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118TH CONGRESS
2D SESSION

H. R. 9258

To amend the Federal Food, Drug, and Cosmetic Act to require pill press molds to bear a unique serial number, to amend the Controlled Substances Act to prohibit the knowing possession of a pill press mold with intent to manufacture certain counterfeit substances, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 2024

Mr. HARDER of California (for himself and Mr. CRENSHAW) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require pill press molds to bear a unique serial number, to amend the Controlled Substances Act to prohibit the knowing possession of a pill press mold with intent to manufacture certain counterfeit substances, 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 Act may be cited as the ''Disrupt Fentanyl Pill Production Act''.

SEC. 2. FDA REGULATION OF LAWFUL USE OF PILL PRESS MOLDS.

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

''(jjj) The intentional introduction or delivery for introduction into interstate commerce of a drug that was manufactured using a pill press mold in violation of section 524C.''.

(b) REQUIREMENTS.—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. 524C. PILL PRESS MOLDS.

''(a) SERIAL NUMBERS.—The Secretary shall require each pill press mold that is used to manufacture a drug intended for introduction into interstate commerce to bear a unique serial number.

''(b) REGISTRATION.—The Secretary shall require each manufacturer that uses a pill press mold to manufacture drugs intended for introduction into interstate commerce—

''(1) to register with the Food and Drug Administration; and

''(2) to include in such registration—

''(A) the serial number required under subsection (a) for each pill press mold so used; and

''(B) such other information regarding such pill press molds as the Secretary may require.

''(c) COORDINATION.—The Secretary and the Attorney General shall ensure coordination and information-sharing in the regulation of pill press molds.

''(d) DEFINITION.—In this section and section 301(jjj), the term 'pill press mold' means any punch, die, plate, stone, or other object designed to print, imprint, or reproduce on a drug (or the container or labeling thereof) the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such product.''.

(c) REGULATIONS.—Not later than1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall promulgate a final regulation to carry out sections 301(jjj) and 524C of the Federal Food, Drug, and Cosmetic Act, as added by this section.

(d) DELAYED APPLICABILITY.—Sections 301(jjj) and 524C of the Federal Food, Drug, and Cosmetic Act, as added by this section, apply beginning on the date that is 2 years after the date on which the final regulation required by subsection (c) is promulgated.

SEC. 3. UNLAWFUL POSSESSION OF PILL PRESS MOLDS.

(a) PROHIBITION.—Section 401 of the Controlled Substances Act (21 U.S.C. 841) is amended by adding at the end the following:

''(i) OFFENSE REGARDING UNLAWFUL POSSESSION OF PILL PRESS MOLDS.—

''(1) IN GENERAL.—Whoever, with intent to manufacture in violation of this title a counterfeit substance in schedule I or II in a capsule, tablet, or other form for distribution, knowingly possesses a pill press mold, shall be imprisoned not more than 20 years and fined in accordance with title 18, United States Code.

''(2) DEFINITIONS.—In this subsection, the term 'pill press mold' means any punch, die, plate, stone, or other object designed to print, imprint, or reproduce on a controlled substance (or the container or labeling thereof) the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer,

distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such product, thereby rendering it a counterfeit substance.''.

(b) SENTENCING GUIDELINES.—Pursuant to its authority under section 994 of title 28, United States Code, and in accordance with this section, the United States Sentencing Commission shall review and amend, as appropriate, the Federal sentencing guidelines and policy statements to ensure that the guidelines provide for a penalty enhancement of not less than 2 offense levels above the offense level otherwise applicable for a violation of section 401(a) of the Controlled Substances Act (21 U.S.C. 841(a)) if the defendant is found, in connection with such violation of section 401(a), to be in violation of section 401(i) of the Controlled Substances Act, as added by subsection (a).

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