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(Original Signature of Member)

115TH CONGRESS
2D SESSION

H. R. 5687

To amend the Federal Food, Drug, and Cosmetic Act to require improved packaging and disposal methods with respect to certain drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. HUDSON introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require improved packaging and disposal methods with respect to certain drugs, 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 "Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018" or the "SOUND Disposal and Packaging Act".

SEC. 2. IMPROVED TECHNOLOGIES, CONTROLS, OR MEASURES WITH RESPECT TO THE PACKAGING OR DISPOSAL OF CERTAIN DRUGS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505–1 (21 U.S.C. 355–1) the following new section:

"SEC. 505–2. SAFETY-ENHANCING PACKAGING AND DISPOSAL FEATURES.

"(a) ORDERS.—

"(1) IN GENERAL.—The Secretary may, after consultation with relevant stakeholders, issue an order requiring the holder of a covered application to implement or modify one or more technologies, controls, or measures with respect to the packaging or disposal of one or more drugs identified in the covered application, if the Secretary determines such technologies, controls, or measures to be appropriate to help mitigate the risk of abuse or misuse of such drug or drugs, including by reducing the availability of unused drugs.

"(2) ASSURING ACCESS AND MINIMIZING BURDEN.—Technologies, controls, or measures required under paragraph (1) shall—

"(A) be commensurate with the specific risk of abuse or misuse of the drug listed in the covered application;

"(B) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular the available evidence regarding the expected or demonstrated public health impact of such technologies, controls, or measures; and

"(C) reduce the risk of abuse or misuse of such drug.

"(3) ORDER CONTENTS.—An order issued under paragraph (1) may—

"(A) provide for a range of options for implementing or modifying the technologies, controls, or measures required to be implemented by such order; and

"(B) incorporate by reference standards regarding packaging or disposal set forth in an official compendium, established by a nationally or internationally recognized standard development organization, or described on the public Internet website of the Food and Drug Administration, so long as the order includes the rationale for incorporation of such standard.

"(4) ORDERS APPLICABLE TO DRUG CLASS.—When a concern about the risk of abuse or misuse of a drug relates to a pharmacological class, the Sec-

retary may, after consultation with relevant stakeholders, issue an order under paragraph (1) which applies to the pharmacological class.

"(b) COMPLIANCE.—The holder of a covered application shall—

"(1) submit a supplement containing proposed changes to the covered application to comply with an order issued under subsection (a) not later than—

"(A) 180 calendar days after the date on which the order is issued; or

"(B)(i) such longer time period as specified by the Secretary in such order; or

"(ii) if a request for an alternative date is submitted by the holder of such application not later than 60 calendar days after the date on which such order is issued—

"(I) such requested alternative date if agreed to by the Secretary; or

"(II) another date as specified by the Secretary; and

"(2) implement the changes approved pursuant to such supplement not later than the later of—

"(A) 90 calendar days after the date on which the supplement is approved; or

"(B) the end of such longer period as is—

"(i) determined to be appropriate by the Secretary; or

"(ii) approved by the Secretary pursuant to a request by the holder of the covered application that explains why such longer period is needed, including to satisfy any other applicable Federal statutory or regulatory requirements.

"(c) ALTERNATIVE MEASURES.—The holder of the covered application may propose, and the Secretary shall approve, technologies, controls, or measures regarding packaging, storage, or disposal other than those specified in the applicable order issued under subsection (a), if such technologies, controls, or measures are supported by data and information demonstrating that such alternative technologies, controls, or measures can be expected to mitigate the risk of abuse or misuse of the drug or drugs involved, including by reducing the availability of unused drugs, to at least the same extent as the technologies, controls, or measures specified in such order.

"(d) DISPUTE RESOLUTION.—If a dispute arises in connection with a supplement submitted under subsection (b), the holder of the covered application may appeal a determination made with respect to such supplement using

applicable dispute resolution procedures specified by the Secretary in regulations or guidance.

"(e) DEFINITIONS.—In this section—

"(1) the term 'covered application' means an application submitted under subsection (b) or (j) of section 505 for approval under such section or an application approved under section 351 of Public Health Service Act, with respect to a drug that is or contains an opioid for which a listing in schedule II or III (on a temporary or permanent basis) is in effect under section 202 of the Controlled Substances Act; and

"(2) the term 'relevant stakeholders' may include scientific experts within the drug manufacturing industry; brand and generic drug manufacturers; standard development organizations; wholesalers and distributors; payers; health care providers; pharmacists; manufacturers; poison centers; and representatives of the National Institute on Drug Abuse, the National Institutes of Health, the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the Drug Enforcement Agency, the Consumer Product Safety Commission, individuals who specialize in treating addiction, and patient and caregiver groups.".

(b) PROHIBITED ACTS.—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended by inserting after paragraph (j) the following:

"(k) If it is a drug approved under a covered application (as defined in section 505–2(e)), the holder of which does not meet the requirements of paragraphs (1) and (2) of subsection (b) of such section.".

(c) REQUIRED CONTENT OF AN ABBREVIATED NEW DRUG APPLICATION.—Section 505(j)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(A)) is amended—

(1) in clause (vii)(IV), by striking "and" at the end;

(2) in clause (viii), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(ix) if the drug is or contains an opioid for which a listing in schedule II or III (on a temporary or permanent basis) is in effect under section 202 of the Controlled Substances Act, information to show that the applicant has proposed technologies, controls, or measures related to the packaging or disposal of the drug that are comparably effective to those required

for the applicable listed drug under section 505–2, if applicable.".

(d) GROUNDS FOR REFUSING TO APPROVE AN ABBREVIATED NEW DRUG APPLICATION.—Section 505(j)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(4), is amended—

(1) in subparagraph (J), by striking "or" at the end;

(2) in subparagraph (K), by striking the period at the end and inserting "; or"; and

(3) by adding at the end the following:

"(L) if the drug is a drug described in paragraph (2)(A)(ix) and the applicant has not proposed technologies, controls, or measures related to the packaging or disposal of such drug that the Secretary determines are comparably effective to those required for the applicable listed drug under section 505–2.".

(e) RULES OF CONSTRUCTION.—

(1) Any labeling describing technologies, controls, or measures related to packaging, storage, or disposal intended to mitigate the risk of abuse or misuse of a drug product that is subject to an abbreviated new drug application, including labeling describing differences from the reference listed drug

resulting from the application of section 505–2 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall not be construed—

(A) as changes to labeling not permissible under clause (v) of section 505(j)(2)(A) of such Act (21 U.S.C. 355(j)(2)(A)), or a change in the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug under clause (i) of such section; or

(B) to prohibit approval of an abbreviated new drug application under subparagraph (B) or (G) of section 505(j)(4) of such Act (21 U.S.C. 355(j)(4)).

(2) For a covered application that is an application submitted under subjection (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), subparagraph (j)(2)(A) of such section 505 shall not be construed to limit the type of data or information the Secretary of Health and Human Services may request or consider in connection with making any determination under section 505–2.

(f) GAO REPORT.—Not later than 12 months after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit to the Congress a report containing—

(1) a description of available evidence, if any, on the effectiveness of site-of-use, in-home controlled substance disposal products and packaging technologies;

(2) identification of ways in which such disposal products intended for use by patients, consumers, and other end users that are not registrants under the Controlled Substances Act, are made available to the public and barriers to the use of such disposal products;

(3) identification of ways in which packaging technologies are made available to the public and barriers to the use of such technologies;

(4) a description of Federal oversight, if any, of site-of-use, in-home controlled substance disposal products, including—

(A) identification of the Federal agencies that oversee such products;

(B) identification of the methods of disposal of controlled substances recommended by these agencies for site-of-use, in-home disposal; and

(C) a description of the effectiveness of such recommendations at preventing the diversion of legally prescribed controlled substances;

(5) a description of Federal oversight, if any, of controlled substance packaging technologies, including—

(A) identification of the Federal agencies that oversee such technologies;

(B) identification of the technologies recommended by these agencies, including unit dose packaging, packaging that provides a set duration, or other packaging systems that may mitigate abuse or misuse; and

(C) a description of the effectiveness of such recommendations at preventing the diversion of legally prescribed controlled substances; and

(6) recommendations on—

(A) whether site-of-use, in-home controlled substance disposal products and packaging technologies require Federal oversight and, if so, which agencies should be responsible for such oversight and, as applicable, approval of such products or technologies; and

(B) the potential role of the Federal Government in evaluating such products to ensure product efficacy.