

has performed an effective correction or action plan for the recall; and

(4) document the basis for each termination by the Food and Drug Administration of a device recall.

**(b) Assessment content**

The program established under subsection (a)(1) shall, at a minimum, identify—

(1) trends in the number and types of device recalls;

(2) devices that are most frequently the subject of a recall; and

(3) underlying causes of device recalls.

**(c) Termination of recalls**

The Secretary shall document the basis for the termination by the Food and Drug Administration of a device recall.

**(d) Definition**

In this section, the term “recall” means—

(1) the removal from the market of a device pursuant to an order of the Secretary under subsection (b) or (e) of section 360h of this title; or

(2) the correction or removal from the market of a device at the initiative of the manufacturer or importer of the device that is required to be reported to the Secretary under section 360i(g) of this title.

(June 25, 1938, ch. 675, §518A, as added Pub. L. 112-144, title VI, §605, July 9, 2012, 126 Stat. 1053.)

**§ 360i. Records and reports on devices**

**(a) General rule**

Every person who is a manufacturer or importer of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. Regulations prescribed under the preceding sentence—

(1) shall require a device manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices—

(A) may have caused or contributed to a death or serious injury, or

(B) has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, which report under this subparagraph—

(i) shall be submitted in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations), unless the Secretary grants an exemption or variance from, or an alternative to, a requirement under such regulations pursuant to section 803.19 of such part, if the device involved is—

(I) a class III device;

(II) a class II device that is permanently implantable, is life supporting, or is life sustaining; or

(III) a type of device which the Secretary has, by notice published in the Federal Register or letter to the person who is the manufacturer or importer of the device, indicated should be subject to such part 803 in order to protect the public health;

(ii) shall, if the device is not subject to clause (i), be submitted in accordance with criteria established by the Secretary for reports made pursuant to this clause, which criteria shall require the reports to be in summary form and made on a quarterly basis; or

(iii) shall, if the device is imported into the United States and for which part 803 of title 21, Code of Federal Regulations (or successor regulations) requires an importer to submit a report to the manufacturer, be submitted by the importer to the manufacturer in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations)<sup>1</sup>

(2) shall define the term “serious injury” to mean an injury that—

(A) is life threatening,

(B) results in permanent impairment of a body function or permanent damage to a body structure, or

(C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure;

(3) shall require reporting of other significant adverse device experiences as determined by the Secretary to be necessary to be reported;

(4) shall not impose requirements unduly burdensome to a device manufacturer or importer taking into account his cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter;

(5) which prescribe the procedure for making requests for reports or information shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

(6) which require submission of a report or information to the Secretary shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information;

(7) may not require that the identity of any patient be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under this chapter; and

(8) may not require a manufacturer or importer of a class I device to—

<sup>1</sup> So in original. Probably should be followed by a semicolon.

(A) maintain for such a device records respecting information not in the possession of the manufacturer or importer, or

(B) to submit for such a device to the Secretary any report or information—

- (i) not in the possession of the manufacturer or importer, or
- (ii) on a periodic basis,

unless such report or information is necessary to determine if the device should be reclassified or if the device is adulterated or misbranded, and<sup>2</sup>

In prescribing such regulations, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (7) of this subsection continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient. The Secretary shall by regulation require distributors to keep records and make such records available to the Secretary upon request. Paragraphs (4) and (8) apply to distributors to the same extent and in the same manner as such paragraphs apply to manufacturers and importers.

**(b) User reports**

(1)(A) Whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device. In the case of deaths, the Secretary may by regulation prescribe a shorter period for the reporting of such information.

(B) Whenever a device user facility receives or otherwise becomes aware of—

- (i) information that reasonably suggests that a device has or may have caused or contributed to the serious illness of, or serious injury to, a patient of the facility, or
- (ii) other significant adverse device experiences as determined by the Secretary by regulation to be necessary to be reported,

the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the manufacturer of the device or to the Secretary if the identity of the manufacturer is not known.

(C) Each device user facility shall submit to the Secretary on an annual basis a summary of the reports made under subparagraphs (A) and (B). Such summary shall be submitted on January 1 of each year. The summary shall be in such form and contain such information from such reports as the Secretary may require and shall include—

- (i) sufficient information to identify the facility which made the reports for which the summary is submitted,
- (ii) in the case of any product which was the subject of a report, the product name, serial number, and model number,

(iii) the name and the address of the manufacturer of such device, and

(iv) a brief description of the event reported to the manufacturer.

(D) For purposes of subparagraphs (A), (B), and (C), a device user facility shall be treated as having received or otherwise become aware of information with respect to a device of that facility when medical personnel who are employed by or otherwise formally affiliated with the facility receive or otherwise become aware of information with respect to that device in the course of their duties.

(2) The Secretary may not disclose the identity of a device user facility which makes a report under paragraph (1) except in connection with—

(A) an action brought to enforce section 331(q) of this title, or

(B) a communication to a manufacturer of a device which is the subject of a report under paragraph (1).

This paragraph does not prohibit the Secretary from disclosing the identity of a device user facility making a report under paragraph (1) or any information in such a report to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.

(3) No report made under paragraph (1) by—

- (A) a device user facility,
- (B) an individual who is employed by or otherwise formally affiliated with such a facility, or
- (C) a physician who is not required to make such a report,

shall be admissible into evidence or otherwise used in any civil action involving private parties unless the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report.

(4) A report made under paragraph (1) does not affect any obligation of a manufacturer who receives the report to file a report as required under subsection (a) of this section.

(5) With respect to device user facilities:

(A) The Secretary shall by regulation plan and implement a program under which the Secretary limits user reporting under paragraphs (1) through (4) to a subset of user facilities that constitutes a representative profile of user reports for device deaths and serious illnesses or serious injuries.

(B) During the period of planning the program under subparagraph (A), paragraphs (1) through (4) continue to apply.

(C) During the period in which the Secretary is providing for a transition to the full implementation of the program, paragraphs (1) through (4) apply except to the extent that the Secretary determines otherwise.

(D) On and after the date on which the program is fully implemented, paragraphs (1) through (4) do not apply to a user facility unless the facility is included in the subset referred to in subparagraph (A).

(E) Not later than 2 years after November 21, 1997, the Secretary shall submit to the Committee on Commerce of the House of Rep-

<sup>2</sup>So in original. The word "and" probably should not appear.

representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the plan developed by the Secretary under subparagraph (A) and the progress that has been made toward the implementation of the plan.

(6) For purposes of this subsection:

(A) The term “device user facility” means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician’s office. The Secretary may by regulation include an outpatient diagnostic facility which is not a physician’s office in such term.

(B) The terms “serious illness” and “serious injury” mean illness or injury, respectively, that—

- (i) is life threatening,
- (ii) results in permanent impairment of a body function or permanent damage to a body structure, or
- (iii) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

**(c) Persons exempt**

Subsection (a) of this section shall not apply to—

(1) any practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of his professional practice;

(2) any person who manufactures or imports devices intended for use in humans solely for such person’s use in research or teaching and not for sale (including any person who uses a device under an exemption granted under section 360j(g) of this title); and

(3) any other class of persons as the Secretary may by regulation exempt from subsection (a) of this section upon a finding that compliance with the requirements of such subsection by such class with respect to a device is not necessary to (A) assure that a device is not adulterated or misbranded or (B) otherwise to assure its safety and effectiveness.

**(d) Repealed. Pub. L. 105-115, title II, § 213(a)(2), Nov. 21, 1997, 111 Stat. 2347**

**(e) Device tracking**

(1) The Secretary may by order require a manufacturer to adopt a method of tracking a class II or class III device—

(A) the failure of which would be reasonably likely to have serious adverse health consequences; or

(B) which is—

- (i) intended to be implanted in the human body for more than one year, or
- (ii) a life sustaining or life supporting device used outside a device user facility.

(2) Any patient receiving a device subject to tracking under paragraph (1) may refuse to release, or refuse permission to release, the patient’s name, address, social security number, or other identifying information for the purpose of tracking.

**(f) Unique device identification system**

Not later than December 31, 2012, the Secretary shall issue proposed regulations estab-

lishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number. The Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized, taking into account patient access to medical devices and therapies.

**(g) Reports of removals and corrections**

(1) Except as provided in paragraph (2), the Secretary shall by regulation require a manufacturer or importer of a device to report promptly to the Secretary any correction or removal of a device undertaken by such manufacturer or importer if the removal or correction was undertaken—

(A) to reduce a risk to health posed by the device, or

(B) to remedy a violation of this chapter caused by the device which may present a risk to health.

A manufacturer or importer of a device who undertakes a correction or removal of a device which is not required to be reported under this paragraph shall keep a record of such correction or removal.

(2) No report of the corrective action or removal of a device may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a) of this section.

(3) For purposes of paragraphs (1) and (2), the terms “correction” and “removal” do not include routine servicing.

**(h) Inclusion of devices in the postmarket risk identification and analysis system**

**(1) In general**

**(A) Application to devices**

The Secretary shall amend the procedures established and maintained under clauses (i), (ii), (iii), and (v) of section 355(k)(3)(C) of this title in order to expand the postmarket risk identification and analysis system established under such section to include and apply to devices.

**(B) Exception**

Subclause (II) of clause (i) of section 355(k)(3)(C) of this title shall not apply to devices.

**(C) Clarification**

With respect to devices, the private sector health-related electronic data provided under section 355(k)(3)(C)(i)(III)(bb) of this title may include medical device utilization data, health insurance claims data, and procedure and device registries.

**(2) Data**

In expanding the system as described in paragraph (1)(A), the Secretary shall use rel-

evant data with respect to devices cleared under section 360(k) of this title or approved under section 360e of this title, including claims data, patient survey data, and any other data deemed appropriate by the Secretary.

### (3) Stakeholder input

To help ensure effective implementation of the system as described in paragraph (1) with respect to devices, the Secretary shall engage outside stakeholders in development of the system, and gather information from outside stakeholders regarding the content of an effective sentinel program, through a public hearing, advisory committee meeting, maintenance of a public docket, or other similar public measures.

### (4) Voluntary surveys

Chapter 35 of title 44 shall not apply to the collection of voluntary information from health care providers, such as voluntary surveys or questionnaires, initiated by the Secretary for purposes of postmarket risk identification, mitigation, and analysis for devices.

(June 25, 1938, ch. 675, §519, as added Pub. L. 94-295, §2, May 28, 1976, 90 Stat. 564; amended Pub. L. 101-629, §§2(a), 3(a)(1), (b)(1), 7, Nov. 28, 1990, 104 Stat. 4511, 4513, 4514, 4520; Pub. L. 102-300, §5(a), June 16, 1992, 106 Stat. 239; Pub. L. 103-80, §3(u), Aug. 13, 1993, 107 Stat. 778; Pub. L. 105-115, title II, §§211, 213(a), (c), Nov. 21, 1997, 111 Stat. 2345-2347; Pub. L. 110-85, title II, §§226(a), 227, Sept. 27, 2007, 121 Stat. 854; Pub. L. 112-144, title VI, §§614, 615, July 9, 2012, 126 Stat. 1061.)

#### AMENDMENTS

2012—Subsec. (f). Pub. L. 112-144, §614, substituted “Not later than December 31, 2012, the Secretary shall issue proposed” for “The Secretary shall promulgate” and inserted at end “The Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized, taking into account patient access to medical devices and therapies.”

Subsec. (h). Pub. L. 112-144, §615, added subsec. (h).

2007—Subsec. (a)(1)(B). Pub. L. 110-85, §227, substituted “were to recur, which report under this subparagraph—” for “were to recur;” and added cls. (i) to (iii).

Subsecs. (f), (g). Pub. L. 110-85, §226(a), added subsec. (f) and redesignated former subsec. (f) as (g).

1997—Subsec. (a). Pub. L. 105-115, §213(a)(1)(A), (F), in introductory provisions, substituted “manufacturer or importer” for “manufacturer, importer, or distributor” and, in closing provisions, inserted at end “The Secretary shall by regulation require distributors to keep records and make such records available to the Secretary upon request. Paragraphs (4) and (8) apply to distributors to the same extent and in the same manner as such paragraphs apply to manufacturers and importers.”

Subsec. (a)(4). Pub. L. 105-115, §213(a)(1)(B), substituted “manufacturer or importer” for “manufacturer, importer, or distributor”.

Subsec. (a)(7). Pub. L. 105-115, §213(a)(1)(C), inserted “and” after semicolon at end.

Subsec. (a)(8). Pub. L. 105-115, §213(a)(1)(D), substituted “manufacturer or importer” for “manufacturer, importer, or distributor” wherever appearing and substituted period for semicolon after “misbranded”.

Subsec. (a)(9). Pub. L. 105-115, §213(a)(1)(E), struck out par. (9) which read as follows: “shall require distributors who submit such reports to submit copies of the reports to the manufacturer of the device for which the report was made.”

Subsec. (b)(1)(C). Pub. L. 105-115, §213(c)(1)(A), in introductory provisions, substituted “on an annual basis” for “on a semi-annual basis” and struck out “and July 1” after “January 1” and struck out closing provisions which read as follows: “The Secretary may by regulation alter the frequency and timing of reports required by this subparagraph.”

Subsec. (b)(2)(A). Pub. L. 105-115, §213(c)(1)(B)(i), inserted “or” after comma at end.

Subsec. (b)(2)(B). Pub. L. 105-115, §213(c)(1)(B)(ii), substituted period for “, or” at end.

Subsec. (b)(2)(C). Pub. L. 105-115, §213(c)(1)(B)(iii), struck out subpar. (C) which read as follows: “a disclosure required under subsection (a) of this section.”

Subsec. (b)(5), (6). Pub. L. 105-115, §213(c)(2), added par. (5) and redesignated former par. (5) as (6).

Subsec. (d). Pub. L. 105-115, §213(a)(2), struck out heading and text of subsec. (d). Text read as follows: “Each manufacturer, importer, and distributor required to make reports under subsection (a) of this section shall submit to the Secretary annually a statement certifying that—

“(1) the manufacturer, importer, or distributor did file a certain number of such reports, or

“(2) the manufacturer, importer, or distributor did not file any report under subsection (a) of this section.”

Subsec. (e). Pub. L. 105-115, §211, amended heading and text of subsec. (e) generally. Prior to amendment, text read as follows: “Every person who registers under section 360 of this title and is engaged in the manufacture of—

“(1) a device the failure of which would be reasonably likely to have serious adverse health consequences and which is (A) a permanently implantable device, or (B) a life sustaining or life supporting device used outside a device user facility, or

“(2) any other device which the Secretary may designate, shall adopt a method of device tracking.”

Subsec. (f)(1). Pub. L. 105-115, §213(a)(3), substituted “or importer” for “, importer, or distributor” wherever appearing.

1993—Subsec. (a). Pub. L. 103-80 substituted “paragraph (7)” for “paragraph (4)” in last sentence.

1992—Subsec. (a). Pub. L. 102-300, §5(a)(1), added pars. (1) to (3) and redesignated former pars. (1) to (6) as (4) to (9), respectively.

Subsec. (b)(1)(A). Pub. L. 102-300, §5(a)(2)(A), substituted “a device has or may have” for “there is a probability that a device has”.

Subsec. (b)(1)(B). Pub. L. 102-300, §5(a)(2)(A), (B), substituted “a device has or may have” for “there is a probability that a device has”, designated existing provisions as cl. (i), and added cl. (ii).

Subsec. (b)(5)(B)(iii). Pub. L. 102-300, §5(a)(2)(C), struck out “immediate” before “medical”.

1990—Subsec. (a)(6). Pub. L. 101-629, §3(a)(1), added par. (6).

Subsecs. (b), (c). Pub. L. 101-629, §2(a), added subsec. (b) and redesignated former subsec. (b) as (c).

Subsecs. (d), (e). Pub. L. 101-629, §3(b)(1), added subsecs. (d) and (e).

Subsec. (f). Pub. L. 101-629, §7, added subsec. (f).

#### CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

#### EFFECTIVE DATE OF 1997 AMENDMENT

Pub. L. 105-115, title II, §211, Nov. 21, 1997, 111 Stat. 2345, provided in part that the amendment made by that section is effective 90 days after Nov. 21, 1997.

Amendment by section 213(a), (c) of 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.

#### EFFECTIVE DATE OF 1992 AMENDMENT

Pub. L. 102-300, §2(b), June 16, 1992, 106 Stat. 238, provided that: "The amendments made by subsection (a) [amending sections 3(b)(3) and 3(c) of Pub. L. 101-629, set out as notes below] shall take effect as of May 27, 1992 and any rule to implement section 519(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(e)] proposed under section 3(c)(2) of the Safe Medical Devices Act of 1990 [Pub. L. 101-629, set out as a note below] shall revert to its proposed status as of such date."

Pub. L. 102-300, §5(b), June 16, 1992, 106 Stat. 240, provided that: "The amendments made by subsection (a) [amending this section] shall take effect—

- "(1) 1 year after the date of the enactment of this Act [June 16, 1992]; or
- "(2) on the effective date of regulations of the Secretary to implement such amendments, whichever occurs first."

#### EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101-629, §2(c), Nov. 28, 1990, 104 Stat. 4513, provided that: "Section 519(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)], as added by the amendment made by subsection (a), shall take effect—

- "(1) upon the effective date of regulations promulgated under subsection (b) [set out below], or
- "(2) upon the expiration of 12 months from the date of the enactment of this Act [Nov. 28, 1990], whichever occurs first."

Pub. L. 101-629, §3(a)(2), Nov. 28, 1990, 104 Stat. 4514, provided that: "Section 519(a)(6) [21 U.S.C. 360i(a)(6)], as added by the amendment made by paragraph (1), shall take effect upon the effective date of final regulations under subsection (c) [set out below]."

Pub. L. 101-629, §3(b)(3), Nov. 28, 1990, 104 Stat. 4514, as amended by Pub. L. 102-300, §2(a)(1), June 16, 1992, 106 Stat. 238, provided that: "Section 519(e) [21 U.S.C. 360i(e)], as added by the amendment made by paragraph (1), shall take effect upon the expiration of 9 months after the issuance of final regulations under subsection (c) [set out below]."

[For effective date of amendment by Pub. L. 102-300, see section 2(b) of Pub. L. 102-300, set out above as an Effective Date of 1992 Amendment note.]

#### REGULATIONS

Pub. L. 101-629, §2(b), Nov. 28, 1990, 104 Stat. 4512, provided that: "The Secretary of Health and Human Services shall promulgate regulations to implement section 519(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)], as added by the amendment made by subsection (a) (including a definition of the summary required by paragraph (1)(C) of such section) not later than 12 months after the date of enactment of this Act [Nov. 28, 1990]. In promulgating the regulations, the Secretary shall minimize the administrative burdens on device user facilities consistent with the need to assure adequate information."

Pub. L. 101-629, §3(c), Nov. 28, 1990, 104 Stat. 4514, as amended by Pub. L. 102-300, §2(a)(2), (3), June 16, 1992, 106 Stat. 238, provided that:

"(1)(A) Not later than 9 months after the date of the enactment of this Act [Nov. 28, 1990], the Secretary of Health and Human Services shall issue proposed regulations—

- "(i) to require distributors of devices to establish and maintain records and to make reports (including reports required by part 803 of title 21 of the Code of Federal Regulations) under section 519(a)(6) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(a)(6)], and
- "(ii) to implement section 519(e) of such Act.

The Secretary may exempt from regulations described in clause (i) classes of distributors of class I and class

II devices from whom reports are not necessary for the protection of the public health.

"(B) Regulations under subparagraph (A) shall—

"(i) require appropriate methods for maintenance of records to ensure that patients who receive devices can be provided the notification required by such Act [this chapter],

"(ii) require that manufacturers adopt effective methods of tracking devices,

"(iii) take into account the position of distributors in the device distribution process, and

"(iv) include such other requirements as the Secretary deems necessary for the adoption of an effective user tracking program under section 519(e) of such Act.

"(2) Not later than 18 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement sections [sic] 519(a)(6) of the Federal Food, Drug, and Cosmetic Act. If the Secretary does not promulgate such final regulations upon the expiration of such 18 months, the Congress finds that there is good cause for the proposed regulations to be considered as the final regulations without response to comment because the implementation of sections [sic] 519(a)(6) of such Act is essential to protect the health of patients who use such devices. Consequently, in such event, the proposed regulations issued under paragraph (1) shall become final regulations as of the expiration of such 18 months. There shall be promptly published in the Federal Register notice of the new status of the proposed regulations.

"(3) Not later than November 28, 1992, the Secretary shall issue final regulations to implement section 519(e) of the Federal Food, Drug, and Cosmetic Act. If the Secretary does not promulgate such final regulations by November 28, 1992, the Congress finds that there is good cause for the proposed regulations to be considered as the final regulations without response to comment because the implementation of section 519(e) of such Act is essential to protect the health of patients who use devices. In such event, the proposed regulations issued under paragraph (1) shall become the issued final regulations on November 29, 1992. There shall be promptly published in the Federal Register notice of the new status of the proposed regulations."

[For effective date of amendment by Pub. L. 102-300, see section 2(b) of Pub. L. 102-300, set out above as an Effective Date of 1992 Amendment note.]

#### INFORMATION CONCERNING REPORTING REQUIREMENTS FOR DEVICE USER FACILITIES

Pub. L. 101-629, §2(d), Nov. 28, 1990, 104 Stat. 4513, directed Secretary of Health and Human Services, during the 18-month period beginning on Nov. 28, 1990, to inform device user facilities (as defined in 21 U.S.C. 360i(b)(5)(A)) and manufacturers and distributors of devices respecting the requirements of 21 U.S.C. 360i(b), and, to the extent practicable, provide persons subject to such requirements assistance in the form of publications regarding such requirements.

#### STUDY OF REPORTING REQUIREMENTS; COMPLIANCE BY DEVICE USER FACILITIES; ACTIONS BY MANUFACTURERS; COST EFFECTIVENESS; RECOMMENDATIONS

Pub. L. 101-629, §2(e), Nov. 28, 1990, 104 Stat. 4513, directed Comptroller General of the United States, not more than 36 months after Nov. 28, 1990, to conduct a study of compliance by device user facilities with the requirements of 21 U.S.C. 360i(b), actions taken by manufacturers of devices in response to reports made to them, cost effectiveness of such requirements and their implementation, and any recommendations for improvements to such requirements, with Comptroller General to complete the study and submit a report on the study not later than 45 months from Nov. 28, 1990, to appropriate committees of Congress.

#### REPORT TO CONGRESS ON REPORTING REQUIREMENTS FOR DEVICE USER FACILITIES

Pub. L. 101-629, §2(f), Nov. 28, 1990, 104 Stat. 4513, directed Secretary of Health and Human Services, not

later than 36 months after Nov. 28, 1990, to prepare and submit to appropriate committees of Congress a report containing an evaluation of the requirements of 21 U.S.C. 360i(b), consisting of an evaluation of the safety benefits of the requirements, the burdens placed on the Food and Drug Administration and on device user facilities by the requirements, and the cost-effectiveness of the requirements and recommendations for legislative reform.

**§ 360j. General provisions respecting control of devices intended for human use**

**(a) General rule**

Any requirement authorized by or under section 351, 352, 360, or 360i of this title applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under section 360c, 360d, or 360e of this title or under subsection (g) of this section, and any requirement established by or under section 351, 352, 360, or 360i of this title which is inconsistent with a requirement imposed on such device under section 360d or 360e of this title or under subsection (g) of this section shall not apply to such device.

**(b) Custom devices**

**(1) In general**

The requirements of sections 360d and 360e of this title shall not apply to a device that—

(A) is created or modified in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing);

(B) in order to comply with an order described in subparagraph (A), necessarily deviates from an otherwise applicable performance standard under section 360d of this title or requirement under section 360e of this title;

(C) is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution;

(D) is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat;

(E)(i) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated); or

(ii) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated);

(F) is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals described in clause (i) or (ii) of subparagraph (E); and

(G) may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices.

**(2) Limitations**

Paragraph (1) shall apply to a device only if—

(A) such device is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations on such device would be impractical;

(B) production of such device under paragraph (1) is limited to no more than 5 units per year of a particular device type, provided that such replication otherwise complies with this section; and

(C) the manufacturer of such device notifies the Secretary on an annual basis, in a manner prescribed by the Secretary, of the manufacture of such device.

**(3) Guidance**

Not later than 2 years after July 9, 2012, the Secretary shall issue final guidance on replication of multiple devices described in paragraph (2)(B).

**(c) Trade secrets**

Any information reported to or otherwise obtained by the Secretary or his representative under section 360c, 360d, 360e, 360f, 360h, 360i, or 374 of this title or under subsection (f) or (g) of this section which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5 by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed and may not be used by the Secretary as the basis for the reclassification of a device from class III to class II or class I or as the basis for the establishment or amendment of a performance standard under section 360d of this title for a device reclassified from class III to class II, except (1) in accordance with subsection (h) of this section, and (2) that such information may be disclosed to other officers or employees concerned with carrying out this chapter or when relevant in any proceeding under this chapter (other than section 360c or 360d of this title).

**(d) Notices and findings**

Each notice of proposed rulemaking under section 360c, 360d, 360e, 360f, 360h, or 360i of this title, or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings is based, and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefor) orally or in writing, which period shall be at least sixty days but may not exceed ninety days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefor.

**(e) Restricted devices**

(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or