106TH CONGRESS
1ST SESSION

S. 1542

To amend the Federal Food, Drug, and Cosmetic Act to require any person who reprocesses a medical device to comply with certain safety requirements, and for other purposes.

IN THE SENATE OF THE UNITED STATES

AUGUST 5, 1999

Mr. DURBIN 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 require any person who reprocesses a medical device to comply with certain safety requirements, and for other purposes.

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

SECTION 1. SHORT TITLE.

This title may be cited as the ''Reprocessed Single Use Medical Device Patient Safety Amendments of 1999''.

SEC. 2. REPROCESSED MEDICAL DEVICES.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"SEC. 524. REPROCESSED MEDICAL DEVICES.

''(a) FINDINGS.—Congress makes the following findings:

''(1) The Food and Drug Administration has information indicating that some reprocessed medical devices labeled for single use have been associated with serious injury and that reprocessed medical devices labeled for single use have the potential to cause injury.

''(2) Reprocessed medical devices labeled for single use are being used on patients without their knowledge, against original manufacturers' warnings, and without a determination by the Food and Drug Administration that such devices are safe and effective.

''(3) The reprocessing of devices that are labeled for single use is currently occurring without premarket approval by or notification to the Food and Drug Administration, such as is required for certain devices under sections 510 and 515.

''(4) The Food and Drug Administration should have the knowledge and expertise to evaluate the

safety and effectiveness of reprocessed medical devices labeled for single use.

''(5) Enforcement by the Food and Drug Administration of the provisions of this Act that address the safety and effectiveness of devices is the only effective way to protect patients exposed to reprocessed medical devices labeled for single use.

''(6) The United States public deserves to know that all devices regulated by the Food and Drug Administration are safe and effective and that the appropriate level of oversight is being implemented in order to guarantee such safety and effectiveness.

''(b) PURPOSE.—The purpose of this section is to—

''(1) require that the Food and Drug Administration implement all provisions of this Act that are applicable to reprocessed medical devices, including device registration, listing, and premarket safety controls; and

''(2) require the informed consent of patients prior to using reprocessed class II and class III medical devices.

''(c) REGISTRATION.—Every person or establishment engaged in the reprocessing of a device labeled for single use shall—

''(1) upon first engaging in the reprocessing of such device, register with the Secretary and provide all information required in accordance with section 510(c);

''(2) for each year in which the person or establishment engages in the reprocessing of such device, register with the Secretary and provide all information required under section 510(b); and

''(3) for each year in which the person or establishment engages in the reprocessing of such device, submit to the Secretary a list of devices labeled for single use that the person or establishment is reprocessing, including the names of the original equipment manufacturers of such devices and the specific models of such devices that are reprocessed.

''(d) INFORMATION.—Every person or establishment engaged in the reprocessing of a device labeled for single use shall, for each reprocessed medical device, provide to each person or establishment that uses such reprocessed medical device, information necessary for such person or establishment to comply with subsection (f).

''(e) SAFETY AND EFFECTIVENESS.—Every person or establishment required to register under subsection (c) with respect to a device shall demonstrate to the Secretary that such reprocessed device is safe and effective or sub-

stantially equivalent to a device the Secretary has deemed safe and effective. The Secretary may exempt class I devices from the requirements of this subsection.

''(f) INFORMED PATIENT CONSENT AND MEDICAL RECORDS.—

''(1) IN GENERAL.—Every person or establishment that uses a class II or class III reprocessed medical device to provide medical care to an individual shall seek informed consent from the patient for the use of such a device.

''(2) MEDICAL RECORDS.—

''(A) IN GENERAL.—Every person or establishment that uses a class II or class III reprocessed medical device to provide medical care to an individual shall keep a record of such use and include a note of such use in such individual's medical record.

''(B) CONTENTS.—The contents of the record described in paragraph (1) shall include—

''(i) the name and place of business of the person or establishment that reprocessed the device labeled for single use and the batch or lot number of such device; and

''(ii) the identity of the original manufacturer of the device.

''(g) REPORT.—Not later than 9 months after the date of enactment of this section, the Secretary shall submit a report to the Committee on Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate that describes findings from current Food and Drug Administration studies (as of the date of submission) on the safety and efficacy of reprocessing of devices labeled for single use.

''(h) MEDWATCH.—Not later than 6 months after the date of enactment of this section, the Secretary shall modify the MEDWATCH forms to facilitate reporting of information relating to reprocessed medical devices, including the name of a reprocessor and the number of times a device has been reused.

''(i) APPLICATION.—All other sections of this Act that govern devices as defined in section 201(h) shall also apply to reprocessed medical devices, if applicable.

''(j) DEFINITIONS.—In this section:

''(1) REPROCESSED MEDICAL DEVICE.—The term 'reprocessed medical device' means a device that—

''(A) is labeled for single use, or is disposable and intended for single use; and

"(B) is cleaned or sanitized after use in order that such a device may be reused upon another individual.

"(2) REPROCESSING.—The term 'reprocessing' means a procedure employed in order to produce a reprocessed medical device.".

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