AMENDMENT TO H.R. 5228

OFFERED BY MR. PALLONE OF NEW JERSEY

Page 2, strike line 5 and all that follows through page 6, line 14.

Page 6, line 23, strike ''is valued'' and insert ''is declared to be valued''.

Page 7, line 4, strike ''public health)'' and insert ''public health), or if such drug is entering the United States by mail,''.

Page 8, line 25, strike ''cause serious adverse health'' and all that follows through ''humans,'' on page 9, line 1 and insert the following: ''present an imminent or serious hazard to the public health,''.

Page 10, line 5, strike ''threat of'' and all that follows through ''humans,'' on line 6 and insert the following: ''or substantial hazard to the public health,''.

Page 12, strike lines 15 through 17 and insert the following: ''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.''.

Page 13, strike line 17 and all that follows through page 14, line 10.

Page 15, strike line 1 and all that follows through page 17, line 15.

Page 17, strike line 16 and all that follows through page 25, line 2 and insert the following:

SEC. 7. 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 sub-

section (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, 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.''.

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