

conduct a study and report on issues related to trade and pharmaceuticals.”

#### FINDINGS

Pub. L. 106-387, §1(a) [title VII, §746(b)], Oct. 28, 2000, 114 Stat. 1549, 1549A-40, provided that: “The Congress finds as follows:

“(1) Patients and their families sometimes have reason to import into the United States drugs that have been approved by the Food and Drug Administration (‘FDA’).

“(2) There have been circumstances in which—

“(A) an individual seeking to import such a drug has received a notice from FDA that importing the drug violates or may violate the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]; and

“(B) the notice failed to inform the individual of the reasons underlying the decision to send the notice.

“(3) FDA should not send a warning notice regarding the importation of a drug without providing to the individual involved a statement of the underlying reasons for the notice.”

### § 382. Exports of certain unapproved products

#### (a) Drugs or devices intended for human or animal use which require approval or licensing

A drug or device—

(1) which, in the case of a drug—

(A)(i) requires approval by the Secretary under section 355 of this title before such drug may be introduced or delivered for introduction into interstate commerce; or

(ii) requires licensing by the Secretary under section 262 of title 42 or by the Secretary of Agriculture under the Act of March 4, 1913 [21 U.S.C. 151 et seq.] (known as the Virus-Serum Toxin Act) before it may be introduced or delivered for introduction into interstate commerce;

(B) does not have such approval or license; and

(C) is not exempt from such sections or Act; and

(2) which, in the case of a device—

(A) does not comply with an applicable requirement under section 360d or 360e of this title;

(B) under section 360j(g) of this title is exempt from either such section; or

(C) is a banned device under section 360f of this title, is adulterated, misbranded, and in violation of such sections or Act unless the export of the drug or device is, except as provided in subsection (f) of this section, authorized under subsection (b), (c), (d), or (e) of this section or section 381(e)(2) of this title. If a drug or device described in paragraphs (1) and (2) may be exported under subsection (b) of this section and if an application for such drug or device under section 355 or 360e of this title or section 262 of title 42 was disapproved, the Secretary shall notify the appropriate public health official of the country to which such drug will be exported of such disapproval.

#### (b) List of eligible countries for export; criteria for addition to list; direct export; petition for exemption

(1)(A) A drug or device described in subsection (a) of this section may be exported to any country, if the drug or device complies with the laws

of that country and has valid marketing authorization by the appropriate authority—

(i) in Australia, Canada, Israel, Japan, New Zealand, Switzerland, or South Africa; or

(ii) in the European Union or a country in the European Economic Area (the countries in the European Union and the European Free Trade Association) if the drug or device is marketed in that country or the drug or device is authorized for general marketing in the European Economic Area.

(B) The Secretary may designate an additional country to be included in the list of countries described in clauses (i) and (ii) of subparagraph (A) if all of the following requirements are met in such country:

(i) Statutory or regulatory requirements which require the review of drugs and devices for safety and effectiveness by an entity of the government of such country and which authorize the approval of only those drugs and devices which have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs and devices on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs and devices.

(ii) Statutory or regulatory requirements that the methods used in, and the facilities and controls used for—

(I) the manufacture, processing, and packing of drugs in the country are adequate to preserve their identity, quality, purity, and strength; and

(II) the manufacture, preproduction design validation, packing, storage, and installation of a device are adequate to assure that the device will be safe and effective.

(iii) Statutory or regulatory requirements for the reporting of adverse reactions to drugs and devices and procedures to withdraw approval and remove drugs and devices found not to be safe or effective.

(iv) Statutory or regulatory requirements that the labeling and promotion of drugs and devices must be in accordance with the approval of the drug or device.

(v) The valid marketing authorization system in such country or countries is equivalent to the systems in the countries described in clauses (i) and (ii) of subparagraph (A).

The Secretary shall not delegate the authority granted under this subparagraph.

(C) An appropriate country official, manufacturer, or exporter may request the Secretary to take action under subparagraph (B) to designate an additional country or countries to be added to the list of countries described in clauses (i) and (ii) of subparagraph (A) by submitting documentation to the Secretary in support of such designation. Any person other than a country requesting such designation shall include, along with the request, a letter from the country indicating the desire of such country to be designated.

(2) A drug described in subsection (a) of this section may be directly exported to a country

which is not listed in clause (i) or (ii) of paragraph (1)(A) if—

(A) the drug complies with the laws of that country and has valid marketing authorization by the responsible authority in that country; and

(B) the Secretary determines that all of the following requirements are met in that country:

(i) Statutory or regulatory requirements which require the review of drugs for safety and effectiveness by an entity of the government of such country and which authorize the approval of only those drugs which have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs.

(ii) Statutory or regulatory requirements that the methods used in, and the facilities and controls used for the manufacture, processing, and packing of drugs in the country are adequate to preserve their identity, quality, purity, and strength.

(iii) Statutory or regulatory requirements for the reporting of adverse reactions to drugs and procedures to withdraw approval and remove drugs found not to be safe or effective.

(iv) Statutory or regulatory requirements that the labeling and promotion of drugs must be in accordance with the approval of the drug.

(3) The exporter of a drug described in subsection (a) of this section which would not meet the conditions for approval under this chapter or conditions for approval of a country described in clause (i) or (ii) of paragraph (1)(A) may petition the Secretary for authorization to export such drug to a country which is not described in clause (i) or (ii) of paragraph (1)(A) or which is not described in paragraph (2). The Secretary shall permit such export if—

(A) the person exporting the drug—

(i) certifies that the drug would not meet the conditions for approval under this chapter or the conditions for approval of a country described in clause (i) or (ii) of paragraph (1)(A); and

(ii) provides the Secretary with credible scientific evidence, acceptable to the Secretary, that the drug would be safe and effective under the conditions of use in the country to which it is being exported; and

(B) the appropriate health authority in the country to which the drug is being exported—

(i) requests approval of the export of the drug to such country;

(ii) certifies that the health authority understands that the drug is not approved under this chapter or in a country described in clause (i) or (ii) of paragraph (1)(A); and

(iii) concurs that the scientific evidence provided pursuant to subparagraph (A) is

credible scientific evidence that the drug would be reasonably safe and effective in such country.

The Secretary shall take action on a request for export of a drug under this paragraph within 60 days of receiving such request.

**(c) Investigational use exemption**

A drug or device intended for investigational use in any country described in clause (i) or (ii) of subsection (b)(1)(A) of this section may be exported in accordance with the laws of that country and shall be exempt from regulation under section 355(i) or 360j(g) of this title.

**(d) Anticipation of market authorization**

A drug or device intended for formulation, filling, packaging, labeling, or further processing in anticipation of market authorization in any country described in clause (i) or (ii) of subsection (b)(1)(A) of this section may be exported for use in accordance with the laws of that country.

**(e) Diagnosis, prevention, or treatment of tropical disease**

(1) A drug or device which is used in the diagnosis, prevention, or treatment of a tropical disease or another disease not of significant prevalence in the United States and which does not otherwise qualify for export under this section shall, upon approval of an application, be permitted to be exported if the Secretary finds that the drug or device will not expose patients in such country to an unreasonable risk of illness or injury and the probable benefit to health from the use of the drug or device (under conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling of the drug or device) outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available drug or device treatment.

(2) The holder of an approved application for the export of a drug or device under this subsection shall report to the Secretary—

(A) the receipt of any credible information indicating that the drug or device is being or may have been exported from a country for which the Secretary made a finding under paragraph (1)(A) to a country for which the Secretary cannot make such a finding; and

(B) the receipt of any information indicating adverse reactions to such drug.

(3)(A) If the Secretary determines that—

(i) a drug or device for which an application is approved under paragraph (1) does not continue to meet the requirements of such paragraph; or

(ii) the holder of an approved application under paragraph (1) has not made the report required by paragraph (2),

the Secretary may, after providing the holder of the application an opportunity for an informal hearing, withdraw the approved application.

(B) If the Secretary determines that the holder of an approved application under paragraph (1) or an importer is exporting a drug or device from the United States to an importer and such importer is exporting the drug or device to a country for which the Secretary cannot make a

finding under paragraph (1) and such export presents an imminent hazard, the Secretary shall immediately prohibit the export of the drug or device to such importer, provide the person exporting the drug or device from the United States prompt notice of the prohibition, and afford such person an opportunity for an expedited hearing.

**(f) Prohibition of export of drug or device**

A drug or device may not be exported under this section—

(1) if the drug or device is not manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practice requirements or does not meet international standards as certified by an international standards organization recognized by the Secretary;

(2) if the drug or device is adulterated under clause (1), (2)(A), or (3) of section 351(a) or subsection (c) or (d) of section 351 of this title;

(3) if the requirements of subparagraphs (A) through (D) of section 381(e)(1) of this title have not been met;

(4)(A) if the drug or device is the subject of a notice by the Secretary or the Secretary of Agriculture of a determination that the probability of reimportation of the exported drug or device would present an imminent hazard to the public health and safety of the United States and the only means of limiting the hazard is to prohibit the export of the drug or device; or

(B) if the drug or device presents an imminent hazard to the public health of the country to which the drug or device would be exported;

(5) if the labeling of the drug or device is not—

(A) in accordance with the requirements and conditions for use in—

(i) the country in which the drug or device received valid marketing authorization under subsection (b) of this section; and

(ii) the country to which the drug or device would be exported; and

(B) in the language and units of measurement of the country to which the drug or device would be exported or in the language designated by such country; or

(6) if the drug or device is not promoted in accordance with the labeling requirements set forth in paragraph (5).

In making a finding under paragraph (4)(B), (5), or (6) the Secretary shall consult with the appropriate public health official in the affected country.

**(g) Notification of Secretary**

The exporter of a drug or device exported under subsection (b)(1) of this section shall provide a simple notification to the Secretary identifying the drug or device when the exporter first begins to export such drug or device to any country listed in clause (i) or (ii) of subsection (b)(1)(A) of this section. When an exporter of a drug or device first begins to export a drug or device to a country which is not listed in clause

(i) or (ii) of subsection (b)(1)(A)<sup>1</sup> of this section, the exporter shall provide a simple notification to the Secretary identifying the drug or device and the country to which such drug or device is being exported. Any exporter of a drug or device shall maintain records of all drugs or devices exported and the countries to which they were exported.

**(h) References to Secretary and term “drug”**

For purposes of this section—

(1) a reference to the Secretary shall in the case of a biological product which is required to be licensed under the Act of March 4, 1913 [21 U.S.C. 151 et seq.] (37 Stat. 832-833) (commonly known as the Virus-Serum Toxin Act) be considered to be a reference to the Secretary of Agriculture, and

(2) the term “drug” includes drugs for human use as well as biologicals under section 262 of title 42 or the Act of March 4, 1913 (37 Stat. 832-833) (commonly known as the Virus-Serum Toxin Act).

**(i) Exportation**

Insulin and antibiotic drugs may be exported without regard to the requirements in this section if the insulin and antibiotic drugs meet the requirements of section 381(e)(1) of this title.

(June 25, 1938, ch. 675, § 802, as added Pub. L. 99-660, title I, § 102(2), Nov. 14, 1986, 100 Stat. 3743; amended Pub. L. 104-134, title III, § 2102(d)(1), Apr. 26, 1996, 110 Stat. 1321-315; Pub. L. 104-180, title VI, § 603(c), Aug. 6, 1996, 110 Stat. 1595; Pub. L. 105-115, title I, § 125(c), Nov. 21, 1997, 111 Stat. 2326.)

REFERENCES IN TEXT

Act of March 4, 1913 (known as the Virus-Serum Toxin Act), referred to in subsecs. (a)(1)(A)(ii), (C), (2)(C) and (h), is the eighth paragraph under the heading “Bureau of Animal Industry” of act Mar. 4, 1913, ch. 145, 37 Stat. 832, as amended, which is classified generally to chapter 5 (§151 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 151 of this title and Tables.

AMENDMENTS

1997—Subsec. (i). Pub. L. 105-115 added subsec. (i).

1996—Pub. L. 104-134 reenacted section catchline without change and amended text generally. Prior to amendment, text related to exports of certain unapproved products, including provisions relating to drugs intended for human or animal use which required approval or licensing, conditions for export, active pursuit of drug approval or licensing, application for export, contents, approval or disapproval, list of eligible countries for export, and criteria for list change, report to Secretary by holder of approved application, events requiring report, and annual report to Secretary on pursuit of approval of drug, export of drug under approved application prohibited under certain conditions, determination by Secretary of noncompliance, failure of active pursuit of drug approval, imminent hazard of drug to public health, or exportation of drug to non-eligible country, notices, hearings, and prohibition on exportation of drug under certain circumstances, drugs used in prevention or treatment of tropical disease, and reference to Secretary and holder of application.

Subsec. (f)(5). Pub. L. 104-180 substituted “if the labeling of the drug or device is not” for “if the drug or device is not labeled”.

<sup>1</sup> So in original. Probably should be subsection “(b)(1)(A)”.

**§ 383. Office of International Relations****(a) Establishment**

There is established in the Department of Health and Human Services an Office of International Relations.

**(b) Agreements with foreign countries**

In carrying out the functions of the office under subsection (a) of this section, the Secretary may enter into agreements with foreign countries to facilitate commerce in devices between the United States and such countries consistent with the requirements of this chapter. In such agreements, the Secretary shall encourage the mutual recognition of—

- (1) good manufacturing practice regulations promulgated under section 360j(f) of this title, and
- (2) other regulations and testing protocols as the Secretary determines to be appropriate.

**(c) Harmonizing regulatory requirements**

(1) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonize regulatory requirements if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of this chapter.

(2) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States.

(3) The Secretary shall regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements.

(4) The Secretary shall, not later than 180 days after November 21, 1997, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections.

(5) Paragraphs (1) through (4) shall not apply with respect to products defined in section 321(ff) of this title.

(June 25, 1938, ch. 675, §803, as added Pub. L. 101-629, §15(a), Nov. 28, 1990, 104 Stat. 4525; amended Pub. L. 105-115, title IV, §410(b), Nov. 21, 1997, 111 Stat. 2373.)

## AMENDMENTS

1997—Subsec. (c). Pub. L. 105-115 added subsec. (c).

## EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105-115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as a note under section 321 of this title.

## REPORT ON ACTIVITIES OF OFFICE OF INTERNATIONAL RELATIONS

Section 15(b) of Pub. L. 101-629 directed Secretary of Health and Human Services, not later than 2 years

after Nov. 28, 1990, to prepare and submit to the appropriate committees of Congress a report on the activities of the Office of International Relations under 21 U.S.C. 383.

**§ 384. Importation of prescription drugs****(a) Definitions**

In this section:

**(1) Importer**

The term “importer” means a pharmacist or wholesaler.

**(2) Pharmacist**

The term “pharmacist” means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

**(3) Prescription drug**

The term “prescription drug” means a drug subject to section 353(b) of this title, other than—

- (A) a controlled substance (as defined in section 802 of this title);
- (B) a biological product (as defined in section 262 of title 42);
- (C) an infused drug (including a peritoneal dialysis solution);
- (D) an intravenously injected drug;
- (E) a drug that is inhaled during surgery;

or

- (F) a drug which is a parenteral drug, the importation of which pursuant to subsection (b) of this section is determined by the Secretary to pose a threat to the public health, in which case section 381(d)(1) of this title shall continue to apply.

**(4) Qualifying laboratory**

The term “qualifying laboratory” means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

**(5) Wholesaler****(A) In general**

The term “wholesaler” means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 353(e)(2)(A) of this title.

**(B) Exclusion**

The term “wholesaler” does not include a person authorized to import drugs under section 381(d)(1) of this title.

**(b) Regulations**

The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

**(c) Limitation**

The regulations under subsection (b) of this section shall—

- (1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 355 of this title (including with respect to being safe and effective for the intended use of