

115TH CONGRESS
2D SESSION

H. R. 5228

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.

IN THE HOUSE OF REPRESENTATIVES

MARCH 8, 2018

Mr. PALLONE introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Budget, 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

A BILL

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,*

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

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

1 (b) TABLE OF CONTENTS.—The table of contents of
 2 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. Seizure.
- Sec. 5. Single source pattern of shipments of adulterated or misbranded drugs.
- Sec. 6. Debarring violative individuals or companies.
- Sec. 7. Account to strengthen efforts of FDA to combat the opioid and substance use epidemic.

3 **SEC. 2. DETENTION, REFUSAL, AND DESTRUCTION OF**
 4 **DRUGS OFFERED FOR IMPORTATION.**

5 (a) CERTAIN IMPORTED PRODUCTS DEEMED TO BE
 6 DRUGS.—Section 201(g) of the Federal Food, Drug, and
 7 Cosmetic Act (21 U.S.C. 321(g)) is amended by adding
 8 at the end the following:

9 “(3) An article being imported or offered for import
 10 is deemed to be a drug if it—

11 “(A) is or contains an active ingredient that is
 12 contained within—

13 “(i) a drug for which an approval is in ef-
 14 fect under section 505 of this Act; or

15 “(ii) biological product for which a license
 16 is in effect under section 351 of the Public
 17 Health Service Act;

18 “(B) is or contains an active ingredient that is
 19 contained within a drug or biological product for
 20 which an investigational use exemption is in effect
 21 under section 505(i) of this Act or section 351(a) of

1 the Public Health Service Act, for which substantial
2 clinical investigations have been instituted, and for
3 which the existence of such investigations has been
4 made public; or

5 “(C) is a chemical analog of a drug or biological
6 product described in clause (A) or (B).”.

7 (b) ARTICLES OF CONCERN.—

8 (1) DELIVERY BY TREASURY TO HHS.—The
9 first sentence of section 801(a) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 381(a)) is
11 amended by striking “and cosmetics” and inserting
12 “cosmetics, and potential articles of concern (as de-
13 fined in subsection (t)), and controlled substances
14 described paragraph (6) in the third sentence of this
15 subsection”.

16 (2) REPEAL OF ANTIQUATED REVIEW PROC-
17 ESS.—

18 (A) REPEAL.—The second sentence of sec-
19 tion 801(a) of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 381(a)) is repealed.

21 (B) TECHNICAL CHANGE TO KEEP NUM-
22 BERING OF SENTENCES THE SAME.—The first
23 sentence of section 801(a) of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 381(a)) is
25 amended by striking “the owner or consignee,

1 who may appear” and inserting “the owner or
2 consignee. The owner or consignee may ap-
3 pear”.

4 (3) REFUSED ADMISSION.—

5 (A) IN GENERAL.—The third sentence of
6 section 801(a) of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 381(a)) is amended—

8 (i) by striking “If it appears from the
9 examination” and inserting “Subject to
10 subsection (b), if it appears from the ex-
11 amination”; and

12 (ii) by striking “then such article shall
13 be refused admission, except as provided in
14 subsection (b) of this section” and insert-
15 ing “or (5) such article is an article of con-
16 cern (as defined in subsection (t)), or (6)
17 such article is a controlled substance (as
18 defined in section 102 of the Controlled
19 Substances Act) for which a listing in any
20 schedule is in effect (on a temporary or
21 permanent basis) under section 201 of the
22 Controlled Substances Act, or (7) such ar-
23 ticle is being imported or offered for im-
24 port in violation of section 301(cc), then
25 such article may be refused admission, and

1 if it appears such article may not be im-
2 ported into the United States pursuant to
3 subsection (d) or it appears that the article
4 is a counterfeit drug, then such article
5 shall be refused admission”.

6 (B) DEFINITION OF ARTICLE OF CON-
7 CERN.—Section 801 of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 381) is amended
9 by adding at the end the following:

10 “(t) ARTICLE OF CONCERN DEFINED.—For purposes
11 of subsection (a), the term ‘article of concern’ means an
12 article that is or contains a drug or other substance—

13 “(1) for which, during the 24-month period
14 prior to the article being imported or offered for im-
15 port, the Secretary of Health and Human Services—

16 “(A) has requested that, based on a deter-
17 mination that the drug or other substance ap-
18 pears to meet the requirements for temporary
19 or permanent scheduling pursuant to section
20 201 of the Controlled Substances Act, the At-
21 torney General initiate the process to control
22 the drug or other substance in accordance with
23 such Act; or

24 “(B) has made a determination, following
25 the publication by the Attorney General of a no-

1 tice in the Federal Register of the intention to
2 issue an order temporarily or permanently
3 scheduling such drug or substance in schedule
4 I of section 202 of the Controlled Substances
5 Act, that such article presents an imminent risk
6 to the public health; and

7 “(2) with respect to which the Attorney General
8 has not—

9 “(A) scheduled the drug or other substance
10 under section 201 of such Act; or

11 “(B) notified the Secretary of Health and
12 Human Services that the Attorney General has
13 made a determination not to schedule the drug
14 or other substance under such section.”.

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

1 section 498(a)(1) of the Tariff Act of 1930 or such higher
2 amount as the Commissioner of Food and Drugs may set
3 based on a finding by the Commissioner that the higher
4 amount is in the interest of public health) and was not
5 brought into compliance as described under subsection
6 (b).”.

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

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

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

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

23 (f) RULE OF CONSTRUCTION.—The last sentence in
24 section 801(a) of the Federal Food, Drug, and Cosmetic
25 Act (21 U.S.C. 381(a)) is amended to read as follows:

1 “Clauses (2), (5), and (6) of the third sentence of this
 2 subsection shall not be construed to prohibit the admission
 3 of narcotic or nonnarcotic drugs or other substances, the
 4 importation of which is permitted under the Controlled
 5 Substances Import and Export Act.”.

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

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

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

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

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

22 “(a) ORDER TO CEASE DISTRIBUTION.—

23 “(1) IN GENERAL.—If the Secretary has reason
 24 to believe that the use or consumption of, or expo-
 25 sure to, a drug may cause serious adverse health

1 consequences or death to humans, the Secretary may
2 issue an order requiring any person who distributes
3 such drug to immediately cease distribution of such
4 drug.

5 “(2) ACTION FOLLOWING ORDER.—Any person
6 who is subject to an order under paragraph (1) shall
7 immediately cease distribution of such drug and pro-
8 vide notification as required by such order, and may
9 appeal to the Secretary within 24 hours of the
10 issuance of such order. Such appeal may include a
11 request for an informal hearing and a description of
12 any efforts to recall such drug undertaken volun-
13 tarily by the person, including after a request under
14 subsection (b). Except as provided in subsection (c),
15 an informal hearing shall be held as soon as prac-
16 ticable, but not later than 5 calendar days, or less
17 as determined by the Secretary, after such an appeal
18 is filed, unless the parties jointly agree to an exten-
19 sion. After affording an opportunity for an informal
20 hearing, the Secretary shall determine whether the
21 order should be amended to require a recall of such
22 drug. If, after providing an opportunity for such a
23 hearing, the Secretary determines that inadequate
24 grounds exist to support the actions required by the
25 order, the Secretary shall vacate the order.

1 “(b) EMERGENCY RECALL ORDER.—

2 “(1) IN GENERAL.—If the Secretary has cred-
3 ible evidence or information that a drug subject to
4 an order under subsection (a) presents an imminent
5 threat of serious adverse health consequences or
6 death to humans, the Secretary may issue an order
7 requiring any person who distributes such drug—

8 “(A) to immediately recall such drug; and

9 “(B) to provide for notice, including to in-
10 dividuals as appropriate, to persons who may be
11 affected by the recall.

12 “(2) ACTION FOLLOWING ORDER.—Any person
13 who is subject to an emergency recall order under
14 this subsection shall immediately recall such drug
15 and provide notification as required by such order,
16 and may appeal to the Secretary within 24 hours
17 after issuance of such order. The person subject to
18 an emergency recall order shall conduct the recall
19 notwithstanding the pendency of any such appeal.
20 An informal hearing shall be held as soon as prac-
21 ticable but not later than 5 calendar days, or less as
22 determined by the Secretary, after such an appeal is
23 filed, unless the parties jointly agree to an extension.
24 After affording an opportunity for an informal hear-
25 ing, the Secretary shall determine whether the order

1 should be amended pursuant to subsection (d)(1). If,
2 after providing an opportunity for such a hearing,
3 the Secretary determines that inadequate grounds
4 exist to support the actions required by the order,
5 the Secretary shall vacate the order.

6 “(c) NOTICE TO CONSUMERS AND HEALTH OFFI-
7 CIALS.—The Secretary shall, as the Secretary determines
8 to be necessary, provide notice of a recall order under this
9 section to—

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

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

13 “(d) ORDER TO RECALL.—

14 “(1) AMENDMENT.—Except as provided under
15 subsection (e), if after providing an opportunity for
16 an informal hearing under subsection (a) or (b), the
17 Secretary determines that an order issued under
18 subsection (a) or (b) should be amended to include
19 a recall of the drug with respect to which the order
20 was issued, the Secretary shall amend the order to
21 require a recall.

22 “(2) CONTENTS.—An amended order under
23 paragraph (1) shall—

24 “(A) specify a timetable in which the recall
25 will occur;

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

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

6 “(3) ASSISTANCE ALLOWED.—In providing for
7 notice under paragraph (2)(C), 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 “(4) NONDELEGATION.—An amended order
12 under this subsection shall be ordered by the Sec-
13 retary or an official designated by the Secretary. An
14 official may not be so designated under this section
15 unless the official is the director of the district in
16 which the drug involved is located, or is an official
17 senior to such director.

18 “(e) 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), as amended by
6 section 2(b)(C), is further amended by inserting “or (8)
7 in the case of a drug, such drug is subject to an order
8 under section 568 to cease distribution of or recall the
9 drug,” before “then such article shall be refused admis-
10 sion”.

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

17 **SEC. 4. SEIZURE.**

18 Section 304(b) of the Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 334(b)) is amended by striking the
20 first sentence and inserting the following: “The article,
21 equipment, or other thing proceeded against shall be liable
22 to seizure by process pursuant to the libel, and the proce-
23 dure in cases under this section shall conform, as nearly
24 as may be, to the procedure in admiralty rather than the
25 procedure used for civil asset forfeiture proceedings set

1 forth in section 983 of title 18, United States Code. On
2 demand of either party any issue of fact joined in any such
3 a case brought under this section shall be tried by jury.
4 A seizure brought under this section is not governed by
5 Rule G of the Supplemental Rules of Admiralty or Mari-
6 time Claims and Asset Forfeiture Actions. Exigent cir-
7 cumstances shall be deemed to exist for all seizures
8 brought under this section, and in such cases, the sum-
9 mons and arrest warrant shall be issued by the clerk of
10 the court without court review.”.

11 **SEC. 5. SINGLE SOURCE PATTERN OF SHIPMENTS OF ADUL-**
12 **TERATED OR MISBRANDED DRUGS.**

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

15 “(u) SINGLE SOURCE PATTERN OF SHIPMENTS OF
16 ADULTERATED OR MISBRANDED DRUGS.—If the Sec-
17 retary identifies a pattern of adulterated or misbranded
18 drugs being offered for import from the same manufac-
19 turer, distributor, or importer, the Secretary may by order
20 choose to treat all drugs being offered for import from
21 such manufacturer, distributor, or importer as adulterated
22 or misbranded unless otherwise demonstrated.”.

1 **SEC. 6. DEBARRING VIOLATIVE INDIVIDUALS OR COMPA-**
2 **NIES.**

3 (a) PROHIBITED ACT.—Section 301(cc) of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331(cc))
5 is amended to read as follows:

6 “(cc) The importing or offering for import into the
7 United States of an article by, with the assistance of, or
8 at the direction of, a person debarred from such activity
9 under section 306(b)(3).”.

10 (b) DEBARMENT.—Section 306(b) of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)) is
12 amended—

13 (1) in paragraph (1)—

14 (A) in the matter preceding subparagraph
15 (A), by striking “paragraph (2)” and inserting
16 “paragraph (2) or (3)”;

17 (B) in subparagraph (B), by striking “or”
18 at the end;

19 (C) in subparagraph (C), by striking the
20 period at the end and inserting “, or”; and

21 (D) by adding at the end the following:

22 “(D) a person from importing or offering
23 to import into the United States—

24 “(i) a controlled substance as defined
25 in section 102(6) of the Controlled Sub-
26 stances Act; or

1 “(ii) any article that is regulated by
2 the Food and Drug Administration that is
3 valued at \$2500 or less (or such higher
4 amount as the Secretary of the Treasury
5 may set by regulation pursuant to section
6 498(a)(1) of the Tariff Act of 1930).”; and

7 (2) by striking paragraph (3) and inserting the
8 following:

9 “(3) PERSONS SUBJECT TO PERMISSIVE DE-
10 BARMENT; IMPORTATION.—

11 “(A) FOOD.—A person is subject to debar-
12 ment under paragraph (1)(C) if—

13 “(i) the person has been convicted of
14 a felony for conduct relating to the impor-
15 tation into the United States of any food;
16 or

17 “(ii) the person has engaged in a pat-
18 tern of importing or offering for import
19 adulterated food that presents a threat of
20 serious adverse health consequences or
21 death to humans or animals.

22 “(B) IMPORTATION OF DRUGS.—A person
23 is subject to debarment under paragraph (1)(D)
24 if—

1 “(i) the person has been convicted of
2 a felony for conduct relating to the impor-
3 tation into the United States of any drug
4 or controlled substance (as defined in sec-
5 tion 102 of the Controlled Substances
6 Act); or

7 “(ii) the person has engaged in a pat-
8 tern of importing or offering for import
9 drugs that are—

10 “(I) adulterated, misbranded, or
11 in violation of section 505; or

12 “(II) controlled substances whose
13 importation is prohibited pursuant to
14 section 401(m) of the Tariff Act of
15 1930.”.

16 **SEC. 7. ACCOUNT TO STRENGTHEN EFFORTS OF FDA TO**
17 **COMBAT THE OPIOID AND SUBSTANCE USE**
18 **EPIDEMIC.**

19 (a) IN GENERAL.—The Commissioner of Food and
20 Drugs (referred to in this section as the “Commissioner”)
21 shall use any funds appropriated pursuant to the author-
22 ization of appropriations under subsection (c) to carry out
23 the programs and activities described in subsection (d) to
24 strengthen and facilitate the Food and Drug Administra-
25 tion’s efforts to address the opioid and substance use epi-

1 demic. Such funds shall be in addition to any funds which
2 are otherwise available to carry out such programs and
3 activities.

4 (b) FDA OPIOID AND SUBSTANCE USE EPIDEMIC
5 RESPONSE FUND.—

6 (1) ESTABLISHMENT OF FUND.—There is es-
7 tablished in the Treasury an account, to be known
8 as the FDA Opioid and Substance Use Epidemic
9 Response Fund (referred to in this subsection as the
10 “Fund”), for purposes of funding the programs and
11 activities described in subsection (d).

12 (2) TRANSFER.—For the period of fiscal years
13 2019 through 2023, \$110,000,000 shall be trans-
14 ferred to the Fund from the general fund of the
15 Treasury.

16 (3) AMOUNTS DEPOSITED.—Any amounts
17 transferred under paragraph (2) shall remain un-
18 available in the Fund until such amounts are appro-
19 priated pursuant to subsection (c).

20 (c) APPROPRIATIONS.—

21 (1) AUTHORIZATION OF APPROPRIATIONS.—For
22 the period of fiscal years 2019 through 2023, there
23 is authorized to be appropriated from the Account to
24 the Food and Drug Administration, for the purpose
25 of carrying out the programs and activities described

1 in subsection (d), an amount not to exceed the total
2 amount transferred to the Account under subsection
3 (b)(2). Notwithstanding subsection (g), such funds
4 shall remain available until expended.

5 (2) OFFSETTING FUTURE APPROPRIATIONS.—

6 For any of fiscal years 2019 through 2023, for any
7 discretionary appropriation out of the Account to the
8 Food and Drug Administration pursuant to the au-
9 thorization of appropriations under paragraph (1)
10 for the purpose of carrying out the programs and
11 activities described in subsection (d), the total
12 amount of such appropriations for the applicable fis-
13 cal year (not to exceed the total amount remaining
14 in the Account) shall be subtracted from the esti-
15 mate of discretionary budget authority and the re-
16 sulting outlays for any estimate under the Congres-
17 sional Budget and Impoundment Control Act of
18 1974 or the Balanced Budget and Emergency Def-
19 icit Control Act of 1985, and the amount transferred
20 to the Account shall be reduced by the same
21 amount.

22 (d) FOOD AND DRUG ADMINISTRATION.—The en-
23 tirety of the funds made available pursuant to subsection
24 (c)(1) shall be for the Commissioner of Food and Drugs,
25 pursuant to applicable authorities in the Public Health

1 Service Act (42 U.S.C. 201 et seq.) or the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and other
3 applicable law, to support widespread innovation in non-
4 opioid and non-addictive medical products for pain treat-
5 ment, access to opioid addiction treatments, appropriate
6 use of approved opioids, and efforts to reduce illicit impor-
7 tation of opioids. Such support may include the following
8 programs and activities:

9 (1) Obligating contract funds beginning in fis-
10 cal year 2019 for an educational campaign that
11 will—

12 (A) educate patients and their families to
13 differentiate opioid medications;

14 (B) raise awareness about preferred stor-
15 age and disposal methods; and

16 (C) inform patients, families, and commu-
17 nities about medication-assisted treatment op-
18 tions.

19 (2) Building the Food and Drug Administra-
20 tion's presence in international mail facilities, includ-
21 ing through—

22 (A) improvements in equipment and infor-
23 mation technology enhancements to identify un-
24 approved, counterfeit, or other unlawful phar-
25 maceuticals for destruction;

1 (B) increased and improved surveillance;

2 (C) renovations at international mail facil-
3 ity locations; and

4 (D) the purchase of laboratory equipment.

5 (3) Enhancing the identification and targeting
6 of firms and products being offered for import into
7 the United States through review and analysis of
8 websites, imports data, and other sources of intel-
9 ligence thereby making best use of the Food and
10 Drug Administration's inspectional and analytical
11 resources.

12 (4) Increasing the number of staff to increase
13 the number of packages being examined, ensuring
14 the safety of the staff undertaking this work, and
15 ensuring that packages identified as illegal, counter-
16 feit, misbranded, or adulterated are removed from
17 commerce through available authorities, including
18 administrative destruction.

19 (5) Enhancing criminal investigations resources
20 (including full-time equivalent employees and equip-
21 ment), imports surveillance, and international work.

22 (6) Obtaining equipment and full-time equiva-
23 lent employees needed to efficiently screen and ana-
24 lyze products offered for import, including by build-
25 ing data libraries of new substances and analogues

1 to facilitate identification and evaluation of pharma-
2 ceutical-based agents and by purchasing screening
3 technologies for use at international mail facilities.

4 (7) Operating the Food and Drug Administra-
5 tion's forensic laboratory facility to ensure adequate
6 laboratory space and functionality for additional
7 work and full-time equivalent employees.

8 (e) ACCOUNTABILITY AND OVERSIGHT.—

9 (1) WORK PLAN.—

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

22 (B) CONTENTS.—The work plan submitted
23 under subparagraph (A) shall include—

24 (i) the amount of money to be obli-
25 gated or expended out of the Account in

each fiscal year for each program and activity described in subsection (d); and

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

(2) REPORTS.—

(A) ANNUAL REPORTS.—Not later than October 1 of each of fiscal years 2020 through 2024, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report including—

(i) the amount of money obligated or expended out of the Account in the prior fiscal year for each program and activity described in subsection (d);

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

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

(B) ADDITIONAL REPORTS.—At the request of the Committee on Health, Education,

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

10 (f) LIMITATIONS.—Notwithstanding any transfer au-
11 thority authorized by this Act or any appropriations Act,
12 any funds made available pursuant to the authorization
13 of appropriations under subsection (c) may not be used
14 for any purpose other than the programs and activities
15 described in subsection (d) strengthen and facilitate the
16 Food and Drug Administration’s efforts to address the
17 opioid and substance use epidemic.

18 (g) SUNSET.—This section shall expire on September
19 30, 2022, except that—

20 (1) this subsection does not apply to reporting
21 under subsection (e)(2); and

22 (2) this section shall remain in effect until such
23 time, and to such extent, as may be necessary for

- 1 the funds transferred by subsection (b)(2) to be fully
- 2 expended.

