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EXPORT OF PHARMACEUTICAL PRODUCTS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

The export provision\(^1\) of the Federal Food, Drug, and Cosmetic Act\(^2\) has been in force since 1906. The Act prohibits the introduction of adulterated or misbranded drugs into interstate commerce.\(^3\) The export provision, however, allows the exportation of such drugs if the product meets the specifications of the foreign purchaser, does not conflict with the laws of the importing nation, bears a label stating that it is intended for export, and is not offered for domestic sale.\(^4\) Amendments and judicial interpretations of the Act have produced a number of inconsistencies in the export law.

In September 1979, the Senate passed a bill\(^5\) to amend the Federal Food, Drug, and Cosmetic Act. If enacted, the Senate bill would result in the first major revision of U.S. drug export law since 1906.\(^6\) The proposed change comes at a time of intense debate over the export of products not approved for use by U.S. citizens.\(^7\) Some critics contend that the United States has a moral responsibility not to export products that it deems unsafe or unhealthy.\(^8\) Other commentators argue that each nation has the sovereign right to decide for itself which products to import.\(^9\)

This Note will examine the present export provision of the Federal Food, Drug, and Cosmetic Act, paying particular attention to the inconsistencies that have developed in the law. It will then analyze the morality and sovereignty arguments and discuss recent proposals to amend the stat-

\(^1\) 21 U.S.C. §381(d) (1976).
\(^2\) Id. §§ 301-392.
\(^3\) Id. §331(a).
\(^4\) Id. §381(d)(1).
\(^6\) See id. § 134.
\(^7\) A House subcommittee recently studied U.S. policy concerning the export of banned products and concluded that it is in need of reform. HOUSE COMM. ON GOVERNMENT OPERATIONS, REPORT ON EXPORT OF PRODUCTS BANNED BY U.S. REGULATORY AGENCIES, H.R. REP. NO. 1686, 95th Cong., 2d Sess. 3 (1978) [hereinafter cited as EXPORT REPORT]. See also U.S. Export of Banned Products: Hearings Before a Subcomm. of the House Comm. on Government Operations, 95th Cong., 2d Sess. (1978) [hereinafter cited as Export Hearings].
\(^9\) See e.g., id. at 245 (testimony of Joseph A. Califano, Jr., Secretary of HEW).
ute. Finally, the Note will suggest an export policy that will accommodate the competing policy considerations and resolve the legislative and judicial inconsistencies.

I

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

The Food and Drugs Act of 1906, the predecessor of the Federal Food, Drug, and Cosmetic Act, prohibited the manufacture and shipment of adulterated or misbranded foods or drugs. Section 2 of the Food and Drugs Act outlawed the transportation of such articles in interstate or foreign commerce, and provided criminal penalties for violations. A proviso to that section, however, exempted articles intended for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped.

The legislative history of the 1906 Act reveals that in exempting exports, Congress was concerned about the use of preservatives in packing meat for overseas shipment. One of the bill's sponsors explained:

> The representatives of the great meat-packing and meat-exporting business called upon me . . . and asked an amendment to the bill . . . .

> . . . [T]he demand in Great Britain, as I understand, is that their meats shall be received as fresh as it is possible to get meat from this country to their country, and the only way to ship the meats with safety is to pack them in borax [boric acid]. They thought that somebody might possibly hold that borax was deleterious, and therefore if there became a law it might suddenly interfere, to their great detriment, with their export business.

During the floor debate, the Senate hotly disputed the exact scope of the exemption. Two of the bill's sponsors maintained that the proviso only covered exports packed in substances that would render them "adulterated" under the Act, not goods contaminated in their manufacture. Other Senators, however, expressed the belief that the courts would interpret the exemption more broadly to include adulterated ingredients. Although

11. Id. §§ 1, 2.
12. Id. § 2.
13. Id. The proviso also stated that articles intended for export but sold or offered for sale in domestic commerce were not exempt from the Act.
15. Mr. HEYBURN. "Prepared" relates to packed.
Mr. SPOONER. "Prepared" does not relate to packed, in my opinion . . . .
Mr. SPOONER. The Senators have been explaining to me for some time that it meant packing in borax.
one Senator called for a provision clear enough to prevent any confusion, the bill passed with the questioned language intact.

Subsequent court decisions confirmed the Senate's fear of judicial misinterpretation. In *Philadelphia Pickling Co. v. United States*, the third circuit held that federal authorities acted properly in seizing adulterated tomato paste. The defendant in *Philadelphia Pickling* had sent the paste from New Jersey to Pennsylvania for examination prior to shipment to England, but, upon testing, the goods failed to meet the English standard. The court emphasized that one of the purposes of the Food and Drugs Act of 1906 was "to keep adulterated articles completely out of the channels of interstate commerce." In dictum, however, the court noted that, due to the section 2 proviso, "if the paste had met the English test . . . (although it might have been adulterated according to the United States standard) [it] would not have been subject to seizure by this government."20

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Mr. HEYBURN. It has no connection with borax, but any injurious packing.

Mr. SPOONER. What would the word "prepared" mean as applied to a bottle containing some drug or to a box of some drug?

Mr. McCUMBER. It certainly would not mean something in the manufacture of the drug.

Mr. SPOONER. It would not?

Mr. McCUMBER. And no court, I maintain, would hold that when the words "prepared and packed for shipment" were used the word "prepared" could be construed to mean the ingredients entering into the drug itself.

Mr. SPOONER. I do not think any court would fail to so hold.

40 CONG. REC. 1132 (1906).

16. Mr. SPOONER. I submit . . . that the language ought to be so plain that there should be no difference of opinion about it.

Id.

17. In considering the bill, the House of Representatives also expressed concern with the packing of meat for overseas shipment. See 38 CONG. REC. 898 (1904). Commenting on the House version, one representative noted that the export exemption was "especially intended for the preparation of certain articles for export, such as meats." 40 CONG. REC. 8890 (1906) (remarks of Rep. Mann) (emphasis added). Shortly before the House passed the bill, one supporter of the legislation observed that his sole objection to the bill was the export provision. Id. at 8979 (remarks of Rep. Goulden).

18. 202 F. 150 (3d Cir. 1913). The manufacturer argued that since the product was intended for export, it was not subject to seizure. The court held, however, that the shipment across state lines placed the goods in interstate commerce, and the Act therefore applied regardless of the purpose of the shipment. Id. at 154.

19. Id. at 152 (emphasis added).

20. Id. at 154. A contemporary observer, however, reading the export proviso in its intended, narrow sense, stated that its apparent purpose was "to permit the use in certain food products for export of preservatives which are declared deleterious under the strict rulings of the Department of Agriculture when applied to food products intended for consumption in the United States." W.W. THORNTON, THE LAW OF PURE FOOD AND DRUGS 181 (1912) (emphasis added).
In *United States v. Catz American Co.*, the ninth circuit went even further in interpreting the 1906 Act. *Catz* involved the seizure of a shipment of dried figs intended for export to Italy. The Government claimed that the goods consisted partly of "filthy, decomposed or putrid vegetable matter," and the court found the figs "wormy in part." Nevertheless, the court affirmed a district court decision that the goods were exportable. According to the *Catz* court, goods intended for export are not "adulterated" if the manufacturer prepares or packs them in conformity with the foreign buyer's specifications, provided that the manufacturer does not use any substance in the preparation or packing that conflicts with the laws of the importing nation. Furthermore, "the words 'prepared or packed' should be held to mean any condition or grade of the merchandise, including any deteriorated state of the goods, considering the class to which they belong."

Thus, as some members of Congress feared, courts interpreted the crucial "prepared and packed" language of the 1906 Act's export provision broadly, holding that the section 2 exemption applied to all exports, whether adulterated during manufacture, preparation or packing, or contaminated by the course of nature.

Decisions such as *Philadelphia Pickling* and *Catz* produced several major inconsistencies in the application of the 1906 Act. Presently, an American manufacturer may not export adulterated or contaminated food

21. 53 F.2d 425 (9th Cir. 1931).
22. Id.
23. Id. at 426.
24. Id. A district court in 1935 reached a similar result in an unreported case involving dried apples. The court permitted shipment of the apples to France despite testimony that the goods contained arsenic and lead and were unsafe for human consumption. [1935] FDA ANN. REP. 19, reprinted in FOOD LAW INSTITUTE, FEDERAL FOOD, DRUG AND COSMETIC LAW, ADMINISTRATIVE REPORTS 1907-1949 at 843 (1951).
25. See note 15 supra and accompanying text. Although it did not refer to the 1906 Act's legislative history, the dissenting opinion in *Catz* interpreted the section 2 exemption in a manner consistent with congressional intent. The dissenting judge felt that exports would be exempt from condemnation only if their contaminated condition was due to their packing or preparation. 53 F.2d at 426.

In several later cases, courts prohibited the export of contaminated domestic or imported products that had been seized after entering interstate commerce. See, e.g., United States v. Kent Food Corp., 168 F.2d 632 (2d Cir.), cert. denied, 335 U.S. 885 (1948) (manufacturer may not export condemned catsup after interstate shipment for the purpose of domestic sale); 230 Boxes, More or Less, of Fish v. United States, 168 F.2d 361 (6th Cir. 1948) (FDA may seize imported fish infested with parasitic worms); United States v. 76,552 Pounds of Frog Legs, 423 F. Supp. 329 (S.D. Tex. 1976) (right to export contaminated frog legs denied when record established some of the goods sold domestically). There have been, however, no recent cases involving seizures of food or drugs intended solely for export to foreign nations. Apparently, the FDA learned from experience and stopped trying to prevent such exports, regardless of the condition of the goods.
or drugs if he offers them for sale in the United States. If he manufactured
the food or drugs solely for export, however, he may sell them overseas.
Furthermore, a single shipment of adulterated food or drugs may be subject
to partial condemnation and partial approval. For instance, a manufac-
turer may intend to divide a shipment for export to two different countries.
The goods may be found to violate the standards of one of the importing
nations, but not of the other. Although the goods were uniform in their
adulteration, the U.S. Government would only be able to seize that portion
of the shipment intended for export to the nation with the stricter standard.

The Federal Food, Drug, and Cosmetic Act, enacted in 1938,26
repealed the 1906 Food and Drugs Act.27 One version of the 1938 Act
included foreign trade in its definition of "interstate commerce," which
would have made the new Act equally applicable to exports and domestic
commerce.28 Industry representatives, however, testified before Congress
that the proposed change would harm U.S. business, create administrative
burdens, and impose American standards on other nations.29 Congress
thereafter amended the bill to reincorporate the 1906 export provision,30
with one minor change.31

Having thus bypassed an opportunity to resolve the inconsistencies cre-
ated by judicial interpretations of the 1906 Act, Congress proceeded to cre-
ate further incongruities in the drug export law. For example, in 1957

27. Id. § 902(a).
28. See Food, Drugs, and Cosmetics: Hearings on S. 1944 Before the Subcomm. of the Sen-
ate Comm. on Commerce, 73d Cong., 2d Sess. 115 (1933).
29. Id. at 143, 426, 477.
30. See Food, Drugs, and Cosmetics: Hearings on S. 2800 Before the Senate Comm. on
Commerce, 73d Cong., 2d Sess. 1 (1934).
31. The only change was a requirement that manufacturers label the goods "for export." 

In 1949, the House of Representatives passed an amendment to the export section. H.R.
562, 81st Cong., 1st Sess., 95 CONG. REC. 7954-55 (1949). The bill required that food and
drugs intended for export meet all of the standards imposed on products sold in domestic
commerce, with three minor exceptions. See H.R. REP. No. 801, 81st Cong., 1st Sess. 3 (1949).
The committee report indicates that the House was concerned with the health of U.S. citizens
abroad who were exposed to adulterated or mislabeled American products. The report also
expresses concern for "international morality," the foreign market for U.S. goods, and "inter-
national good will and peace." Id. at 2. Top officials of several federal agencies, including the
Department of Commerce, expressed support for the measure. Id. at 5-7. The bill, however,
met its demise in a Senate committee. See 95 CONG. REC. 7998 (1949).
Congress amended section 304(d) of the Act\(^2\) to permit the export of imported goods condemned after entry into domestic commerce.\(^3\) The amendment, however, prohibits exportation if the imported goods contain poisonous or deleterious substances or are mislabeled so as to endanger human health.\(^4\) Consequently, the amended law prohibits the export of some contaminated imported goods, but permits the export of similar articles produced domestically.\(^5\)

The 1962 drug amendments,\(^6\) the first major change in the Food, Drug, and Cosmetic Act of 1938, did not alter the language of the export provision.\(^7\) Amendments to other sections of the Act, however, added another inconsistency to the law concerning drug exports. "New drugs," which the statute defines as those not recognized as safe and effective or used only in investigations,\(^8\) are not exportable.\(^9\) Drugs that were subject to the 1906 Act, however, are exempt from this provision.\(^10\) Therefore, drugs developed before 1938 may be exported even if the FDA has banned or never approved them for domestic use, and even if they are adulterated or mislabeled.\(^11\)

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33. Act of Aug. 31, 1957, Pub. L. No. 85-250, 71 Stat. 567. The person seeking release of the imported article must establish that the adulteration or contamination did not occur after importation and that he had no reason to believe that the article was in violation of the law.
34. Id. See H.R. REP. No. 933, 85th Cong., 1st Sess. 2 (1957). When the goods are to be returned to the original foreign supplier, however, they may be shipped regardless of their condition. Id. at 3.
35. Two executive branch officials pointed out that the 1957 bill would result in different treatment for exports and imports. See id. at 4. Apparently, Congress was unconcerned with the inconsistency.
37. The amendments passed in the aftermath of the thalidomide tragedy in Europe, when Congress was under considerable pressure to prevent such an occurrence in the United States. See, e.g., 108 CONG. REC. 21,058-59 (1962).
41. Export Hearings, supra note 7, at 151 (testimony of Dr. Donald Kennedy, Commissioner, Food and Drug Administration). See USV Pharmaceutical Corp. v. Weinberger, 412 U.S. 655, 667 (1973) ("[T]he legislative history indicates that it was Congress' purpose to exempt only those drugs that had never been subject to the new drug regulation.").

The most recent amendments to the Food, Drug, and Cosmetic Act, adopted in 1976, provide special treatment for medical devices. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539. The export provision is similar to that for drugs, but permits the export of unapproved, investigational, or banned devices if the Secretary of HEW determines that the export is not contrary to public health and safety and has the approval of the importing country. 21 U.S.C. § 381(d)(2) (1976). See H.R. CONF. REP. 1090, 94th Cong., 2d Sess. 66, reprinted in 1976 U.S. CODE CONG. & AD. NEWS 1103, 1118. The medical devices amendments, therefore, produced yet another inconsistency in the seemingly straightforward statute.
The drug export law has evolved substantially from Congress' original concern with preserving meat for overseas shipment. Highly questionable judicial interpretations and piecemeal amendments have created a number of anomalies in the statute. The law's treatment of products sold in the domestic market and imported goods differs from its treatment of goods produced specifically for export. Drugs lacking FDA approval are exportable only if developed before 1938. As a recent FDA Commissioner admitted, the law "is so internally inconsistent that it is very hard to know what the policy is."

II

POLICY CONSIDERATIONS

The need for reform of the U.S. drug export law is clear. In order to develop a consistent policy, Congress will have to reconcile two conflicting viewpoints. Proponents of moral responsibility contend that the United States has an obligation not to "dump" its unwanted products abroad. Conversely, advocates of international sovereignty argue that the United States should not attempt to police the rest of the world, but rather permit other nations to import the drugs they consider necessary or desirable. Each view has its merits and its flaws.

A. MORAL RESPONSIBILITY

From the enactment of the first federal food and drug statute in 1906, critics have argued that the United States has a responsibility to other nations in selecting which drugs to export. Currently, there exist many compelling reasons for monitoring U.S. drug exports. International trade has grown exponentially during this century. A number of countries are only beginning to benefit from global development and still import large quantities of vital products, including drugs. The laws of many countries,

43. See, e.g., United States v. 484 Bags, More or Less, 423 F.2d 839 (5th Cir. 1970).
44. See notes 38-41 supra and accompanying text.
45. Export Hearings, supra note 7, at 150 (testimony of Dr. Donald Kennedy).
46. A Congressman who wanted to strike the export exemption from the 1906 Act framed the question: "[A]s a matter of public policy should we knowingly permit to go away from our shores an impure food article? This bill says yes. It is not the best advertisement for us as a people or our goods; it is not the best evidence of high morals." 38 CONG. REC. 900 (1904) (remarks of Rep. Gaines).
47. For example, the Central American nations import 90% of the raw materials they use in manufacturing pharmaceutical products. Competitive Problems in the Drug Industry: Hearings Before the Subcomm. on Monopoly of the Senate Select Comm. on Small Business, 94th Cong., 2d Sess., pt. 32, at 15,396 (1976) [hereinafter cited as Drug Industry Hearings].
however, provide little, if any, protection against potentially hazardous drugs. Therefore, critics argue, the developed nations have a moral responsibility to insure the safety of the drugs they export.

The absence of a readily available remedy for injuries caused by adulterated drugs is further reason for controlling the quality of exported pharmaceuticals. Due to the disproportionate expense involved, it is virtually certain that no foreign consumer would bring suit against an American corporation in a U.S. court. Furthermore, foreign governments may be unable to litigate on behalf of their citizens. In some cases, a citizen or government may be able to obtain jurisdiction over the American corporation in a foreign court. As a practical matter, however, few governments will bring such cases, particularly in less-developed countries.

Unfortunately, unilateral action by the United States would do little to improve the quality of drugs sold internationally and would harm American business interests. Major pharmaceutical companies based in other nations will continue to export dangerous drugs, to the detriment of American firms. Furthermore, American-based companies will be able to evade U.S. laws through various devices, such as the establishment of subsidiaries in countries that have lenient regulations.

48. Only one-half of the Latin American countries have the legal authority to assess the scientific value of imported drugs. The Depo-Provera Debate: Hearings Before the House Select Comm. on Population, 95th Cong., 2d Sess. 198 (1978) [hereinafter cited as Depo-Provera Hearings]. Latin American nations' policies concerning the disclosure of risks associated with drugs fall into three categories. Some countries have no laws requiring risk disclosure. Others have laws that apparently authorize government officials to require disclosure of risks, but these laws are unclear and rarely enforced. As of 1976, only four Latin American countries had strict laws, and these were widely violated. Drug Industry Hearings, supra note 47, at 15372 (statement of Dr. Milton Silverman).

49. In 1975, the World Health Organization (WHO) adopted a "certification scheme on the quality of pharmaceutical products moving in international commerce." W.H.A. Res. 28.65, 28 WORLD HEALTH ASSEMBLY OFFICIAL RECORDS, pt. 1, 35, 94 (1975). Under this scheme, exporting countries must either certify that each drug they export is authorized for sale within their borders or state the reason why it is not approved. They must also provide assurances that the drug is produced according to manufacturing standards set by WHO. Id. at 88. The United States and at least 24 other nations have agreed to abide by these standards. See 31 WHO CHRONICLE (Dec. 1977 Supp.). The European Economic Community has developed a similar scheme for its member nations. See 10 J. WORLD TRADE LAWS 393 (1976).

50. See, e.g., Pfizer, Inc. v. Lord, 522 F.2d 612 (8th Cir. 1975), cert. denied, 424 U.S. 950 (1976) (foreign governments may not sue as parens patrie for antitrust damages).

51. One congressional witness noted that health agencies in many countries "simply do not have the clout to compete with other parts of their own government when commercial interests are involved." Drug Industry Hearings, supra note 47, at 15385 (testimony of Dr. Myron E. Wegman, University of Michigan).


53. American companies could also evade the law through what one expert terms "the
The imposition of severe regulations would also have undesirable effects on domestic competition. American corporations that have large-scale international operations and foreign subsidiaries will find it easy to evade governmental supervision. Smaller U.S. pharmaceutical firms, however, may be unable to begin or expand foreign operations in order to circumvent American laws. Finally, a ban or strict limitation of exports would also have an adverse impact on the balance of trade.54

B. Sovereignty

Proponents of the sovereignty position contend that the United States must respect other nations' choices of what goods to allow into their marketplaces, rather than appointing itself guardian of the health of persons beyond its borders. Several factors support this position. The FDA's decisions about drugs are subject to American political pressures and should not be binding on the rest of the world. Furthermore, the FDA may not approve certain drugs, such as those used in the treatment of tropical diseases, because there is no domestic demand for them.55

Finally, the considerations that influence FDA decisions may have little or no meaning abroad, since the risk-benefit ratio of many drugs varies from country to country.56 Depo-Provera, an injectible contraceptive, is a striking example of such a drug. Because Depo-Provera is associated with breast tumors, and because other safe and effective methods of contraception are readily available, the FDA has not approved it for use as a contraceptive.57 Depo-Provera, however, requires only one injection every three to six months, and is therefore significantly more convenient and effective in the developing countries than the more traditional methods of birth control. In such nations, higher birth rates, lower physician-patient ratios, and fewer available or acceptable means of contraception favor the drug's use.58

South Slobovian connection." Under this scheme, an American-manufactured drug is put into its final form outside of the United States. The other country then becomes the product's "country of origin," and may export the drug, certifying that it is safe and effective, even if the FDA does not approve its sale. Drug Regulation Reform Act: Hearings on H.R. 11611 Before the Subcomm. on Health and Environment of the House Comm. on Interstate and Foreign Commerce, 95th Cong., 2d Sess. 1324 (1978) [hereinafter cited as House Drug Bill Hearings] (statement of Dr. Milton Silverman).

54. See Export Hearings, supra note 7, at 5-6.
56. Depo-Provera Hearings, supra note 48, at 310-11.
57. Export Hearings, supra note 7, at 93-96. The FDA has approved the drug for U.S. use in the treatment of endometrial cancer. Id. at 152.
58. About 70 countries approve the use of Depo-Provera as a contraceptive. Id. at 93.
Nevertheless, the United States cannot abandon all responsibility for American products. A sizeable percentage of U.S. exports go to countries that have neither the resources nor the technical capacity to monitor and test them. Furthermore, the FDA admits that its efforts to notify other countries of its findings regarding particular drug products are often ineffective.

Private channels are also unreliable sources of important medical information. In a number of cases, American pharmaceutical companies have used questionable methods in promoting drugs in less-developed countries. For instance, the FDA only approves the use of the antibiotic chloramphenicol for life-threatening infections, and U.S. labeling warns that misuse can cause aplastic anemia, which has a thirty to sixty percent mortality rate. In Latin America, however, U.S. companies have promoted the drug as a cure for tonsilitis, bronchitis, and the common cold, frequently without mention of risk. In response to such tactics, the developing nations have begun to request that exporting countries regulate the information disseminated by multinational corporations.

III

PROPOSALS

A unified and workable export policy must strike a balance between morality and sovereignty considerations, bearing in mind the unequal distribution of resources among nations. Recent proposals considered by Con-

59. The CIA recently estimated that one-third of all U.S. exports are sent to the less-developed nations. [1978] INTERNATIONAL TRADE REPORTER'S U.S. EXPORT WEEKLY (BNA) No. 231, C-4.

60. See Export Report, supra note 7, at 22-23. See also note 62 infra.

61. See generally Drug Industry Hearings, note 47 supra.

62. House Drug Bill Hearings, supra note 53, at 1324 (testimony of Dr. Milton Silverman). This drug also provides an example of the inadequacy of providing notice through international channels. The FDA notified WHO in 1971 that it considered chloramphenicol dangerous and warned that detailed labeling should accompany all sales of the drug. The State Department notified all U.S. diplomatic posts of the FDA's action. Export Hearings, supra note 7, at 112-25. Five years later, however, researchers found that pharmaceutical company detailmen were still misinforming Latin American physicians about the drug. By the middle of 1977, about one-half of the U.S. firms doing business in Latin America had conformed their promotion of chloramphenicol to U.S. standards. House Drug Bill Hearings, supra note 53, at 1324.

63. A report commissioned by the U.N. Economic and Social Council recommended that "home countries should publicize prohibitions and restrictions on products, or ingredients of products, found to be hazardous to health, and should consider whether their export should also be prohibited or made conditional upon specific approval by the importing country." UNESC, The Report of the Group of Eminent Persons to Study the Role of Multinational Corporations on Development and on International Relations, E/5500/Add. 1 (Pt. I), reprinted in 13 INT'L LEGAL MATERIALS 800, 856 (1974).
gress are not successful in this respect. The Drug Regulation Reform Act of 1978,\footnote{S.2755, 95th Cong., 2d Sess. (1978), reprinted in Senate Drug Bill Hearings, supra note 8, at 7.} modeled on the Medical Device Amendments of 1976,\footnote{Pub. L. No. 94-295, 90 Stat. 539. \textit{See} note 41 supra.} proposed significant changes in the export law. The bill permitted the export of those drugs the FDA has approved for domestic sale. It also allowed the export of unapproved drugs if the manufacturer obtained a permit from the FDA.\footnote{S.2755, 95th Cong., 2d Sess. § 134(a),(c) (1978), Senate Drug Bill Hearings, supra note 8, at 125.} To obtain a permit, the manufacturer had to certify that it had notified the government of the importing nation of the drug's U.S. status and that the foreign government did not disapprove of the importation.\footnote{Id. § 135(a)(8), Senate Drug Bill Hearings, supra note 8, at 126. The bill also retained the current law's requirements that the drug meet the foreign purchaser's specifications and that the label state that the drug is intended solely for export. \textit{Id.} § 135(a)(6),(7), Senate Drug Bill Hearings, supra note 8, at 126.} The bill required the FDA Commissioner to issue the permit unless he or she determined that the manufacturer had not met one of several specified conditions for approval.\footnote{Id. § 135(b), Senate Drug Bill Hearings, supra note 8, at 126-27. The permit was deemed issued after 30 days unless the Commissioner notified the applicant that further deliberations were necessary. \textit{Id.} § 135(e), Senate Drug Bill Hearings, supra note 8, at 127-28.}

The 1978 proposal did not get beyond the subcommittee level in either House of Congress. In 1979, Senator Kennedy introduced a less comprehensive Drug Regulation Reform Act.\footnote{S. 1075, 96th Cong., 1st Sess. (1979).} The 1979 bill's original export provision required a permit for the export of drugs not approved for U.S. use. The FDA was to issue export permits for unapproved drugs only if they were to be used to treat or prevent diseases of low incidence in the United States or if the benefits of use in the foreign country exceeded the risks.\footnote{Id. sec. 134, § 802(c) (original bill). Although the applicant met one of these conditions, an export permit would not have issued under the original 1979 proposal if the application was incomplete or contained a false statement, the drug did not accord to the specifications of the foreign purchaser, the applicant could not be expected to comply with the requirements for export, or the export would have been contrary to the public health or result in the deception of patients. \textit{Id.} sec. 134, § 802(c)(2)(A)-(D) (original bill).} Furthermore, the bill required certification from the importing government that it had reviewed scientific data concerning the drug.\footnote{Id. § 802(b)(6)(A) (original bill). The bill also extended the time period for denial of a permit to 60 days, \textit{id.} § 802(f), and provided for public comment on all permit applications, \textit{id.} § 802(d).}

After holding hearings on the bill, a Senate committee revised the
export provision to more closely parallel the Medical Device Amendments of 1976.\textsuperscript{72} The bill, as altered by the subcommittee and passed by the Senate, allows the export of an unapproved drug if the Secretary of HEW determines that exportation "is not contrary to public health and safety and has the approval of the country to which it is intended for export."\textsuperscript{73} The Senate bill also establishes a Task Force on Drug Export Policy and directs it to develop a Drug Export Policy Plan within 180 days of enactment of the statute.\textsuperscript{74}

All of the recent proposals represent advances over the current law. They impose uniform requirements for all drugs, regardless of the date of their initial manufacture.\textsuperscript{75} They also enable the FDA to prevent exports because of concerns for public health abroad as well as in the United States.\textsuperscript{76} Furthermore, the 1978 bill and the original 1979 proposal required exported drugs to meet U.S. manufacturing, quality, and labeling standards.\textsuperscript{77}

None of the proposals, however, adequately reconcile the conflicting

\textsuperscript{72} See note 65 supra and accompanying text. The committee report on the revised bill states that one purpose of the legislation is "to create new jobs for American workers and markets for American drug products by liberalizing drug export policy." S. REP. NO. 321, 96th Cong., 1st Sess. 13 (1979). This may explain why the committee chose to retreat from the more stringent export provisions of the original 1979 bill. See notes 69-71 supra and accompanying text.

\textsuperscript{73} S. 1075, 96th Cong., 1st Sess., sec. 134, § 801(d)(3), 125 CONG. REC. S13,479 (daily ed. Sept. 26, 1979) (revised bill). The manufacturer must also comply with the requirements of § 801(d)(1) of the present law. \textit{Id.} See text accompanying note 4 supra.

\textsuperscript{74} S. 1075, 96th Cong., 1st Sess., sec. 134, § 801(d)(3), 125 CONG. REC. S13,479 (daily ed. Sept. 26, 1979) (revised bill). The bill orders the task force, in developing a drug export policy, to consider the differing health needs of other countries; respect risk-benefit assessments made by foreign governments; assist international efforts to improve health; consider foreign countries' means of regulating drugs; consider U.S. foreign and economic policies; and suggest the type of notice that manufacturers should give the FDA before exporting unapproved drugs. \textit{Id.}

\textsuperscript{75} See notes 38-41 supra and accompanying text.


\textsuperscript{77} The 1979 bill passed by the Senate directs the task force to consider a number of factors, see note 74 supra, one of which is to "recognize that the manufacture of drugs exported from the United States should be regulated by standards regarding manufacturing requirements and practices that are the same as those applied to the manufacture of drugs approved for use in this country." S. 1075, 96th Cong., 1st Sess., sec. 134, § 801(d)(3), 125 CONG. REC. S13,479 (daily ed. Sept. 26, 1979) (revised bill). This provision could be read as a statement of congressional intent to impose U.S. quality standards on exports. Nevertheless, by listing quality standards as only one of several considerations entering into the Export Policy Plan, the Senate has not given the task force a clear mandate. For example, the bill also requires the task force to consider American economic and foreign policies. The task force could determine that requiring exports to meet U.S. quality standards would conflict with these policies. Congress should make a clear statement on this issue, either through a specific directive to the task force or, preferably, through an explicit provision in the statute.
morality and sovereignty policies. Several considerations should guide Congress and any future task force in their attempts to develop a coherent drug export policy.

First, the law should permit the export of all drugs that the FDA has approved for U.S. use. Manufacturers that wish to export unapproved drugs should notify the importing nation’s government whether the drug is 1) new and undergoing evaluation; 2) new and not being evaluated; 3) approved for investigational use only; or 4) banned. The importing country should also receive full information about the drug, including the diseases or conditions for which the FDA approves or bans its use, those conditions or diseases for which it might be used under close medical supervision, and possible side effects and their incidence. Once the foreign government has received this information, it will be able to make an informed judgment whether to allow importation of the drug. Thus, the importing nation will make the final decision and retain its sovereign right to accept or ban any pharmaceutical product. At the same time, the United States can fulfill its moral responsibility to that nation by only allowing exportation when the Secretary of HEW ascertains that the drug manufacturer has presented full and fair information to the importing country.

Second, the law should require exported drugs to meet the quality standards established for the domestic sale of pharmaceuticals. Thus, a manufacturer would not be able to export a drug if it contained “filthy, putrid, or decomposed” substances, if it was packed under insanitary conditions, or if the drug or its container was made of poisonous or deleterious materials. Furthermore, the new law should allow drugs to be exported only if they are of the strength, purity, and quality set forth on their labels.


80. The 1979 bill passed by the Senate requires an affirmative ruling that exportation is not contrary to public health and that the importing nation approves of the shipment. See note 73 supra and accompanying text. This is an improvement over the prior proposals, which deemed an export permit issued unless the FDA explicitly denied the application within a specified period. See notes 68 & 71 supra.


83. See id. § 351(b)-(d). Since the United States has already agreed to ensure compliance with WHO quality and labeling standards for exported drugs, see note 49 supra, requiring
Third, all drugs exported from this country should meet U.S. labeling standards. This would compel all manufacturers that export drugs to prevent any false or misleading labeling and to place on labels their names and places of business, the quantity of the contents, warnings about habit forming ingredients, the established name of each active substance in the drug, and directions for use. Furthermore, since the Food, Drug, and Cosmetic Act requires drug manufacturers to present this information on the label "in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use," exported drugs would be labeled in the language of the importing country. In addition, if U.S. law requires patient package inserts for drugs sold domestically, it should also require them for exported pharmaceuticals.

No justification exists for not requiring exporting drug producers to fully label their products. Label requirements would give consumers more information concerning the potential hazards of a drug so that they may make a rational decision about its use. Requiring full disclosure of pertinent information certainly would not violate the importing nation's sovereignty, provided that the U.S. legislation only established minimum standards, thereby leaving the foreign government free to require the manufacturer to supply other information on the label.

Finally, any new export law should provide special consideration for investigational drugs. One justification for allowing the export of compliance with domestic standards would not increase administrative burdens and would reaffirm the country's commitment to international cooperation in health-related matters.

84. See 21 U.S.C. § 352 (1976). The law should require full compliance with the labeling requirements for approved as well as unapproved drugs. Drugs routinely used in the United States may not be safe when used by citizens of other nations. For example, the nutritional status of persons in developing countries results from diets significantly different from the typical American diet and can affect reactions to a drug. Genetic factors also have a role. Perhaps due to their Indian blood, Mexicans are more susceptible to aplastic anemia than are many U.S. citizens. Drug Industry Hearings, supra note 47, at 15,367. Aplastic anemia is one severe side effect that may result from misuse of the drug chloramphenicol. See text accompanying note 62 supra. Since most drugs are tested in the United States on American citizens, some risks may not be apparent at the time of export.


86. 21 U.S.C. § 352(c) (1976).


88. The Pharmaceutical Manufacturers Association opposed the 1978 bill's labeling requirements for exported drugs on the ground that the importing nation's laws and regulations could require revised labeling. Senate Drug Bill Hearings, supra note 8, at 362.
unapproved drugs is that they may treat diseases that are virtually non-existent in the United States. For this reason, American companies may wish to conduct research in another country. In such cases, the FDA should require the exporting manufacturer to certify that it is granting any human subjects used in such research abroad the same privacy and informed consent rights as are accorded to participants in experiments conducted in this country.

CONCLUSION

Congress enacted the export provision of the Federal Food, Drug, and Cosmetic Act in 1906. Since that time, courts and Congress itself have fractured the statute and it now contains unsupportable inconsistencies. For instance, whether a given drug may be exported may depend on when it was first introduced into U.S. commerce, or whether it is imported, made and sold domestically, or manufactured for export. The law also permits the export of certain drugs that are banned, contaminated, or not approved for U.S. use.

A new drug export statute must strike a balance between U.S. moral responsibility for the health of foreign citizens and the sovereignty of other nations. The Drug Regulation Reform Act of 1979, as passed by the Senate, fails in its attempt to reconcile these policy considerations. Future development of drug export policy should have as its cornerstone full disclosure of the risks and benefits of exported pharmaceuticals.

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89. The original 1979 bill permitted exportation under such conditions. See note 70 supra and accompanying text.
