

(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.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Securing Opioids and  
5 Unused Narcotics with Deliberate Disposal and Packaging  
6 Act of 2018” or the “SOUND Disposal and Packaging  
7 Act”.

1   **SEC. 2. IMPROVED TECHNOLOGIES, CONTROLS, OR MEAS-**  
2                           **URES WITH RESPECT TO THE PACKAGING OR**  
3                           **DISPOSAL OF CERTAIN DRUGS.**

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

7   **“SEC. 505–2. SAFETY-ENHANCING PACKAGING AND DIS-**  
8                           **POSAL FEATURES.**

9       “(a) ORDERS.—

10           “(1) IN GENERAL.—The Secretary may, after  
11 consultation with relevant stakeholders, issue an  
12 order requiring the holder of a covered application to  
13 implement or modify one or more technologies, con-  
14 trols, or measures with respect to the packaging or  
15 disposal of one or more drugs identified in the cov-  
16 ered application, if the Secretary determines such  
17 technologies, controls, or measures to be appropriate  
18 to help mitigate the risk of abuse or misuse of such  
19 drug or drugs, including by reducing the availability  
20 of unused drugs.

21           “(2) ASSURING ACCESS AND MINIMIZING BUR-  
22 DEN.—Technologies, controls, or measures required  
23 under paragraph (1) shall—

24           “(A) be commensurate with the specific  
25 risk of abuse or misuse of the drug listed in the  
26 covered application;

1           “(B) considering such risk, not be unduly  
2           burdensome on patient access to the drug, con-  
3           sidering in particular the available evidence re-  
4           garding the expected or demonstrated public  
5           health impact of such technologies, controls, or  
6           measures; and

7           “(C) reduce the risk of abuse or misuse of  
8           such drug.

9           “(3) ORDER CONTENTS.—An order issued  
10          under paragraph (1) may—

11           “(A) provide for a range of options for im-  
12           plementing or modifying the technologies, con-  
13           trols, or measures required to be implemented  
14           by such order; and

15           “(B) incorporate by reference standards  
16           regarding packaging or disposal set forth in an  
17           official compendium, established by a nationally  
18           or internationally recognized standard develop-  
19           ment organization, or described on the public  
20           Internet website of the Food and Drug Admin-  
21           istration, so long as the order includes the ra-  
22           tionale for incorporation of such standard.

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

1       retary may, after consultation with relevant stake-  
2       holders, issue an order under paragraph (1) which  
3       applies to the pharmacological class.

4       “(b) COMPLIANCE.—The holder of a covered applica-  
5       tion shall—

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

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

11              “(B)(i) such longer time period as speci-  
12       fied by the Secretary in such order; or

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

17              “(I) such requested alternative date if  
18       agreed to by the Secretary; or

19              “(II) another date as specified by the  
20       Secretary; and

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

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

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

1                   “(i) determined to be appropriate by  
2                   the Secretary; or

3                   “(ii) approved by the Secretary pursu-  
4                   ant to a request by the holder of the cov-  
5                   ered application that explains why such  
6                   longer period is needed, including to satisfy  
7                   any other applicable Federal statutory or  
8                   regulatory requirements.

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

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

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

3 “(e) DEFINITIONS.—In this section—

4 “(1) the term ‘covered application’ means an  
5 application submitted under subsection (b) or (j) of  
6 section 505 for approval under such section or an  
7 application approved under section 351 of Public  
8 Health Service Act, with respect to a drug that is  
9 or contains an opioid for which a listing in schedule  
10 II or III (on a temporary or permanent basis) is in  
11 effect under section 202 of the Controlled Sub-  
12 stances Act; and

13 “(2) the term ‘relevant stakeholders’ may in-  
14 clude scientific experts within the drug manufac-  
15 turing industry; brand and generic drug manufactur-  
16 ers; standard development organizations; wholesalers  
17 and distributors; payers; health care providers; phar-  
18 macists; manufacturers; poison centers; and rep-  
19 resentatives of the National Institute on Drug  
20 Abuse, the National Institutes of Health, the Cen-  
21 ters for Disease Control and Prevention, the Centers  
22 for Medicare & Medicaid Services, the Drug En-  
23 forcement Agency, the Consumer Product Safety  
24 Commission, individuals who specialize in treating  
25 addiction, and patient and caregiver groups.”.

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

4 “(k) If it is a drug approved under a covered applica-  
5 tion (as defined in section 505–2(e)), the holder of which  
6 does not meet the requirements of paragraphs (1) and (2)  
7 of subsection (b) of such section.”.

8 (c) REQUIRED CONTENT OF AN ABBREVIATED NEW  
9 DRUG APPLICATION.—Section 505(j)(2)(A) of the Fed-  
10 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
11 355(j)(2)(A)) is amended—

12 (1) in clause (vii)(IV), by striking “and” at the  
13 end;

14 (2) in clause (viii), by striking the period at the  
15 end and inserting “; and”; and

16 (3) by adding at the end the following:

17 “(ix) if the drug is or contains an  
18 opioid for which a listing in schedule II or  
19 III (on a temporary or permanent basis) is  
20 in effect under section 202 of the Con-  
21 trolled Substances Act, information to  
22 show that the applicant has proposed tech-  
23 nologies, controls, or measures related to  
24 the packaging or disposal of the drug that  
25 are comparably effective to those required

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

3       (d) GROUNDS FOR REFUSING TO APPROVE AN AB-  
4 BREVIATED NEW DRUG APPLICATION.—Section 505(j)(4)  
5 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
6 355(j)(4), is amended—

7           (1) in subparagraph (J), by striking “or” at the  
8       end;

9           (2) in subparagraph (K), by striking the period  
10       at the end and inserting “; or”; and

11          (3) by adding at the end the following:

12               “(L) if the drug is a drug described in  
13       paragraph (2)(A)(ix) and the applicant has not  
14       proposed technologies, controls, or measures re-  
15       lated to the packaging or disposal of such drug  
16       that the Secretary determines are comparably  
17       effective to those required for the applicable  
18       listed drug under section 505–2.”.

19       (e) RULES OF CONSTRUCTION.—

20           (1) Any labeling describing technologies, con-  
21       trols, or measures related to packaging, storage, or  
22       disposal intended to mitigate the risk of abuse or  
23       misuse of a drug product that is subject to an abbrevi-  
24       ated new drug application, including labeling de-  
25       scribing differences from the reference listed drug



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

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

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

14              (2) For a covered application that is an applica-  
15       tion submitted under subsection (j) of section 505 of  
16       the Federal Food, Drug, and Cosmetic Act (21  
17       U.S.C. 355), subparagraph (j)(2)(A) of such section  
18       505 shall not be construed to limit the type of data  
19       or information the Secretary of Health and Human  
20       Services may request or consider in connection with  
21       making any determination under section 505–2.

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

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

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

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

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

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

19                (B) identification of the methods of dis-  
20                posal of controlled substances recommended by  
21                these agencies for site-of-use, in-home disposal;  
22                and

23                (C) a description of the effectiveness of  
24                such recommendations at preventing the diver-  
25                sion of legally prescribed controlled substances;

1 (5) a description of Federal oversight, if any, of  
2 controlled substance packaging technologies, includ-  
3 ing—

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

6 (B) identification of the technologies rec-  
7 ommended by these agencies, including unit  
8 dose packaging, packaging that provides a set  
9 duration, or other packaging systems that may  
10 mitigate abuse or misuse; and

11 (C) a description of the effectiveness of  
12 such recommendations at preventing the diver-  
13 sion of legally prescribed controlled substances;  
14 and

15 (6) recommendations on—

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

22 (B) the potential role of the Federal Gov-  
23 ernment in evaluating such products to ensure  
24 product efficacy.