107TH CONGRESS
2D SESSION

S. 3130

To amend the Federal Food, Drug, and Cosmetic Act to add requirements regarding device reprocessing and reuse.

IN THE SENATE OF THE UNITED STATES

OCTOBER 17, 2002

Mr. DURBIN (for himself and Mr. GREGG) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to add requirements regarding device reprocessing and reuse.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Safe Reprocessed Medical Devices Act of 2002''.

SEC. 2. PURPOSE.

The purpose of this Act is to—

(1) increase the safety and medical devices labeled as single-use devices that are reprocessed for additional use;

(2) provide health professionals with more accurate information on the medical devices that they are using; and

(3) provide the Food and Drug Administration with more accurate information on adverse events that may be caused by device failure.

SEC. 3. DEVICE REPROCESSING AND REUSE.

(a) IN GENERAL.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(u)(1) The reprocessing for reuse of a device (including the manufacture or repeated manufacture of a previously used device) that is intended for use on a single patient, unless such reprocessed device—

''(A)(i) is subject to an order under section 515 approving the reprocessed device as safe and effective for the number of intended uses by the reprocessor as set forth in its submission, or

''(ii) is subject to an order determining that the reprocessed device is substantially equivalent under subsections (f) and (i) of section 513 to a legally marketed device, specifically taking into account the number of uses specified in the label of the reprocessed device;

''(B) is labeled with the number of times the device has been reprocessed;

''(C) prominently and conspicuously bears the name of the reprocessor and the original manufacturer of the device, a generally recognized abbreviation of such names, or a unique and generally recognized symbol identifying such manufacturers, except that the Secretary may waive any requirement under this subparagraph with respect to a device if the Secretary determines that compliance with the requirement is not feasible or would compromise the provision of reasonable assurance of the safety or effectiveness of the device; and

''(D) prominently and conspicuously bears on its label the following statement: 'Reprocessed device for single use reprocessed by _____' (the name of the reprocessor shall be placed in the blank space to identify the person responsible for reprocessing).

''(2)(A) Not later than 60 days after the date of enactment of this subsection, the Secretary shall review each reprocessed device that is exempt on such date from the requirement to submit a report under section 510(k) and shall—

''(i) in the case of an exempt class I reprocessed device, determine whether the device is intended for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury, including a review of the risks presented by reprocessing the device; and

''(ii) in the case of an exempt class II reprocessed device, determine whether such a report is necessary to assure the safety and effectiveness of the devices, including a review of the risks presented by reprocessing the device.

The Secretary shall solicit public comment during such 60 day period concerning whether each device should remain exempt.

''(B) Based on the finding of the review conducted under subparagraph (A) the Secretary shall, not later than 120 days after such date of enactment, publish in the Federal Register a list of the reprocessed devices that are no longer exempt from submission of a report under section 510(k). The reprocessor of any such device will be required to make a submission under section 510(k) not later than 120 days after the publication by the Secretary of such list in the Federal Register.

''(C) During such 120-day period, the Secretary may not determine that the device is misbranded under subsection (o) or adulterated under section 501(f)(1)(B) on the basis that such report has not been submitted to the Secretary. After the submission of the report to the Secretary, the Secretary may not determine that the device is misbranded under subsection (o) or adulterated under section 501(f)(1)(B) until the Secretary determines the classification of the device under section 513 or the Secretary determines that the submission was insufficient to make a classification.

''(D) Subsection (o) applies with respect to a failure to submit a report under subsection (k) that is required pursuant to subparagraph (A), including a failure of the report to include validation data required in such subparagraph.

''(E) The termination under subparagraph (A) of an exemption under subsection (l) or (m) for a reprocessed device does not terminate the exemption under subsection (l) or (m) for the original device.

''(v) The introduction or delivery for introduction into interstate commerce of a device which was previously used in a patient and labeled in a manner that represents directly or indirectly that the device is new or unused.''.

(b) EXEMPTIONS.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended—

(1) in subsection (l), by adding at the end the following: ''The Secretary, in determining whether an exemption under this subsection applies, shall consider whether such an exemption would also apply to such a device when reprocessed with consideration given to whether additional risks, if any, from reprocessing should preclude such an exemption.''; and

(2) in subsection (m), by adding at the end the following:

''(3) The Secretary in determining whether an exemption under this subsection applies shall consider whether such an exemption would also apply to such a device when reprocessed with consideration given to whether additional risks, if any, from reprocessing should preclude such an exemption.''.

(c) PREMARKET NOTIFICATION.—Section 510 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360) is amended by adding at the end the following:

''(o) With respect to reprocessed single-use devices for which reports are required under subsection (k):

''(1)(A) The Secretary shall identify such devices or types of devices for which reports under

such subsection must, in order to ensure that the device is substantially equivalent to a predicate device, include validation data, the types of which shall be specified by the Secretary, regarding cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially equivalent to its predicate device, after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

''(B) Not later than 60 days after the date of enactment of this subsection, the Secretary shall publish in the Federal Register a list of the device types identified under subparagraph (A), and shall revise the list as appropriate.

''(C) Reports under subsection (k) for devices or types of devices within a type included on the list under subparagraph (B) are, upon publication of the list, required to include such validation data.

''(2)(A) In the case of each report under subsection (k) that was submitted to the Secretary prior to the publication of the initial list under paragraph (1), or any revision thereof, and that was for a device or type of device included on such list, the person who submitted the report under subsection (k)

shall submit validation data as described in paragraph (1) to the Secretary not later than 9 months after the publication of the list under paragraph (1)(B).

''(B) During the 9-month period described in subparagraph (A), the Secretary may not take any action under this Act against a device solely on the basis that the validation data for the device has not been submitted to the Secretary.

''(C) After the submission of the validation data to the Secretary, the Secretary may not determine that the device is misbranded under section 502(o) adulterated under section 501(f)(1)(B), or take action against the device under section 301(p) for failure to provide any information required by subsection (k) until—

''(i) the review is terminated by withdrawal of the submission of the report under subsection (k);

''(ii) the Secretary finds the data to be acceptable and issues a letter; or

''(iii) the Secretary determines that the device is not substantially equivalent to a predicate device.

Upon a determination that a device is not substantially equivalent to a predicate device under clause (iii), the device may no longer be legally marketed.

''(3) In the case of a report under subsection (k) for a device identified under paragraph (1) that is of a type for which the Secretary has not previously received a report under such subsection, the Secretary may, in advance of revising the list under paragraph (1) to include such type, require that the report include the validation data specified in paragraph (1).

''(4) Section 502(o) applies with respect to the failure of a report under subsection (k) to include validation data required under paragraph (1).''.

(d) DEFINITIONS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(ll) The term 'single-use device' means a disposable device that is intended for one use or use on a single patient in a single procedure.

''(mm)(1) The term 'reprocessed', with respect to a single-use device, means an original device that was used as intended and then subsequently was subject to additional processing and manufacturing for the purpose of

an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single use device shall result in a device that is reprocessed within the meaning of this definition.

''(2) A single-use device that meets the definition under paragraph (1) shall be considered a reprocessed device without regard to any description of the device used by the manufacturer of the device or other persons, including a description that uses the term 'recycled' rather than the term 'reprocessed'.

''(nn) The term 'original device' means a new, unused single use device.''.

SEC. 4. MEDWATCH.

Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall modify the MEDWATCH voluntary and mandatory forms to facilitate the reporting of information by user facilities or distributors as appropriate relating to reprocessed devices, including the name of the reprocessor and whether the device has been reused.

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