

for these substance abuse services in America's emergency rooms far exceeds their availability. Treatment is particularly scarce in rural counties, in spite of having an average overdose rate that is 45 percent higher than more urban areas.

In March, the Centers for Disease Control reported that the emergency room visits for opioid overdoses had risen 30 percent since July of 2016, in less than 2 years, a 30 percent increase.

That is why I am honored to be joined by Congressman DOYLE in introducing this bipartisan act, also known as the POWER Act. This legislation will provide competitive grants to ensure that overdose patients receive the treatment they need while still in the emergency room, giving them a better shot at recovery. This bill, hopefully, is intended to reduce repeat overdoses and thereby save lives.

I want to thank the cosponsor of this bill, Mr. DOYLE, and particularly our chairman, Mr. WALDEN, for their work on this important issue. I urge my colleagues to support this legislation.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

I rise in support of H.R. 5176, Preventing Overdoses While in Emergency Rooms Act. This legislation would provide grant funding for emergency departments to develop protocols for treating and discharging patients who have presented with an opioid overdose or are at increased risk for overdose.

These protocols will help increase the uptake of evidence-based treatment services by promoting the initiation of medication-assisted treatment in emergency departments, as well as referral to community-based providers for treatment and recovery support services.

This is particularly important since an individual's willingness to seek substance use disorder treatment often increases immediately following a nonfatal overdose.

The protocols also will help reduce the risk of future fatal overdoses by such individuals by requiring the provision of naloxone at discharge. This helps ensure that these individuals at high risk of overdose have this life-saving drug available if it is needed to reverse a potentially fatal overdose.

So I urge my colleagues to support this legislation, and I yield back the balance of my time.

Mr. WALDEN. Mr. Speaker, I just want to, again, thank our leaders on this effort, Mr. DOYLE and certainly Mr. MCKINLEY. I would encourage passage of the bill, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. FRANCIS ROONEY of Florida). The question is on the motion offered by the gentleman from Oregon (Mr. WALDEN) that the House suspend the rules and pass the bill, H.R. 5176, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

STOP COUNTERFEIT DRUGS BY REGULATING AND ENHANCING ENFORCEMENT NOW ACT

Mr. WALDEN. Mr. Speaker, I move to suspend the rules and pass the bill (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, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5228

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 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.”.

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)).

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Oregon (Mr. WALDEN) and the gentleman from New Jersey (Mr. PALLONE) each will control 20 minutes.

The Chair recognizes the gentleman from Oregon.

GENERAL LEAVE

Mr. WALDEN. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and insert extraneous materials in the RECORD on the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Oregon?

There was no objection.

Mr. WALDEN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise to speak in support of this legislation, and I want to

commend my friend and ranking member of the Energy and Commerce Committee, Representative FRANK PALLONE of New Jersey. He has worked tirelessly on this very important policy.

Hundreds of millions of parcels containing illicit or unapproved drugs enter the United States supply chain each year, and they do it through international mail facilities. Through the mail, Mr. Speaker.

That poses a major threat to public health. These parcels are often difficult to identify as they contain little or no labeling, and the Food and Drug Administration's current detention and destruction authorities over these parcels, turns out, it is pretty limited.

H.R. 5228 seeks to strengthen FDA's authority to refuse and destroy substances identified through these international mail facilities and improve enforcement mechanisms available to the agency to combat the influx of illegally manufactured opioids into the country.

I know, in my conversations with Dr. Scott Gottlieb, who heads the FDA, he has added the resources he could find within his agency and has brought many of these issues to our attention. He has been a real leader on this issue for the Trump administration, and I thank him for his work.

But it is clear this bipartisan legislation that Mr. PALLONE brings to us today is essential as we join together to interdict and stop the flow of illegal drugs into the United States of America.

Mr. Speaker, I encourage passage of this bill, and I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise to voice my strong support for H.R. 5228, legislation that I authored that will strengthen FDA's ability to prevent illicit opioids from coming in through our international mail facilities by providing the agency with additional enforcement authority and financial resources.

In April, Mr. Speaker, I had the opportunity to visit an international mail facility in my home State of New Jersey with the Food and Drug Administration, Customs and Border Patrol, and the U.S. Postal Service, and to see firsthand the problems that these agencies are facing when it comes to illegal, unapproved drugs entering our country through international mail facilities.

FDA staff showed us boxes of pills that had limited labeling, labeling in foreign languages, or no labeling at all, and were sent from unknown and unregistered facilities. FDA staff explained that it takes the agency days to catalog these boxes, identify what products contained inside are legitimate, and identify what products, under current law, the agency can destroy.

FDA then had no other option but to return that box to the sender. This leaves open the possibility that the

sender will just drop the box of illegal pills back in the mail and try to enter the country again through another international mail facility.

The agency also showed me a series of similarly wrapped and marked packages that contained little labeling and were misidentified as gifts. Upon inspection, these packages included bags of drugs, some labeled and some labeled in another language. Again, the agency faced the task of trying to identify if the product was a drug before it could take further action.

Now, the SCREEN Act, the bill before us, which passed the Energy and Commerce Committee by a voice vote, would give FDA authority to act in these situations to stop illicit drugs from entering the marketplace and allow the agency to better target their resources.

Specifically, the SCREEN Act would, first, expand FDA's authority to refuse or destroy illegal drugs; second, provide FDA with the ability to order manufacturers to cease distribution or to recall drugs that pose an imminent or substantial hazard to the public health. Third, it would allow FDA to refuse admission or to destroy bulk shipments of drugs from manufacturers, distributors, or importers, if they are found to be misbranded or adulterated. Then it would authorize new resources to help provide additional capacity at international mail facilities and to upgrade infrastructure, equipment, and other needed technology for screening purposes.

Mr. Speaker, having worked closely with FDA on this legislation, I know that the authorities outlined in the SCREEN Act will go a long way toward empowering the agency to take on repeated illicit drug traffickers and ensure that dangerous, unapproved drugs are stopped at our ports and at our mail facilities.

I urge my colleagues to vote in support of this bill, and I reserve the balance of my time.

Mr. WALDEN. Mr. Speaker, I yield myself such time as I may consume. I just want to again say, as my friend and colleague from New Jersey has outlined, you understand the importance of why we need to make these changes under the law. I again commend him for his work on this.

I encourage all my colleagues to support this very critical piece of legislation. This could do more to stop the flow of this illegal fentanyl and the death it brings to our country than any other thing we can do.

I commend the gentleman for his work on this. I encourage support of the bill, and I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I have no additional speakers. I urge my colleagues to support the bill, and I yield back the balance of my time.

Ms. JACKSON LEE. Mr. Speaker, I rise in strong support of H.R. 5228, the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, or the SCREEN Act.

Mr. Speaker, one way the nation can express its concern for our citizens' health is by addressing the issue regarding counterfeit drugs and synthetic opioids.

Among other things, H.R. 5228 will strengthen the ability of the Food and Drug Administration to combat counterfeit drugs, illegal and synthetic opioids, and opioid-like substances.

Because the capabilities of counterfeit drugs and opioids are rapidly and continuously evolving, there is no "single" technology that provides long-term assurance of drug security.

H.R. 5228 will implement new, holistic technology to better protect our drug supply.

Opioids are a class of drugs that include the illegal drug heroin.

All opioids are chemically related and interact with opioid receptors on nerve cells in the body and brain.

According to a recent study, Centers for Disease Control and Prevention (CDC) report there were 63,632 drug overdose deaths in 2016 in America, 42,249 of which were related to opioid overdoses.

This issue directly affects my state of Texas, because in 2016, there were 1,375 opioid-related overdose deaths, according to the National Institute on Drug Abuse.

In the city of Houston alone, there were 364 drug-related overdose deaths.

Another issue that H.R. 5228 will address is the prevalence of counterfeits, or fake medicines which are produced and sold with the intent to deceptively represent its authenticity or effectiveness.

Fake medicine may contain harmful or inactive ingredients that harm users, or might have the right active ingredient but at the wrong dosage.

Counterfeit drugs are illegal and can be harmful to your health.

Mr. Speaker, critics of the FDA say the entire screening system is underutilized and filled with incomplete and late information.

By enacting H.R. 5228, the FDA will have the authority to combat the scourge of opioids and counterfeit drugs.

I urge my colleagues to join me in supporting H.R. 5228.

Mr. GENE GREEN of Texas. Mr. Speaker, I rise in support of H.R. 5228, the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, or SCREEN Act.

I am proud to champion an important provision that was added to the SCREEN Act during the Energy and Commerce Committee's markup that clarifies the U.S. Food and Drug Administration's authority to consider the potential for misuse and abuse as part of the approval process.

In March, the Health Subcommittee received testimony from FDA Commissioner Scott Gottlieb that opioid misuse and abuse is one of the agency's highest priorities.

Last year, the FDA acted when it requested the withdrawal of the opioid pain medication Opana ER, finding, "the benefits of the drug may no longer outweigh its risks."

Clarifying the FDA's authority to examine the potential risks for abuse and misuse as a consideration in the approval process is an important step in combatting the opioid crisis.

I thank our committee's chairman, GREG WALDEN, and our Ranking Member, FRANK PALLONE, for supporting the inclusion of this important provision.

I ask my colleagues to join me in supporting the underlining bill, which will strengthen the

FDA's authority to stop and destroy illicit substances identified through international mail facilities, and my misuse and abuse language which will help protect Americans from opioid and substance use abuse.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Oregon (Mr. WALDEN) that the House suspend the rules and pass the bill, H.R. 5228, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

TREATMENT, EDUCATION, AND COMMUNITY HELP TO COMBAT ADDICTION ACT OF 2018

Mr. WALDEN. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5261) to amend the Public Health Service Act to provide for regional centers of excellence in substance use disorder education, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5261

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "Treatment, Education, and Community Help to Combat Addiction Act of 2018" or the "TEACH to Combat Addiction Act of 2018".

SEC. 2. ESTABLISHMENT OF REGIONAL CENTERS OF EXCELLENCE IN SUBSTANCE USE DISORDER EDUCATION.

Part D of title V of the Public Health Service Act is amended by inserting after section 549 (42 U.S.C. 290ee-4) the following new section:

"SEC. 550. REGIONAL CENTERS OF EXCELLENCE IN SUBSTANCE USE DISORDER EDUCATION.

"(a) IN GENERAL.—The Secretary, in consultation with such other agencies as are appropriate, shall, subject to the availability of appropriations, establish a solicitation process and award cooperative agreements to eligible entities for the designation of such entities as Regional Centers of Excellence in Substance Use Disorder Education and support of such regional centers of excellence to enhance and improve how health professionals are educated in substance use disorder prevention, treatment, and recovery through development, evaluation, and distribution of evidence-based curricula for health profession schools. An eligible entity designated by the Secretary as a Regional Center of Excellence in Substance Use Disorder Education shall carry out the activities described in subsection (b).

"(b) SELECTION OF CENTERS OF EXCELLENCE.—

"(1) ELIGIBLE ENTITIES.—To be eligible to receive a cooperative agreement under subsection (a), an entity shall—

"(A) be an entity specified by the Secretary that offers education to students in various health professions, which may include—

"(i) a health system;

"(ii) a teaching hospital;

"(iii) a medical school;

"(iv) a certified behavioral health clinic; or

"(v) any other health profession school, school of public health, or Cooperative Ex-

tension Program at institutions of higher education engaged in an aspect of the prevention, treatment, or recovery of substance use disorders;

"(B) be accredited by the appropriate educational accreditation body;

"(C) demonstrate an existing strategy, and have in place a plan for continuing such strategy, or a proposed strategy to implement a curriculum based on best practices for substance use disorder prevention, treatment, and recovery;

"(D) demonstrate community engagement and participation through community partners, including other health profession schools, mental health counselors, social workers, peer recovery specialists, substance use treatment programs, community health centers, physicians' offices, certified behavioral health clinics, law enforcement, and the business community; and

"(E) provide to the Secretary such information, at such time, and in such manner, as the Secretary may require.

"(2) DIVERSITY.—In awarding cooperative agreements under subsection (a), the Secretary shall take into account regional differences among eligible entities and shall make an effort to ensure geographic diversity.

"(c) DISSEMINATION OF INFORMATION.—

"(1) PUBLIC POSTING.—The Secretary shall make information provided to the Secretary under subsection (b)(1)(E) publicly available on the Internet website of the Department of Health and Human Services.

"(2) EVALUATION.—The Secretary shall evaluate each project carried out by a Regional Center of Excellence in Substance Use Disorder Education under this section and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

"(d) FUNDING.—There is authorized to be appropriated to carry out this section, \$4,000,000 for each of fiscal years 2019 through 2023."

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Oregon (Mr. WALDEN) and the gentleman from New Jersey (Mr. PALLONE) each will control 20 minutes.

The Chair recognizes the gentleman from Oregon.

□ 1615

GENERAL LEAVE

Mr. WALDEN. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days to revise and extend their remarks and insert extraneous materials in the RECORD on the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Oregon?

There was no objection.

Mr. WALDEN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today to express my strong support for H.R. 5261. This is the Treatment, Education, and Community Help to Combat Addiction Act, or more easily known as the TEACH to Combat Addiction Act. This legislation will designate and support centers of excellence or institutions of learning that have championed substance use disorder treatment.

Improving how professionals are taught to effectively teach substance use disorder will also increase access to evidence-based treatment, in other