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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

(b) TABLE OF CONTENTS.—The table of contents of 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.

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

(a) INCREASING THE MAXIMUM DOLLAR AMOUNT OF DRUGS SUBJECT TO DESTRUCTION.—The sixth sentence in section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended by striking ''except that the Secretary'' and all that follows through the two periods at the end and inserting ''except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug refused admission under this section, if such drug is declared to be valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 498(a)(1) of the Tariff Act of 1930 or such higher amount as the Commissioner of Food

and Drugs may set based on a finding by the Commissioner that the higher amount is in the interest of public health), or if such drug is entering the United States by mail, and was not brought into compliance as described under subsection (b).''.

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

(c) TECHNICAL AMENDMENTS.—The seventh, eighth, and ninth sentences of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) are amended—

(1) by striking ''a drug'' each place it appears and inserting ''an article''; and

(2) by striking ''the drug'' each place it appears and inserting ''the article''.

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

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

SEC. 3. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUG PRODUCTS.

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

''(eee) The failure to comply with any order issued under section 569D.''.

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

''SEC. 569D. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUGS.

''(a) ORDER TO CEASE DISTRIBUTION AND RECALL.—

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

the public health, the Secretary shall issue an order requiring any person who distributes the drug to immediately cease distribution of the drug.

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

''(A) the actions required by the order; and

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

''(3) INADEQUATE GROUNDS.—If, after providing an opportunity for a hearing under paragraph (2), the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

''(4) AMENDMENT TO ORDER TO REQUIRE RECALL.—If, after providing an opportunity for an informal hearing under paragraph (2), the Secretary determines that the order should be amended to include a recall of the drug with respect to which the order was issued, the Secretary shall—

''(A) amend the order to require a recall; and

''(B) after consultation with the drug sponsor, specify a timetable in which the recall will occur.

''(5) NOTICE TO PERSONS AFFECTED.—An order under this subsection shall require any person who distributes the drug to provide for notice, including to individuals as appropriate, to persons who may be affected by the order to cease distribution of or recall the drug, as applicable.

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

''(b) NOTICE TO CONSUMERS AND HEALTH OFFICIALS.—The Secretary shall, as the Secretary determines to be necessary, provide notice of a recall order under this section to—

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

''(2) appropriate State and local health officials.

''(c) ORDER TO RECALL.—

''(1) CONTENTS.—An order to recall a drug under subsection (a) shall—

''(A) require periodic reports to the Secretary describing the progress of the recall; and

''(B) provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

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

''(3) NONDELEGATION.—An order under this section shall be ordered by the Secretary or an official designated by the Secretary. An official may not be so designated under this section unless the official is the Director of the Center for Drug Evaluation and Research, is an official senior to such Director, or is so designated by such Director.

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

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

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

drug subject to this Act or the Public Health Service Act.''.

(c) DRUGS SUBJECT TO REFUSAL.—The third sentence of subsection (a) of section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by inserting ''or (5) in the case of a drug, such drug is subject to an order under section 568 to cease distribution of or recall the drug,'' before ''then such article shall be refused admission''.

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

SEC. 4. SINGLE SOURCE PATTERN OF SHIPMENTS OF ADULTERATED OR MISBRANDED DRUGS.

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

''(t) SINGLE SOURCE PATTERN OF SHIPMENTS OF ADULTERATED OR MISBRANDED DRUGS.—If the Secretary identifies a pattern of adulterated or misbranded drugs being offered for import from the same manufacturer, distributor, or importer, the Secretary may by order choose to treat all drugs being offered for import from

such manufacturer, distributor, or importer as adulterated or misbranded unless otherwise demonstrated.''.

SEC. 5. FUND TO STRENGTHEN EFFORTS OF FDA TO COMBAT THE OPIOID AND SUBSTANCE USE EPIDEMIC.

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

''SEC. 1015. FUND TO STRENGTHEN EFFORTS OF FDA TO COMBAT THE OPIOID AND SUBSTANCE USE EPIDEMIC.

''(a) IN GENERAL.—The Commissioner of Food and Drugs shall use any funds appropriated pursuant to the authorization of appropriations under subsection (c) to carry out the programs and activities described in subsection (d) to strengthen and facilitate the Food and Drug Administration's efforts to address the opioid and substance use epidemic. Such funds shall be in addition to any funds which are otherwise available to carry out such programs and activities.

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

''(1) ESTABLISHMENT OF FUND.—There is established in the Treasury a fund, to be known as the FDA Opioid and Substance Use Epidemic Response

Fund (referred to in this subsection as the 'Fund'), for purposes of funding the programs and activities described in subsection (d).

''(2) TRANSFER.—For the period of fiscal years 2019 through 2023, $110,000,000 shall be transferred to the Fund from the general fund of the Treasury.

''(3) AMOUNTS DEPOSITED.—Any amounts transferred under paragraph (2) shall remain unavailable in the Fund until such amounts are appropriated pursuant to subsection (c).

''(c) APPROPRIATIONS.—

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

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

thorization of appropriations under paragraph (1) for the purpose of carrying out the programs and activities described in subsection (d), the total amount of such appropriations for the applicable fiscal year (not to exceed the total amount remaining in the Fund) shall be subtracted from the estimate of discretionary budget authority and the resulting outlays for any estimate under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985, and the amount transferred to the Fund shall be reduced by the same amount.

''(d) FOOD AND DRUG ADMINISTRATION.—The entirety of the funds made available pursuant to subsection (c)(1) shall be for the Commissioner of Food and Drugs, pursuant to applicable authorities in the Public Health Service Act (42 U.S.C. 201 et seq.) or this Act and other applicable Federal law, to support widespread innovation in non-opioid and non-addictive medical products for pain treatment, access to opioid addiction treatments, appropriate use of approved opioids, and efforts to reduce illicit importation of opioids. Such support may include the following programs and activities:

''(1) Obligating contract funds beginning in fiscal year 2019 for an educational campaign that will—

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

''(B) raise awareness about preferred storage and disposal methods; and

''(C) inform patients, families, and communities about medication-assisted treatment options.

''(2) Building the Food and Drug Administration's presence in international mail facilities, including through—

''(A) improvements in equipment and information technology enhancements to identify unapproved, counterfeit, or other unlawful pharmaceuticals for destruction;

''(B) increased and improved surveillance;

''(C) renovations at international mail facility locations; and

''(D) the purchase of laboratory equipment.

''(3) Enhancing the identification and targeting of entities offering products and products being offered by such entities for import into the United

States through review and analysis of Internet websites, import data, and other sources of intelligence for purposes of making the best use of the Food and Drug Administration's inspection and analytical resources.

''(4) Increasing the number of staff of the Food and Drug Administration to increase the number of packages being examined, ensuring the safety of the staff undertaking such examinations, and ensuring that packages identified as illegal, counterfeit, misbranded, or adulterated are removed from commerce through available authorities, including administrative destruction.

''(5) Enhancing the Food and Drug Administration's criminal investigations resources (including full-time equivalent employees and equipment), imports surveillance, and international work.

''(6) Obtaining for the Food and Drug Administration equipment and full-time equivalent employees needed to efficiently screen and analyze products offered for import, including by building data libraries of new substances and analogues to facilitate identification and evaluation of pharmaceutical-based agents and by purchasing screening technologies for use at international mail facilities.

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

''(e) ACCOUNTABILITY AND OVERSIGHT.—

''(1) WORK PLAN.—

''(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Commissioner of Food and Drugs 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 work plan including the proposed allocation of funds appropriated pursuant to the authorization of appropriations under subsection (c) for each of fiscal years 2019 through 2023 and the contents described in subparagraph (B).

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

''(i) the amount of money to be obligated or expended out of the Fund 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 that includes—

"(i) the amount of money obligated or expended out of the Fund 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, Labor and Pensions of the Senate or the Committee on Energy and Commerce of the House

of Representatives, the Commissioner shall provide an update in the form of testimony and any additional reports to the respective congressional committee regarding the allocation of funding under this section or the description of the programs and activities undertaken with such funding.

''(f) LIMITATIONS.—Notwithstanding any transfer authority authorized by this section or any appropriations Act, any funds made available pursuant to the authorization of appropriations under subsection (c) may not be used for any purpose other than the programs and activities described in subsection (d) to strengthen and facilitate the Food and Drug Administration's efforts to address the opioid and substance use epidemic.

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

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

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

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

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

(1) in the first sentence—

(A) by striking ''or (7)'' and inserting ''(7)''; and

(B) by inserting ''or (8) if the drug is or contains a controlled substance for which a listing in any schedule is in effect under the Controlled Substances Act or that is permanently scheduled pursuant to section 201 of such Act, on the basis of information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, the drug is unsafe for use due to the risks of abuse or misuse or there is insufficient information to show that the drug is safe for use considering such risks;'' before ''he shall issue an order refusing to approve the application''; and

(2) in the second sentence, by striking ''(6)'' and inserting ''(8)''.

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

(1) by striking ''or (5)'' and inserting ''(5)''; and

(2) by inserting the following: ''; or (6) that, in the case of a drug that is or contains a controlled substance for which a listing in any schedule is in effect under the Controlled Substances Act or that is permanently scheduled pursuant to section 201 of such Act, on the basis of new information before him with respect to such drug, evaluated together with the information available to him when the application was approved, that the drug is unsafe for use due to the risks of abuse or misuse'' after ''of a material fact''.

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

Cosmetic Act (21 U.S.C. 355(d)) or paragraphs (1) and (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.