

115TH CONGRESS
2D SESSION

H. R. 5228

IN THE SENATE OF THE UNITED STATES

JUNE 13, 2018

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

AN ACT

To strengthen the authorities of the Food and Drug Administration to address counterfeit drugs, illegal and synthetic opioids, and opioid-like substances, 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,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Stop Counterfeit Drugs by Regulating and Enhancing
4 Enforcement Now Act” or the “SCREEN Act”.

5 (b) TABLE OF CONTENTS.—The table of contents of
6 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Detention, refusal, and destruction of drugs offered for importation.
- Sec. 3. Notification, nondistribution, and recall of adulterated or misbranded drug products.
- Sec. 4. Single source pattern of shipments of adulterated or misbranded drugs.
- Sec. 5. Fund to strengthen efforts of FDA to combat the opioid and substance use epidemic.
- Sec. 6. Consideration of potential for misuse and abuse required for drug approval.

7 **SEC. 2. DETENTION, REFUSAL, AND DESTRUCTION OF**
8 **DRUGS OFFERED FOR IMPORTATION.**

9 (a) INCREASING THE MAXIMUM DOLLAR AMOUNT OF
10 DRUGS SUBJECT TO DESTRUCTION.—The sixth sentence
11 in section 801(a) of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 381(a)) is amended by striking “ex-
13 cept that the Secretary” and all that follows through the
14 two periods at the end and inserting “except that the Sec-
15 retary of Health and Human Services may destroy, with-
16 out the opportunity for export, any drug refused admission
17 under this section, if such drug is declared to be valued
18 at an amount that is \$2,500 or less (or such higher
19 amount as the Secretary of the Treasury may set by regu-
20 lation pursuant to section 498(a)(1) of the Tariff Act of
21 1930 or such higher amount as the Commissioner of Food

1 and Drugs may set based on a finding by the Commis-
2 sioner that the higher amount is in the interest of public
3 health), or if such drug is entering the United States by
4 mail, and was not brought into compliance as described
5 under subsection (b).”.

6 (b) DESTRUCTION OF ARTICLES OF CONCERN.—The
7 sixth sentence of section 801(a) of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 381(a)), as amended
9 by subsection (a), is further amended by inserting before
10 the period at the end the following: “; and the Secretary
11 of Health and Human Services may destroy, without the
12 opportunity for export, any article refused admission
13 under clause (6) of the third sentence of this subsection”.

14 (c) TECHNICAL AMENDMENTS.—The seventh, eighth,
15 and ninth sentences of section 801(a) of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 381(a)) are amend-
17 ed—

18 (1) by striking “a drug” each place it appears
19 and inserting “an article”; and

20 (2) by striking “the drug” each place it appears
21 and inserting “the article”.

22 (d) RULE OF CONSTRUCTION.—The last sentence in
23 section 801(a) of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 381(a)) is amended to read as follows:
25 “Clauses (2), (5), and (6) of the third sentence of this

1 subsection shall not be construed to prohibit the admission
 2 of narcotic or nonnarcotic drugs or other substances, the
 3 importation of which is permitted under the Controlled
 4 Substances Import and Export Act.”.

5 **SEC. 3. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
 6 **OF ADULTERATED OR MISBRANDED DRUG**
 7 **PRODUCTS.**

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

11 “(eee) The failure to comply with any order issued
 12 under section 569D.”.

13 (b) NOTIFICATION, NONDISTRIBUTION, AND RECALL
 14 OF ADULTERATED OR MISBRANDED DRUGS.—Subchapter
 15 E of chapter V of the Federal Food, Drug, and Cosmetic
 16 Act (21 U.S.C. 360bbb et seq.) is amended by adding at
 17 the end the following:

18 **“SEC. 569D. NOTIFICATION, NONDISTRIBUTION, AND RE-**
 19 **CALL OF ADULTERATED OR MISBRANDED**
 20 **DRUGS.**

21 “(a) ORDER TO CEASE DISTRIBUTION AND RE-
 22 CALL.—

23 “(1) IN GENERAL.—Upon a determination that
 24 the use or consumption of, or exposure to, a drug
 25 may present an imminent or substantial hazard to

1 the public health, the Secretary shall issue an order
2 requiring any person who distributes the drug to im-
3 mediately cease distribution of the drug.

4 “(2) HEARING.—An order under paragraph (1)
5 shall provide the person subject to the order with an
6 opportunity for an informal hearing, to be held not
7 later than 10 days after the date of issuance of the
8 order, on—

9 “(A) the actions required by the order; and

10 “(B) whether the order should be amended
11 to require a recall of the drug.

12 “(3) INADEQUATE GROUNDS.—If, after pro-
13 viding an opportunity for a hearing under paragraph
14 (2), the Secretary determines that inadequate
15 grounds exist to support the actions required by the
16 order, the Secretary shall vacate the order.

17 “(4) AMENDMENT TO ORDER TO REQUIRE RE-
18 CALL.—If, after providing an opportunity for an in-
19 formal hearing under paragraph (2), the Secretary
20 determines that the order should be amended to in-
21 clude a recall of the drug with respect to which the
22 order was issued, the Secretary shall—

23 “(A) amend the order to require a recall;

24 and

1 “(B) after consultation with the drug
2 sponsor, specify a timetable in which the recall
3 will occur.

4 “(5) NOTICE TO PERSONS AFFECTED.—An
5 order under this subsection shall require any person
6 who distributes the drug to provide for notice, in-
7 cluding to individuals as appropriate, to persons who
8 may be affected by the order to cease distribution of
9 or recall the drug, as applicable.

10 “(6) ACTION FOLLOWING ORDER.—Any person
11 who is subject to an order under paragraph (1) or
12 (4) shall immediately cease distribution of or recall,
13 as applicable, the drug and provide notification as
14 required by such order.

15 “(b) NOTICE TO CONSUMERS AND HEALTH OFFI-
16 CIALS.—The Secretary shall, as the Secretary determines
17 to be necessary, provide notice of a recall order under this
18 section to—

19 “(1) consumers to whom the drug was, or may
20 have been, distributed; and

21 “(2) appropriate State and local health officials.

22 “(c) ORDER TO RECALL.—

23 “(1) CONTENTS.—An order to recall a drug
24 under subsection (a) shall—

1 “(A) require periodic reports to the Sec-
2 retary describing the progress of the recall; and

3 “(B) provide for notice, including to indi-
4 viduals as appropriate, to persons who may be
5 affected by the recall.

6 “(2) ASSISTANCE ALLOWED.—In providing for
7 notice under paragraph (1)(B), the Secretary may
8 allow for the assistance of health professionals, State
9 or local officials, or other individuals designated by
10 the Secretary.

11 “(3) NONDELEGATION.—An order under this
12 section shall be ordered by the Secretary or an offi-
13 cial designated by the Secretary. An official may not
14 be so designated under this section unless the offi-
15 cial is the Director of the Center for Drug Evalua-
16 tion and Research, is an official senior to such Di-
17 rector, or is so designated by such Director.

18 “(d) SAVINGS CLAUSE.—Nothing contained in this
19 section shall be construed as limiting—

20 “(1) the authority of the Secretary to issue an
21 order to cease distribution of, or to recall, an drug
22 under any other provision of this Act or the Public
23 Health Service Act; or

24 “(2) the ability of the Secretary to request any
25 person to perform a voluntary activity related to any

1 drug subject to this Act or the Public Health Service
2 Act.”.

3 (c) DRUGS SUBJECT TO REFUSAL.—The third sen-
4 tence of subsection (a) of section 801 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 381) is amended by
6 inserting “or (5) in the case of a drug, such drug is sub-
7 ject to an order under section 568 to cease distribution
8 of or recall the drug,” before “then such article shall be
9 refused admission”.

10 (d) APPLICATION.—Sections 301(eee) and 569D of
11 the Federal Food, Drug, and Cosmetic Act, as added by
12 subsections (a) and (b), shall apply with respect to a drug
13 as of such date, not later than 1 year after the date of
14 the enactment of this Act, as the Secretary of Health and
15 Human Services shall specify.

16 **SEC. 4. SINGLE SOURCE PATTERN OF SHIPMENTS OF ADUL-**
17 **TERATED OR MISBRANDED DRUGS.**

18 Section 801 of the Federal Food, Drug, and Cosmetic
19 Act is amended by adding at the end the following:

20 “(t) SINGLE SOURCE PATTERN OF SHIPMENTS OF
21 ADULTERATED OR MISBRANDED DRUGS.—If the Sec-
22 retary identifies a pattern of adulterated or misbranded
23 drugs being offered for import from the same manufac-
24 turer, distributor, or importer, the Secretary may by order
25 choose to treat all drugs being offered for import from

1 such manufacturer, distributor, or importer as adulterated
2 or misbranded unless otherwise demonstrated.”.

3 **SEC. 5. FUND TO STRENGTHEN EFFORTS OF FDA TO COM-**
4 **BAT THE OPIOID AND SUBSTANCE USE EPI-**
5 **DEMIC.**

6 Chapter X of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 391 et seq.) is amended by adding at the
8 end the following:

9 **“SEC. 1015. FUND TO STRENGTHEN EFFORTS OF FDA TO**
10 **COMBAT THE OPIOID AND SUBSTANCE USE**
11 **EPIDEMIC.**

12 “(a) IN GENERAL.—The Commissioner of Food and
13 Drugs shall use any funds appropriated pursuant to the
14 authorization of appropriations under subsection (c) to
15 carry out the programs and activities described in sub-
16 section (d) to strengthen and facilitate the Food and Drug
17 Administration’s efforts to address the opioid and sub-
18 stance use epidemic. Such funds shall be in addition to
19 any funds which are otherwise available to carry out such
20 programs and activities.

21 “(b) FDA OPIOID AND SUBSTANCE USE EPIDEMIC
22 RESPONSE FUND.—

23 “(1) ESTABLISHMENT OF FUND.—There is es-
24 tablished in the Treasury a fund, to be known as the
25 FDA Opioid and Substance Use Epidemic Response

1 Fund (referred to in this subsection as the ‘Fund’),
2 for purposes of funding the programs and activities
3 described in subsection (d).

4 “(2) TRANSFER.—For the period of fiscal years
5 2019 through 2023, \$110,000,000 shall be trans-
6 ferred to the Fund from the general fund of the
7 Treasury.

8 “(3) AMOUNTS DEPOSITED.—Any amounts
9 transferred under paragraph (2) shall remain un-
10 available in the Fund until such amounts are appro-
11 priated pursuant to subsection (c).

12 “(c) APPROPRIATIONS.—

13 “(1) AUTHORIZATION OF APPROPRIATIONS.—
14 For the period of fiscal years 2019 through 2023,
15 there is authorized to be appropriated from the
16 Fund to the Food and Drug Administration, for the
17 purpose of carrying out the programs and activities
18 described in subsection (d), an amount not to exceed
19 the total amount transferred to the Fund under sub-
20 section (b)(2). Notwithstanding subsection (g), such
21 funds shall remain available until expended.

22 “(2) OFFSETTING FUTURE APPROPRIATIONS.—
23 For any of fiscal years 2019 through 2023, for any
24 discretionary appropriation out of the Fund to the
25 Food and Drug Administration pursuant to the au-

1 thorization of appropriations under paragraph (1)
2 for the purpose of carrying out the programs and
3 activities described in subsection (d), the total
4 amount of such appropriations for the applicable fis-
5 cal year (not to exceed the total amount remaining
6 in the Fund) shall be subtracted from the estimate
7 of discretionary budget authority and the resulting
8 outlays for any estimate under the Congressional
9 Budget and Impoundment Control Act of 1974 or
10 the Balanced Budget and Emergency Deficit Control
11 Act of 1985, and the amount transferred to the
12 Fund shall be reduced by the same amount.

13 “(d) FOOD AND DRUG ADMINISTRATION.—The en-
14 tirety of the funds made available pursuant to subsection
15 (c)(1) shall be for the Commissioner of Food and Drugs,
16 pursuant to applicable authorities in the Public Health
17 Service Act (42 U.S.C. 201 et seq.) or this Act and other
18 applicable Federal law, to support widespread innovation
19 in non-opioid and non-addictive medical products for pain
20 treatment, access to opioid addiction treatments, appro-
21 priate use of approved opioids, and efforts to reduce illicit
22 importation of opioids. Such support may include the fol-
23 lowing programs and activities:

1 “(1) Obligating contract funds beginning in fis-
2 cal year 2019 for an educational campaign that
3 will—

4 “(A) educate patients and their families to
5 differentiate opioid medications;

6 “(B) raise awareness about preferred stor-
7 age and disposal methods; and

8 “(C) inform patients, families, and commu-
9 nities about medication-assisted treatment op-
10 tions.

11 “(2) Building the Food and Drug Administra-
12 tion’s presence in international mail facilities, includ-
13 ing through—

14 “(A) improvements in equipment and in-
15 formation technology enhancements to identify
16 unapproved, counterfeit, or other unlawful
17 pharmaceuticals for destruction;

18 “(B) increased and improved surveillance;

19 “(C) renovations at international mail fa-
20 cility locations; and

21 “(D) the purchase of laboratory equip-
22 ment.

23 “(3) Enhancing the identification and targeting
24 of entities offering products and products being of-
25 fered by such entities for import into the United

1 States through review and analysis of Internet
2 websites, import data, and other sources of intel-
3 ligence for purposes of making the best use of the
4 Food and Drug Administration’s inspection and ana-
5 lytical resources.

6 “(4) Increasing the number of staff of the Food
7 and Drug Administration to increase the number of
8 packages being examined, ensuring the safety of the
9 staff undertaking such examinations, and ensuring
10 that packages identified as illegal, counterfeit, mis-
11 branded, or adulterated are removed from commerce
12 through available authorities, including administra-
13 tive destruction.

14 “(5) Enhancing the Food and Drug Adminis-
15 tration’s criminal investigations resources (including
16 full-time equivalent employees and equipment), im-
17 ports surveillance, and international work.

18 “(6) Obtaining for the Food and Drug Admin-
19 istration equipment and full-time equivalent employ-
20 ees needed to efficiently screen and analyze products
21 offered for import, including by building data librar-
22 ies of new substances and analogues to facilitate
23 identification and evaluation of pharmaceutical-
24 based agents and by purchasing screening tech-
25 nologies for use at international mail facilities.

1 “(7) Operating the Food and Drug Administra-
2 tion’s forensic laboratory facility to ensure adequate
3 laboratory space and functionality for additional
4 work and full-time equivalent employees.

5 “(e) ACCOUNTABILITY AND OVERSIGHT.—

6 “(1) WORK PLAN.—

7 “(A) IN GENERAL.—Not later than 180
8 days after the date of enactment of this Act,
9 the Commissioner of Food and Drugs shall sub-
10 mit to the Committee on Health, Education,
11 Labor and Pensions of the Senate and the
12 Committee on Energy and Commerce of the
13 House of Representatives, a work plan includ-
14 ing the proposed allocation of funds appro-
15 priated pursuant to the authorization of appro-
16 priations under subsection (c) for each of fiscal
17 years 2019 through 2023 and the contents de-
18 scribed in subparagraph (B).

19 “(B) CONTENTS.—The work plan sub-
20 mitted under subparagraph (A) shall include—

21 “(i) the amount of money to be obli-
22 gated or expended out of the Fund in each
23 fiscal year for each program and activity
24 described in subsection (d); and

1 “(ii) a description and justification of
2 each such program and activity.

3 “(2) REPORTS.—

4 “(A) ANNUAL REPORTS.—Not later than
5 October 1 of each of fiscal years 2020 through
6 2024, the Secretary of Health and Human
7 Services shall submit to the Committee on
8 Health, Education, Labor and Pensions of the
9 Senate and the Committee on Energy and Com-
10 merce of the House of Representatives a report
11 that includes—

12 “(i) the amount of money obligated or
13 expended out of the Fund in the prior fis-
14 cal year for each program and activity de-
15 scribed in subsection (d);

16 “(ii) a description of all programs and
17 activities using funds provided pursuant to
18 the authorization of appropriations under
19 subsection (c); and

20 “(iii) how the programs and activities
21 are advancing public health.

22 “(B) ADDITIONAL REPORTS.—At the re-
23 quest of the Committee on Health, Education,
24 Labor and Pensions of the Senate or the Com-
25 mittee on Energy and Commerce of the House

1 of Representatives, the Commissioner shall pro-
2 vide an update in the form of testimony and
3 any additional reports to the respective congres-
4 sional committee regarding the allocation of
5 funding under this section or the description of
6 the programs and activities undertaken with
7 such funding.

8 “(f) LIMITATIONS.—Notwithstanding any transfer
9 authority authorized by this section or any appropriations
10 Act, any funds made available pursuant to the authoriza-
11 tion of appropriations under subsection (c) may not be
12 used for any purpose other than the programs and activi-
13 ties described in subsection (d) to strengthen and facilitate
14 the Food and Drug Administration’s efforts to address the
15 opioid and substance use epidemic.

16 “(g) SUNSET.—This section shall expire on Sep-
17 tember 30, 2022, except that—

18 “(1) this subsection does not apply to reporting
19 under subsection (e)(2); and

20 “(2) this section shall remain in effect until
21 such time, and to such extent, as may be necessary
22 for the funds transferred by subsection (b)(2) to be
23 fully expended.”.

1 **SEC. 6. CONSIDERATION OF POTENTIAL FOR MISUSE AND**
2 **ABUSE REQUIRED FOR DRUG APPROVAL.**

3 (a) IN GENERAL.—Section 505(d) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) is
5 amended—

6 (1) in the first sentence—

7 (A) by striking “or (7)” and inserting
8 “(7)”; and

9 (B) by inserting “or (8) if the drug is or
10 contains a controlled substance for which a list-
11 ing in any schedule is in effect under the Con-
12 trolled Substances Act or that is permanently
13 scheduled pursuant to section 201 of such Act,
14 on the basis of information submitted to him as
15 part of the application, or upon the basis of any
16 other information before him with respect to
17 such drug, the drug is unsafe for use due to the
18 risks of abuse or misuse or there is insufficient
19 information to show that the drug is safe for
20 use considering such risks;” before “he shall
21 issue an order refusing to approve the applica-
22 tion”; and

23 (2) in the second sentence, by striking “(6)”
24 and inserting “(8)”.

1 (b) WITHDRAWAL AUTHORITY.—Section 505(e) of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 355(e)) is amended in the first sentence—

4 (1) by striking “or (5)” and inserting “(5)”;
5 and

6 (2) by inserting the following: “; or (6) that, in
7 the case of a drug that is or contains a controlled
8 substance for which a listing in any schedule is in
9 effect under the Controlled Substances Act or that
10 is permanently scheduled pursuant to section 201 of
11 such Act, on the basis of new information before him
12 with respect to such drug, evaluated together with
13 the information available to him when the applica-
14 tion was approved, that the drug is unsafe for use
15 due to the risks of abuse or misuse” after “of a ma-
16 terial fact”.

17 (c) RULE OF CONSTRUCTION.—Nothing in the
18 amendments made by this section shall be construed to
19 limit or narrow, in any manner, the meaning or applica-
20 tion of the provisions of paragraphs (1), (2), (3), (4), (5),
21 and (7) of section 505(d) of the Federal Food, Drug, and

- 1 Cosmetic Act (21 U.S.C. 355(d)) or paragraphs (1) and
- 2 (2) of section 505(e) of such Act (21 U.S.C. 355(e)).

Passed the House of Representatives June 12, 2018.

Attest:

KAREN L. HAAS,
Clerk.