Exporting Unapproved New Drugs: Saving American Jobs or Imperiling Foreign Consumers?

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EXPORTING UNAPPROVED NEW DRUGS: SAVING AMERICAN JOBS OR IMPERILING FOREIGN CONSUMERS?

The last day of the 99th Congress saw a momentous piece of health legislation enacted. Called the "Omnibus Health Act" ("OHA"), it is an amalgam of health and health-related measures, key among them being the Drug Export Amendments Act of 1986 ("Drug Export Act" or "Act"). Passage of the Drug Export Act alters radically the long-standing American regulatory practice forbidding the export of "new drugs" not approved for use in the United States by the federal Food and Drug Administration ("FDA").

Although critics of the ban claimed that it resulted only from an inadvertent drafting error during passage of 1938 amendments to the federal Food, Drug, and Cosmetic Act ("FDCA"), others viewed the policy, whatever its origin, "as an important deterrent to the dumping of unsafe drugs in developing countries."

Irrespective of the ban's origin or purpose, Congress' decision to modify it and allow United States manufacturers to ship unapproved new drugs to

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This article focuses almost solely on the debate that took place during the 99th session of Congress on the subject of drug export and the legislative changes that resulted. For an in-depth discussion on the history and origin of the ban on drug exports and earlier proposals to amend it, see Comment, Export of Pharmaceutical Products Under the Federal Food, Drug, and Cosmetic Act, 13 CORNELL INT' L L. J. 125 (1980).

2. The Drug Export Act was part of a last minute legislative compromise. Drug export legislation was never formally considered by the House of Representatives or by a House-Senate Conference Committee in the 99th Congress. The Senate was the only chamber to formally approve a measure authorizing the export of unapproved new drugs during the 99th Congress. See 132 CONG. REC. HI1, 591-92 (daily ed. Oct. 17, 1986, pt. II) (explanation of the recent legislative history of drug export bill by Rep. Waxman).

3. The term "new drug" applies to a category of drugs created by the reenactment of the Federal Food, Drug, and Cosmetic Act ("FDCA") in 1938, and generally refers to drugs not on the market at the time that are not generally recognized as safe and effective by scientific experts. See 21 U.S.C. § 321(a)(2)(p) (1982).

4. Drugs not deemed "new", i.e., those that were on the market prior to the 1938 reenactment of the FDCA, are exempt from the export restrictions. 21 U.S.C. §§ 321(a)(2)(p)(1), 381(d) (1982); see infra note 23 and accompanying text.


countries designated in the legislation represents a fundamental change in American public policy. However, although the pharmaceutical industry played a key role in securing enactment of the Drug Export Act, the major impetus for this policy reversal was the mood of trade protectionism present in the 99th Congress. In this case, Congress's protectionist fervor was piqued by the fledgling biotechnology industry. Specifically, the industry contended that the export ban forced it to transfer vital technology to overseas partners, thus precipitating the loss of American jobs and injuring the nation's competitive advantage in biotechnology.

This comment will examine key portions of the Drug Export Act and the arguments for and against the policy changes they represent. Special attention will be focused on the issue of transshipment or re-export (terms used interchangeably throughout this comment) and whether the Act contains safeguards sufficient to prevent unapproved new drugs from being shipped to Third World countries.

THE DRUG EXPORT ACT — AN OVERVIEW

This portion of the comment will discuss the conflicting ways in which members of Congress viewed the drug export legislation and will examine some specific provisions in the Act, contrasting them, when useful, with some other recent proposals. The purpose of this section is to present a cogent picture of the Drug Export Act as a prelude to a discussion of its ethical implications.

The Drug Export Act was the subject of extensive deliberations in the Senate. In the House, the legislation received far less public scrutiny and was never formally approved by either the committee with jurisdiction over it or the full House, until it came to the floor for a vote as part of the OHA.

Not only did the progress of the legislation differ between the two chambers, but the way in which each chamber viewed the legislation was also quite different.

In the Senate, drug export legislation was viewed and promoted largely on the basis of the salutary effect it would have on the economy and the current trade imbalance. This view is expressed in Senator Orrin Hatch's description.
tion of the bill\textsuperscript{12} to his Senate colleagues:

This legislation will save American jobs, prevent the export of American biotechnology, and decrease our balance-of-payments deficit, without increasing the health risk to foreign consumers, without erecting trade barriers that invite retaliation and without costing the taxpayer money.\textsuperscript{13}

In the House, however, drug export legislation was viewed more skeptically. In stark contrast to Hatch's remarks, Representative Henry Waxman\textsuperscript{14} described the drug export legislation he sponsored\textsuperscript{15} as something of a damage control measure, to rein in, if necessary, the sweeping reforms under consideration in the Senate.\textsuperscript{16} Waxman indicated that the purpose of the legislation he introduced was to assure that any unapproved drugs sold abroad were labeled accurately and did not omit necessary health warnings or contain unfounded health claims.\textsuperscript{17} Further, Waxman conceded that he was "troubled by the proposition that unapproved drugs should be exported from the U.S. under any circumstances."\textsuperscript{18}

Thus, the leadership of the two chambers of Congress approached the drug export legislation from seemingly irreconcilably different perspectives; while the Senate leadership actively championed drug export reform as a desirable trade and economic measure, the House leadership expressed deep reservations about the need for reform. If forced to compromise, however, the House intended to assure that such legislation contained safeguards to protect foreign consumers from what it believed were foreseeable harms.\textsuperscript{19}

\textsuperscript{12} Human Resources Committee. This Committee has primary jurisdiction over the FDCA. CONGRESSIONAL YELLOW BOOK, I-45, III-36 (Fall 1986).


\textsuperscript{14} In the 99th Congress, Representative Henry Waxman was Chairman of the House Committee on Energy and Commerce's Subcommittee on Health and the Environment. This subcommittee has primary jurisdiction over the FDCA. CONGRESSIONAL YELLOW BOOK II-253, IV-29 (Fall 1986).


\textsuperscript{17} Id.

\textsuperscript{18} Id.

\textsuperscript{19} Given the concerns expressed by Representative Waxman, it may seem somewhat anomalous that he eventually agreed to support enactment of drug export legislation at all. Waxman's acquiescence can, however, be explained as a political compromise or deal; he agreed to accept drug export legislation in exchange for Senator Hatch's agreement to include the vaccine injury compensation measure he was promoting in the Omnibus Health Package. See F-D-C Reports, Oct. 27, 1986, at 3.
Not surprisingly, the Drug Export Act reflects both the enthusiasm of the Senate and, albeit to a lesser extent, the reluctance of the House.

The provisions of the Drug Export Act that are examined here include: (a) countries to which unapproved drugs can be shipped, (b) export application requirements, (c) assurances that FDA approval will be actively pursued for any drug exported, and (d) the safeguards intended to prevent any re-export of unapproved new drugs. These provisions are of particular interest because they establish a framework for the legislation and were among the topics most vigorously debated by the Congress as it considered the legislation.

Approved Countries

The Drug Export Act lists twenty-one countries, most of them European, to which American manufacturers may export drugs not approved by the FDA. Such drugs must, however, be approved for use in the country to which they are being shipped by that country's drug regulatory authority. The ostensible basis on which these twenty-one countries were chosen for inclusion in the bill was that they had a regulatory apparatus that was sufficiently sophisticated to protect the health of their consumers. Under current law, new drugs not approved for use in the United States cannot be exported, even if the country of destination has approved the same drug for its own use.

This somewhat simplistic approach to determining which countries are exempt from the ban on unapproved new drug exports (simply listing the approved countries) was derived from the bill sponsored by Waxman. By contrast, the Senate legislation proposed a tiered system; the Congress would designate certain countries that were exempt automatically from the ban but would allow other countries to be added to this list at the behest of the Secretary of the Department of Health and Human Services ("Secretary"), under

21. Id. at § 102, 100 Stat. at 3744 (to be codified at 21 U.S.C. § 3606).
23. Drugs that are not "new drugs" can be exported if they adhere to the specifications of the foreign purchaser, are not in conflict with the laws of the country to which they are intended for export, are labeled on the outside of the shipping package that they are intended for export, and are not sold or offered for sale in domestic commerce. 21 U.S.C. § 381(d)(1) (1982).
certain guidelines. This so-called tiered approach was criticized widely on the basis that the Secretary would find it difficult, if not impossible, to resist demands from United States allies that they be added to the list of approved countries, irrespective of whether they met the guidelines prescribed. Ultimately, the chambers compromised by adopting the House approach but expanded the list of approved countries by nearly threefold. Further, the power to add countries to the approved list was retained by the Congress.

Export Application Requirements

Although unapproved new drugs may be shipped to the countries designated in the Act, would-be exporters must make application to the Secretary ninety days prior to shipping. An application must identify the drug to be shipped, list the country of destination and person to whom it is to be shipped, and make specific “certifications.” The required certifications include assurances that: (a) unapproved drugs will be exported only to approved countries, (b) only reasonable quantities of the drug will be exported, (c) FDA approval of the drug will be pursued actively, (d) the drug's exporter and importer have signed a written agreement not to re-export the drug to an unapproved country, and (e) the importer has agreed to notify the exporter of any unauthorized re-export. The Secretary must review the application and approve it conditionally if it contains the requisite information and certifications, other than verification that the drug has been approved in the country of destination; the application is to receive automatic approval within five days of the submission of this verification. In addition to these provisions, ten days following the Secretary’s receipt of an export

24. Senate Report, supra note 5, at 31-34. The guidelines in the Senate bill, which were incorporated into the Drug Export Act, specify that to be added to the list of approved countries a country must have: (a) a government entity to review the safety and effectiveness of a drug, (b) methods and facilities used in the manufacturing, processing and packing of drugs that are adequate to preserve strength, identity, quality and purity, (c) adequate procedures to report adverse drug reactions and remove unsafe drugs from the market, and (d) labeling and promotion practices which accord with the indications for which the drug is approved. Pub. L. No. 99-660, § 102, 100 Stat. at 3746-47 (to be codified at 21 U.S.C. § 381).


26. H.R. 3962, supra note 15, at § 802(c) (only 7 countries were listed in the bill).

27. The authority for the Secretary to add countries to the list of those approved that appeared in the Senate bill was not included in the Drug Export Act as enacted, thus by implication reserving that power to the Congress. Compare S.1848, supra note 12, at § 801 with Pub. L. No. 99-660, § 102, 100 Stat. at 3747 (to be codified at 21 U.S.C. § 381).

28. Id. at § 102, 100 Stat. at 3745 (to be codified at 21 U.S.C. § 381).

29. Id.

30. Id.

31. Id. at § 102, 100 Stat. at 3745-46 (to be codified at 21 U.S.C. § 381).
application a notice must be placed in the Federal Register.\textsuperscript{32}

Prior to the addition of the notice requirement, there was some criticism that the legislation lacked any provision for public notification of a sponsor's intent to export unapproved new drugs.\textsuperscript{33} Consequently, the provision for publication in the Federal Register of intent-to-ship notices was designed specifically to meet those concerns.

Another point of criticism that was not addressed in the Act was the provision for virtual automatic approval of an application if an exporter provides the required information and certifications. Critics charged that such automatic approval relegates the FDA to a purely ministerial role, as it is only effectively authorized to insure that certain technical requirements are met, and is inconsistent with the FDA's policy in other areas.\textsuperscript{34} The FDA's view on this matter is consistent, however, with the provisions in the Act. During Senate hearings on export legislation, the FDA indicated that it should not be obligated to affirmatively approve an application for export because of its inability to judge the reasonableness of marketing a drug in another country.\textsuperscript{35}

\textit{FDA Approval}

To gain approval for an application to ship an unapproved new drug, an applicant must have an investigational new drug application ("IND") on file with the FDA\textsuperscript{36} and must certify that it is actively pursuing FDA approval.\textsuperscript{37} Both of these requirements were somewhat controversial throughout the debate on this legislation.\textsuperscript{38} The underlying concern was that some provision was needed to insure that drugs that had been withdrawn from approval, or could not be approved in the United States because of problems with their safety and/or efficacy, would not be eligible for export.\textsuperscript{39}

\begin{itemize}
\item[\textsuperscript{32}] \textit{Id.} at § 102, 100 Stat. at 3745 (to be codified at 21 U.S.C. § 381).
\item[\textsuperscript{33}] \textit{Hearing, supra} note 8, at 211.
\item[\textsuperscript{34}] \textit{Id.} By "other policies" Dr. Wolfe was referring to the FDA regulations on the export of drugs for investigational use that require the FDA take affirmative steps to approve an export request. \textit{New Drug, Antibiotic, and Biologic Drug Product Regulations; Export Provisions}, 49 Fed. Reg. 2095, 2096 (1984) (codified at 21 C.F.R. § 312.110).
\item[\textsuperscript{35}] \textit{Hearing, supra} note 8, at 61.
\item[\textsuperscript{36}] In order to obtain the "substantial evidence" necessary for FDA approval of a drug, well controlled investigations by experts are required. Advance approval for such investigations is required and can be obtained by filing an acceptable "Notice of Claimed Investigational Exemption for a New Drug," commonly referred to as an "IND". 21 C.F.R. § 312.1 (1986).
\item[\textsuperscript{38}] \textit{Hearing, supra} note 8, at 41 (statement of Sen. Kennedy).
\item[\textsuperscript{39}] \textit{Id.} at 209-10.
\end{itemize}
Thus, to insure that approval is being sought actively for exported unapproved new drugs, the Act provides that an applicant must report to the Secretary annually on the actions taken in pursuit of FDA approval. If this report is found wanting, the applicant has sixty days to take whatever steps are necessary to demonstrate compliance and is given the opportunity for an informal hearing.

Requiring only that a manufacturer file an IND and be able to demonstrate active pursuit of FDA approval may seem to provide scant assurance that a drug is safe and effective. Yet, these requirements appear to offer a measure of protection for foreign consumers commensurate with the requirement embodied in the House legislation that a new drug application ("NDA") be on file with the FDA. Specifically, submission of an NDA would signify that the drug is beyond the IND stage in the approval process, and thus, would seem to provide greater assurance that the drug is not harmful. The FDA complained that requiring that an NDA be on file would only "encourage the filing of frivolous, incomplete and premature [NDA's] and [would] not assure the safety and effectiveness of an exported new drug." Thus, in light of the FDA's lack of confidence in the NDA requirement, it appears that the Act's mandate that an applicant file an IND and provide the agency with assurances that it is actively pursuing approval, offers virtually as much assurance of a drug's safety and effectiveness as would a formal NDA filing.

Transshipment

Indisputably, the issue most vigorously contested as the Congress debated

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40. Drug Export Amendment Act of 1986, Pub. L. No. 99-660, § 102, 100 Stat. 3747 (to be codified at 21 U.S.C. § 381). See F-D-C Reports, Jan. 19, 1987 at 8 (FDA Compliance Office Director Daniel Michels is reported to have complained that IND sponsors are not now particularly prompt or forthcoming in their annual reports: a problem he described as "troublesome at its face and even more troublesome" in the context of the requirements of the Drug Export Act).


42. A drug may not be sold commercially in the U.S. until it is approved by the FDA. Such approval is contingent on the filing of a new drug application ("NDA") containing acceptable scientific data related to its safety and efficacy. See 21 C.F.R. § 314 (1986) (listing the FDA's NDA requirements in exhaustive detail).


44. Letter from FDA Comm'r Frank E. Young to Rep. Edward Madigan (May 9, 1986) (answering a series of questions on the proposed drug export legislation) [hereinafter FDA Letter]. The FDA is, however, reportedly considering adoption of a formal plan to monitor the submission of reports under an IND to verify that sponsors are actively pursuing FDA approval of an exported new drug. F-D-C Reports, Jan. 19, 1987 at 8.

45. FDA Letter, supra note 44.
the drug export legislation was transshipment of unapproved drugs from countries on the approved list to Third World countries. Senator Edward Kennedy, a leading figure in the debate stated that he would not support any legislation that did not contain safeguards to "minimize the risk that [United States] unapproved drugs . . . could be diverted." The Drug Export Act contains a number of safeguards intended to prevent unapproved new drugs from being exported and/or re-exported to unapproved countries. As noted earlier, a drug's exporter must certify to the Secretary that the importer has agreed not to transship and to report any unauthorized transshipment. The bill also provides authority for the Secretary to seize drugs, seek an injunction against the exporter, and impose criminal penalties if a drug is shipped in violation of any provision of the Drug Export Act. Further, if an importer ships drugs to an unauthorized country in violation of these restrictions, the Secretary can prohibit further shipments to that importer, unless the importer's action is deemed unintentional. Finally, the Secretary can prohibit immediately the shipping of a drug, even to a country authorized to receive it, if it poses an imminent hazard to that country.

Although the concerns that made this issue central in the debate will be examined in more detail, the major criticism of the proposed safeguards against transshipment was that the FDA had no authority to actively police compliance. FDA officials, however, testified that such authority was unnecessary because once a drug left the United States it had no ability to police compliance. Thus, it is at least arguable that legislative prohibitions against transshipment, no matter how restrictive, would be inadequate to prevent unapproved drugs from being re-exported to Third World countries. Although opponents of the bill argued against its enactment on this basis,

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46. Behr, supra note 9.
47. In the 99th Congress, Senator Kennedy served as the ranking minority member of the Senate Labor and Human Resources Committee. CONGRESSIONAL YELLOW BOOK I-57, III-36 (Fall 1986).
48. Behr, supra note 9.
50. Id. at § 103, 100 Stat. 3751 (to be codified at 21 U.S.C. 333). The Export Act relies on provisions contained in the FDCA for authority to obtain an injunction and impose criminal penalties for violations. The pertinent authority related to injunctions is embodied in Section 302 of the FDCA. 21 U.S.C. § 332(a) (1982). The applicable criminal penalties are found in the FDCA at Section 303(a)-(b) and constitute a maximum fine of $1,000 and prison term of not more than one year. 21 U.S.C. § 333(a)-(b) (1982).
52. Id.; see also infra note 129 (discussion of imminent hazard authority).
53. SENATE REPORT, supra note 5, at 65.
54. Hearing, supra note 8, at 54 (statement of Thomas Scarlett, General Counsel, FDA).
55. "Transshipping bans for unapproved drugs would be as futile as they have already
they ultimately failed to convince Congress to reject the legislation because of the potential problems in controlling transshipment.

**Drug Export — The Issue in Perspective**

The struggle over enactment of the Drug Export Act pitted the American pharmaceutical and biotechnology industries against public opinion and consumer groups throughout the world. Both sides made compelling arguments for and against the legislation. The industry argued that the ban on exporting unapproved new drugs created an unfair advantage for foreign pharmaceutical companies, and was paternalistic and unnecessary. Conversely, opponents argued that the legislation, not the ban, was unnecessary, and worse, would serve to codify an immoral double standard. This section of the comment will examine the arguments of both the legislation’s supporters and detractors in an effort to establish the merits of and risks posed by the Drug Export Act.

**Drug Export’s Proponents — Economic Benefits and Jobs**

The major arguments advanced by the pharmaceutical and biotechnology industries in favor of lifting the export ban were that it worked an unfair hardship on these industries, resulted in the loss of American jobs and the transfer of American technology, and was based on misguided paternalism. Testifying before the Senate Labor and Human Resources Committee, Michael B. Smith, Acting U.S. Trade Representative, reinforced the industry’s concerns. Specifically, Smith described the effect of the ban as detrimental to United States companies desiring to compete for international business because it forced them to export capital, technology, and jobs at a time of increasing foreign competition and unprecedented trade deficits.

The concerns expressed by the Acting Trade Representative and the industry were based on supportable evidence. In 1985 the United States Department of Commerce reported that United States drug imports rose thirty-five percent, representing a trend that could lead to a negative balance of

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56. See Hearing, supra note 8, at 222-40 (listing groups opposed to the legislation, reprinting newspaper editorials in opposition to the legislation and letters from international consumer groups opposed to the legislation).

57. Id. at 68-80 (statement of Gerald J. Mossinghoff, President, PMA).

58. Senate Report, supra note 5, at 56 (views of Sen. Metzenbaum).

59. Id. at 5-6.

60. Id.

61. Hearing, supra note 8, at 340.
trade in pharmaceuticals by the year 1986.62 This statistic was of particular relevance because the drug industry, in contrast to many other sectors of the United States economy, had shown consistently a hefty trade surplus.63 In addition, a number of pharmaceutical companies proffered evidence that the export ban was directly responsible for their decisions to locate or expand facilities abroad64—decisions that typically resulted in the permanent loss of jobs for Americans.65

The advantages to be gained by removing the export restrictions were extremely attractive to legislators concerned about the state of the United States economy. Specifically, a study conducted by American Cyanamid's Lederle Laboratories projected that lifting the ban would boost the number of jobs in the United States by some 2,482 to 40,000 over five years.66 Similarly, industry estimates were that $400 to $500 million in additional exports would be generated by the abolition of the ban.67

It was the emerging biotechnology industry, however, that made the most lasting impression on the Congress with respect to its arguments on trade and economic policy. Reliable estimates are that future markets for biotechnology could yield $15 to $100 billion worth of products sold by the year 2000.68 Although the United States is currently acknowledged as the world leader in biotechnology, foreign governments have become actively involved in efforts to enhance the development of commercial biotechnology in their countries—a development which analysts fear could have "an undesirable long-term impact on the competitiveness of the United States biotechnology industry."69 Thus, when Genentech, a leading biotechnology firm, testified that the impact of the export ban was to drain technology, capital and jobs from the United States70 in this new field of growth, the response from the


63. Hearing, supra note 8, at 342 (statement of Ambassador Smith, Acting U.S. Trade Representative).

64. Id. at 106-07 (statement of David D. Sharrock, President, Merrell Dow Pharmaceuticals U.S.A.).

65. Id. at 308-09 (statement submitted by Merck & Co.).

66. Id. at 5 (statement of Senator Hatch); see 1986 INDUSTRIAL OUTLOOK, supra note 61 at 17-1 (estimating that 4,000 jobs a year could be created by lifting the ban).

67. Hearing, supra note 8, at 343.

68. 2 OFFICE OF SCIENCE AND TECHNOLOGY POLICY, REPORT OF A WORKING GROUP ON COMPETITIVE AND TRANSFER ASPECTS OF BIOTECHNOLOGY app. at 5-6 (1983).

69. Id. at 103.

Congress was one of genuine concern. In fact, two long time and influential opponents of drug export legislation recanted their blanket opposition to it based on the potential impact on the biotechnology industry. Certain features unique to the biotechnology industry made the export ban particularly problematic. Although the biotechnology industry is not a dominant force in the pharmaceutical arena, in 1985 there were over 200 biotechnology companies, 62 percent of which were applying their technology to the pharmaceutical area. It is the smaller biotechnology companies, however, that are considered particularly important in the pharmaceutical industry because of the high proportion of innovation attributable to them. These companies were, however, the most disadvantaged internationally by the export ban, as compared to the larger, more well-established pharmaceutical companies, because the United States drug approval process is so complex and time consuming, and because they did not have the option of manufacturing products overseas at facilities maintained by subsidiaries. Thus, if these smaller companies were to supply foreign markets, where their products had been approved for use, they were forced to license their technology overseas. Such licensing arrangements, however, result most often and most directly in the transfer of valuable technology, and thus damage further the United States’ international balance of trade. Consequently, the biotechnology companies located in the United States were extremely anxious to have the export ban lifted in order to protect and enhance their competitive lead and to enable them to build and/or retain production facilities in this country.

Another frequently heard charge from the supporters of the drug export legislation was that the FDA’s policy was paternalistic. As a basis for

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71. Hearing, supra note 8, at 123 (the biotechnology industry estimated that the number of jobs at risk in their industry is between 10,000 and 20,000 over five years).
72. Id. at 347-52 (reprint of a letter from Philip R. Lee and Milton Silverman to Sen. Orrin Hatch).
73. Id. at 347 (statement of Robert Swanson, Chief Exec. Officer, Genentech, Inc.).
74. Id.
75. Id. at 130-41 (statement of Tim Hart, Exec. Dir., Ass’n of Biotechnology Co.).
76. Id. at 309-12; See, Fox & Allard, Exporting United States Pharmaceuticals in the 1980’s, 30 FED. B. NEWS & J. 496 (1983); See also Scotland Lures Biotech Plant, 137 CHEM. WEEK 12 (1985) (describing how one company actually elected to locate its facilities abroad in order to elude the FDA ban).
77. OFFICE OF TECHNOLOGY ASSESSMENT OF THE CONGRESS OF THE UNITED STATES, COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 6-7 (1984); Prokesch, Stopping the High-Tech Giveaway, N.Y. Times, Mar. 22, 1987, § 3 at 1, col. 2 (warning that if American companies do not change their approach to cooperative ventures the resulting transfer of technology to foreign countries could ultimately threaten the nation’s dominance of other key industries, including biotechnology).
78. See generally, Fox & Allard, supra note 75.
regulation, paternalism is one that demands constant reexamination, and supporters of the drug export legislation claimed that upon reexamination it seemed "inappropriate . . . for a supplier of medicines to many nations to hold up any one country's medical judgment as universal authority." Even Senator Edward Kennedy described the ban as "arrogance" which threatened to deny needed drugs to those in countries in which they had been approved. The FDA took the position that each sovereign government has the primary responsibility for determining the types of drugs that can be imported from abroad and that the agency's judgment about a drug should not be controlling. Other commentators noted that the FDA's decisions may not be applicable to foreign countries because decisions related to a drug's risk-benefit ratio can vary significantly between countries.

Drug Export's Opponents — Morals and Health

Opponents of the drug export legislation were not persuaded by the industry's arguments and charged that the legislation created an immoral double standard, did not promote public health and would besmirch, or even ruin the United States' reputation for high quality pharmaceuticals. Moreover, opponents disputed claims by the pharmaceutical industry that lifting the ban would create a plethora of new jobs or was needed for the industry to remain competitive. Finally, in response to the charge of paternalism, opponents cited strong evidence that the United States' system for drug approval is, in fact, superior to that of other countries, and thus it is not paternalistic for the United States to refuse to export drugs to the rest of the world that have not been proven to be safe and effective for use in this country.

One of the most repeated criticisms of the drug export legislation was that it represented an invidious double standard by protecting American consumers from potentially unsafe drugs while leaving the rest of the world to fend for itself. In testimony before the Senate, Sidney M. Wolfe, M.D., Director

80. Hearing, supra note 8, at 312.
82. Hearing, supra note 8, at 51-57.
83. Comment, supra note 1, at 133.
84. Senate Report, supra note 5, at 58; see also Criticism of Senate Export Bill, Distributed by Public Citizen (Feb. 14, 1986) (unpublished document) [hereinafter Public Citizen Criticism].
85. Senate Report, supra note 5, at 59-60.
86. Hearing, supra note 8, at 203-07.
of Public Citizen's Health Research Group, described this double standard as the most fundamental argument against the bill, and one that he believed was a compelling reason for retaining the ban, outweighing the industry's claims that lifting the export ban would lead to the creation of jobs and halt the loss of technology and capital.  

Somewhat related to the double standard argument is the charge, by the legislation's opponents, that lifting the export ban would diminish the regard in which United States pharmaceuticals are held throughout the world. During debate on the legislation the FDA was described by one foreign commentator as the "envy" of many other countries; and hence the removal of the protection afforded foreign consumers by FDA approval a "retrograde" step.  

Further, there is some evidence that the stringent United States drug approval process may actually serve as a competitive advantage for the industry. Thus, critics charged that lifting the ban could both diminish the value of and prestige associated with United States' pharmaceutical products and consequently could impair the United States' competitive status on international markets.

Opponents of the drug export legislation also contested vigorously the industry's estimate of the number of jobs that would be created by lifting the ban, claiming that a maximum of 8,000 to 9,000 jobs would result from this change in export policy. Moreover, critics noted that there are many factors other than the ban that influence companies to manufacture or locate abroad, such as labor costs, international exchange rates, domestic production requirements, tariffs and the uncertainty of FDA approval, and that these factors would not be affected by the abolition of the ban on exports. Further, it appeared likely that any jobs created or retained in the United States by a change in export policy would be concentrated in Puerto Rico because of certain tax advantages and the absence of a union presence in that territory.

With respect to the biotechnology industry, opponents of the legislation

88. Hearing, supra note 8, at 196.
89. Senate Debate, supra note 13, at S5664 (letter from University College of London's Department of Medicine).
92. Senate Report, supra note 5, at 59; Senate Debate, supra note 13, at S5665.
93. Hearing, supra note 8, at 216.
94. Id. at 216-17, 335.
noted that foreign partnerships, and thus technology transfer, would continue irrespective of the absence of export restrictions, because small biotechnology companies' partnerships with foreign firms are often highly beneficial and in some cases essential. Moreover, a great deal of the technology transfer about which the industry was concerned, occurs by means of scientific journals, research institutions, and conferences that are not affected whatsoever by the export ban.

In addition, critics of the bill dismissed arguments that the export ban was paternalistic and suggested that the FDA's approval procedures were superior to those in other countries. There are a number of examples of drugs that were approved in other countries, but not in the United States, that had to be withdrawn from the market because they were later found to have severe adverse effects. The most publicized among this list is thalidomide, a drug never approved for use by the FDA but approved in a number of European countries, which caused thousands of children to be born deformed or brain damaged. These examples suggest that FDA's more stringent standards, even as compared with many other developed countries that have sophisticated systems for drug approval, are superior and do offer foreign consumers a higher assurance of protection from ineffective or dangerous drugs.

**Balancing Both Sides of the Debate**

Both sides in the debate over drug export restrictions represent legitimate points of view. Thus, it is impossible to determine categorically that the bill is inherently unethical or immoral because the health-benefit risks of particular medicines can be judged differently, and still ethically, for and by other countries. It is at least arguably overly paternalistic of the United States to refuse to recognize that other developed and some developing countries are in the best position to assess this risk for themselves. Moreover, the FDA, which is a recognized authority on this subject, albeit not one entirely unbiased by political considerations, has had some experience dealing with the

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96. *Hearing, supra* note 8, at 220.
97. Senate Debate, *supra* note 13, at S5671-72 (in a letter addressed to Senator Edward Kennedy, fifty-two members of the European Parliament indicated that the drug approval standards in Europe were not as high as those of the U.S.).
98. *Hearing, supra* note 8, at 203.
99. *Id.*
100. When asked during Senate hearings how he would rate the drug approval process in the U.S., FDA Comm'r Frank Young indicated that it is "excellent" and that he "would not trade it for any other system." *Id.* at 58.
problems that international recalls of unapproved products entail. The FDA believes that its methods are adequate to assure that foreign governments will be notified promptly if significant safety issues arise following the export of a drug.  

The legislation does, however, create a double standard for pharmaceutical products. Indeed, the United States may find itself the butt of international criticism if an exported unapproved new drug, unavailable to American consumers, causes illness or deaths abroad.

THE DEBATE OVER TRANSSHIPMENT CONTROLS

No issue was more controversial during the course of debate on the drug export legislation than that of transshipment. Most opponents of the bill agreed that developed countries, such as Great Britain or West Germany, were in a position to adequately regulate the pharmaceuticals that were received from the United States. The concern was, however, that the countries approved for export would become mere way stations for unapproved drugs, and that such drugs would be re-exported to Third World countries which had either an inadequate regulatory system or no system at all with which to protect the health of their people.

The Case Against Transshipment

The fear that unapproved American drugs would end up in Third World countries was not simply conjecture. In 1976 and 1982, Drs. Milton Silverman, Philip R. Lee and Mia Lydecker published books documenting the unethical practices of pharmaceutical companies in Third World countries. Among the abuses these authors discovered were that many products withdrawn from the markets or never approved for marketing in industrialized countries were readily available in Third World countries. In these studies, multinational companies located in the United States were cited for a large share of the blame for these practices.

This phenomenon, known as dumping, is not as pervasive today as it was

101. FDA letter, supra note 44.
102. Senator Howard Metzenbaum, one of the legislation’s sharpest critics, stated during the debate on drug export that if it were not for the issue of transshipment there would be “no problem” with this bill. Senate Debate, supra note 13, at S5662.
103. Id.
104. Id.
105. Id.
106. See generally PRESCRIPTIONS FOR DEATH, supra note 104.
107. Id.
in the 1970's. It is, however, a problem that continues to generate international concern, particularly among Third World countries. This concern was amply demonstrated by the number of letters that members of Congress received from individuals and organizations throughout the world opposing any relaxation in the export ban. Many of the writers from Third World countries expressed fears that there was no practical way to control re-export once the FDA ban was lifted, and thus abolition of the ban would aggravate the drug dumping problem in their countries.

Third World countries were not the only ones with reservations about the legislation however. Fifty-two members of the European Parliament also expressed concern. These members concluded that because the European Economic Community had no laws prohibiting the re-export of unapproved new drugs, it simply was not possible to prevent them from reaching Third World countries.

Excerpts of a debate in the Australian Parliament indicate a different, but related concern with re-export. The Australians' concern with the drug export legislation stemmed, at least in part, from their experience with unapproved medical devices imported from the United States and their fear that unapproved drugs, like devices, had a lower order of reliability.

Specifically, there have been a number of cases in which exported unapproved devices, such as heart valves and pacemakers, were found to be defective. In each instance, the FDA reported that it was notified by the device manufacturer on a timely basis of safety problems, and promptly alerted the health authorities in the countries to which the devices had been exported, presumably limiting or preventing any resulting health problems. The FDA acknowledges, however, that drugs and devices "pose different potential problems" but believes, nevertheless, that it has in place "appropriate methods to ensure notification if significant safety issues [arose] with regard to the export of unapproved new drugs." It is questionable whether the FDA's system for notification would function adequately, or in fact at all,

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109. See Senate Debate, supra note 13, at S5664-72 (excerpts from a number of letters to Sen. Kennedy expressing concern about the export bill are reprinted).
110. Id. at S5664.
111. Id. at S5671.
112. Id.
113. Id. at S5664. Current law allows unapproved medical devices to be exported to any nation if the sale of the product is not in conflict with the law of the importing country. 21 U.S.C. § 381(d) (1982).
114. FDA letter, supra note 44.
115. Id.
despite the agency's best efforts, if a drug were re-exported to an unapproved country without the FDA's knowledge.

**Perspectives on Transshipment**

Although most involved with the legislation acknowledged that re-export was a concern, opinion was divided as to whether the legislation addressed or even needed to address the problem. Some observers believed that the bill contained safeguards adequate to contain re-export, while others felt that once the ban was relaxed, no safeguard, no matter how well intentioned, would stop it.

The FDA's position was that the safeguards proposed in the Senate bill were adequate to prevent any re-export. 116 In fact, the FDA contended that "since drugs unapproved for use in the United States are already reaching developed and developing nations . . . there [was no] obvious public health purpose to the export restrictions now in place."117 Moreover, relaxing the ban would allow drugs that might have been manufactured elsewhere to be manufactured in the United States in compliance with rigid FDA standards, and thus could result in foreign consumers receiving higher quality, albeit unapproved, new drugs.118

A former FDA Commissioner contended that lifting the ban could actually have positive effects outweighing concerns about the efficacy of the proposed safeguards.119 Specifically, he argued that abolishing the ban could encourage international development agencies to use drugs, such as contraceptives, that might not be approved for use in the United States because equally reliable methods of a somewhat lower order of risk were available, but which could be of great benefit to women in Third World countries.120

For those who considered that lifting the ban on drug exports entailed substantial risks, opinion was divided on whether the safeguards in the legislation would control the problem. When the Senate considered its drug export legislation, strong representations were made that its bill contained safeguards sufficient to prevent unapproved American drugs from being dumped in Third World countries.121 Specifically, the Senate bill122 included

117. FDA letter, *supra* note 44.
118. *Id.*
120. *Id.*
121. *Senate Debate, supra* note 13, at S5658.
safeguards such as: (a) the outside of the shipping package had to be labeled as follows: "[t]his drug may be sold or offered for sale only in the following countries," (with a list of authorized countries printed directly on the label),
(b) the exporter had to obtain from each of its importers an agreement, to be renewed annually, that the importer would not re-export the drug to countries other than those authorized by the law, (c) importers that violated the law could be prohibited from receiving further exports, and (d) the United States General Accounting Office ("GAO") had to monitor compliance with the law. Senator Kennedy displayed a great deal of confidence in these safeguards and pronounced them to be "carefully tailored to safeguard the use of United States manufactured pharmaceuticals sold overseas."

Not all of the safeguards included in the Senate's bill, however, are embodied in the Drug Export Act. Most notably, there is no provision for the GAO to monitor compliance with the law. Even if all those safeguards had remained intact in the Drug Export Act, however, in view of the legislation's critics they would be "meaningless in the absence of active policing by the FDA." Active policing was believed to be particularly important because of a requirement—which was retained in the final Act—that before taking any action to halt the export of an unapproved new drug the Secretary had to receive "credible" evidence that an importer was re-exporting drugs to an authorized country. Because the Secretary was granted no power or responsibility to determine if the law was being broken, i.e., receive credible evidence, the bill's critics claimed that the safeguards were effectively unenforceable.

In addition to the lack of investigatory or enforcement authority, critics charged that the standard for empowering the Secretary to immediately prohibit further shipments to an importer who had shipped drugs to an unauthorized country, was inordinately difficult to apply. Specifically, the Secretary had to determine that an unapproved drug posed an "imminent hazard" in the country to which it was being exported in order to circumvent the legislation's due process requirements. The term imminent haz-

123. Id.
124. Senate Debate, supra note 13, at S5661.
126. Public Citizen Criticism, supra note 84.
128. Public Citizen Criticism, supra note 83.
129. Id.
ard is not, however, defined in the Act or the FDCA and according to the bill's critics, has been used only once in the last twenty years to haul a drug off the market. Moreover, in the only pertinent legislative history for the Drug Export Act, the Senate Labor and Human Resources Committee stressed that in order for the Secretary to invoke this authority, there must be "'a substantial certainty that death or serious bodily injury will result from the . . . failure to act.'" Thus, although the Secretary has the technical authority to prohibit immediately further shipments of an unapproved drug, he is virtually precluded from using this authority until deaths or serious injuries result from the drug's use.

Are the Transshipment Safeguards Adequate?

Indisputably, the safeguards embodied in the Drug Export Act intended to address the transshipment problem are not fail-safe. And in comparison to the controls against transshipment that the Department of Commerce exercises over the commodities that it regulates, the Secretary's authority is much less far-reaching. It may be the case, however, that no controls would be sufficient to prevent transshipment, and thus the provisions in the Drug Export Act are adequate to the task. But in any case, because the provisions for monitoring compliance with the law were not incorporated into the Drug Export Act, the FDA and the Congress' ability to determine whether the safeguards are adequate is impaired substantially. Thus, it may be impossible for anyone to judge reliably whether the safeguards are in fact effective or simply a reassuring window dressing.

CONCLUSION

In many respects, the Drug Export Act represents a reasonable balance between the legitimate needs of American industry and Third World concerns over the dumping of unsafe drugs. To its credit, the Act will encourage the burgeoning biotechnology industry to retain and expand its production facilities in this country and enable it to compete more effectively with foreign competitors. The new law is not, however, free from risk.

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report accompanying the Senate bill, however, under this imminent hazard standard the Secretary's authority is limited to "exceptional case[s]" which do not permit correction by other means. Compare *Senate Report*, supra note 5, at 38 with *Environmental Defense Fund Inc. v. EPA*, 465 F.2d 528, 540 (D.C. Cir. 1972) (the situation needed to invoke the Secretary's authority under an imminent hazard standard need not rise to the level of a crisis).


132. *Id.* at 38.

133. 15 C.F.R. § 347.1(a)-(b) (1986).

134. In an interview on the effect of the new drug export law Thomas D. Kiley, Genentech
American companies could find themselves in the unenviable position of becoming the focal point of international criticism, or worse, if unapproved pharmaceuticals manufactured in the United States are the cause of deaths or injuries in developed or developing countries. And if the drug dumping problem is reignited by this relaxation, the industry will undoubtedly be further reviled by international consumer organizations and perhaps even the Congress.

The most unfortunate (and even cowardly) aspect of the Drug Export Act is, however, the omission of a mechanism to determine whether its safeguards are effective or merely a placebo. A future Congress, of course, could remedy this problem with legislation mandating that the GAO, or some other intra-or extra-governmental agency track or monitor compliance with the Act's re-export prohibitions. Then the Congress and the public would know for certain that the industry has, as it has represented, "absolutely no intention of engaging in . . . abhorrent, unethical behavior" and "merely wish[es] to pursue valuable and viable markets that have requested [U.S.] product[s]." Absent this sort of a monitoring mechanism, there will continue to be doubts about the industry's good faith and ability to comply with the spirit and the letter of the new law as well as the law's real impact on the health of foreign consumers.

Mindy Hatton

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Vice President of Corporate Development confirmed that the biotechnology industry now has "less need to transfer technology." Prokesch, supra note 76.

135. Hearing, supra note 8, at 123 (statement of Robert A. Swanson, Chief Exec. Officer, Genentech, Inc.).