AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 5228
OFFERED BY MR. PALLONE OF NEW JERSEY

Strike all after the enacting clause and insert the following:

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. 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 Sec-
retary 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 (c), 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 RE-
CALL OF ADULTERATED OR MISBRANDED
DRUGS.

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

“(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 im-
mediately 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 pro-
viding 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 RE-
call.—If, after providing an opportunity for an in-

formal hearing under paragraph (2), the Secretary
determines that the order should be amended to in-
clude 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, in-
cluding 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 OFFI-
CIALS.—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.”.

(e) 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:
“(u) **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:

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“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
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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 es-
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 trans-
ferred to the Fund from the general fund of the
Treasury.

“(3) AMOUNTS DEPOSITED.—Any amounts
transferred under paragraph (2) shall remain un-
available in the Fund until such amounts are appro-
priated 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 authorization 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, appro-
priate use of approved opioids, and efforts to reduce illicit
importation of opioids. Such support may include the fol-
lowing programs and activities:

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

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

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

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

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

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

“(B) increased and improved surveillance;

“(C) renovations at international mail fa-
cility locations; and
“(D) the purchase of laboratory equip-

ment.

“(3) Enhancing the identification and targeting

of entities offering products and products being of-

fered by such entities for import into the United

States through review and analysis of Internet

websites, import data, and other sources of intel-

ligence for purposes of making the best use of the

Food and Drug Administration’s inspection and ana-

lytical 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, mis-

branded, or adulterated are removed from commerce

through available authorities, including administra-

tive destruction.

“(5) Enhancing the Food and Drug Adminis-

tration’s criminal investigations resources (including

full-time equivalent employees and equipment), im-

ports surveillance, and international work.

“(6) Obtaining for the Food and Drug Admin-

istration equipment and full-time equivalent employ-

ees needed to efficiently screen and analyze products
offered for import, including by building data librarians 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.”.