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Regulation of the Export of Pharmaceuticals to Developing Countries

Nancy E. Pirt*

It is modern science that has vastly enlarged the scope of modern law. We have found that the scope of measures necessary for common defense calls for this enlargement of function. The law has become involved in the necessities of applied science. Is it equal to the task? Will old and settled principles serve? Do the new measures call merely for new applications of old principles, or for their destruction and the creation of new ones? Is it merely a changed phase of the conflict between individual liberty and general welfare—between executive discretion and fixed law—between officialism and laissez faire?

J.H. Wigmore

I. Introduction

In 1915, 100 out of every 1,000 babies born in the United States would die within the ensuing 12 months. By 1950, this rate had dropped to 29.2 per 1,000, and by 1978, it was 13.8. Consequently, a child born in the United States in 1978 is expected to live on average 26 years longer than one born in 1900. The principal factor in this dramatic increase in life expectancy is the prevention and control of communicable diseases. Pharmaceuticals, particularly antibiotics, have played a starring role in this regard. As a result, the leading causes of death in the United States in 1975 were from the chronic degenerative diseases—heart disease, malignant neoplasms (cancer) and stroke.

The situation is quite different in much of the developing world,

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4. Id.
where communicable, infectious and parasitic diseases are epidemic. The causes of these diseases are no mystery. Inadequate sanitation, lack of safe drinking water and poor nutrition are all the sources of disease. The problem is only exacerbated by the inadequate health delivery infrastructures in these countries. Pharmaceuticals have the potential to alter this bleak picture considerably. Modern drugs can cure many of the diseases now afflicting the peoples of the developing world, yet the most minimal pharmaceutical needs of these societies go unmet.

The purpose of this article is to explore the role which governmental regulations play in the export of pharmaceuticals to the developing world. The history of Anglo-American pharmaceutical legislation will be traced up to the present day. Next, the characteristics of the United States pharmaceutical industry will be examined, as will the characteristics of the market in the developing world. Finally, some possible regulatory responses to the pharmaceutical needs of developing countries will be offered.

II. A HISTORY OF ANGLO-AMERICAN LEGISLATION

A. An Overview of Legislation Prior to 1938

Regulation of medicine/pharmacology has a lineage that can be traced back to ancient Egypt and Biblical times. In the history of Anglo-American jurisprudence, one of the earliest efforts at controlling the practice of medicine was the English Licensure Act of 1511, which required physicians to obtain a license before practicing. In 1518, King Henry VIII founded the College of Physicians. A few years later, in 1525, a further statute on medical practice was enacted, mandating that pharmacists accept prescriptions only from qualified and registered medical practitioners, and further requiring that pharmacists keep these prescriptions on file so that members of the College of Physicians could review them to determine whether the compounds prescribed were suitable for medical

6. Id.
10. Penn, supra note 8, at 297.
use. A later statute, enacted in 1540, gave the College of Physicians the authority to enter apothecary shops and search for drugs that were “defective, corrupted and not meet nor convenient to be ministered in any medicine for the health of mans [sic] body.”

However, in 1542, Parliament did some de-regulating. Upon observing that licensed physicians were refusing to treat the poor, Parliament took to task the medical profession for “minding only their owne lucre[sic],” and for having “troubled and vexed” their competitors in the practice of medicine, the folk-healers, “honest men and women whom God hath endowed with the knowledge of the nature, kind and operation of certain herbs, rootes and water.” The folk-healers were thereby granted the right to “practise, use and minister in and to any outward sore, uncome, wound, apostemation, outward swelling or disease, any herb or herbs, ointments, baths, pultes and emplaisters according to their cunning, experience and knowledge.”

In America, one of the first attempts to proscribe the sale of fraudulent drugs was made in 1630, when a Massachusetts colonist was punished for selling a cure for scurvy that the authorities determined to be “a water of no worth nor value.” The regulation of medical practice and of drugs was to remain within the purview of local authorities or with the state government for the next several centuries.

The first federal drug law in the United States was the Import Drugs Act of 1848, which prohibited the import of drugs lacking in quality or purity, or unfit for medical use. Further federal legislation came in 1906 with the Pure Food and Drugs Act, which prohibited misbranding and adulteration of drugs. However, the

11. Cooper, supra note 9, at 422.
13. Cooper, supra note 9, at 422.
14. Penn, supra note 8, at 300, quoting G. Goodall, The Royal College of Physicians of London (1684). See also Cooper, supra note 9, at 422. As Cooper observed, “Quackery thus became the officially sanctioned medicine for the poor.” Id.
15. Cooper, supra note 9, at 422.
17. Cooper, supra note 9, at 422. See generally Sonnedecker, Contribution of the Pharmaceutical Profession Toward Controlling the Quality of Drugs in the Nineteenth Century, in Safeguarding the Public: Historical Aspects of Medicinal Drug Control 97 (J. Blake ed. 1970).
Act of 1906 failed to provide for the review of drugs for efficacy before distribution. This loophole was soon the subject of litigation in a prosecution involving a drug called “Dr. Johnson’s Mild Combination Treatment for Cancer, Tumor and Other Chronic Diseases.” In its case against Dr. Johnson, the government argued that Dr. Johnson had misbranded his drug in violation of the Act of 1906, because the drug was not effective for treating cancer as it was touted to be. Mr. Justice Holmes, speaking for the United States Supreme Court in 1911, rejected the government’s position, the Court instead holding that under the Act, the term “misbranding” meant only the misleading statement of a drug’s ingredients, and not misleading statements as to its effectiveness. President William Howard Taft reacted quickly, and within a month of the Supreme Court’s decision, he urged Congress to amend the Act of 1906, stating,

Fraudulent misrepresentations of curative value of nostrums not only operate to defraud purchasers, but are a distinct menace to the public health. There are none so credulous as sufferers from disease. The need is urgent for legislation which will prevent the raising of false hopes of speedy cures of serious ailments by misstatements of fact as to worthless mixtures on which the sick will rely while their diseases progress unchecked.

Congress soon amended the statutory definition of “misbranding” to include false statements of curative or therapeutic effect.

B. The Federal Food, Drug and Cosmetic Act

Modern legislation regarding the safety of drugs, on the other hand, did not come about until 1938. In the 1930’s, pharmaceutical companies were in the business of supplying pharmacists with the basic array of essential ingredients that were needed to compound doctors’ prescriptions. However, the pharmaceutical industry was

19. Cooper, supra note 9, at 422.
21. 47 CONG. REC. 2379-80 (1911), as quoted by Cooper, supra note 9, at 423.
22. 37 Stat. 416 (1912) (popularly known as the “Sherley Amendment”), as cited by Cooper, supra note 9, at 423.

An illustration of the nature of the industry prior to World War II can be found in this statement by Harold Clymer, who was employed by SmithKline Corporation during that time:

R&D as such was nonexistent in most firms. . . [I]t was in 1939 that I joined SmithKline; you can judge the magnitude of their R&D at that time by the fact that I was told I would have to consider the position temporary since they had already hired two people within the previous year for their laboratory and were not sure that
soon to be transformed with the discovery of the sulfa "wonder drugs" in the mid-1930's.\textsuperscript{24} In 1936, when the son of President Franklin Roosevelt was stricken with a streptococcal sore throat, the nation watched expectantly as the heretofore experimental drug, prontosil, a type of sulfanilamide, was used successfully to treat his illness.\textsuperscript{25} Shortly thereafter, the Tennessee firm of Massengill & Company marketed a liquid form of sulfanilamide because in the powder form the drug had an unpleasant taste and precise dosage was difficult to measure.\textsuperscript{26} It was discovered that the drug would dissolve in diethylene glycol, and soon Massengill introduced its Elixir Sulfanilamide. It is not known whether this elixir was ever tested for safety in animals or humans; indeed, the law required no such tests.\textsuperscript{27} History does tell us that almost immediately, the American Medical Association (AMA) received numerous reports of possible drug-related deaths from the elixir. What the chemist who invented the elixir did not know, although others did, was that diethylene glycol, when ingested, would convert into deadly oxalic acid, a poison that destroys the kidneys. All told, Elixir Sulfanilamide was blamed for the deaths of 100 people, mostly children. Included among the death toll was the chemist who invented the elixir. He committed suicide.\textsuperscript{28}

Prior to the sulfanilamide disaster, the Roosevelt administration had for years been pressing for comprehensive reform of food and drug legislation, but Congress dragged its feet.\textsuperscript{29} Following the disaster, Congress knew that it could delay no longer, and it enacted the business would warrant the continued expenditure.


24. The discovery of the sulfa drugs was a "spin-off" of research done by Gerhard Domagk for the Bayer division of the German chemical company, I.G. Farben. At the time, Domagk was investigating the bacteria-killing properties of dyestuffs. Gereffi, supra note 23, at 174 n.2.

Many of the large European pharmaceutical companies of the present day originally were either manufacturers of dyestuffs—e.g., the German company, Hoechst, and the Swiss companies, Ciba-Geigy and Sandoz—or of organic chemicals—e.g., the German company, Bayer, and the Swiss company, Hoffman-La Roche. Id. at 170-74. The situation is different with the large United States pharmaceutical companies, most of which originated as pharmaceutical supply houses and for which today pharmaceuticals remain their main products. Id.


27. Id.

28. Id. at 12-13.

29. Id. at 13; Cooper, supra note 9, at 423.
the Federal Food, Drug and Cosmetic Act. For the first time in this country, manufacturers would be required to obtain pre-marketing approval for a drug by submitting to the Food and Drug Administration (FDA) evidence that the drug was safe. The FDA, however, had to timely act upon the application, within sixty days, or the drug would automatically become marketable. Once marketed, it was extremely difficult for the FDA to get a drug withdrawn, absent overwhelming evidence of the drug’s dangers. The FDA could, however, temporarily extend the review period by requesting additional data on the grounds that the application was not complete, a contingency which was to figure prominently a few decades later with thalidomide.

C. The Kefauver-Harris Amendments of 1962

It was 1956 when thalidomide first went on sale in West Germany. Developed by the West German company Chemie-Grunenthal, thalidomide was marketed as a drug to treat vomiting during pregnancy and as a sleeping aid. While thalidomide was widely available in Europe, it was never approved by the FDA for marketing in the United States, principally as a result of the efforts of one person, FDA pharmacologist Frances Kelsey. Kelsey became suspicious of thalidomide after reading a report in the British Medical Journal which indicated that in a small percentage of patients, there appeared to be a connection between thalidomide and peripheral neuritis, a “tingling of the nerves,” a side effect which disappeared, however, when the patient ceased taking the drug. Kelsey called to mind the results of some research she had done fifteen years before, which showed that drugs which irritated the nerves in adult rabbits stunted the growth of, and produced deformities in, the fetuses of pregnant rabbits. Although there was no evidence that Chemie-Grunenthal had found similar side effects with thalidomide when tested on rats, mice and other experimental animals, Kelsey stalled the introduction of


31. ASBURY, supra note 26, at 13; Cooper, supra note 9, at 423.

32. ASBURY, supra note 26, at 13.

33. Id. at 25.

34. Penn, supra note 8, at 303.

35. ASBURY, supra note 26, at 24-25.
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thalidomide into the United States market by repeatedly requesting additional information from the drug’s American licensee, Merrell.\textsuperscript{36}

The rest of the tragic thalidomide story is generally known. By 1961, an unusual increase in a rare birth defect was being reported in West Germany. Children suffering from this defect were born with phocomelia, a condition characterized by foreshortened limbs and rudimentary hands or feet resembling seal flippers. Where there had been no reported cases of this particular birth defect in West Germany during the preceding ten years, suddenly in 1959 there were twelve cases, in 1960, eighty-three, and in 1961, four hundred and seventy-seven.\textsuperscript{37} The thalidomide tragedy was by no means confined to West Germany. Some 10,000 infants in twenty different countries, including Sweden, Italy, Great Britain, Scotland, Switzerland, Lebanon, Israel, Australia, Brazil and Peru were likewise harmed.\textsuperscript{38} Furthermore, although thalidomide had not yet been approved for marketing in the United States, it had been distributed by Merrell to more than 1,200 physicians in this country for clinical testing.\textsuperscript{39} Consequently, a large percentage of the phocomelia in the United States was seen in children born to the wives of doctors.\textsuperscript{40}

Once again, tragedy mobilized Congress, and the Kefauver-Harris amendments became law.\textsuperscript{41} These amendments provided for the abolition of the automatic approval of a drug by default; specified labeling, package insert and advertising requirements; established

\textsuperscript{36} M. Silverman and P.R. Lee, Pills, Profits, and Politics 95 (1974). It was later found that the laboratory tests performed on pregnant rats, mice and other commonly used laboratory animals were not enough to uncover the danger of phocomelia. It was only when the tests were performed on certain species of rabbits that the potential of this birth defect was shown. Because of the thalidomide tragedy, the FDA today requires that before a drug can be marketed, its safety in pregnancy must be adequately demonstrated. Id. at 96.

\textsuperscript{37} Penn, supra note 8, at 299; Silverman and Lee, supra note 36, at 95.

\textsuperscript{38} Asbury, supra note 26, at 25; Silverman and Lee, supra note 36, at 96.

\textsuperscript{39} Asbury, supra note 26, at 26.

\textsuperscript{40} Silverman and Lee, supra note 36, at 96.


Senator Estes Kefauver (D-Tenn.), then chairman of the Senate Subcommittee on Antitrust and Monopoly, originally began his investigation into the pharmaceutical industry in 1959 for the purpose of reviewing the alleged monopolistic pricing practices of the industry. After the thalidomide incident, drug safety was included in the Amendments. Campbell and Smith, Profitability and the Pharmaceutical Industry, in The Pharmaceutical Industry 105, 108-09 (C.M. Lindsay ed. 1978).

The co-sponsor of the Amendments was Representative Orren Harris (D-Ark.), Chairman of the House Committee on Interstate and Foreign Commerce. Asbury, supra note 26, at 27.
certain quality control measures and record keeping measures; and required proof of efficacy for all drugs. 42 Certainly, the most important features of the amendments were those eliminating automatic approval and requiring proof of efficacy, for now the burden of proof was upon the pharmaceutical manufacturer and not the FDA.

The Federal Food, Drug and Cosmetic Act as amended by the 1962 Kefauver-Harris amendments essentially stands as the basis still for the regulation of pharmaceuticals in the United States. However, the FDA's policies developed pursuant to the amendments, requiring extensive clinical tests before marketing, have been criticized as raising the cost of research and development of pharmaceuticals substantially and as causing a "drug lag" in this country, i.e., new drugs are said to be introduced in the United States later than they are in other countries. 43 Regardless of the correctness of the drug lag argument, at least one study concluded that the high standards that the FDA established after the Kefauver-Harris amendments, rather than hurting United States manufacturers, have actually turned out to give a competitive advantage by ensuring a reputation worldwide for safety and efficacy. 44 The subject of the characteristics of the pharmaceutical industry is discussed more fully in section III.

D. Regulation by Executive Order

In October of 1977, the Consumer Product Safety Commission (CPSC) banned the sale and distribution within the United States of fabrics treated with the chemical flame retardant TRIS. 45 The ban was based on evidence that TRIS, which was being used to treat children's pajamas, could be absorbed through the skin and cause cancer. 46 The CPSC did not attempt to extend this ban to

42. ASBURY, supra note 26, at 29.
44. Industry Analysis Division, supra note 43, at 72, 86.

For other discussions of the TRIS incident and exports, see generally Agege, Dumping of Dangerous American Products Overseas: Should Congress Sit Back and Watch?, 19 J. WORLD TRADE L. 403 (1985); Street, Comment: U.S. Exports Banned for Domestic Use, But
include the export of TRIS-treated fabrics, since the CPSC did not believe that its statutory authority encompassed the regulation of exports.47 Thereafter, the United States manufacturers wasted no time in shipping the banned pajamas abroad, exporting millions of dollars worth of the garments to Africa, Asia and South America.48 A few months later, the CPSC, after undergoing a change in its political makeup, decided that it could, after all, ban the export of TRIS-treated fabrics, and did so.49

Because of the wide media exposure to the TRIS incident, attention was drawn to the United States' lack of a uniform policy regarding banned products. Accordingly, in May of 1978, President Jimmy Carter convened an interagency working group50 to examine this country's export policy and to determine what changes, if any, were needed.51 The working group studied the question for

49. 43 Fed. Reg. 25,711 (1978). The CPSC concluded that the Hazardous Substances Act gave it jurisdiction over any goods originally manufactured for sale in the United States, but the CPSC still did not believe it could ban the export of goods originally manufactured and labelled for export. Comment, United States Export, supra note 46, at 334 n.13.

The CPSC stuck with this ban for the next several years, until 1983, when the CPSC again reversed itself and allowed the export of carpeting which had been recalled for non-compliance with the Federal Flammable Fabrics Act, 15 U.S.C. §§ 1261 et seq. In re Imperial Carpet Mills, Inc., CPSC Docket 80-2 (July 6, 1983). For a criticism of this latest reversal, see Agege, supra note 46.


two and one-half years before making its recommendation to President Carter. Based on the working group's conclusions, on January 15, 1981, just five days before he left office, President Carter issued an executive order entitled "On Federal Policy Regarding the Export of Banned or Significantly Restricted Substances." As authority for such an order, the President relied upon the Export Administration Act of 1979, which empowered the President to establish export restrictions in cases of national security or where scarce materials were involved or "to the extent necessary to further significantly the foreign policy of the United States or to fulfill its declared international obligations." The term "banned or significantly restricted substance" was defined in the order by reference to seven statutes each of which separately regulated either food, drugs, chemicals, medical devices or electronics. Essentially, the order established two methods of regulating the items in question: (a) notification; and (b) export controls for "extremely hazardous substances," for which notification would not provide ade-

Subcommittee's proposed Act would have permitted the export of unapproved drugs if the manufacturer first notified the government of the importing country of the drug's unapproved status in the United States. If the foreign sovereign did not disapprove of the importation, the manufacturer could apply for a permit from the FDA allowing the export. This bill died in committee and never became law. Export Of Pharmaceutical Products Under the Federal Food, Drug and Cosmetic Act, 13 CORNELL INT'L L.J. 125, 134-35 (1980).


57. Under this notification requirement, the agencies regulating the various products involved were to send to the Department of State information regarding (a) the name of the product, (b) a summary of agency action regarding the product and (c) a summary of potential risks to human health, safety or the environment. The Department of State would then transmit such information to the foreign government importing the product so as to allow the foreign government to make an informed decision as to whether local conditions within the country necessitated the use of the product in spite of the potential dangers. 22 HARV. INT'L L.J. 683, 684-86 (1981).
58. The identification of the "extremely hazardous substances" was to be made by the agency primarily responsible for regulating the product, upon a finding that (a) the product was a substantial threat to health, safety or the environment and (b) export would clearly and significantly harm United States foreign policy interests; licenses for export would be granted only in exceptional cases. Carter Exec. Order, supra note 54, § 1-301, at 4,662.
quate protection.

Shortly after taking office, on February 17, 1981, President Ronald Reagan issued an executive order entitled "Federal Exports and Excessive Regulation," revoking President Carter's order. The stated goal of President Reagan's order was "to ensure that the Export Administration Act of 1979 [was] implemented with the minimum regulatory burden." As a means of achieving this end, President Reagan issued an additional executive order, authorizing the Departments of State and Commerce to review current regulatory statutes under a cost-benefit analysis, with the watchword that regulatory action only be undertaken when "the potential benefits to society for the regulation outweigh the potential cost to society." The FDA has, as a result of this latest executive order, modified some regulations. It is possible, although probably not likely absent specific statutory amendments, that the FDA may alter some of its export policies governing new, not-yet-approved drugs, since the prohibition on the export of unapproved drugs was established by means of an FDA regulation interpreting the Federal Food, Drug and Cosmetic Act. However, the authority of the FDA to extensively repeal its regulatory framework strictly on the basis of a cost-benefit analysis has been questioned on the grounds that it is outside of the FDA's statutory powers to consider matters other than the public health effects.

These products were then to be placed upon a "Commodity Control List" by the Department of State with the concurrence of the Department of Commerce. It was then up to these three executive offices to determine if an export license should issue, but only if the foreign government had raised no objections and if the export would not cause clear and significant harm to United States foreign policy interests. 22 HARV. INT'L L.J. 683, 685 (1981).

60. Id.
62. Id.
64. See generally Halperin, Multinational And International Regulation of Pharmaceuticals and U.S. Policy, 17 DRUG INFORMATION J. 153 (1983).
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III. THE PHARMACEUTICAL INDUSTRY

We direct our attention now from the efforts at regulating the pharmaceutical industry to a look at the industry itself. By appreciating how it is that the industry functions, we can begin to define the reasons why developing countries are experiencing difficulties in obtaining pharmaceuticals.

A. A Profile of the Pharmaceutical Industry Today

At a time when so many American industries are suffering as a result of foreign competition, the United States' pharmaceutical industry stands out as being highly successful and competitive. The percentage of exports vis-a-vis domestic sales has risen in the industry from 6.8% in 1960 to 9.8% in 1979. Historically, the industry has shown a surplus in the United States trade balance and, according to figures from 1980, the United States was the world's largest net exporter of pharmaceuticals. Moreover, the pharmaceutical industry in the United States is the world's largest producer of drugs, being responsible for 24.9% of world production in 1980, just inching out Japan, the number two producer with 23.9% of world production. In terms of world consumption, America is the second largest consumer, with 25.8% of world consumption. The leader in consumption is Japan, with 26.9% of world consumption.

Nevertheless, while American-owned companies are leading in production, an ever-increasing percentage of this production is being performed by foreign-based subsidiaries of United States par-

67. Industry Analysis Division, supra note 43, at i.
68. Id. at 19.
69. Id.
70. Id. at 32. Our best customers are Japan, accounting for 21.3% of our exports, France, 8.2%, West Germany, 5.9% and Belgium, 5.2%. Id. at 34. The United States, in turn, purchases 15.4% of its imported pharmaceuticals from the United Kingdom, 12.9% from West Germany, 10.0% from Japan, 9.0% from Italy, 8.3% from Switzerland, 7.3% from Denmark and 5.0% from France. Id.
71. Id. at 30. Notwithstanding its leading position as a producer, Japan actually imports $421.4 million more in pharmaceuticals than it exports, according to figures from 1980-81. Moreover, Japan exports less than 2% of its pharmaceutical production. Id. at 32.
72. Id. at 32. The pattern of consumption for pharmaceuticals is quite different in Japan from that seen in the United States and Western Europe. Japan has the largest per capita consumption of pharmaceuticals in the world. Pharmaceuticals make up 40% of Japan's health care expenditures, a figure markedly higher than the 13% averaged by the United States and Western Europe combined. Only 6% of prescription drugs in Japan are purchased from pharmacies. The rest come from Japanese doctors, who earn approximately 50% of their incomes by prescribing and dispensing drugs. Id. at 80.
ent firms. In 1960, sales of overseas subsidiaries as a percentage of total company sales stood at 20.6%; by 1972, this figure had increased to 32.2% and by 1979 it stood at 41.5%.\(^7\) In fact, for some United States companies, sales of foreign subsidiaries account for 50% or more of total world sales.\(^7\)

Despite claims to the contrary by some,\(^7\) several industry analysts have concluded that there is no clear cause and effect relationship between FDA regulation and the establishment of foreign subsidiaries by United States pharmaceutical companies.\(^7\) Analysts cite other important factors as causing this migration, for example, the pharmaceutical regulation in the foreign market itself. Some countries, such as Japan, place higher restrictions on drugs that are not manufactured within their own borders,\(^7\) or are reluctant to accept the results of clinical trials which were not performed within their country.\(^7\) For these same reasons, foreign owned pharmaceutical companies have established U.S.-based subsidiaries, since the FDA did not, until recently, accept the results of clinical trials conducted outside of the United States.\(^7\) The move is also seen as part of a more general trend of increased collaboration between American and foreign pharmaceutical companies.\(^8\)

Today in the United States, there are approximately 1,000 pharmaceutical firms. Only 25 of these firms are United States companies with subsidiaries in foreign countries.\(^8\) Another 25 companies are actually U.S.-based subsidiaries of foreign parent companies. Notwithstanding their small numbers, these foreign owned, U.S.-based companies are responsible for 15% of total sales of pharmaceuticals in the United States and employ 18% of the pharmaceutical personnel in this country.\(^8\)

\(^7\) Id. at 21.
\(^7\) Id. at x.
\(^7\) See, e.g., Sen. O. Hatch, Areas for Change in the Food and Drug Laws, 38 Food Drug Cosm. L.J. 97 (1983). Senator Hatch presently has a bill in the Senate proposing some of the changes to the Federal Food, Drug & Cosmetic Act which he feels are needed to prevent further pharmaceutical production from going abroad. See infra note 151.


77. Industry Analysis Division, supra note 43, at 81.
78. See generally DUKES, supra note 12, at 16.
79. Grabowski, supra note 43, at 8.
80. Industry Analysis Division, supra note 43, at 38.
81. Id. at 2.
82. Id. However, results of a study done in 1973 indicated that the United States mar-
The industry is highly competitive in the American market and no single company accounts for more than 8% of total United States sales. This reflects a below average concentration of production as compared with such industries as auto, steel, aluminum or aircraft, placing the pharmaceutical industry in the lowest third of 450 primary and secondary United States industries rated for concentration of production.

A key element of competitiveness in the pharmaceutical trade is the development and marketing of new drugs. A company makes most of its money from just a few commercially successful products, which can be eclipsed in the market by the introduction of a safer, more efficacious drug by a competitor. Thus, the industry is characterized by market share instability and continuous entry into new therapeutic fields.

In contradistinction to the diffusion of production facilities throughout the world, pharmaceutical research typically originates from one of five countries: the United States, the United Kingdom, Switzerland, West Germany and Japan. Another hallmark of the pharmaceutical industry, particularly of the large multinational firms, is the high level of investment in research and development (R&D). Since the 1960's, global R&D expenditures as a percentage of sales has been around 9%. In 1986, United States manufacturers spent $3.8 billion on R&D, as compared with the $1.8 billion spent in 1980. R&D is expensive in part because only 10% to

ket had the least penetration by foreign rivals, at 16% of sales, while the market in the United Kingdom had the greatest penetration, with 63% of sales going to foreign-owned pharmaceutical companies, of which 36% was to the U.S.-owned companies. Grabowski, supra note 43, at 11.

83. Industry Analysis Division, supra note 43, at 3.
84. Id. at 3.
85. Id. at ix.
86. Id. at 24.
88. M. STATMAN, COMPETITION IN THE PHARMACEUTICAL INDUSTRY 48, 56 (1983). See also Conrad, The Pharmaceutical Industry in the Year 2000, in PHARMACEUTICALS IN THE YEAR 2000 at 107, 113 (C. Bezold ed. 1983). ("History simply proves that research and development is an elusive temptress that causes yesterday's leading therapy to become just that—yesterday's leading therapy.")
89. Parker, supra note 87, at 140.
90. Campbell and Smith, supra note 41, at 111; Industry Analysis Division, supra note 43, at viii, 13.
20% of the drugs that reach the clinical testing stage are actually marketed. Furthermore, in the United States, the time from basic research/discovery to FDA approval/marketing can take a decade, so financial rewards are delayed. As of 1984, development costs for a new drug that ultimately reached the market were as high as $90-$95 million, although the average cost is more in the range of $50 million.

The news is not all bad, however. The pharmaceutical industry also is one of the most profitable of all industries in this country, as are its counterparts abroad, a fact which has drawn complaints from some developing countries. During the period from 1958 to 1975, the rates of return for all manufacturing in the United States averaged 11%, while the rate during the same period for the pharmaceutical industry as a whole was 18.1%, and for the larger pharmaceutical companies, 19.7%. Additionally, a unique character-

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93. Industry Analysis Division, supra note 43, at ix. Moreover, if one includes in the count all of the promising compounds, even those which do not make it as far as the clinical testing stage, then the ratio of successfully marketed compounds over unsuccessful is only 1 in 10,000. Smith, This Company Could Lead a Revolution in Drugs, Bus. Wk., Mar. 24, 1986, at 100.

94. DUKES, supra note 12, at 97. Of this time period, a mean of approximately 2.4 years is taken up in the processing time of an FDA new drug application. Id.

95. Industry Analysis Division, supra note 43, at 50.
96. ASBURY, supra note 26, at 2.
98. See DUKES, supra note 12, at 86-87.
99. See, e.g., Fazal, The Right Pharmaceuticals at the Right Prices: Consumer Perspectives, in PHARMACEUTICALS AND HEALTH IN THE THIRD WORLD 265 (S. Patel ed. 1983). It should be noted that the developing countries' complaints regarding pharmaceutical profits are not directed solely at United States companies but are levied against all of the multinational manufacturers.
100. Measday, The Pharmaceutical Industry, in THE STRUCTURE OF AMERICAN INDUSTRY (W. Adams ed. 1977), as cited by Industry Analysis Division, supra note 43, at 26. But cf. D. SCHWARTZMAN, INNOVATION IN THE PHARMACEUTICAL INDUSTRY 347 (1976), wherein the author states that as of 1976, the return on investment for the pharmaceutical industry was only 3.3%, as compared with 10% for other industries. See also Cuatrecasas, Opportunities for Research—American Industry, in CONFERENCE ON PHARMACEUTICALS FOR DEVELOPING COUNTRIES 371 (National Academy of Sciences 1979); D. SCHWARTZMAN, THE EXPECTED RETURN FROM PHARMACEUTICAL RESEARCH 40 (1975).

Schwartzman's results have been questioned, however, as being so low that they do not make sense, since such results would mean that the pharmaceutical industry has allowed the
istic of the pharmaceutical market to date has been the apparent inelasticity of demand for pharmaceuticals in relation to price.\textsuperscript{101} Consumers, besides being unaware of price at the time that the choice of product is made, generally consider price to be less important than quality or availability.\textsuperscript{102} This picture may be changing, however, with the move even in the industrialized countries to contain health care costs.\textsuperscript{103}

\section*{B. \textit{Great Expectations—The Future for the Pharmaceutical Industry}}

The future for the pharmaceutical industry worldwide looks good, indeed. Earnings in 1986 were expected to be up as much as 13\%, reflecting a 10\% average increase in prices over 1985 and the income resulting from the introduction that year of a dozen or so new products.\textsuperscript{104} Moreover, it is predicted that global demand for pharmaceuticals will grow throughout the 1980’s at a rate of 10\% to 11\% per year, with real growth of about 3\% to 4\%, for both the industrialized and the developing world.\textsuperscript{105} Part of this increase is expected to come about as a result of the nascent biotechnology industry.\textsuperscript{106}
Yet the significance of the growth in demand for the developing countries is not certain. In a comprehensive study of the United States pharmaceutical industry undertaken by the Office of Industry Assessment of the International Trade Administration, (United States Department of Commerce), the Office reached this conclusion as to the market potential in the developing countries:

The low per capita income of the LDCs [less developed countries], at present, however, does not offer increased opportunities for a significant increase in the sales of pharmaceutical products. Marketing new products should prove much easier in high-income industrialized countries where the marketing environment is similar to the U.S.; whereas marketing new products in countries with low per capita income may prove difficult because of differences in the medical, legal and commercial environments.\(^{107}\)

Perhaps a sign of the times for developing countries can be seen in the 1985 closing by Squibb Corporation of unprofitable operations in Brazil, Argentina and Uruguay.\(^{108}\)

What, then, are these differences in environment which make the less developed countries a “difficult” market? That is the subject to which we now direct our focus.

IV. PHARMACEUTICALS AND DEVELOPING COUNTRIES

A. The Need for Pharmaceuticals in the Developing World

Out of world sales (at manufacturer’s prices) of $80 billion in 1980, it has been estimated that only 20% went to developing countries, though three-quarters of the world’s population lives in the developing world.\(^{109}\) Whereas the developed countries spend 5% of their GNPs on public health expenditures, countries in the developing world spend little more than 1% of GNP on public health.\(^{110}\) Moreover, of the money which developing countries spend on public health, 20% to 40% of the annual budget is spent on pharmaceuticals, as contrasted with developed countries, in which pharmaceuticals account for 7% to 12% of health care...
costs.\textsuperscript{111}

In consideration of this disparity, the World Health Organization (WHO) in 1981, at the 34th World Health Assembly, adopted the Global Strategy of "Health for All by the Year 2000."\textsuperscript{112} Indira Gandhi, then the Prime Minister of India, addressed the opening session of the Assembly and summed up the position of the developing countries with regard to the multinational pharmaceutical industry:

Affluent societies are spending vast sums of money understandably on the search for new products and processes to alleviate suffering and to prolong life. In the process, drug manufacture has become a powerful industry, subject to the same driving considerations of other big industries, that is, concentration on profit, fierce competition and recourse to hard-sell advertising. Medicines which may be of the utmost value to poorer countries can be bought by us only at exorbitant prices, since we are unable to have adequate independent bases of research and production. This apart, sometimes dangerous new drugs are tried out on populations of weaker countries although their use is prohibited within the countries of manufacture. It also happens publicity makes us victims of habits and practices which are economically wasteful or wholly contrary to good health. . . . My idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death. The world community should also work some form of recompense for the loss suffered by developing countries because of this migration of trained doctors and nurses.\textsuperscript{113}

As can be seen from this quote from Gandhi's speech, the dissatisfaction of the developing world with the multinational pharmaceutical industry focuses on three points: (1) marketing practices; (2) pricing policies; and (3) technology transfer policies. Each of these points will be addressed in turn.


On a related subject, WHO is also active in setting standards for the marketing of breastmilk substitutes in the developing countries. For a discussion of WHO's policies in this regard, see \textit{The Implementation Process of the International Code of Marketing of Breastmilk Substitutes}, 11 \textit{Syracuse J. Int'l L. \\& Com.} 161 (1984).

\textsuperscript{113} Address by Prime Minister Indira Ghandi, 34th World Health Assembly, \textit{as quoted by} S. Patel, Editor's Introduction to \textit{Pharmaceuticals and Health in the Third World} 165, 165-66 (S. Patel ed. 1983).
Pharmaceutical Exports

B. Marketing Practices Within Developing Countries

Entire books have been written on the marketing abuses of the multinational pharmaceutical industry in the developing world. One cited example pertains to the marketing of the drug lomotil, used in the treatment of diarrhea. In the United States, lomotil is available only by prescription and is not recommended for children because the drug is highly toxic, with the difference between a proper dose and a fatal one being only slight. The manufacturer also marketed this drug in Sudan, where it was sold over the counter. Not only did the package fail to warn of the risks of the drug, but the label boasted of the product's use by the astronauts of Gemini and Apollo and went on to recommend the drug for children as young as one year.

Another example involves Novobiocin, an antibiotic whose use was restricted in the United States in 1969 after one in five patients taking the drug had an allergic reaction and because some patients developed blood disorders from it; Novobiocin continued to be marketed in Brazil without warnings. Similarly, the use of the antibiotic chloramphenicol is restricted in the United States, West Germany, Denmark and the United Kingdom to life-threatening infections since the drug can cause fatal aplastic anaemia. However, chloramphenicol is sold over the counter in Mexico without warnings.

These examples, besides chronicling some of the marketing abuses by the pharmaceutical industry, also serve to illustrate some of the marketing problems faced by the industry. It should be noted that in all of the above examples, the drug in question had been approved for marketing in the country of manufacture. Nevertheless, a drug which may be safely administered while under the supervision of a doctor can be very harmful when marketed in a country where drugs are sold over the counter, some-


116. U.N. Centre, supra note 5, at 34.

117. Id. For further examples and discussion, see Silverman and Lydecker, The Promotion of Prescription Drugs and Other Puzzles, in Pharmaceuticals and Health Policy 78 (R. Blum, A. Herxheimer, C. Stenzl, & J. Woodcock eds. 1981).
times illegally,\textsuperscript{118} without a doctor's prescription.\textsuperscript{119} Additionally, a drug which might be considered safe for marketing if appropriate warnings are included may be in practice quite unsafe in a country such as Colombia, which prohibits the inclusion of package leaflets with pharmaceuticals, or in Malaysia, where doctors will distribute drugs directly to the patient by dispensing individual pills or by giving the patient the entire bottle after all labels have been removed.\textsuperscript{120}

The marketing problems of developing countries are made worse still by a general inability to implement effective pharmaceutical legislation.\textsuperscript{121} Effective pharmaceutical regulations require a cadre of highly educated personnel, something which many developing countries lack. For example, one member of the pharmacy board in Trinidad and Tobago described pharmaceutical training there as being in total disarray, with facilities for quality control being non-existent.\textsuperscript{122} The West African Pharmaceutical Federation, which includes members from Gambia, Ghana, Liberia, Nigeria and Sierra Leone, reports that the shortage of pharmacists in that area of the world is so acute that countries have been forced to allow non-professional personnel to dispense drugs.\textsuperscript{123} Moreover, pharmacists are needed in governmental health bodies to enforce the licensing and other requirements of any effective pharmaceutical legislation.\textsuperscript{124}

No drug is absolutely safe. The meaning of a "safe" pharmaceutical is relative to the circumstances and requires a reassessment of the risk-benefit analysis in each country, for every drug has inher-
ent risks, great or small. This is not to suggest that the industry can be absolved of responsibility for marketing abuses, such as those noted above, but rather to highlight the complexity of the problems in marketing.

C. Price Policies and Developing Countries

Pricing practices raise a different set of issues. The developing countries, which already have far too little money with which to buy pharmaceuticals, feel resentful and victimized when they see the sometimes great disparity in prices for the same drug in different countries. In one study, price variations of up to 600% were observed among the Andean Pact countries. In a separate study of the Caribbean market, drugs said to be identical or similar in effect were compared for price. Differences of between 50% to 5000% were reported to have been found.

Price variations between countries are explained by the industry as being the result of factors such as regional price controls and freezes, currency devaluations, taxes, retail versus wholesale margins and other market factors. The primary concerns of the developing countries, however, are with the matter of "transfer pricing," where the price goes up with each sale between subsidiaries of the same company.

In an effort to improve their purchasing power, developing countries are pooling their drug purchases into one order to lower the manufacturer's overhead costs and to take advantage of wholesale pricing. Other countries are buying their pharmaceuticals in unpackaged, bulk orders and are completing the packaging process themselves as a way of lowering costs. Yet another approach to make drugs more affordable for developing countries is the World Health Organization's list of 200 essential drugs. The list is meant to assist developing countries in choosing their purchases carefully so as not to waste resources on drugs which have limited health value. To this end, one manufacturer, Ciba-Geigy, has begun

125. U.N. Centre, supra note 5, at 31.
126. Id. at 15.
129. Von Wartensleben, supra note 127, at 171-72.
130. Fattorusso, Essential Drugs for the Third World, in Pharmaceuticals and
marketing an inexpensive, generic line of the drugs included on the WHO list.\textsuperscript{131}

D. Technology Transfer Policies

The third category of complaints raised by the developing countries pertains to technology transfer policies. The countries of the Third World would like to get out of the position of depending upon imports for their pharmaceutical needs. To accomplish this goal, some countries have tried the approach of limiting a manufacturer’s patenting rights. For example, Argentina, Colombia and Egypt only allow patents on the manufacturing process, and not on the product itself. Other countries, such as Brazil and Korea, issue no patents at all.\textsuperscript{132} The drawback of such approaches, it would seem, is that these policies would deter the introduction of the latest and perhaps most desired drugs in that market.\textsuperscript{133} A different tactic is taken by India and Costa Rica, which have established compulsory licensing requirements, setting up a royalty arrangement with the pharmaceutical company.\textsuperscript{134}

Yet, still other problems have arisen in connection with attempts by developing countries at establishing their own pharmaceutical plants. Local production has not always proven to be cheaper, and there have been difficulties in maintaining quality.\textsuperscript{135} Moreover, countries in the developing world often do not have the technically trained personnel to operate these plants. On this latter point, many of the multinational companies have been making some efforts to help. For example, Ciba-Geigy has started a school for laboratory technicians in Indonesia and a research center/technical

\textsuperscript{131} Leisinger, \textit{supra} note 128.
\textsuperscript{132} U.N. Centre, \textit{supra} note 5, at 46.
\textsuperscript{133} The Reagan Administration is not happy with the countries that do not honor patents or copyrights. For this reason, the Administration has recently threatened to take back the preferential tariff status of several countries, including Argentina, Brazil, Singapore, Taiwan and Thailand. Additionally, the Administration wants to amend the Trade Act of 1974 to make it easier to retaliate against illegal imports by lifting the evidentiary requirement that companies prove that they have been injured. The Administration is also looking to use its influence at the World Bank and the International Monetary Fund to put pressure on the countries to crack down on patent infringements, and there are plans to include reciprocal patent protection on the agenda of the next round of talks on the General Agreement on Tariffs & Trade. \textit{Reagan Turns Up the Heat on Patent-Pilfering Countries}, \textit{Bus. Wk.}, Apr. 21, 1986, at 47.
\textsuperscript{134} Id. at 46.
\textsuperscript{135} Treharne, \textit{Commentary}, in \textit{The International Supply of Medicines} 153, 155 (R. Helms ed. 1980); Leisinger, \textit{supra} note 128.
school in India. Additionally, Ciba-Geigy and another Swiss company, Hoffman-La Roche, have jointly set up a research and training center in Tanzania for tropical diseases. Similarly, ten United States companies are working with the government of Gambia in conjunction with Africare to improve that nation's health care system. More generally, the American company SmithKline & French is financing the production of educational material in Zimbabwe to assist village health workers.136

Certainly, these efforts will help, but still the health problems of the developing world persist. Moreover, as portended by the Industrial Analysis Division report, supra section IIIB, the developing countries stand to be left behind in the biotechnical revolution. It has been said that while current antibiotics and vaccines are capable of curing the communicable diseases—smallpox, measles, polio, rheumatic fever and pneumonia—these traditional therapies will not eliminate the major infectious or parasitic diseases which chronically afflict almost one billion people.137 Biotechnology, specifically recombinant-DNA (r-DNA) techniques, are seen as the only means of developing vaccines to eliminate these health hazards, yet commercial development of such vaccines is not following technological breakthroughs.138 As of 1982, only 1% of all federally funded research projects in the United States were looking into vaccine development.139

What sort of regulatory frameworks might be used to assist the developing world with its health needs? Some possibilities will be explored, infra, in section V.

V. RECOMMENDATIONS

The health needs of the developing world are readily apparent. Insofar as pharmaceuticals can alleviate these needs, the focus of

136. Drug Distribution and Legislative Problems, supra note 111, at 618.
138. Id.
139. Id., citing a 1982 survey performed by the Smithsonian Science Information Exchange. But cf. Conrad, supra note 88, at 115, wherein the author, who is Vice President for Pharmaceuticals and a member of the Executive Committee and Board of Directors for Hoffman-La Roche, predicts:

Because of its potential to facilitate the development of exceptionally pure antibodies, rDNA technology may stimulate a reemergence of vaccine research. Presently, only a few companies are involved in such research, primarily because of long-term liability problems associated with the difficulties in achieving sufficiently pure products. As rDNA eliminates many of the problems of producing highly purified vaccines on a broad scale, more companies will again enter this research area.
United States regulations must be on both the necessity of encouraging R&D of future useful pharmaceuticals and on the necessity of getting currently available pharmaceuticals to the developing world.

One possibility for encouraging R&D in this area might be found in the Orphan Drug Act\textsuperscript{140} enacted by the United States Congress in January of 1983. Implicit in the Orphan Drug Act is the acknowledgement that while the United States pharmaceutical industry might be considered to be a highly regulated industry, it is, nevertheless, made up of privately owned, as opposed to governmentally operated, companies, in business for a profit. Thus, an "orphan drug" is a drug that, while medically important, is financially unprofitable for the pharmaceutical industry to develop. There are several reasons why a drug may be unprofitable, such as: (a) the drug is not patentable; (b) the drug is highly toxic, e.g., cancer treatments, and companies may decide that the potential earnings do not outweigh the potential liabilities; (c) the drug is for a rare disease and, ergo, a small commercial market; or (d) the drug has been approved for one particular use and it is later discovered to be effective for another disease which is more rare.\textsuperscript{141}

To encourage research and development of such drugs, the Orphan Drug Act allows for special financial incentives in the form of tax credits equaling 50% of clinical testing expenses,\textsuperscript{142} grants to cover qualified clinical testing,\textsuperscript{143} and exclusive seven-year marketing rights for unpatentable drugs.\textsuperscript{144}

While the Orphan Drug Act was not drafted with a mind toward the problems of the developing world, it nevertheless would seem to have some potential for application in this area, an idea which has been recognized by some.\textsuperscript{145} For example, Ciba-Geigy's U.S.-based subsidiary\textsuperscript{146} has obtained an Orphan Drug designation from


\textsuperscript{141} ASBURY, supra note 26, at 3. For a discussion of the costs of research and development, see supra notes 81-87 and accompanying text.


\textsuperscript{143} 21 U.S.C. § 360ee (Supp. 1986).

\textsuperscript{144} 21 U.S.C. § 360cc (Supp. 1986).

\textsuperscript{145} ASBURY, supra note 26, at 194-95. See also Lappe', supra note 137, at 78.

\textsuperscript{146} Ciba-Geigy Corp. is a Swiss company. For a discussion of the origins of Ciba-Geigy see supra note 24.
the FDA for clofazimine (Lamprene), a drug for the treatment of leprosy. Within the United States, there is a small (around 5000) but growing number of cases of leprosy among the community of recent immigrants from areas of the world such as southeast Asia and Latin America.\textsuperscript{147} Clofazimine, although being developed for the United States market under the umbrella of the Orphan Drug Act, could have a wider application in the developing nations where leprosy is more of a problem.\textsuperscript{148}

Nevertheless, as it stands, the Orphan Drug Act has not alone satisfied the pharmaceutical needs of developing countries. Stronger incentives in the form of tax breaks or government grants towards the required R&D could be specifically targeted for work on the infectious and parasitic diseases now afflicting almost 1 billion people worldwide.\textsuperscript{149}

The Orphan Drug Act, or an equivalent statute drafted with a mind toward the Third World, could help to encourage research and development for new drugs and biotechnologies to be applied in developing countries.\textsuperscript{150} Still, there are many drugs already available which can alleviate morbidity and mortality in developing countries. The Orphan Drug Act will not affect the distribution of these latter products. The problem here is not the absence of interest by the pharmaceutical industry in the necessary research and development work, but rather a lack of money on the part of the developing world with which to purchase pharmaceuticals. The United States government could promote interest by the pharmaceutical industry in the market in developing countries by making certain that a sufficient percentage of the United States' foreign aid money to the Third World is designated for the purchase of essential pharmaceuticals.

It is sometimes suggested that the export of pharmaceuticals should not be regulated at all, and that the decisions regarding a

\textsuperscript{147} Leisinger, supra note 128. See also Asbury, supra note 26, at 194-95.

\textsuperscript{148} Leisinger, supra note 128; Asbury, supra note 26, at 194-95.

\textsuperscript{149} Lappe', supra note 137, at 14.

\textsuperscript{150} Lappe', supra note 137, at 78.
drug's safety and efficacy should be left to the importing country.\textsuperscript{151} Under the present state of the law, United States pharmaceutical manufacturers may not export from this country drugs which have not been approved by the FDA, with a limited exception for experimental drugs.

There are basically three different ratings of drugs for marketing approval. The first is approved, which means that the drug can be marketed in the United States or abroad. The second is unapproved, which means that this drug has neither been approved nor disapproved by the FDA. This could mean either that the manufacturer has not applied for approval, or that it applied but withdrew its application, or that the application is pending before the FDA. The third is nonapproved, or banned, which means that the FDA has reviewed the application but has refused permission to market the drug because it was found to be not safe or effective.\textsuperscript{152} Only approved drugs can be exported from the United States, and this includes drugs supplied to developing countries through the Agency for International Development (AID).\textsuperscript{153}

Manufacturers argue that it is paternalistic of the United States to prohibit all export of unapproved drugs and they argue for a policy of unregulated export of pharmaceuticals. This simply is not a creditable position vis-a-vis the developing world. As discussed previously, many developing countries lack sufficient numbers of the highly educated personnel needed to establish meaningful review of pharmaceuticals. If the United States export law is pater-

\textsuperscript{151} On October 18, 1986, the United States Senate and the House of Representatives unanimously passed an omnibus health bill. S. 1744, 99th Cong., 2d Sess. (1986). One subsection of this bill would allow U.S. pharmaceutical manufacturers to export pharmaceuticals which are awaiting approval in the United States to medically sophisticated countries in which these pharmaceuticals have already been approved. The stated purpose of this bill is to safeguard the scientific advances of the emerging biotechnology industry and to keep jobs and technology in the United States. This bill has yet to be signed by President Reagan.

\textsuperscript{152} \textit{Asbury}, supra note 26, at 184.

\textsuperscript{153} \textit{Id.} The total amount of federal assistance to developing countries via AID will amount to $600 million in 1986. Private foundations in the United States also contribute financial support to efforts to promote economic and social development in the developing world. For example, the Rockefeller Foundation recently expanded its program of global aid, with plans to spend as much as $300 million over the next five years. A specific focus of the Rockefeller Foundation program is the implementation of biotechnological discoveries, such as vaccines and improved contraceptives, in Third World countries. N.Y. Times, May 4, 1986, at A24, col. 1.

Other private foundations which supply aid to developing countries include the Ford Foundation, which contributes $60 million annually to this cause, the Carnegie Corporation, with $10 million in annual contributions and the Kellogg Foundation, also contributing $10 million annually. \textit{Id.}
nalistic, then it is a case of responsible paternalism.

Moreover, there is a trend among other industrialized countries to move toward more restrictive pharmaceutical regulations, not less.¹⁵⁴ For example, in West Germany, drugs already on the market are being reconsidered, and as a result, in 1984, 171 drugs were recalled from the market.¹⁵⁵ This trend should only intensify as the biotechnologically produced drugs enter the market.¹⁵⁶ As the Industry Analysis Division concluded in its study of the pharmaceutical industry:

Perhaps the most important implication of the future competitive environment, however, is the potential impact on regulatory requirements resulting from the emergence of new classes of drugs. Not only will these drugs touch on the most personal and sensitive aspects of an individual’s life (mental functions, reproductive systems, etc.), and hence raise special concerns for drug safety, but some will raise ethical and societal issues that may be more far-reaching than current arguments about safety and efficacy . . . Society will resist leaving decisions on the development and distribution of such drugs to the marketplace, based only on criteria of economic efficiency. Pressure for regulation, moreover, will come from all sides of the political spectrum—from the right as well as the left. Thus, while there are some forces at work to reduce the level of government regulation over drug development and marketing, the convergence of concerns related to safety and societal impact as these new drugs emerge will create pressures for more, rather than less, government regulation.¹⁵⁷

It would therefore seem inappropriate to deregulate exports to developing countries.

In summary, regulation for the developing countries should address both the need to get currently available pharmaceuticals to the developing world and the need to encourage research into future useful pharmaceuticals. It was suggested that the United States government should ascertain that a sufficient percentage of its foreign aid is specifically designated for the purchase of essential pharmaceuticals for the developing countries. It was also suggested that the Orphan Drug Act, or an equivalent statute, could do much to encourage future research for these projects. These measures alone will not solve all of the health problems of the de-

¹⁵⁴. Industry Analysis Division, supra note 43, at 73, 92. See also Dukes, supra note 12, at 25-28.
¹⁵⁵. Industry Analysis Division, supra note 43, at 73.
¹⁵⁷. Industry Analysis Division, supra note 43, at xiv (emphasis in original).
veloping world, absent improvements in the conditions within those countries, but such measures will still go a long way towards assisting those countries with their critical health problems.

VI. AUTHOR'S POSTSCRIPT

Since the completion of the preceding article by this author, President Reagan has, on November 14, 1986, signed into law an omnibus health bill, included in which was the Drug Export Amendments Act of 1986. The Drug Export Amendments Act significantly changes the Federal Food, Drug and Cosmetic Act in that the amendments for the first time permit the export of unapproved drugs, while an application for approval is pending, to certain developed countries if those countries have already approved the drug in question.

The Drug Export Amendments Act also addresses itself in part to the health problems of the developing world. The amendments allow for the export of an unapproved drug for the prevention or treatment of a tropical disease if it can be shown that the drug would be safe and effective in the country importing the drug.

Another significant provision of the Drug Export Amendments Act comes as an amendment to section 241 of the Public Health Service Act, adding this section: "The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States." Thus, with the Drug Export Amendments Act, the Congress has expressed its support for biomedical research to alleviate the health problems endemic to the developing world.

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