to devise or enforce such legislation, nor the health care services necessary to prevent and treat the effects of such goods. We believe therefore that the governments of exporting countries should restrict exports of hazardous goods.

Yours sincerely,

David N. Bull.

APPENDIX 18

LETTER DATED JULY 22, 1980, FROM A. A. ABBAS, EMBASSY OF NIGERIA

Congressman J. B. Bingham
C/O House Foreign Affairs Committee
House of Representatives
Washington DC 20515

Honourable Bingham,

The Natural Resources Defence Council Inc., of Washington DC have, on May 30, 1980 intimated the Government of the Federal Republic of Nigeria, through the latter's Ministry of Housing and Environment, that on June 5th, 1980, the Subcommittee on International Economic Policy and Trade of the House Foreign Affairs Committee will begin hearings on the serious problem of exports of banned products, primarily, to consider an important bill introduced by Congressman Michael Barnes (D.Md.), which would restrict the export of products from the U.S which have been found to be hazardous to the public health and are prohibited from use in the United States.

2. In response to such an information, the Federal Ministry of Housing and Environment reiterated its disappontment and concern at the attempts being made by some U.S companies to export to the West Coast of Africa products from the United States which have been found to be hazardous to the public health and are banned in the U.S.

3. Consequently, the Federal Ministry of Housing and Environment has this to say in respect of Congressman Michael Barnes' initiative:

> "This Ministry supports the move being discussed by the U.S Government.....to ban the exports of products (from U.S which have been found to be hazardous to the public health and are prohibited from use in the U.S), particularly with reference to Nigeria."

4. I regret to point out that the Federal Ministry of Housing and Environment's response came very much belated. However, the response is intended to reaffirm Nigeria's stance on the issue.

Yours Sincerely,

A. A. Abbas
for Ambassador

APPENDIX 19

LETTER DATED JULY 4, 1980, FROM THE INDONESIAN CONSUMERS ORGANIZATION

YAYASAN LEMBAGA KONSUMEN,
Jakarta, July 4, 1980.

Re Request from Natural Resources Defense Council, Inc.

Congressman JONATHAN B. BINGHAM,
Chairman, Subcommittee on International Economic Policy and Trade, U.S. House of Representatives, Washington, D.C.

In the letter written to us by the Natural Resources Defence Council, Inc. of May 30, 1980 the Indonesian Consumers Organization (YLK) is invited to submit views and suggestions on the problem of hazardous products which will be discussed at the Senate hearings.

We are honored to have this opportunity, unfortunately this letter was delivered after the intended deadline of June 10th.

However, we would like to express our views on this particular subject because Indonesia is one of the nations being flooded with these kind of banned products. We are especially concerned because it relates to the products banned by FDA and the U.S. Government such as DDT, depoprovera, MSG, certain medicines, but known dumped in Indonesia. We think this is an offense to the consumers health and safety the more so because Indonesia is not in a position to protect or even reject the flow of these hazardous products.

In this case of absence of laws or regulations concerning the imports and marketing of these goods it is expected that Governments of developed countries bear the burden of legal prevention.

The YLK is trying to have more elaborate information on this particular issue and we have close relationship with the International Organization of Consumers Union (IOCU) through the dissemination of information on hazardous products. Although we missed the opportunity to submit our views, we would like very much to hear the outcome of the June 12th Senate hearings.

This is the information we have for you, thank you once again for your kind interest, we remain,

Yours sincerely,

IR. NIKENTARI MUSDIYONO,
Secretary.

PERMADI SH,
Chairman.

APPENDIX 20

LETTER DATED JUNE 10, 1980, FROM BARRY I. CASTLEMAN, ENVIRONMENTAL CONSULTANT, KNOXVILLE, MD.

Hon. JONATHAN B. BINGHAM,
Chairman, Subcommittee on International Economic Policy and Trade, U.S. House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: I am writing to comment on H.R. 6587, a Bill to amend the Export Administration Act of 1979 to restrict the export of goods which have been recognized as hazardous to the public health. The problem of "hazard export" has been a special interest of mine for six years, and the passage of Congressman Barnes' Bill would certainly be an important step forward.

However, the scope of this legislation ought to be expanded to cover a newly recognized problem; namely, the export of hazardous wastes. The export of deadly chemical (and radioactive) wastes produced by our industries simply cannot be justified, and hence ought to be banned. Now that there is such a widespread concern about chemical wastes in this country, we are at the threshold of developing advanced technologies that do not produce such abundant harmful waste products. The honor of the United States would be irreparably damaged if we now try to put off the inevitable by dumping lethal chemicals in other lands.

Hazardous wastes can be distinguished from other export products in that they are shipped for disposal, not for use and not for sale. The Bill could include a penalty for misrepresenting waste export as product export, as well as explicit instruction to uncertain exporters to check in advance with the Secretary of State if they think their intended exports might be considered hazardous wastes.

With provisions on exporting hazardous wastes, the Bill would go a long way toward the control of hazardous product exports. Separate legislation should also be considered to deal with the export of hazardous industrial processes. The use of foreign export platforms by multinational corporations seeking to avoid workplace and pollution control costs is a growing problem. Hazard export in any form retards technological progress, undermines domestic programs to protect the public health, discriminates against reputable manufacturers, and is widely resented as immoral conduct in the family of nations.

Sincerely yours,

BARRY I. CASTLEMAN.

APPENDIX 21

LETTER DATED JULY 24, 1980, FROM LINDSAY MATTISON, DIRECTOR, CENTER FOR DEVELOPMENT POLICY

Chairman JONATHAN B. BINGHAM,
Subcommittee on International Economic Policy and Trade, Committee on Foreign Affairs, U.S. House of Representatives, Washington, D.C.

DEAR CHAIRMAN BINGHAM: Enclosed is a letter that extends its support to the legislation introduced this past winter by Representative Michael Barnes, H.R. 6587, the Hazardous Goods Export Control Act of 1980. As Director of the Center for Development Policy, I wish to call this to your attention.

The Center for Development Policy monitors the flow of resources to developing nations, primarily from the United States, and conducts independent nonpartisan research and analysis of development policies and their implementation. This analysis is then disseminated to the public, the press, interested public officials and offices of government.

Data compiled by the Center for Development Policy indicates that the Export-Import Bank has helped finance hazardous industry export. Here are a few examples taken from the minutes of meetings of the Board of Directors of the Export-Import Bank.

Industry	*Importing nation*	*Date of loan approval*
Liquidified Petroluem Gas Plant	Algeria	1/11/1979
Liquidified Petroluem Gas Plant	Malaysia	1/18/1979
Nickel-Cadmium Battery Manufacturing Facility	Yugoslavia	2/1/1979
Liquidified Natural Gas Plant	Algeria	2/9/1979
Petrochemical Complex	Yugoslavia	5/10/1979
Chemical Complex to Produce Chlorine, VCM and PVC	Poland	8/9/1979
Agrichemicals	Nicaragua	8/23/1979
Carbon Black Plant	Nigeria	10/11/1979
Large Textile Project	Tanzania	10/11/1979
Construction of Steel Melt Shop/manufacture of by-product Benzene	Algeria	1/31/1980.

Further discussion of the question of hazardous exports follows.

Sincerely,

LINDSAY MATTISON.

WASHINGTON, D.C., *July 24, 1980.*

Chairman JONATHAN B. BINGHAM,
Subcommittee on International Economic Policy and Trade, Committee on Foreign Affairs, U.S. House of Representatives, Washington, D.C.

DEAR CHAIRMAN BINGHAM: This letter supports the bill, H.R. 6587, introduced by Representative Michael Barnes to restrict the export of hazardous products from the United States.

The purpose of this bill is tangential to the human rights of people in all countries that should be considered in U.S. policy making. The export of hazardous substances, whose sale is banned in the United States, is weak foreign policy. The U.S. should not use other countries as their dumping grounds for hazardous products, wastes or industries. Can it be justified to export substances unfit for American use to foreign peoples? Why must our foreign trade policy be based on a double standard? The ramifications of this injustice are becoming evident, as testified to in the Subcommittee hearings.

The focus of this letter is aimed at what William A. Hayne of the Department of State called the second of two identifiable components of international trade; the trade between developed and less developed countries as opposed to the trade

among developed countries. The governments in most less developed countries are not able to regulate and control the flow of commodities as the United States can. The U.S. has a responsibility to the importing nation to supply a safe product.

If this bill is passed, the safety and health standards of exported U.S. goods would be trusted by all importers. This improved international trade standing would also improve the present balance of payment deficit.

Let it be recommended that this piece of legislation be broadened to include considerations of the flight abroad of hazardous industry. It is a double standard to allow an industry to be exported devoid of U.S. health and safety regulations to a less developed country. How can the United States allow and help finance, through the Export-Import Bank, hazardous industry such as PVC chemical complexes and argichemical plants to be exported? After establishing domestic standards for health and safety, it is irresponsible foreign policy to ignore these during export.

Not only is the United States allowing exports of unsafe and unhealthy means of production and its subsequent products but the multinational corporations are creating international competition for American workers. The absence of health and safety regulation is a contributing factor to the inviting incentives for the multinational corporations to move their production facilities to less developed countries. There is virtually no control over the U.S. companies that establish plants in these countries. The cheaply produced goods are sold in the United States at low prices that may cause U.S. produced goods to become noncompetitive.

Support for this bill is extended along with the preceding recommendation. I look forward to staying informed and involved in the legislative process for H.R. 6587.

Thank you for your consideration.

Sincerely,

PATRICIA A. POWER,
Center for Development Policy.[1]

[1] For identification purposes only.

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APPENDIX 22

LETTER DATED SEPTEMBER 29, 1980, FROM STEPHEN MINKIN

Representative JONATHAN BINGHAM,
House of Representatives,
Rayburn House Office Building,
Washington, D.C.

DEAR REPRESENTATIVE BINGHAM: Following the House of Representatives Committee on Foreign Affairs Subcommittee on International Economic Policy and Trade hearings on Sept. 9, 1980, at which I represented the National Women's Health Network, I should like to add the following salient points to the record. I regret that time constraints precluded my doing so at the time of my testimony.

1. On the question of obtaining full information about research findings from the Upjohn Company, it is important to note that the Freedom of Information Act does not give the public access to materials termed "trade secret" by the industry. This means that toxicity data from long-term animal studies are not available until the end of the study—which can be as long as seven to ten years.

2. FDA's Obstetrics and Gynecology Committee (now called the Fertility and Maternal Health Drugs Advisory Committee), considered the question of approving Depo-Provera years ago, before the evidence on uterine cancer in Rhesus monkeys was made available to FDA by Upjohn Co.

3. While testimony at the hearings spoke primarily to morbidity (cancer) and/or mortality as the only significant negative effects to consider, there is also a wide range of dramatic health problems resulting from Depo-Provera. Last year, the National Women's Health Network established a Registry for Depo-Provera victims. We have hundreds of letters documenting the experience of women in this country and abroad who have suffered acute depression, loss of libido, significant weight gain/loss, loss of hair, temporary and permanent loss of fertility, and other relevant side effects.

There are several lawsuits pending against Upjohn Co. brought by American women who developed breast and uterine cancer. In her testimony, Dr. Senanayake continually looked to the fact that to date "not a single woman has died as the result of Depo-Provera." Although there is little evidence to support this claim, we at the National Women's Health Network, do not believe it should take the death of a woman to draw attention to the wide spectrum of real health risks experienced by women worldwide!

Please understand that cancers have a latency period of as much as 20-30 years. With the lack of medical care and followups no one would expect to see the first cancers until the late 1980s.

In conclusion, I should like to point out to the Committee that in referring to birth control measures as the "treatment of choice," it is imperative that one ask "whose choice?" Women who are led to believe that a miraculous new family planning technique exists which carries no inherent risk to their minds or bodies are not able to give informed consent. Let us not promote the error of believing that women of a lower socio-economic status and a different culture have any less ability or human right to protect their own health and well being as we do in this country.

Respectfully,

STEVE MINKIN,
Health Policy Analyst.

APPENDIX 23

Correspondence Between Hon. Jonathan B. Bingham and the Agency for International Development

Congress of the United States,
House of Representatives,
Committee on Foreign Affairs,
Washington, D.C., September 22, 1980.

Hon. Douglas J. Bennet, Jr.,
Administrator, Agency for International Development,
Washington, D.C.

Dear Mr. Bennet: During a hearing of the Subcommittee on International Economic Policy and Trade on September 9 concerned with U.S. policy regarding the export of Depo-provera, witness Stephen Minkin raised a question about AID's provision of Depo-provera. Mr. Minkin made the following statement:

"For example, did you know that Depo-provera is used in at least three AID family planning programs in Bangladesh, Mexico, and Sri Lanka? Our tax dollars are used to support programs in which an unapproved drug is given to tens of thousands of women."

When questioned about this statement, Mr. Minkin added:

"I don't have it with me [the Select Committee proceedings], but the submission by Dr. Ravenholt contains references to AID-supported programs in Bangladesh, Sri Lanka and Mexico. These are described as operations research programs, and my understanding is that AID facilities and personnel are directly involved in distributing Depo-provera. I'm not sure who does the actual purchase, but people on the AID payroll are directly involved in the operation of these programs."

Your cooperation in providing the subcommittee with complete information about any AID-supported programs in Bangladesh, Sri Lanka or Mexico involving Depo-provera would be appreciated.

Sincerely,

Jonathan B. Bingham,
Chairman, Subcommittee on International Economic Policy and Trade.

U.S. International Development Cooperation Agency,
Agency for International Development,
Washington, D.C., October 10, 1980.

Hon. Jonathan B. Bingham,
Chairman, Subcommittee on International Economic Policy and Trade, Committee on Foreign Affairs, House of Representatives, Washington, D.C.

Dear Mr. Chairman: Thank you for your letter to Administrator Bennet of September 22, 1980, concerning the provision of Depo-Provera in operations research projects supported by the Agency for International Develpment in Bangladesh, Sri Lanka, and Mexico. The Agency has supported operations research projects in these three countries which, as part of their research protocol, provided Depo-Provera. Depo-Provera is approved for usage in each of these countries, and in each of these research programs their respective national governments cooperated in its distribution. In each case, the Agency did not finance procurement of Depo- Provera; it was supplied by other donors.

Enclosed is an issue of the journal Studies in Family Planning with an article by Dr. Shushum Bhatia describing the Matlab Family Planning Program-Health Services Project, the activity in Bangladesh to which Mr. Minkin referred. This project is an excellent example of the usefulness of Depo-Provera in a developing country setting. As seen in Table 4, page 208, Depo-Provera was the most popular method with about 2.200 users as of April 1979. As seen in table 5. continuation with Depo-Provera was much better than with either pills or condoms.

The Depo-Provera used in this project was not supplied by the Agency for International Development, but came from the Bangladesh Government storehouse of medical supplies from stocks originally donated by a variety of donors, including the United Nations Fund for Population Activities and the International Planned Parenthood Federation, which do receive general support from A.I.D Although the Agency's support for this project terminated in September 1979, it has continued under other support.

In Sri Lanka the program has supported research within a family planning services program. This operations research project is primarily a four-way comparative study of low dose and very low dose oral contraceptives with and without vitamin supplementation. It is being carried out in collaboration with the Sri Lankan affiliate of the International Planned Parenthood Federation which routinely offers its own Depo-Provera in its clinics. In the urban phase of the study, these oral contraceptive users are drawn from the usual clinic population who are routinely offered a variety of methods including Depo-Provera. The rural phase of the study, which involves a household visit, includes referrals to a Government of Sri Lanka hospital for those women who prefer Depo-Provera rather than oral contraceptives. The most recent data indicate that 167 such referrals have been made. The project is ongoing.

A small operations research project supported by A.I.D. in San Pablo, Mexico was completed in 1977. Approximately 60 women in this project were users of Depo-Provera which was supplied by the Government of Mexico.

Thus, the Agency for International Development has supported these research programs, but has not supplied the Depo-Provera. In addition, the assertion that "Our tax dollars are used to support programs in which an unapproved drug is given to tens of thousands of women" is clearly a gross exaggeration. Less than 3,000 women were involved. To say the drug is "unapproved" belies the fact that it is available and approved in the specific countries in which it was used and the national governments cooperated in providing the drug.

While the Agency has not supplied Depo-Provera, whether it *should* be supplied remains a complex and important question. As you know from Dr. Roger Rochat's testimony before your Subcommittee, an ad hoc group of experts, representing a broad range of disciplines, has recommended that the Agency make Depo-Provera available to requesting nations under specific circumstances. We are continuing our review of this very important issue.

If I can provide you with further information, please let me know.

Sincerely yours,

JOSEPH C. WHEELER,
Acting Administrator.

Enclosure: Studies in Family Planning.[1]

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[1] See "The Matlab Family Planning—Health Services Project," Studies in Family Planning, June 1980, vol. 11, No. 6.

APPENDIX 24

Responses by the Interagency Working Group to Additional Questions Submitted for the Record by Representative Michael D. Barnes

Q.1. The intent of section 2(3)(A) (iii) is to require the appropriate authorities to make a judgment as to whether the export of a hazardous product is justified despite the hazards posed by the product. The working group says this is inappropriate and unworkable. Would not the working group's own plan require that such a judgment be made for some products that would be placed under export controls under the plan? Why is this judgment appropriate and workable under the working group's plan but not under the bill?

A.1. H. R. 6587 specifically calls for the Secretary of Commerce and the head of the relevant regulatory agency to make a determination that the "potential benefits of the intended use of the good outweigh the possible hazards," before permitting export. Such a provision appears to constitute a legislative mandate to these agencies to conduct a cost-benefit analysis of the kind required for domestic rulemaking. It is the opinion of EPA and others that the courts would interpret such a provision as requiring agencies to gather specific numerical data on the possible benefits and costs of an export -- a task that would probably require, for a pesticide, for example, the sending of research teams to the foreign country to determine how the product would be used, crop losses to be expected if it were not shipped, number of people likely to experience negative health effects if it were used, the costs of dealing with those health effects, and so forth. This task would be extremely difficult, time consuming, and expensive. Were EPA and the other regulatory agencies required to conduct such analyses without increased staff and budget, the task would only be accomplished at the expense of domestic regulatory efforts.

While the Working Group's proposal suggests some examination of costs and benefits at certain points, no formal cost-benefit analyses are called for. In addition, the policy specifies that any evaluation regarding costs and benefits shall be conducted on the basis of available, existing information and in the context of determining whether an export would constitute a foreign policy problem for the United States.

In sum, we fear that H. R. 6587 would create a difficult, expensive burden, whereas the less formal determination advocated by the Administration proposal, tied to effects on foreign policy interests, would accomplish many of the same basic goals, with less trouble and expense.

Q.2. The intent of section 2(1) is to require that goods regulated under any of the laws set forth in paragraph (6) be subject to export licensing procedures unless the sale of the good is permitted in the United States under that law. The intent of section 2(2) is to require that goods whose sale in the United States is subject to restrictions, such as prescription, labeling, or use requirements, under any of the laws set forth in paragraph (6), be likewise subject to export licensing procedures. The working group says these provisions cover "a very large universe of substances."

How many goods regulated under the laws in paragraph (6) have not been approved for sale in the United States, and would thus be subject to licensing procedures under paragraph (1)?

How many goods are sold in the United States subject to restrictions imposed under the laws of paragraph (6), and would thus be subject to licensing procedures under paragraph (2)?

How do these break down among the various product categories: drugs, pesticides, consumer products, etc.?

How does this "universe" compare in quantity with the "universe" of goods that would be covered under the working group's plan?

A.2. Our analysis indicates that H. R. 6587 would subject a very large number of products and substances to export licensing procedures. The number which would be subject to export controls under the Administration proposal would be substantially smaller.

All pesticides sold in the United States must be registered and approved by EPA for specific uses. H. R. 6587 would subject all pesticides -- both registered and unregistered -- to export controls. This would amount to about 1,500 generic pesticide chemicals (about 35,000 pesticide products). By contrast, the Administration proposal would consider for export controls only those registered pesticides whose use is significantly restricted, unregistered pesticides whose registration was denied or cancelled for all proposed uses, and pesticides for which an FDA tolerance has been denied or revoked. It is estimated that these categories would include perhaps 70 generic pesticide chemicals in all. In addition, under the working group's proposal, only certain of these 70 pesticides -- those constituting an especially severe hazard and posing significant foreign policy concerns -- would actually be selected for export controls.

H. R. 6587 would also impose export controls on any chemical regulated under the Toxic Substances Control Act. At present, this is a small number -- less than half a dozen. However, conceivably as implementation of the Act proceeds, EPA may impose manufacturing, sales and/or use restrictions, ranging from minor to sweeping, on hundreds of chemical substances. By contrast, under the working group's proposal, these regulated substances would be candidates for export controls only if their

manufacture, sale or use were prohibited or significantly restricted. An even smaller number -- those constituting an especially severe hazard and posing significant foreign policy concerns -- would actually be selected for export control.

H. R. 6587 would also impose export controls on all 3,000 prescription drugs, since they are subject to approval and labeling restrictions. The working group's proposal would consider for export controls only those approved drugs which fail to meet FDA quality control standards, a very small proportion of the whole. An even smaller number -- those constituting a severe hazard and posing significant foreign policy concerns -- would actually be subject to export controls. *

In addition, all medical devices, radiation-emitting electronic products (like x-ray machines), food products, and cosmetics which do not meet FDA standards would be placed on the Commodity Control List under H. R. 6587.

Under the working group's proposal, such non-complying products would be considered for export controls, but only those which constitute especially severe hazards and pose significant foreign policy problems would be selected.

Finally, there are about 30 classes of consumer products for which the Consumer Product Safety Commission prohibits sale or imposes restrictions under the three statutes it administers. Among these products are bicycles, refuse bins, asbestos patching compounds, pacifiers, children's pajamas, mattresses, and baseball pitching machines. H. R. 6587 again would impose export controls on all such products. The working group's proposal would select from this list those products which constitute especially severe hazards and pose significant foreign policy concerns.

In sum, we believe H. R. 6587 would impose export controls on thousands of products, including all drugs and all pesticides. The working group's proposal would begin by considering only a few hundred products and substances for export controls, and would actually select a very much smaller number -- those constituting an especially severe hazard and posing significant foreign policy problems -- for inclusion on the Commodity Control List.

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* The working group is seeking an opinion from the Department of Justice to determine the scope of the term "medicine and medical supplies" as it appears in the exclusion contained in section 6(f). The extent to which FDA-regulated substances would be candidates for the Commodity Control List will depend upon the meaning of this term.

Q.3. H. R. 6587 requires review of hazardous product exports. Whether or not a given export is actually denied or restricted is left to the discretion of the implementing agencies. Under the bill, it would be within the discretion of those agencies to determine that "bicycles without rear reflectors" can be exported. What, then, is the basis of your contention that the bill would necessarily entail denial of such exports?

A.3. H. R. 6587 would not entail denial of all exports which are subject to export controls. It is presumed that in many cases, an export license would be granted. However, by subjecting this very large universe of products and substances to export controls, H. R. 6587 would put unnecessary and time-consuming obstacles in the way of the shipment of a large number of products for which approval for export might eventually be granted. There might be delays while the regulatory agency reviewed the application for the export license. In the interim, a sale might go to a foreign competitor. The time and effort which the regulatory agencies would have to put into this very extensive review process would also be considerable, possibly taking them away from pressing domestic regulatory concerns. For this reason, the working group is proposing that export licenses be required for only a very limited number of especially hazardous products and substances.

APPENDIX 25

RESPONSES BY THE INTERAGENCY WORKING GROUP TO ADDITIONAL QUESTIONS SUBMITTED IN WRITING FOR THE RECORD BY SUBCOMMITTEE CHAIRMAN BINGHAM

Q: You say a State-chaired Task Force will advise State of which products should be considered for inclusion on the Commodity Control List. Why is State advising itself?

A: Section 6(a) of the Export Administraton Act of 1979 provides that the Secretary of Commerce shall consult with the Secretary of State in implementing the foreign policy control provisions of the Act. This statutory requirement is reflected in the proposed policy by the establishment of a Task Force chaired by the State Department and composed of other agencies which have a particular interest or expertise in hazardous substances exports. The Task Force serves, in a sense, as an advisor to the Secretary of State in providing the necessary technical information and expertise needed for the Secretary to make his recommendations to the Commerce Department. Thus, as chair of the Task Force, the State Department is serving as a facilitator to gather the necessary information that it needs in order to perform its statutorily mandated function.

Q: How will this Task Force make decisions on which products to "advise" the State Department should be considered for inclusion on the list? Will the non-regulatory agency members of the Task Force (State, Commerce, STR) be able to block the recommendation of a regulatory agency?

A: Under the Export Administration Act, it is the function of the Secretary of State to advise the Secretary of Commerce on the establishment of foreign policy export controls. The function of the regulatory agencies on the Task Force is to provide technical advice to the Secretary of State, on the basis of available information compiled in the course of previous regulatory proceedings pertaining to the substance or product under consideration. In the final analysis, it is the State Department which has the only "vote" in deciding whether or not it will recommend to the Commerce Department that export controls be imposed. It is the role of the Commerce Department, based on certain statutory requirements, to determine whether or not export controls will actually be imposed. The other agencies on the Task Force are present for the purpose of assuring that the State Department has a solid base of information from which to make its recommendation.

Q: You list the criteria the Task Force will use in determining its "advice" to State. Few if any of these are within the competence of State, Commerce, or STR. Why are those agencies involved at this stage?

A: The purpose of the Task Force is to assure that the State Department has the necessary expertise and technical knowledge to determine whether or not export controls are necessary for a particular substance to further significantly the foreign policy of the United States or to fulfill its declared international obligations. It is for this reason that the State Department sits, and indeed chairs, the Task Force. The Working Group believed that it was important for the Commerce Department to be a member of the Task Force so that it would be exposed, at the very earliest stages, to the discussion and deliberation among the Task Force agencies as to the reasons why a substance is particularly hazardous. The Working Group believes that this will ultimately enable the Commerce Department to make a more expeditious, and competent decision on the question of export controls. Finally, the Working Group agreed to place the Special Trade Representative on the Task Force so that it could offer its expertise on the trade ramifications of establishing, or the failure to establish, export controls.

Q: Then you say that, based on the Task Force's advice, State would identify (with Commerce's concurrence) which products would be placed on the Control List. How will State do that? What expertise does State have to make the determinations? How can State choose among the recommendations of this with expertise, when State has no such expertise itself?

A: The function of the State Department is to determine whether or not export controls should be established for a particular substance to further significantly the foreign policy of the United States or to fulfill its declared international obligations. In order to make this determination, it must have a complete understanding of the nature and extent of the potential hazards involved in exporting a particular substance. This expertise would be provided by the regulatory agencies that are represented on the Task Force. Of particular importance on the Task Force is the regulatory agency which has domestic jurisdiction over the particular substance being considered. However, the other agencies can also make a contribution because of their generic expertise about product hazards. Indeed, this Task Force will represent the best knowledge that the Federal government, as a whole, has regarding potential human and environmental hazards posed by particular substances. The State Department will, in the end, have to rely upon the technical expertise and judgement of the regulatory agencies in making its determinations about the ramifications of export of a particular substance on the foreign policy interests of the United States.

Q: You say State would identify products for controls when the controls would "further significantly the foreign policy of the United States..." (the language of the Act). What does that mean? Among the products identified by the Task Force as posing "especially severe hazards", how will State determine which severe hazards are OK from a foreign policy point of view and which are not? What criteria could they use except those that the Task Force has already used, which makes State redundant?

A: State's role on the Task Force is not redundant. Rather, the Task Force exists for the purpose of advising the Secretary of State of the nature and extent of the hazards that may be involved in the export of a particular substance. With the knowledge and expertise provided by the regulatory agencies about the nature and extent of the hazard, the State Department and the Task Force will evaluate a variety of factors in determining whether the State Department should recommend the imposition of export controls. Those factors include, to the extent possible within the limits of available information, the type, extent, and severity of the potential detrimental effects of each substance proposed for inclusion on the Commodity Control List, the likelihood of the effects, the duration of the effects, the ability of the foreign countries to avoid or mitigate the effects, the availability of the substance from sources other than the United States, the availability of other substances or methods that would serve the same purpose as the substance to be exported, and the importance of the beneficial uses of the substance. Each of the agencies represented on the Task Force will be able to contribute to the evaluation of each of these criteria. However, under the Export Administration Act, it is the State Department which ultimately makes the recommendation on whether or not to impose export controls to the Commerce Department.

Q: Then you say Commerce will make the licensing decisions, and you spell out the criteria. What's the difference between those criteria and the Task Force criteria you give on page 5? Why should another agency without expertise go through these same considerations all over again? Isn't giving this responsibility to Commerce something like letting the wolf guard the henhouse? Isn't Commerce inclined to approve exports?

A: Under Section 6(a) of the Export Administration Act of 1979, the Secretary of Commerce is assigned the responsibility for exercising the authority to impose foreign policy controls under the Act. The Secretary of Commerce will be aided in this function by the deliberations of the Task Force, of which the Commerce Department is a member. Because of its statutory responsibilities under the Export Administration Act, the Commerce Department has developed an expertise in the use of commodity controls for foreign policy purposes. It therefore is quite reasonable and indeed necessary under the law, to assign this responsibility to that Department. One of the functions of the Department of Commerce in general is to promote exports from the United States. In fulfilling this responsibility, the Department would be cognizant of the adverse ramifications on our long term export interests of allowing the exportation of a product which is especially hazardous. The Working Group believes that with the technical assistance of the Task Force, the Commerce Department is well suited for the function which would be mandated under the proposed policy.

Q: In summary, haven't you set up a very cumbersome system, with successive bureaucratic layers considering and reconsidering the same criteria, and with the only agencies with expertise - the regulatory agencies - confined to the very earliest stages of the process?

A: The policy proposal establishes a system which makes the best use of available expertise in the government. The regulatory agencies are present for their technical expertise; the State Department is present for its expertise on U.S. foreign policy and the effects thereon by the export of hazardous substances; and the Commerce Department is present for its expertise on the use of export controls. The procedure also is consistent with the Export Administration Act of 1979, the statute which gives the basic necessary authority to implement the program that has been proposed.

APPENDIX 26

LETTER DATED JULY 9, 1980, FROM HON. REUBIN O'D. ASKEW, UNITED STATES TRADE REPRESENTATIVE

Honorable Jonathan B. Bingham
Chairman, Subcommittee on
International Economic Policy
& Trade
Committee on Foreign Affairs
House of Representatives
Washington, D.C. 20515

Dear Chairman Bingham:

The Office of the U.S. Trade Representative (USTR) herein submits its views on H.R. 6587, a bill to amend the Export Administration Act of 1979 to restrict the export of goods that have been found hazardous to the public health. Our interest in this matter stems from the new responsibility assigned to USTR by the President and the Congress for the coordination of U.S. Government export policy, effective January 2, 1980. USTR has been charged with ensuring that U.S. export policy is balanced and does not overly inhibit or restrain U.S. exports.

We endorse the objective of H.R. 6587; however, we believe that this objective can be better achieved in a manner that will not create new disincentives to U.S. exports. Our preferred approach is the development of a set of principles by the Executive Branch for hazardous substances exports. As you know, such principles have been developed by the Hazardous Substances Export Policy Working Group, which is chaired by Esther Peterson. Consultations with a variety of affected interests have been held as the Working Group has deliberated the basic principles for this policy. Many of their concerns are reflected in the present draft. Further consultations will be held in the course of finalizing the principles over the next few weeks. One mechanism that will be used is the USTR industry/agriculture/labor advisory committee structure. Any legitimate concerns that these sectors might have will be considered before the principles are made final.

The proposed principles would charge the Department of State to consult with a task force of regulatory agencies, Commerce, USTR, and other relevant agencies to determine which substances should be subjected to export controls. State could then recommend to the Department of Commerce that a product be placed on the Commodity Control List for foreign policy reasons. Although the number of hazardous products to be placed on the Commodity Control List is not yet known, the Working Group believes that only a small dollar volume of trade will be affected.

In time, we would hope that a U.S. hazardous substances export policy could be supplemented by internationally agreed rules on trade in hazardous substances. The possibility for such rules is presently being discussed within the Organization for Economic Cooperation and Development.

We believe that H.R. 6587 would restrain U.S. exports more than is necessary to accomplish its legitimate objective. The bill would ban exports of U.S. regulated goods, including goods subject to U.S. registration, licensing or use requirements, unless the following steps are taken: (1) the government of the country to which the product is to be exported is notified of the proposed shipment and its possible hazards, (2) the government of such country requests the export of the goods, (3) a determination is made by the U.S. Government that the potential benefits from the use of the good outweigh its hazards, and (4) a determination is made by the U.S. Government that the sale of the good in the importing country is subject to registration, licensing or use restrictions comparable to those of the United States.

These procedures would place burdensome and questionable requirements on U.S. exporters and on foreign governments. Numerous repetitious notices would be necessary in the case of more than one shipment per year of the same product by an exporter to the same country. Regardless of the severity of hazard posed by the product, the importing country would be required to request exportation.

The bill requires that a cost-benefit assessment be made and that a determination of comparable regulatory requirements be issued even though a shipment is requested by a foreign country. These requirements do not balance the moral responsibility of the United States to regulate hazardous exports with other nations' sovereign rights, and they do not reflect the fact that the use of products banned in the United States might be perfectly justifiable in other countries due to differing economic, social, and cultural conditions. One result of such requirements, if implemented, might be the displacement of U.S. exports by exports of similar products from third countries with little or no additional benefits to the world environment or human safety.

Similarly, the requirements that U.S. Government agencies make cost-benefit and regulatory comparability determinations are impractical because of, inter alia, differing social and cultural conditions and differing regulatory objectives and capabilities. The bill contains no criteria for guidance in making these determinations.

Section 2(5) of the bill provides that no good may be exported for the purpose of using that good in the manufacture of another good, the export of which is prohibited by this bill. Such a requirement could potentially severely restrict exports of thousands of non-hazardous products that may have multiple end uses. The burden of proof for determining end use would presumably fall on the U.S. exporter. This type of data may be extremely difficult and sometimes impossible to obtain because of inadequate record keeping by importers and general business confidentiality considerations. The only conceivable result of this course of action would be the displacement of U.S. exports to the benefit of exports from other countries and to the industry within the country in question.

The Office of Management and Budget advises that there is no objection, from the standpoint of the Administration's program, to the presentation of these comments.

Sincerely,

Reubin O'D. Askew

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