OLL19B17 S.L.C.

116TH CONGRESS
1ST SESSION

S. _____

To modify reporting requirements under the Controlled Substances Act.

IN THE SENATE OF THE UNITED STATES

Mrs. FEINSTEIN (for herself, Mr. GRASSLEY, Mr. DURBIN, and Mrs. CAPITO) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To modify reporting requirements under the Controlled Substances Act.

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 "Preventing Pill Mills Through Data Sharing Act".

SEC. 2. REPORTING REQUIREMENTS.

(a) RECORDS AND REPORTS OF REGISTRANTS.—Section 307 of the Controlled Substances Act (21 U.S.C. 827) is amended—

(1) in subsection (d), by striking "(d)(1)" and all that follows through the end of paragraph (1) and inserting the following:

"(d)(1)(A) Except as provided in subparagraph (B), every person registered under section 303 shall, not less frequently than monthly, make reports to the Attorney General through the Automated Reports and Consolidated Orders System, or any subsequent automated system developed by the Drug Enforcement Administration to monitor controlled substances, of every sale, delivery, or other disposal by the person of any controlled substance, identifying by the registration number assigned under this title the person or establishment (unless exempt from registration under section 302(d)) to whom such sale, delivery, or other disposal was made.

"(B) Subparagraph (A) shall not apply to—

"(i) the retail sale or delivery of a controlled substance by a pharmacy registered under section 303 to another pharmacy registered under that section to fulfill a specific patient need, as defined in section 581 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee); or

"(ii) the retail dispensing of a controlled substance by a pharmacy registered under section 303.

"(C) A person registered under section 303 that does not sell, deliver, or otherwise dispose of a controlled substance during a month shall not be required to submit a report for that month under subparagraph (A)."; and

(2) in subsection (f)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A)—

(I) by striking "manufacturer and distributor registrants" and inserting "persons registered under section 303"; and

(II) by striking "selected";

(ii) in subparagraph (A)—

(I) by inserting "or pharmacy" after "distributor"; and

(II) by inserting before the period at the end the following: "to whom controlled substances are distributed"; and

(iii) in subparagraph (B), by striking "opioids" and inserting "controlled substances";

(B) in paragraph (2)—

(i) by striking "made available not later" and inserting the following: "made available—

"(A) not later";

(ii) by striking the period at the end and inserting a semicolon; and

(iii) by adding at the end the following:

"(B) in a format that allows the raw data to be queried and sorted for analytical purposes; and

"(C) in a manner such that the information may be accessed simultaneously by more than 1 user at each registered location of a specific manufacturer, distributor, or pharmacy."; and

(C) in paragraph (3)—

(i) in subparagraph (A), by striking "registered manufacturers and distributors" and inserting "persons registered under section 303"; and

(ii) in subparagraph (B), by striking "registered manufacturer or distributor" and inserting "person registered under section 303".

(b) PENALTIES.—

(1) IN GENERAL.—Section 402 of the Controlled Substances Act (21 U.S.C. 842) is amended—

(A) in subsection (a), by striking paragraph (17) and inserting the following:

"(17) in the case of a person registered under section 303, to fail to review the most recent information, directly related to the customers of the person, made available by the Attorney General in accordance with section 307(f).''; and

(B) in subsection (c)(1)(B), by striking clause (ii) and inserting the following:

"(ii) In the case of a violation described in clause (i) committed by a person registered under section 303 and related to the reporting of suspicious orders of controlled substances, failing to maintain effective controls against diversion of such substances, or failing to review the most recent information made available by the Attorney General in accordance with section 307(f), the penalty shall not exceed $100,000.''.

(2) TECHNICAL AND CONFORMING AMENDMENT.—Section 402(a)(16) of the Controlled Substances Act (21 U.S.C. 842(a)(16)) is amended by striking "section 825 of this title'' and inserting "section 305''.

(c) AUTOMATED REPORTS AND CONSOLIDATED ORDERS SYSTEM.—Section 503(c)(1) of the Controlled Substances Act (21 U.S.C. 873(c)(1)) is amended—

(1) by inserting after "of States" the following: ", and to the Committee on the Judiciary of the Senate, the Committee on Health, Education, Labor, and Pensions of the Senate, the Caucus on International Narcotics Control of the Senate, the Committee on the Judiciary of the House of Representatives, and the Committee on Energy and Commerce of the House of Representatives,";

(2) by inserting after "registrants," the following: "including unusual volumes of controlled substances that are disposed of rather than sold, and unusual numbers of deleted transactions of high volumes of controlled substances,"; and

(3) by striking "contained in schedule II,".

SEC. 3. REGULATIONS AND GUIDANCE.

Not later than 90 days after the date of enactment of this Act, the Attorney General shall—

(1) amend part 1304 of title 21, Code of Federal Regulations, to implement the amendments made by section 2, including the requirements that—

(A) persons registered under section 303 of the Controlled Substances Act (21 U.S.C. 823) make the reports under section 307(d)(1) of that Act (21 U.S.C. 827(d)(1)) on a monthly basis; and

(B) the reports described in subparagraph (A) include all controlled substances; and

(2) issue guidance to persons described in paragraph (1)(A) to clarify the meaning of each of the data sets contained in the Automated Reports and Consolidated Orders System.