(d) Effect on other liability

Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

(e) Recall authority

(1) If the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device)—

(A) to immediately cease distribution of such device, and

(B) to immediately notify health professionals and device user facilities of the order and to instruct such professionals and facilities to cease use of such device.

The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such device. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

(2)(A) If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the device with respect to which the order was issued, the Secretary shall, except as provided in subparagraphs (B) and (C), amend the order to require a recall. The Secretary shall specify a timetable in which the device recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

(B) An amended order under subparagraph (A)—

(i) shall—

(I) not include recall of a device from individuals, and

(II) not include recall of a device from device user facilities if the Secretary determines that the risk of recalling such device from the facilities presents a greater health risk than the health risk of not recalling the device from use, and

(ii) shall provide for notice to individuals subject to the risks associated with the use of such device.

In providing the notice required by clause (ii), the Secretary may use the assistance of health professionals who prescribed or used such a device for individuals. If a significant number of such individuals cannot be identified, the Secretary shall notify such individuals pursuant to section 375(b) of this title.

(3) The remedy provided by this subsection shall be in addition to remedies provided by subsections (a), (b), and (c).

(June 25, 1938, ch. 675, §518, as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 562; amended Pub. L. 101–629, §8, Nov. 28, 1990, 104 Stat. 4520; Pub. L. 102–300, §4, June 16, 1992, 106 Stat. 239.)

AMENDMENTS

1992—Subsec. (b)(1)(A)(ii). Pub. L. 102–300 substituted ''or'' for ''and'' after ''properly designed'' and ''time of its design''.

1990—Subsec. (e). Pub. L. 101–629 added subsec. (e).

§ 360h–1. Program to improve the device recall system

(a) In general

The Secretary shall—

(1) establish a program to routinely and systematically assess information relating to device recalls and use such information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices;

(2) clarify procedures for conducting device recall audit checks to improve the ability of investigators to perform those checks in a consistent manner;

(3) develop detailed criteria for assessing whether a person performing a device recall 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) 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; amended Pub. L. 114–255, div. A, title III, §3101(a)(2)(K), Dec. 13, 2016, 130 Stat. 1154.)

AMENDMENTS

2016—Subsecs. (c), (d). Pub. L. 114–255 redesignated subsec. (d) as (c) and struck out former subsec. (c). Prior to amendment, text read as follows: ''The Secretary shall document the basis for the termination by the Food and Drug Administration of a device recall.''

§ 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)[1]

(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—

(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[2]

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

[1] So in original. Probably should be followed by a semicolon.

[2] So in original. The word ''and'' probably should not appear.

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).

(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 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) 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 sub-

section (a) 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 establishing 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, or 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).

(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 relevant 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.

(i) Postmarket pilot

(1) In general

In order to provide timely and reliable information on the safety and effectiveness of devices approved under section 360e of this title, cleared under section 360(k) of this title, or classified under section 360c(f)(2) of this title, including responses to adverse events and malfunctions, and to advance the objectives of part 803 of title 21, Code of Federal Regulations (or successor regulations), and advance the objectives of, and evaluate innovative new methods of compliance with, this section and

section 360*l* of this title, the Secretary shall, within one year of August 18, 2017, initiate one or more pilot projects for voluntary participation by a manufacturer or manufacturers of a device or device type, or continue existing projects, in accordance with paragraph (3), that—

(A) are designed to efficiently generate reliable and timely safety and active surveillance data for use by the Secretary or manufacturers of the devices that are involved in the pilot project;

(B) inform the development of methods, systems, data criteria, and programs that could be used to support safety and active surveillance activities for devices included or not included in such project;

(C) may be designed and conducted in coordination with a comprehensive system for evaluating medical device technology that operates under a governing board with appropriate representation of stakeholders, including patient groups and device manufacturers;

(D) use electronic health data including claims data, patient survey data, or any other data, as the Secretary determines appropriate; and

(E) prioritize devices and device types that meet one or more of the following criteria:

(i) Devices and device types for which the collection and analysis of real world evidence regarding a device's safety and effectiveness is likely to advance public health.

(ii) Devices and device types that are widely used.

(iii) Devices and device types, the failure of which has significant health consequences.

(iv) Devices and device types for which the Secretary—

(I) has received public recommendations in accordance with paragraph (2)(B); and

(II) has determined to meet one or more of the criteria under clause (i), (ii), or (iii) and is appropriate for such a pilot project.

(2) Participation

The Secretary shall establish the conditions and processes—

(A) under which a manufacturer of a device may voluntarily participate in a pilot project described in paragraph (1); and

(B) for facilitating public recommendations for devices to be prioritized under such a pilot project, including requirements for the data necessary to support such a recommendation.

(3) Continuation of ongoing projects

The Secretary may continue or expand projects, with respect to providing timely and reliable information on the safety and effectiveness of devices approved under section 360e of this title, cleared under section 360(k) of this title, or classified under section 360c(f)(2) of this title, that are being carried out as of August 18, 2017. The Secretary shall, beginning on such date, take such steps as may be necessary—

(A) to ensure such projects meet the requirements of subparagraphs (A) through (E) of paragraph (1); and

(B) to increase the voluntary participation in such projects of manufacturers of devices and facilitate public recommendations for any devices prioritized under such a project.

(4) Implementation

(A) Contracting authority

The Secretary may carry out a pilot project meeting the criteria specified in subparagraphs (A) through (E) of paragraph (1) or a project continued or expanded under paragraph (3) by entering into contracts, cooperative agreements, grants, or other appropriate agreements with public or private entities that have a significant presence in the United States and meet the following conditions:

(i) If such an entity is a component of another organization, the entity and the organization have established an agreement under which appropriate security measures are implemented to maintain the confidentiality and privacy of the data described in paragraph (1)(D) and such agreement ensures that the entity will not make an unauthorized disclosure of such data to the other components of the organization in breach of requirements with respect to confidentiality and privacy of such data established under such security measures.

(ii) In the case of the termination or nonrenewal of such a contract, cooperative agreement, grant, or other appropriate agreement, the entity or entities involved shall comply with each of the following:

(I) The entity or entities shall continue to comply with the requirements with respect to confidentiality and privacy referred to in clause (i) with respect to all data disclosed to the entity under such an agreement.

(II) The entity or entities shall return any data disclosed to such entity pursuant to this subsection and to which it would not otherwise have access or, if returning such data is not practicable, destroy the data.

(iii) The entity or entities shall have one or more qualifications with respect to—

(I) research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this subsection, including the capability and expertise to provide the Secretary access to de-identified data consistent with the requirements of this subsection;

(II) an information technology infrastructure to support electronic data and operational standards to provide security for such data, as appropriate;

(III) experience with, and expertise on, the development of research on, and surveillance of, device safety and effectiveness using electronic health data; or

(IV) such other expertise which the Secretary determines necessary to carry out such a project.

(B) Review of contract in the event of a merger or acquisition

The Secretary shall review any contract, cooperative agreement, grant, or other appropriate agreement entered into under this paragraph with an entity meeting the conditions specified in subparagraph (A) in the event of a merger or acquisition of the entity in order to ensure that the requirements specified in this subsection will continue to be met.

(5) Compliance with requirements for records or reports on devices

The participation of a manufacturer in pilot projects under this subsection or a project continued or expanded under paragraph (3) shall not affect the eligibility of such manufacturer to participate in any quarterly reporting program with respect to devices carried out under this section 360i[3] or section 360*l* of this title. The Secretary may determine that, for a specified time period to be determined by the Secretary, a manufacturer's participation in a pilot project under this subsection or a project continued or expanded under paragraph (3) may meet the applicable requirements of this section or section 360*l* of this title, if—

(A) the project has demonstrated success in capturing relevant adverse event information; and

(B) the Secretary has established procedures for making adverse event and safety information collected from such project public, to the extent possible.

(6) Privacy requirements

With respect to the disclosure of any health information collected through a project conducted under this subsection—

(A) individually identifiable health information so collected shall not be disclosed when presenting any information from such project; and

(B) any such disclosure shall be made in compliance with regulations issued pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) and sections 552 and 552a of title 5.

(7) Limitations

No pilot project under this subsection, or in coordination with the comprehensive system described in paragraph (1)(C), may allow for an entity participating in such project, other than the Secretary, to make determinations of safety or effectiveness, or substantial equivalence, for purposes of this chapter.

(8) Other projects required to comply

Paragraphs (1)(B), (4)(A)(i), (4)(A)(ii), (5), (6), and (7) shall apply with respect to any pilot project undertaken in coordination with the comprehensive system described in paragraph (1)(C) that relates to the use of real world evidence for devices in the same manner and to the same extent as such paragraphs apply with respect to pilot projects conducted under this subsection.

(9) Report to Congress

Not later than 18 months after August 18, 2017, and annually thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report containing a description of the pilot projects being conducted under this subsection and projects continued or expanded pursuant to paragraph (3), including for each such project—

(A) how the project is being implemented in accordance with paragraph (4), including how such project is being implemented through a contract, cooperative agreement, grant, or other appropriate agreement, if applicable;

(B) the number of manufacturers that have agreed to participate in such project;

(C) the data sources used to conduct such project;

(D) the devices or device categories involved in such project;

(E) the number of patients involved in such project; and

(F) the findings of the project in relation to device safety, including adverse events, malfunctions, and other safety information.

(10) Sunset

The Secretary may not carry out a pilot project initiated by the Secretary under this subsection after October 1, 2022.

(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; Pub. L. 114–255, div. A, title III, § 3101(a)(2)(L), Dec. 13, 2016, 130 Stat. 1154; Pub. L. 115–52, title VII, § 708(a), Aug. 18, 2017, 131 Stat. 1062.)

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (i)(6)(B), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of Title 42, The Public Health and Welfare.

AMENDMENTS

2017—Subsec. (i). Pub. L. 115–52 added subsec. (i).

2016—Subsec. (f). Pub. L. 114–255 substituted ''or life sustaining'' for ''and life sustaining''.

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).

[3] So in original. The section number probably should not appear.

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;