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Recommended Citation
Lairold M. Street, U.S. Exports Banned for Domestic Use, but Exported to Third World Countries, 6 Md. J. Int’l L. 95 (1980).
Available at: http://digitalcommons.law.umaryland.edu/mjil/vol6/iss1/10

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Comment: U.S. Exports Banned For Domestic Use, But Exported to Third World Countries
Lairold M. Street*

Although the doctrine of caveat emptor has been rejected as an appropriate policy upon which to ground sales law in the United States, the attitude of this country towards foreign consumers remains very much one of "let the buyer beware." Consumers in foreign nations are frequently the recipients of products which may not be sold in the United States because the agency with jurisdiction over the product has either banned it from the domestic market or has promulgated standards to which the exported product does not conform. In addition, United States manufacturers frequently use deceptive marketing practices abroad.

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Their comments on an earlier draft of this article were most helpful.

1. Let the buyer beware, a maxim of the common law expressing the rule that a buyer purchases at his peril. Ballentine's Law Dictionary 183 (3rd. ed. 1969).

2. The doctrine of caveat emptor has evolved into a less harsh rule. See Farmer State Bank v. Cook, 251 Iowa 942, 103 N.W.2d 704 (1970); Daily v. Holiday Distributing Corp., 260 Iowa 859, 151 N.W.2d 477 (1967). In the case of goods the effects of the maxim are considerably ameliorated by implied warranties which may accompany them by law. See U.C.C. §§ 2-314 and 2-315 (1978 version). In addition, certain federal regulatory acts provide that certain standards must be met before an item is introduced into interstate commerce. See e.g. the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq.


5. 1978 Hearings, supra note 3, at 35 (statement of S. Jacob Scherr).
The results of these practices can be truly shocking. One of the worst incidents involved the pesticide Leptophos, which cannot be sold in the United States because it has never been registered by the Environmental Protection Agency for domestic use. S. Jacob Scherr, who appeared before a House subcommittee of the Committee on Government Operations during its hearings on the United States export of banned products, testified that

In 1975 alone, Velsicol, a Texas-based corporation exported 3,092,842 pounds of Leptophos to thirty countries. Over half of that was shipped to Egypt, a country with no procedures for pesticide regulation or tolerance setting. In December 1976, the Washington Post reported that Leptophos use in Egypt resulted in the death of a number of farmers and illness in rural communities. In addition, over 1,000 water buffalo died from Leptophos poisoning. But despite the accumulation of data on Leptophos' severe neurotoxicity, Velsicol continued to market the product abroad for use on grain and vegetable crops while proclaiming the products safety.

Mr. Scherr also described an incident involving 8,000 tons of wheat and barley imported by Iraq in 1972. The grain was coated with an organic mercury fungicide, the use of which had been banned in the United States and other developed countries. An estimated 400 Iraqis died after consuming the grain and up to 5,000 were hospitalized.

Deceptive advertising and marketing practices are especially prevalent with respect to drugs. Mr. Scherr gave some particularly shocking examples of this type of practice. Winstrol, a synthetic male sex hormone manufactured by a subsidiary of Sterling Drug, Inc., causes a number of side effects which the Food and Drug Administration (FDA) describes as "virtually irreversible." Among these side effects are baldness and the stunting of growth in children and deepening of voices and clitoral enlargement in girls. Mr. Scherr testified that

While Winstrol is drastically limited for domestic use, the Brazilian magazine Opiniao reported that it is available in virtually every pharmacy in Brazil. A two page advertisement in a Brazilian medical journal pictured a healthy boy and recommended the drug to combat poor appetite, fatigue and weight loss.

6. Id. at 47.
7. See note 3 supra.
8. Id. at 47–48.
9. Id. at 49.
10. See 1978 Hearings, supra note 3, at 50–53.
11. Id. at 50.
12. Id. at 50–51.
He also described the practices of the same company with respect to the
painkiller Dipyrone which it markets in the Dominican Republic as
Novaldin. The drug causes a fatal blood disease and the American Medical
Association warns that it should be used only as "a last resort." However,
Sterling advertises this product "with pictures of a contented child smiling
about the 'agreeable flavor' of the Novaldin drops."\textsuperscript{13}

The incident which, in large part, sparked the Committee's interest in
the problem of the export by U.S. manufacturers of products not marketable
domestically, was one involving the export of Tris-treated children's sleep-
wear. After the Consumer Product Safety Commission (CPSC) banned
Tris-treated products from the domestic market because of mounting
evidence that Tris would "cause cancer in the children exposed to it,"\textsuperscript{14} many
U.S. manufacturers exported Tris-treated products to countries with no ban.
They did this even though it was highly likely that the sleepwear would
seriously endanger the health of children exposed to it.\textsuperscript{15}

Trade in these hazardous products may have adverse effects on U.S.
citizens as well.\textsuperscript{16} For example, many of the workers at the Texas plant at
which Leptophos was manufactured\textsuperscript{17} suffered severely as a result of exposure
to the pesticide; among the symptoms exhibited were partial paralysis,
blurred vision, dizziness and spastic paralysis of the lower extremities.\textsuperscript{18} Said
one worker, "My spine is deteriorating. It's dissolving."\textsuperscript{19}

Incidents like these have fueled concern both at home and abroad over
the laxity of the current U.S. export policy. Esther Peterson, Special
Assistant to the President for Consumer Affairs, testified before the
subcommittee during the 1978 hearings that

on numerous occasions, representatives of various consumer organiza-
tions have expressed concern to me about the potential hazards of
products exported form the United States and other countries . . . . in

\textsuperscript{13} Id. at 51. Other examples may be found at pages 51 to 53; see also Weir, "For
\textsuperscript{14} \textit{1978 Hearings, supra} note 3, at 1 (opening statement of Chairman Rosenthal)
and at 3 (statement of Esther Peterson).
\textsuperscript{15} Id. at 53; see \textit{House Comm. on Government Operations, Report on Export of
Products Banned by U.S. Regulatory Agencies, H.R. Doc. No. 95-1686, 95th Cong.,
2d Sess. 7 [hereinafter cited as \textit{House Report on Banned Products}].
\textsuperscript{16} \textit{1978 Hearings, supra} note 3, at 48 (statement of S. Jacob Scherr).
\textsuperscript{17} See text at notes 6 to 8, supra.
\textsuperscript{18} \textit{1978 Hearings, supra} note 3, at 48.
\textsuperscript{19} Id. Mr. Scherr also reported that a Senate subcommittee had revealed that
from 1972 to 1976 American imports of certain produce from Mexico contained residues
of this dangerous pesticide. The residue tolerance for Leptophos was revoked by the
EPA in November 1976. \textit{Id.} The FDA is the agency responsible for testing imports in
order to see if they comply with the tolerance levels set by the EPA.
almost every delegation that comes to us, this is an issue that is raised [which] is of growing concern.  

Mr. Scherr testified at the same hearings that

There is a sense of outrage on the part of many poor countries where citizens are the most vulnerable to exports of hazardous drugs, pesticides and food products. At the 1977 meeting of the UNEP Governing Council, Dr. J. C. Kiano, the Kenyan minister for water development, warned that developing nations will no longer tolerate being used as dumping grounds for products that had not been adequately tested "and that their peoples should not be used as guinea pigs for determining the safety of chemicals."  

It is anticipated that the problems posed by the export of banned and substandard products and by deceptive marketing practices will continue to worsen unless something is done. Mrs. Peterson cited a group of factors which will contribute to an increase in the dimension of the problem. They are: (1) an expected substantial growth in world population which will generate enormous demand for food, drugs, and pesticides; (2) acceleration of demand in developing countries for U.S. technologies and consumer goods; (3) mounting economic pressures for U.S. firms to increase exports, and; (4) predictions that the discovery of new suspected carcinogenic substances likely to be present in consumer products will increase significantly.

The problems generated by the export from the United States of hazardous products, adulterated and misbranded food and drugs, and the use of deceptive marketing practices by U.S. manufacturers are likely to be particularly acute in developing nations because many of these countries lack the capability to evaluate incoming products. Mr. Scherr testified that

Some developing countries have enacted virtually no legislation to govern the importation, domestic use and disposal of potentially toxic

20. Id. at 3 (statement of Esther Peterson).
21. Id. at 44 (statement of S. Jacob Scherr). Dr. Kiano's views were incorporated in a decision passed by the 58-nation Governing Council and the council urged governments to "take steps to ensure that potentially harmful chemicals, in whatever form or commodity, which are unacceptable for domestic purposes in the exporting country, are not permitted to be exported without the knowledge and consent of appropriate authorities in the importing countries." Id., quoting Human and Environmental Health, Decision 85(V) adopted May 25, 1977.
22. Id. at 3 (statement of Esther Peterson). Mr. Scherr remarked that "the use of chemicals has spread throughout the developing world much faster than the capability to ensure their safe use." Id. at 45–46 (statement of S. Jacob Scherr).
23. Id. at 10 (statement of Esther Peterson).
chemicals, and few maintain any facilities for monitoring the effects of the products on health in the environment. Even where decent laws are on the books, many governments lack the technical and administrative capacity to implement them.24

Developing countries lack "enough trained staff to work as food control officials at various levels, starting with the inspector or controller-policeman who draws the samples, right through to the laboratory chemist and magistrate who finally deals with the final inspection of goods which have been imported and offered for sale."25

It is maintained that the failure of the United States to adopt any meaningful policy in this area has demonstrated a lack of sensitivity to the problems faced by the developing countries,26 has led to damage to health and environment at home27 and abroad and has tarnished the image of the United States abroad.28 This note will examine the problem with particular attention to the issues as they relate to one of the agencies primarily responsible for the control of hazardous products, the Food and Drug Administration.29

The FDA administers the Federal Food, Drug and Cosmetic Act30 and regulates a group of products which include food,31 food additives,32 food

24. Id. at 46 (statement of S. Jacob Scherr).
27. See text at notes 6 to 19, supra.
29. This note will not examine in detail the criteria for export under the statutes administered by the EPA and the CPSC. See note 4, supra. The provisions of these statutes are nearly as lax as those of the FDA, discussed infra, in that exports are generally exempted from the provisions of the acts provided certain criteria are met. Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 1360; Toxic Substances Control Act, 15 U.S.C. § 2611; Consumer Product Safety Act, 15 U.S.C. § 2067; Federal Hazardous Substances Act, 15 U.S.C. § 1273; Flammable Fabrics Act, 15 U.S.C. § 1202. However, the notification and reporting requirements are stricter. The EPA has the statutory obligation to notify foreign governments about cancellations or suspensions of domestic registration of pesticides. In addition, exporters must notify the government of the importing nation that the product cannot be sold in the United States. The Toxic Substances Control Act requires that any person who intends to export a chemical for which regulatory action has been taken must notify the EPA which must in turn supply the importing government with notice that its information on the chemical is available. All three statutes administered by the CPSC require exporters of banned products to report to the CPSC the fact of their intention to export nonconforming goods. The CPSC in turn notifies the importing government.
30. 21 U.S.C. §§ 301 et. seq.
coloring,\textsuperscript{22} drugs,\textsuperscript{24} medical devices\textsuperscript{25} and cosmetics.\textsuperscript{26} Products within the jurisdiction of the FDA which may not be marketed in the United States may nonetheless be exported provided that certain requirements are met. Section 381(d)(1) provides that a food, drug, device or cosmetic intended for export shall not be deemed to be adulterated or misbranded if it (a) accords to the specifications of the foreign purchaser, (b) is not in conflict with the laws of the country to which it is intended for export, (c) is labeled on the outside of the shipping package that it is intended for export, and (d) is not sold or offered for sale in domestic commerce.\textsuperscript{23} Generally, products which meet these criteria may be exported, though there are variations with respect to drugs and medical devices. New drugs\textsuperscript{28} which have not been approved by the FDA for use in the United States may not be exported for sale in other countries.\textsuperscript{29} This is true no matter how much a foreign government may wish to have the drug imported. Certain drugs intended solely for investigational use may be exported for research purposes.\textsuperscript{40} However, drugs which are not classified as "new," including insulin, antibiotics and pre-1938 drugs, may be exported provided the provisions of § 381(d) are met even if the drugs are adulterated or misbranded.\textsuperscript{41} Medical devices banned under § 360 of the Act may be exported provided that they qualify under § 381(d)(1) and the Secretary of Health and Human Resources has determined that exportation of the device is not contrary to public health and safety and has the approval of the country to which it is intended for export.\textsuperscript{42}

Unlike the EPA and the CPSC, the FDA has neither the statutory authority to require notification to the agency by manufacturers who plan to export products not marketable domestically,\textsuperscript{33} nor the statutory obligation to

\begin{itemize}
  \item 33. 21 U.S.C. §§ 321(t)(1), 348.
  \item 34. 21 U.S.C. §§ 351–360b.
  \item 35. 21 U.S.C. §§ 351–360j.
  \item 37. 21 U.S.C. § 381(d).
  \item 38. 21 U.S.C. § 321(p).
  \item 40. 21 U.S.C. § 355(i).
  \item 42. 21 U.S.C. § 381(d)(2).
  \item 43. See note 29 supra; 1978 Hearings, supra note 3, at 108–09 (statement of Dr. Donald Kennedy). The rules for drugs vary slightly, see text at notes 38 to 40, supra. There is a reporting requirement with respect to medical devices in 21 U.S.C. 381(d)(2), see text at note 42, supra, but there are none with respect to food, food additives, old drugs or cosmetics. In addition, once a new approved drug is exported, manufacturers may still engage in deceptive practices abroad and the drug may still be sold if it becomes adulterated.
\end{itemize}
communicate the fact of such an export to the government of the country which is destined to receive it. Nonetheless, it is the policy of the FDA to attempt to inform authorities in the importing country if the FDA has reason to believe that products being exported to that country may be harmful. However, since the exporter need not report to the FDA before he exports, the agency does not always learn about shipments of hazardous products, and thus the government of the importing country may not be notified. Dr. Kennedy, Commissioner of the FDA, testified before the subcommittee that the FDA was "prepared to concede that present notification mechanisms are totally lacking in the case of foods and probably inadequate in the case of drugs and perhaps other product categories ...." He testified that the agency notifies the World Health Organization (WHO) of negative FDA drug approval decisions and that the WHO in turn notifies the governments of the U.N. member nations. The agency also notifies, through State Department channels, governments on its list of those which have indicated a "desire to know about the nature of negative drug approval decisions in the United States."

The notification procedures are plainly inadequate. They provide no notification at all in the case of food or drug shipments unless the FDA happens fortuitously to learn of a particular shipment and communicates this knowledge to the foreign government. In the case of drugs, the procedures may provide governments with information about the general status of a drug in the United States, but again they do not inform governments about particular shipments. When these facts are considered in light of the situation that prevails in many developing countries with respect to health and safety regulation, the enormity of the problem becomes apparent. Notice

44. 1978 Hearings, supra note 3, at 108–09 (statement of Dr. Donald Kennedy).
45. Id.
46. Id. at 110.
47. Id.
48. This procedure has been criticized as "kind of an elegant way of saying we are going to pass the buck. The record of the international organizations in this area has been that they have not been terribly effective in disseminating information on health hazards." 1978 Hearings, supra note 3, at 41 (statement of S. Jacob Scherr).
49. 1978 Hearings, supra note 3, at 110 (statement of Dr. Donald Kennedy). This procedure has been criticized: "The State Department has failed to coordinate an effective information exchange program which communicates to foreign governments the hazards of products which may be imported to their countries." HOUSE REPORT ON BANNED PRODUCTS, supra note 15, at 4; see 1978 Hearings, supra note 3, at 40.
50. HOUSE REPORT ON BANNED PRODUCTS, supra note 15, at 4.
52. But see note 49 supra.
that the United States considers a product unsafe as a general rule cannot help a country which lacks the capacity to inspect and control imports on a broad scale or which lacks health and safety laws. At the very least, these countries need to be apprised of the hazards of particular shipments because a general notice is insufficient.\textsuperscript{53}

Efforts are now underway to ameliorate these problems through the development and implementation of a consistent national policy with respect to products exported from the United States.\textsuperscript{54} An interagency regulatory liaison group was formed for the purpose of doing just that.\textsuperscript{55} In addition, the subcommittee which held the hearings on the U.S. export of banned products recommended such a policy. The subcommittee noted that two policies underlay its recommendations:

1. The United States has a significant responsibility for the safety of the goods it sells abroad. It cannot condone the export of regulated

\textsuperscript{53} 1978 Hearings, supra note 3, at 46 (statement of S. Jacob Scherr); Mollenhauer, supra note 25, at 260.

Less developed countries, however, may request from the U.S. government a "Certificate of Free Sale." This certificate indicates that those products offered for entry into less developed countries comply with the requirements of U.S. law, and as such, those products are freely sold in the United States as the country of origin. FDA: Compliance Policy Guidelines Request for "Certificate of Free Sale", § 50 General Policy Guide 7150.02 (1975).

At present developing countries are not entitled to "Certificates of Free Sale" as a matter of course, or right, according to FDA official policy guidelines. FDA guidelines stipulate that the FDA does not issue a "Certificate of Free Sale" for articles for export. A factual statement of the status of a specific article subject to FDA jurisdiction may be provided on request. See Id. This factual statement issued by the FDA does not serve as certification of a particular product.

The statement is in letter form addressed 'to whom it may concern.' When necessary, and upon specific request, the statement may be a certified copy under Seal of the Department of Health, Education, and Welfare. A certified copy under seal authenticates the letter as a document issued by the Food and Drug Administration; it does not constitute a certification of the article itself in any respect. Id. at 2. Certification as viewed by this writer is the application of a legitimate safety requirement which may insure that sanitary and health characteristics of imported food, drugs and other articles are safe for consumption purposes.

\textsuperscript{54} At this writing the regulatory agencies administer statutes containing inconsistent policies with respect to export. See note 29 and text at notes 30–44 supra.

\textsuperscript{55} 1978 Hearings, supra note 3, at 3 (statement of Esther Peterson). The group included representatives from the Departments of State, Agriculture, Commerce, Energy, Justice and Treasury. Also represented were the Food and Drug Administration, Environmental Protection Agency, Consumer Product Safety Commission, Export-Import Bank, the Overseas Private Investment Corporation, and several executive offices.
products which it knows to be harmful either to foreign consumers or the local or world environment.

(2) This responsibility must be exercised in a way which respects the sovereignty of other nations and accounts for differing conditions which may affect judgments of health and safety.56

The subcommittee's recommendations were as follows57:

No product which is banned from the domestic market should be allowed to be exported without a determination from the appropriate regulatory agency. The agency may determine that export can be justified for any of the following reasons:

(1) Circumstances would render the product safe for use in foreign countries;
(2) A company has requested permission to export the product.58
(3) A foreign country has requested that the export be allowed.59

In formulating this recommended policy, the subcommittee considered testimony it received during the hearings. The witnesses generally agreed that the government should neither prohibit nor approve the export of all items banned by federal regulatory agencies.60 The witnesses also agreed on the need for "improved notification procedures, statutory authority and coordination with respect to an articulated policy."61 With all these points the subcommittee was in substantial agreement.62 Mrs. Peterson pointed out that the development of a uniform policy would require a careful balancing of a variety of complex factors.63 First, a moral responsibility on the part of the

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56. HOUSE REPORT ON BANNED PRODUCTS, supra note 15, at 31.
57. Id.
58. The subcommittee recommended that such an export be allowed "if the exporter has satisfactorily completed an application for an export permit which includes a description of the product, the name and address of the establishment where the product will be manufactured, the country of destination, evidence that the product conforms to the specifications of the foreign purchasers, a sample of the proposed labeling and evidence that the government of the importing country has received notification of the U.S. regulatory action." Id., at 31–32.
59. The subcommittee recommended that such an export be allowed "after full and complete notification of agency action and the reasoning has been made available."
60. HOUSE REPORT ON BANNED PRODUCTS, supra note 15, at 3.
61. Id.
62. Id.
63. 1978 Hearings, supra note 3, at 5–6 (statement of Esther Peterson).
United States to limit the exportation of hazardous products must be balanced with the sovereign rights of foreign governments to determine the health and safety standards and needs of their own people. Second, the health and safety of U.S. citizens must be protected. Hazardous products shipped abroad may return to this country in another and perhaps equally dangerous form. Third, differing economic, social and cultural conditions in a foreign country may suggest that a product, the use of which is banned in the United States, may be suitable for use in that country. Fourth, an export policy must take into account economic burdens that the policy may impose. Fifth, recognition of the need to cooperate with relevant international organizations and with foreign governments must be considered. Sixth, the feasibility of administering the policy must be analyzed. The subcommittee was in "substantial agreement with Mrs. Peterson's assessment of the elements of a policy and with the need for a consistent and balanced result.

64. On the issue of U.S. moral responsibility with respect to the export of banned products see Comment, United States Export of Products Banned for Domestic Use, 20 Harv. Int'l. L. Rev. 331, 368-373 (1979). Because the moral responsibility of the United States must be balanced with the rights of sovereign nations to set their own safety and health standards, a complete prohibition of the export of products banned in the United States would be inappropriate.

65. Banned pesticides may return to the United States as residues on imported food and "[t]oxic chemicals introduced into the environment in Canada, Mexico, or even overseas can be travelling by water or air [and] cause harm in the U.S.; traces of DDT have been found in the most remote corners of the world." 1978 Hearings, supra note 3, at 70 (statement of S. Jacob Scherr). In addition, the manufacturing process may endanger U.S. citizens and environment. See text at notes 6-8, supra; 1978 Hearings, supra note 3, at 68-70 (statement of S. Jacob Scherr); HOUSE REPORT ON BANNED PRODUCTS, supra note 15, at 28-29.

66. For example, the drug Depo Provera is an injectible contraceptive which cannot be offered for sale in the United States. As it is classified as a new drug, it cannot be exported even though it has been approved for use as a contraceptive in nearly 70 nations. The FDA has not approved the drug for use in the United States because of its determination that the risks outweigh the benefits for the U.S. population. However, Dr. Kennedy, Commissioner of the FDA has pointed out that the contraceptive "may well have favorable benefit/risk ratios in...other countries." 1978 Hearings, supra note 3, at 93 (statement of Dr. Donald Kennedy). Other examples of this type of situation are given by Dr. Kennedy at pp. 93, 108-110. See also, HOUSE REPORT ON BANNED PRODUCTS, supra note 15, at 25-28.

67. See 1978 Hearings, supra note 3, at 5-6 (statement of Esther Peterson). Mrs. Peterson pointed out that a restrictive policy could exacerbate the problem of a worsening U.S. trade deficit by making it more difficult for domestic manufacturers to compete with foreign producers.

68. HOUSE REPORT ON BANNED PRODUCTS, supra note 15, at 31.
CONCLUSION

Current laws which permit the export of products which may not be sold in the United States should be modified. This should be done as soon as is practicable because the problems caused by the export of these products will continue to grow and at an accelerating pace. The laws should be modified to reflect a consistent national policy; the current policy is internally inconsistent as different products must meet different criteria if they are to be exported. A national policy should consider and balance the factors discussed at the House hearings and should also take into account the ability of developing countries to assess and effectuate their own safety and health needs. Where necessary, technical assistance should be provided by the United States.

A new policy should be formulated for several reasons. First, the United States has a moral responsibility to stem the tide of dangerous products leaving its shores. Second, it is in the interest of the United States to further good relations with developing nations. The current policy is not conducive to such relations. Third, in many cases a more restrictive policy will protect U.S. citizens as well as those of foreign nations. Fourth, a more restrictive policy is necessary in order to protect the world environment including the environment of the United States. Unless some action is taken, there may well be a critical escalation in the incident of harm caused by the current laxity of U.S. export policy.

69. See text at notes 21–22 supra.
70. The proposed Drug Regulation Reform Act (H.R. 11611) contains a provision for providing technical assistance to a government of an importing nation if such is necessary in order to aid the government in deciding whether a drug should be imported. 1978 Hearings, supra note 3, at 153 (statement of Dr. Donald Kennedy).