117TH CONGRESS
1ST SESSION

S. _____

To expand the enforcement authority of the Food and Drug Administration with respect to counterfeit devices.

IN THE SENATE OF THE UNITED STATES

Mr. MURPHY (for himself and Mr. BRAUN) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To expand the enforcement authority of the Food and Drug Administration with respect to counterfeit devices.

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 ''Protecting Patients from Counterfeit Medical Devices Act''.

SEC. 2. EXPANDING ENFORCEMENT AUTHORITY AND PENALTIES FOR COUNTERFEIT DEVICES.

(a) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

"(fff)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device upon any device or container, packaging, or labeling thereof so as to render such device a counterfeit device.

"(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any device or container, packaging, or labeling thereof so as to render such device a counterfeit device.

"(3) The doing of any act which causes a device to be a counterfeit device, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit device.".

(b) PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended—

(1) in subsection (b)(8), by inserting ", or who violates section 301(fff)(3) by knowingly making, selling or dispensing, or holding for sale or dispensing, a counterfeit device," after "a counterfeit drug"; and

(2) in subsection (c), by inserting "; or (6) for having violated section 301(fff)(2) if such person

acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a device being a counterfeit device, or for having violated section 301(fff)(3) if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the device was a counterfeit device'' before the period.

(c) SEIZURE.—Section 304(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(a)(2)) is amended—

(1) by striking '', and (E)'' and inserting '', (E)''; and

(2) by inserting '', (F) Any device that is a counterfeit device, (G) Any container, packaging, or labeling of a counterfeit device, and (H) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit device or devices'' before the period.