THE INTERNATIONAL LIABILITY FOR HAZARDOUS EXPORTS

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I. INTRODUCTION

There is an increasing awareness of the problems anent products, particularly certain chemicals and pharmaceuticals considered hazardous to human health or safety or are dangerous to the environment Hazardous products are being restricted or banned from the domestic use of the exporting country but nevertheless, are exported to less regulated markets in developing countries.[1] International law seems to provide a duty on the part of each nation to refrain from such action.[2] The duty is implied from what may be considered a necessary ingredient of every legal system, which is the general principle of *sic utere tuo ut alienum non laedas*—that one may exercise his rights so as not to injure the rights of others. "As a principle of international law, it imposes a duty on a state to exercise its rights in a manner that does not unreasonably harm the interests of other states, which, significantly, includes a duty to regulate activities within its territory."[3]

Unfortunately, there are no international agreements or treaties which expressly or explicitly hold liable an exporter of banned products. In 1972, however, the Declaration on the Human Environment of the United Nations Stockholm Conference laid down the basic rule governing the international responsibility of states with regard to the environment.[4] Principle 21 of the Declaration provides:

> "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other states or of areas beyond the limits of national jurisdiction."[5]

Although the Stockholm Declaration is not a binding legal instrument, nonetheless its twenty-six principles may be considered as "common convictions" which reinforce the Principles and Purposes of the Charter of the

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1 C. Galli, *Hazardous Exports to the Third World: The Need to Abolish the Double Standard*, 12 COLUM. J. ENVT'L. L. 71 (1987).

2 D. Magraw, *The International Law Commission's Study of International Liability for Nonprohibited Acts as it relates to Developing States*, 61 WASH. L. REV. 1041 (1986).

3 *Ibid.*

4 S. Sohn, *The Stockholm Declaration on the Human Environment*, 14 HARV. INT'L. L. J. 423 (1973).

5 *U.N. Declaration on the Human Environment*, U.N. YEARBOOK, 16 June 1972.

United Nations.[6] After the Stockholm Conference, the United Nations Environmental Program (UNEP) was established to promote international environmental cooperation.[7] One of the objectives of the UNEP is to establish a warning system to provide notice to countries whose environment and human health may be affected by the export of hazardous substances.[8]

Movements in environmental law, especially in its international aspect, indicate current response to hazardous exports. This paper, after making an examination of the problem, will outline the directions of international responsibility for such exports and finally comment on related Philippine legislation, by way of conclusion.

II. THE PHARMACEUTICAL INDUSTRY

Most potentially hazardous products are related to the chemical and pharmaceutical industries. In the case of the chemical industry, the products involved are intermediates which require further processing, and therefore the hazardous aspects occur during the process of manufacture resulting in unsafe worker exposure, emissions, or plant effluents. Controls are targeted at the production process, not at the finished product. In the case of the pharmaceutical industry, end products intended for direct medical application are produced, and therefore, most safety problems are related to end use.[9]

According to 1980 figures, the United States is the world's largest net exporter of pharmaceuticals. The pharmaceutical industry in the U.S. is the world's largest producer of drugs, being responsible for 24.9% of world production. But an ever-increasing percentage of this figure is being performed by foreign-based subsidiaries of American parent firms. The sales of subsidiaries as a percentage of total company sales in 1960 stood at 20.6%; in 1972 at 32.2%; and in 1979 at 41.5%. World sales of pharmaceuticals at manufacturer's prices was estimated at $80 billion in 1980. Only 20% of this amount went to developing countries, although three-fourths of the world's population live there. The percentage of the GNP spent on public health also differ between developed and developing countries. The former allot 5% of their GNP on public health expenditures, while the latter spend little more than 1% of their GNP on public health.[10]

The late Prime Minister Indira Gandhi, addressing the 34th World Health Assembly in 1981, summed up the problem thus: "Sometimes, dangerous new drugs are tried out on populations of weaker countries although

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[6] See note 4, *supra*.

[7] P. Seferovich, *United States Exports of Banned Products: Legal and Moral Implications*, 10 DENVER J. INT'L. L. & POL'Y 537 (1981).

[8] *Ibid.*

[9] *Role of the Information System on Transnational Corporations Regarding the Exchange of Information on Banned Hazardous Chemicals and Unsafe Pharmaceuticals* U.N. ECOSOC E/C.10/90 (1981).

[10] N. Pirt, *Regulation of the Export of Pharmaceuticals To Development Countries*, 25 DUQUESNE L. REV. 255 (1987).

their use is prohibited within the countries of manufacture. It also happens that publicity makes us victims of habits and practices which are economically wasteful or wholly contrary to good health."[11]

Why are developing countries used as the dumping ground of the pharmaceutical industry? The reason may lie in the highly competitive nature of the industry. A currently commercially successful product can at any moment be eclipsed in the market by the introduction of a safer, more efficacious drug by a competitor. Thus, there is a need for continuing research and development. This, however, requires a huge outlay for only 10% to 20% of the drugs that reach the clinical testing stage are actually marketed; and, in the U.S., the time from basic research or discovery up to the approval by the Food and Drug Administration can take a decade, so that financial rewards are delayed.[12]

Furthermore, when a product is found to be toxic, it is either banned (withdrawn from use and/or sale) or severely restricted (subjected to controls that exclude its use in a substantial proportion of the target population of patients, but for which certain specific uses remain authorized).[13] The imposition of such controls on the domestic use of a toxic product may lead to an increase in exports to other countries with less strict regulations on use. Several companies have short-run fixed costs due to the capital-intensive nature of production. If the capital equipment cannot be readily utilized for other products, a firm, just to break even, will continue producing in order to cover the variable costs, for the export market. Products are then vended to less restrictive economies such as that of developing countries.[14]

Another reason why firms engage in dumping is to effect price discrimination — that is, the selling of the same good to different consumers (domestic and foreign) at different prices, in order to increase the seller's profits by allowing it to capture more of the extra amount that consumers are willing to pay for a product above its marginal cost. When a firm sells domestically, it cannot price discriminate because it cannot separate customers into several groups willing to buy the same product at different prices. Even if it could, arbitrage would still prevent the firm from selling at different prices. The different groups would seek each other out and buy at the market where the good is least-priced to sell at the market where it is priced highest. Soon, there will be no more price differences. But in the international market, the potential for price discrimination increases because consumer elasticity of demand often differs between countries, presenting a convenient division between groups of consumers willing to pay different

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11 *Ibid.*

12 *Ibid.*

13 *Consolidated List of Products Whose Consumption, and/or Sale Have Been Banned, Withdrawn, Severely Restricted, or Not Approved by Governments,* ST/ESA/192 (1986).

14 See note 9, *supra.*

prices, the group with the most inelastic demand the most willing to pay the highest price.[15]

Inevitably, the developing countries have the most inelastic demand. They set aside 20% to 40% of their public health budget for pharmaceuticals, whereas pharmaceuticals account for only 7% to 12% of health care expenditures in developed countries.[16] Developing countries rely on pharmaceuticals as a first line of defense against a wide range of diseases, because of a general lack of adequate sanitary, nutritional, and primary health care facilities for the bulk of their population.[17] Ironically, developing countries pay excessive prices for pharmaceuticals.

According to the stage of development of its pharmaceutical industry, the Philippines, along with Singapore, Thailand, and Indonesia, is classified in Group 3 by the United Nations Commission on Transnational Corporations. As of 1979, Group 3 countries manufacture a broad range of drugs into dosage forms and manufacture some simple bulk drugs from intermediates.[18] Imports, therefore, are substantial, which may consist either of finished products, like drugs ready for use, or bulk drugs in final dosage form ready for repacking, or of semi-finished products, like pharmaceutical chemicals for dosage formulation, and chemical intermediates requiring further chemical processing.[19]

Transnational corporations (TNCs) account for 70% to 80% of the total pharmaceutical production in developing countries like the Philippines.[20] This translates into the predominant share of the TNCs in the global production and marketing of chemicals, and therefore into their significant role in the manufacture and sale of products which may be toxic or hazardous. It is, however, difficult to define the specific extent and magnitude of the activities of the TNCs in the production and sale of such products because of the confidentiality of the information and the difficulties in the identification and categorization of specific toxic and hazardous products in relation to standards and criteria applicable under different conditions and circumstances.[21]

Compounding the problem are the questionable marketing practices by TNCs. These practices include the distribution of free samples, extensive advertising, frequent visits by sales representatives and other offerings to medical personnel which tend to influence the decisions made by the latter in prescribing particular brands. Drug firms also resort to excessive claims

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15 S. Semeraro, *Distinguishing International from Domestic Predation: A New Approach to Predatory Dumping*, 23 STAN. J. INT'L. L. 621 (1987).

16 See note 10, *supra*.

17 *Transnational Corporations in the Pharmaceutical Industry of Developing Countries*, UN ECOSOC E/C.10/85 (1981).

18 *Ibid.*

19 *Ibid.*

20 *Ibid.*

21 *Ibid*

concerning the properties of their products without information on side-effects, furnish questionable data on testing experiments, and promote ineffective drugs.[22] These practices create seriou health hazards, without full and accurate disclosure of information regarding the merits of products, consumers in developing countries are not guaranteed maximum efficient and safe use of such products.[23] The disclosure, preferably in the national language, assumes greater importance in developing countries where a drug is sold over the counter, sometimes illegally, without a doctor's prescription. A drug can be very harmful when marketed under these conditions although it may be safely administered while under the supervision of a doctor. The meaning of a "safe" pharmaceutical is thus relative to the circumstances obtaining in each country.[24]

Another result of the extensive marketing and promotional activities of the TNCs are the high prices which consumers must pay. Consumers do not realize that there is no great difference among drugs of the same genre and end up buying the more expensive, better-known brands.[25] High-priced branded products thus take a greater share of the market than their less expensive generic equivalents. That drug firms spend so much on advertising is an indication that brand name products are mere modifications of each other. According to a report of *The Economist* of London, out of the 1,500 drug patents filed in 1974, only 45 were genuinely new drugs, 150 were major modifications of other drugs, while the rest were purely imitative.[26]

III. INTERNATIONAL LIABILITY

Private individuals and corporations are increasingly engaging in activities that may result in significant accidental damage to the transnational environment.[27] Currently under study by the International Law Commission (ILC) of the United Nations is a topic entitled "International Liability for Injurious Consequences Arising Out of Acts Not Prohibited by International Law." This topic refers to harmful transnational environmental effects of internationally lawful activities.[28] The ILC studies international liability and state responsibility separately.[29] It views state responsbiility as deriving from prohibited, or wrongful, acts or omissions.[30] International liability,

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[22] *Ibid.*

[23] See note 9, *supra.*

[24] See note 10, *supra.*

[25] "Cutting Drug Prices," *The Manila Chronicle,* 17 January 1988, p. 13.

[26] E. Bautista, "Multinationals and the Drug Industry in the Philippines," in *The First Annual Report of the Asian Council for Law and Development,* ed. Froilan Bacungan and Merlin Magallona (Quezon City: UP Law Center, 1977).

[27] G. Handl, *State Liability for Accidental Transnational Environmental Damage by Private Persons,* 74 AM. J. INT'L. L. 525 (1980).

[28] D. Magraw, *Transboundary Harm: The International Law Commission's Study of International Liability,* 80 AM. J. INT'L. L. 305 (1986).

[29] *Ibid.*

on the other hand, may stem from both prohibited and permissible acts or omissions.[31] The Special Rapporteur Robert Quentin-Baxter, before his death in 1984, submitted five draft articles on international liability in his fifth report to the ILC. Draft Article 1 delineates the scope of the topic as follows:

> "These draft articles apply with respect to activities and situations which are within the territory or control of a state, and which do or may give rise to a physical consequence, affecting the use or enjoyment of areas within the territory or control of any other state."[32]

Three express limitations are included. First, the effect must be felt within the territory or control of one state (the "affected state"), but must arise as a consequence of an activity or situation occurring, partly or wholly, within the territory or control of another state (the "source state").[33] Second, the activity or situation must have a physical effect and a physical quality, and that effect must flow from that quality via a "physical linkage."[34] This criterion apparently requires that the transboundary effect occur or be transmitted via physical media, such as the atmosphere, water, or earth, rather than via economic, political, or cultural media.[35] Thus, trade in chemicals, pharmaceuticals, and similar products of a dangerous nature, the use of which was banned in the state where they were manufactured, would not result in international liability under the Draft Articles because the requisite physical linkage is absent.[36] Third, there must be an effect on the use or enjoyment by the affected state.[37]

But this does not mean that no international liability lies for exporters of hazardous products. The only reason why the scope of the topic is confined to physical activities giving rise to physical transboundary harm is that State practice is at present insufficiently developed in other areas.[38]

Special Rapporteur Quentin-Baxter submitted a schematic outline in 1982, which serves two purposes: "(1) to encourage the creation of conventional regimes for particular types or instances of transboundary harm, so as to increase the specificity of rules governing acts not prohibited by international law and decrease the incidence of confrontation between states; and (2) in the absence of such a regime, to assert a fourfold duty regarding transboundary harm to prevent, inform, negotiate, and repair without a prior finding of responsibility for a wrongful act or omission."[39]

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30 *Ibid.*
31 *Ibid.*
32 *Ibid.*
33 *Ibid.*
34 *Ibid.*
35 See note 2, *supra.*
36 *Ibid.*
37 See note 28, *supra.*
38 *International Liability for Injurious Consequences Arising Out of Acts Not Prohibited by International Law*, U.N. Doc. A/CN.4/373 (1983).
39 See note 28, *supra.*

The series of four duties (to prevent, inform, negotiate, and repair) are based on the concepts of cooperation, good faith, and bon voisinage between the source state and the affected state. The duty to prevent is a continuing duty — that the source state take measures of prevention as far as possible to avoid a risk of loss or injury. The second duty mandates that the source state provide the affected state with all relevant and available information when it is or may be harmed by an activity occurring within the second state's territory or control. But if for reasons of national or industrial security, the source state considers it necessary to withhold any relevant information that would otherwise be available, it must inform the affected state that information is being withheld. The affected state may propose fact-finding, and the source state must cooperate in good faith to reach an agreement regarding the details of the inquiry. The third duty involves the obligation of States to enter into negotiations at the request of either the source state or the affected state, regarding the necessity and form of conventional regime to deal with the situation. The fourth and final duty is the duty of the acting state to make reparations to the affected state, in case no conventional regime has been entered into, and harm occurs. But reparations need not be made if it is established that the making of reparation for loss or injury of that kind or character is not in accordance with the "shared expectations" of those states.[40]

Members of the ILC, during their discussions of international liability, have expressed the opinion that special account should be taken of the problems confronting developing States. Two conflicting views regarding the international liability of developing States have been put forward, in the light of the fact that TNCs operate within the territorial boundaries of these States, and that such operations may give rise to "transboundary harm." The first is the view that a developing State cannot protect itself; the second is the view that a developing State has the duty to regulate within its territory and that the liability rules should take into account that duty and the fact that developing States do regulate in certain areas.[41]

The doctrinal basis for providing special consideration to developing States may be found in Principle 23 of the Stockholm Declaration which provides:

> "Without prejudice to such criteria as may be agreed upon by the international community, or to standards which will have to be determined nationally, it will be essential in all cases to consider the systems of values prevailing in each country, and the extent of the applicability of the standards which are valid for the most advanced countries but which may be inappropriate and of unwarranted social cost for the developing countries."[42]

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[40] *Ibid.*
[41] See note 2. *supra.*
[42] See note 5, *supra.*

The ILC cited the following difficulties that particularly affect developing States:

> "(1) a developing State may not have sufficient information to predict the potential for transboundary harm created by activities within its territory of foreign or foreign-owned entities because the developing State may not receive full information from these entities;
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> "(2) a developing State may not have sufficient technical expertise to evaluate complex technological proposals or to monitor ongoing performance, especially where control of the day-to-day operations is effectively foreign; and
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> "(3) the need to develop may force, or at a minimum prompt, a developing State to accept foreign (or domestic) investment that carries with it a high risk of transboundary harm."[43]

It has been suggested that the State of which a multinational corporation is a national should be liable when it "exports" dangerous industries to developing States and harm ensues. But such activities are not covered either by the schematic outline or by the draft articles. Quentin-Baxter argued that States remain "primarily accountable" for things that happen within their own territory. Developing countries may choose whether to allow the importation of dangerous industries and they can stipulate that the "exporting" State retain its liability. The approach taken by Quentin-Baxter appears more tenable because the State where the activity occurred is in the best geographical position to regulate that activity. In the absence of an agreement permitting such regulation, attempts to regulate extra-territorially might be viewed as interfering with the sovereignty of the State where the activity occurred. Furthermore, holding the "exporting" State liable might easily have undesirable effects on the international flow of capital and technology.[44]

IV. THE EXCHANGE OF INFORMATION ON BANNED HAZARDOUS PRODUCTS

The "duty to inform" might necessitate the collection, compilation, analysis, and retention of a wide variety and an enormous amount of information from the private sector, which might be considered objectionable. It would entail a great administrative burden and would raise the issue of privacy and government intrusion into the private sector.[45] As it is, only developed countries are able to collect such information. Developing countries have only marginally funded and staffed environmental agencies with inadequate research facilities, limited regulatory programs, and even more limited educational and enforcement capabilities. Developing countries must therefore rely on industrial countries for information, regulatory judgments, and help in controlling the trade in hazardous productions. International information exchange programs would give the much needed assistance.[46]

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[43] See note 2, *supra.*
[44] *Ibid.*
[45] See note 28, *supra.*
[46] F. Halter, *Regulating Information Exchange and International Trade in Pesti-*

Halter describes such programs as follows:

> "Only the United States and the United Nations have programs for notifying other governments about new regulatory decisions. The more common type of information exchange program involves notification about exports of banned and severely restricted substances. The notices summarize the program, identify the substance that is being exported, confirm that an export has occurred or is about to occur, and explain how to obtain additional information. Exporters are required to notify their own government on or before the date of export. Some programs also require the exporter to notify directly the foreign importer or importing government about the regulatory status of the chemical in question. The exporting government then notifies the importing government after receiving the required information from the exporter. The purpose of the notice is to inform the importing government about the transaction rather than to enable it to stop an unwanted shipment. Notice is required for either the first shipment of designated chemical to a particular country after the program begins, or for the first shipment in each calendar year. Regulatory and export notices may be transmitted to: (1) the overseas embassy of the country issuing the notice, for transmittal to their host governments; (2) other governments' foreign embassies based within the country issuing the notice; (3) designated contact points in other countries; or (4) an international organization that will transmit notices to member countries participating in the program."[47]

International organizations have also addressed the hazardous exports problem. While resolutions of the United Nations General Assembly do not amount to a declaration of current international law, they evince a willingness by many nations to work together to solve this problem. There are various programs relating to toxic products under way in the World Health Organization (WHO), the United Nations Environmental Program (UNEP), the Food and Agriculture Organization (FAO), and the International Labour Organization (ILO). Information exchange programs also exist for members of the European Economic Community (EEC), the Organization for Economic Cooperation and Development (OECD), and the International Organization of Consumers Unions (IOCU).[48]

Recently, the EEC environment ministers rejected proposed legislation requiring developing countries to consent to import dangerous chemicals before shipments are made. In February 1986, there was a call for a "prior informed choice" before dangerous chemicals, such as pesticides, are shipped. This would have required prior consent on the basis of information provided by the EEC on the chemicals. The EEC environment ministers, however, opted to adopt instead the UNEP principle of prior notification, which calls on any country banning or restricting certain products to inform other countries as to the reasons for the restrictions, so they can evaluate the risks and take appropriate action. The ministers believed that adding a

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cides and Other Toxic Substances to Meet the Needs of Developing Countries, 12 COLUM. J. INT'L. L. 1 (1987).

[47] *Ibid.*

[48] See note 1, *supra.*

third stage to this process, in the form of prior informed choice, would not add significantly to the protection provided developing countries.[49]

In 1982, the General Assembly, "aware of the damage to health and the environment that the continued production and export of products that have been banned and/or permanently withdrawn on grounds of human health and safety from domestic markets is causing in the importing countries," and "considering that many developing countries lack the necessary information and expertise to keep up with developments in this fields," requested the Secretary General to prepare a consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted, or not approved by Governments.[50] It was specified that the list should contain both generic/chemical and brand names, as well as the names of all manufacturers and a short reference to the decision taken by Governments that had led to the banning, withdrawal, or severe restriction of the products.[51] The list was to be based on the work already being done within the FAO, the WHO, the ILO, the U.N. Center on Transnational Corporations and other intergovernmental organizations. The first issue was prepared on December 30, 1983.[52]

The U.N. Commission on Transnational Corporations has shown itself sensitive to the problems of hazardous exports. The Draft Code of Conduct on TNCs contains several relevant provisions which would impose substantial duties on corporations exporting hazardous products.[53] Improving the information available to users of products manufactured and marketed by TNCs is dealt with by Sections 38 to 41 of the Draft Code, which reads in part that:

> "Transnational Corporations shall/should also perform their activities with due regard to relevant international standards, so that they do not cause injury to the health or endanger the safety of consumers or bring about variations in the quality of products in each market which would have detrimental effects on consumers. Transnational corporations shall/should, in respect of the products or services which they produce or market or propose to produce or market in any country, supply to the competent authorities of that country on request or on a regular basis, as specified by these authorities, all relevant information concerning characteristics of the products or services which may be injurious to the health and safety of consumers including experimental uses and other aspects."[54]

Attempts at export regulation by developed countries are met by two arguments: the sovereignty argument and the paternalism argument. Proponents of the first argument say that when a country bars exportation

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[49] "Toxic Exports to the Third World," *The Manila Chronicle*, 15 February 1988, page 5.
[50] See note 13, *supra*.
[51] *Ibid.*
[52] *Ibid.*
[53] See note 9, *supra*.
[54] *Ibid.*

for the sole purpose of protecting ultimate consumers who are nationals of another country, such is an interference with that country's sovereignty. Even if it possesses the information that the drugs are hazardous, the importing country may claim its sovereign right to make the critical decision regarding importation. That decision is reached based on its view of the needs of its own population ,its disease patterns, and health service delivery resources. The importing country may reach a totally different conclusion regarding the foreseeable benefits of a product from that reached by the exporting country. One country's resolution of the risk and benefit of a product is not necessarily relevant to another country's circumstances.[55]

However, at a public hearing conducted by the UNEP, it was recognized that developing countries have no choice but to purchase hazardous products because they are needed. The real problem is that the expertise for evaluation is not available in developing countries, the way it is in the industrialized world. At this point, the sovereignty argument fails, because such argument is persuasive only if Third World countries had the technology to regulate hazardous imports, and that they depend on developed countries for such imports only because they lack the ability to manufacture them. The usual case is that a deficiency of industrialization is accompanied by a deficiency in regulation. Therefore, if developing countries depend on industrialized nations for their hazardous imports, they should also depend on their accompanying regulatory safeguards.[56]

Proponents of the paternalism argument view the problem in a different way. They deem it inappropriate that an exporting country imposes export restrictions on an importing country that does not share its environmental and economic concerns.[57]

In the United States, the Drug Exports Amendments Act of 1986 was enacted through agreement and compromise among advocates of philosophically opposing views in Congress. The Act maintains export prohibitions against drugs disapproved or withdrawn from the U.S. domestic market. At the same time, it permits the regulated export of drugs actively progressing through the pipeline of Food and Drug Administration (FDA) approval, to a number of listed countries, the management of such list being the responsibility of Congress. The U.S. thus respects the sovereignty of the countries on the list. It feels little obligation to protect foreign nations against U.S. pipeline drugs when their own governments have adequate and sophisticated control mechanisms. But the small number of countries on the list reflects the attitude that the majority of nations are still incapable of making a responsible risk-benefit assessment of drugs

[55] R. Cook, *The U.S. Export of Pipeline Therapeutic Drugs*, 12 COLUM. J. INT'L. L. 39 (1987).

[56] See note 1, *supra.*

[57] *Ibid.*

or the decision to import them, notwithstanding known or suspected hazards.[58]

V. CONCLUSION

Reciprocity of domestic standards should govern an international system that purports to solve the problem of hazardous exports. No country should export products which it considers unsafe for domestic use. But an export license may be granted, on the condition that the exporting company put into effect the domestic regulations in the use and application of the product abroad. The importing country may waive the regulations of the exporting country, being free to impose more or less stringent regulations, depending on its national priorities.[59]

It is imperative that a national policy on hazardous products, as well as the role of the State in their regulation, be clearly defind. The 1986 Constitution gives the guidelines. Article XVI, section 9 provides that "The State shall protect consumers from trade malpractices and from substandard or hazardous products." This provision guarantees to consumers certain enforceable rights, such as the right to safety, information, redress, and consumer education.[60] A National Drug Policy was announced last April 1987, the goal of which is to achieve self-sufficiency in drug products and to wrest control of the local pharmaceutical industry from transnational corporations.[61]

The present law on the matter of imports and exports of hazardous pharmaceutical products is embraced in the Customs Code of 1978 as amended by PD 1464, and in the Food, Drug, and Cosmetic Act (RA 3720). Section 102(h) of the 1978 Customs Code provides that any adulterated or misbranded drug in violation of the provisions of the Food and Drugs Act is a prohibited importation. The Food and Drugs Act defines "drug" as

> (1) articles recognized in the official United States Pharmacopeia, official Momeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
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> (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
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> (3) articles (other than food) intended to affect the structure or any function of the body of man or animals; and
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> (4) articles intended for use as a component of any articles specified in clauses (1), (2), or (3), but does not include devices or their components, parts, or accessories.[62]

The same Act provides that the "Commissioner of Customs shall cause to be delivered to the Food and Drug Administration samples taken at

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[58] See note 55, *supra.*
[59] See note 1, *supra.*
[60] 3 JOURNAL OF THE CONSTITUTIONAL COMMISSION, 1533-1534 (1986).
[61] See note 25, *supra.*
[62] Rep. Act No. 3720 (1963), sec. 10 (f).

random from every incoming shipment of food, drugs, devices, and cosmetics which are being imported or offered for import into the Philippines giving notice thereof to the owner or consignee. The quantity of such samples shall be fixed by regulation issued by the Secretary. If it appears from the examination of such samples or otherwise that

> (1) such article has been manufactured, processed, or packed under insanitary conditions, or
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> (2) such article is forbidden or restricted from sale in the country in which it was produced or from which it was exported, or
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> (3) such article is adulterated, misbranded, or in violation of Section twenty-one,

then the Food and Drug Administrator shall so inform the Commissioner of Customs and such article shall be refused admission unless such article is exported, under regulations prescribed by the Commissioner of Customs, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations."[63]

"A food, drug, device, or cosmetic intended for export shall not be adulterated or misbranded under this Act if it (1) conforms with the specification of the foreign purchaser, (2) is not in conflict with laws of the country to which it is intended for export, and (3) is labelled on the outside of the shipping package to show that it is intended for export. But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this Act."[64]

Senate Bill No. 272 was recently introduced by Senator Orly Mercado. If approved, it shall be known as the "Consumer Code of the Philippines." It seeks to "revise and to add to present laws, new measures in order to better safeguard and protect the consumers," and thereby implement section 9, Article XVI of the 1987 Constitution.[65]

The Bill adds to the RA 3720 definition of a drug. When used in the proposed Consumer Code, the term shall include herbal and/or traditional drugs, which "are defined as articles from indigenous plant or animal origin used in folk medicine which are:

> (1) recognized in the Philippine National Formulary;
>
> (2) intended for use in the treatment or cure, mitigation of disease symptoms, injury, or bodily defect for use in man;
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> (2) intended for use in the treatment or cure, mitigation of disease symptoms, injury, or bodily defect for use in man;
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> (3) other than food, intended to affect the structure of any function of the body of man;
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> (4) put into finishes, ready-to-use form by means of formulation, dosage, or dosage directions; and
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> (5) intended for use as a component of any of the articles specified in clauses (1) to (4)."[66]

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[63] Rep. Act No. 3720 (1963), sec. 30 (a).
[64] Rep. Act No. 3720 (1963), sec. 30 (d).
[65] S. No. 272, 8th Congress, 1st Regular Session (1988), Explanatory Note.
[66] S. No. 272, 8th Congress, 1st Regular Session (1988), art. 6(g).

The proposed Consumer Code also adds a "banned rug or device" to the RA 3027 enumeration of "adulterated drugs and devises."[67]

The intention of the Department of Health to legislate generic prescribing and labeling is also reflected in the proposed Code. Generics are drugs sold under the name of their active ingredients or the International Nonproprietary Name (INN), as approved by the WHO.[67a] If a drug is not designated solely by its generic name recognized in an official compendium it shall be considered misbranded, unless its label bears "(1) the trade or brand name of the drug, if such there be;" and "2) in case it is fabricated from two or more ingredients, the generic, or common, or usual name of each active ingredient x x x Provided, that where compliance with this paragraph is impracticable, exemptions shall be established x x x."[68] Moreover, a prescription drug distributed or offered for sale shall be deemed misbranded "unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the trade or brand name x x x printed prominently and in type at least half as large as that used for any trade or brand name thereof; (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels x x x and such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary, upon recommendation of the Director."[69]

The proposed Code also penalizes any person who "shall advertise any food, drug, cosmetic, device, or hazardous substance in a manner that is false, misleading, or deceptive, or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit, or safety."[70]

The imposition of such stricter controls would go a long way in preventing the influx of products which have been banned or the use of which has been severely restricted. And to identity the TNCs involved in the production and marketing of products considered hazardous, the help of the UN CENTRE on Transnational Corporations may be elicited. In the final analysis, the global solution to the problem of hazardous exports, rests equally with the developing countries, as it does with the industrialized world. Before any Third World nation objects to the imposition of other countries' standards, it should first set up its own regulatory machinery, and acquire the necessary knowledge and administrative capability to protect its citizens and its environment.

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67 S. No. 272, th Congress, 1st Regular Session (1988), art. 13(f).
67a "Danger of Generic Labeling of Drugs," *The Journal*, 29 February 1988, page 3.
68 S. No. 272, 8th Congress, 1st Regular Session (1988), art. 14(e).
69 S. No. 272, 8th Congress, 1st Regular Session (1988), art. 14(1).
70 S. No. 272, 8th Congress, 1st Regular Session (1988), art. 122(d).