The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 5668, 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.

FAIRNESS IN ORPHAN DRUG EXCLUSIVITY ACT

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4712) to amend the Federal Food, Drug, and Cosmetic Act with respect to limitations on exclusive approval or licensure of orphan drugs, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 4712

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 ''Fairness in Orphan Drug Exclusivity Act''.

SEC. 2. LIMITATIONS ON EXCLUSIVE APPROVAL OR LICENSURE OF ORPHAN DRUGS.

(a) IN GENERAL.—Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

(1) in subsection (a), by striking ''Except as provided in subsection (b)'' and inserting ''Except as provided in subsection (b) or (f)''; and

(2) by adding at the end the following:

''(f) LIMITATIONS ON EXCLUSIVE APPROVAL, CERTIFICATION, OR LICENSE.—

''(1) IN GENERAL.—For a drug designated under section 526 for a rare disease or condition pursuant to the criteria set forth in subsection (a)(2)(B) of such section, the Secretary shall not grant, recognize, or apply exclusive approval or licensure under subsection (a), and, if such exclusive approval or licensure has been granted, recognized, or applied, shall revoke such exclusive approval or licensure, unless the sponsor of the application for such drug demonstrates—

''(A) with respect to an application approved or a license issued after the date of enactment of this subsection, upon such approval or issuance, that there is no reasonable expectation at the time of such approval or issuance that the cost of developing and making available in the United States such drug for such disease or condition will be recovered from sales in the United States of such drug, taking into account all sales made or reasonably expected to be made within 12 years of first marketing the drug; or

''(B) with respect to an application approved or a license issued on or prior to the date of enactment of this subsection, not later than 60 days after such date of enactment, that there was no reasonable expectation at the time of such approval or issuance that the cost of developing and making available in the United States such drug for such disease or condition would be recovered from sales in the United States of such drug, taking into account all sales made or reasonably expected to be made within 12 years of first marketing the drug.

''(2) CONSIDERATIONS.—For purposes of subparagraphs (A) and (B) of paragraph (1), the Secretary and the sponsor of the application for the drug designated for a rare disease or condition described in such paragraph shall consider sales from all drugs that—

''(A) are developed or marketed by the same sponsor or manufacturer of the drug (or a licensor, predecessor in interest, or other related entity to the sponsor or manufacturer); and

''(B) are covered by the same designation under section 526.

''(3) CRITERIA.—No drug designated under section 526 for a rare disease or condition pursuant to the criteria set forth in subsection (a)(2)(B) of such section shall be eligible for exclusive approval or licensure under this section unless it met such criteria under such subsection on the date on which the drug was approved or licensed.''.

(b) RULE OF CONSTRUCTION.—The amendments made in subsection (a) shall apply to any drug that has been or is hereafter designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition pursuant to the criteria under subsection (a)(2)(B) of such section regardless of—

(1) the date on which such drug is designated or becomes the subject of a designation request under such section;

(2) the date on which such drug is approved under section 505 of such Act (21 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) or becomes the subject of an application for such approval or licensure; and

(3) the date on which such drug is granted exclusive approval or licensure under section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) or becomes the subject of a request for such exclusive approval or licensure.

SEC. 3. DETERMINATION OF BUDGETARY EFFECTS.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled ''Budgetary Effects of PAYGO Legislation'' for this Act, submitted for printing in the Congressional Record by the Chairman of the House Budget Committee, provided that such statement has been submitted prior to the vote on passage.

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

The Chair recognizes the gentleman from New Jersey.

GENERAL LEAVE

Mr. PALLONE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include any extraneous material on H.R. 4712.

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

There was no objection.

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

Mr. Speaker, today I rise in support of H.R. 4712, the Fairness in Orphan Drug Exclusivity Act, a bill that will close a loophole in the orphan drug program to ensure generic drugs are not unfairly being blocked from entering the market.

Since it was first passed in 1983, the Orphan Drug Act has been successful in driving research and discovery of new therapies to treat and even cure rare diseases. The law creates two pathways for manufacturers to be designated as an orphan drug and to gain certain incentives, including 7 years of market exclusivity.

The first and most commonly used pathway is for developing drugs approved to treat diseases with patient populations of 200,000 or fewer. There is also the rarely used cost-recovery pathway, where the drug research and development costs are not expected to be recouped by sales of the underlying drug.

Now, under certain circumstances, a manufacturer may also receive additional rounds of exclusivity for drugs in their portfolio if they treat the same conditions and have the same active ingredient, even if the second drug does not meet the orphan drug qualifications. This provision has allowed some manufacturers to circumvent the original intent of the Orphan Drug Act, which was to incentivize creation of novel drugs for small populations, all the while blocking generic competitors from coming to market.

An example of this recently occurred when a formulation of Buprenorphine, a drug to treat opioid use disorder, was approved in 2017. It was allowed to carry the orphan drug designation granted to its manufacturer's original Buprenorphine drug more than 20 years earlier, in 1994.

When the original 1994 orphan drug designation was granted, it was expected that Buprenorphine would not be prescribed frequently; however, as the opioid crisis worsened and our response to the crisis evolved, millions were eventually prescribed the drug, generating billions of dollars in sales.

Clearly, we knew in 2017 that Buprenorphine was not an orphan drug. Nevertheless, the drug was granted orphan drug status and exclusivity, delaying additional forms of generic competition. So while the Food and Drug Administration eventually recognized this issue with this particular drug and revoked its orphan drug designation, its exclusivity delayed generic competition that otherwise would have been on the market.

We need every tool available to us to combat the opioid epidemic, and loopholes like this one should not be allowed to limit access to treatment, Mr. Speaker.

H.R. 4712 will stop this from happening again in the future by requiring drug manufacturers to demonstrate in their application to the FDA that each drug application considered under the cost recovery pathway would fail to recoup development costs.

This bill is narrowly tailored. It is a fix for a small but very real loophole in the law, and I want to thank Representative DEAN for introducing the legislation.

Mr. Speaker, I urge all of my colleagues to support it, and I reserve the balance of my time.

□ 1230

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

Mr. Speaker, I too rise in support of H.R. 4712. This is the Fairness in Orphan Drug Exclusivity Act as you have heard. I want to thank Representatives CARTER, MCKINLEY, DEAN, and VEASEY for their work and leadership on this important legislation.

The Orphan Drug Act was enacted to incentivize the development of drugs for rare diseases by providing products that receive an orphan drug designation 7 years of market exclusivity. That means a drug produced by another manufacturer that contains the same active ingredient to treat the same condition is barred from entering the market during this time period.

One way a drug can receive an orphan designation and subsequent marketing exclusivity is by the manufacturer's demonstration that there is no reasonable expectation that the cost of developing the drug will be recovered.

However, we have seen in recent years that some drug manufacturers, in an effort to block competitors from entering the market, have taken advantage of a loophole in this law. Existing law allows an orphan drug designation and marketing exclusivity to carry forward to future versions of the same drug without requiring the manufacturer to demonstrate the drug has not been, and remains unlikely to be, profitable. This legislation closes that loophole. It requires manufacturers to demonstrate there is no reasonable expectation that the costs of research and development will be recovered for each successor drug, while still preserving incentives for orphan drug development.

While disagreements do remain, Mr. Speaker, on whether these amendments should apply retroactively, those differences should not prevent us from addressing this important issue today.

So I look forward to continuing negotiations on these differences as we work with the Senate and get a bill down to the President's desk for signature.

Mr. Speaker, I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to the gentlewoman from Pennsylvania (Ms. DEAN), who is the sponsor of the legislation.

Ms. DEAN. Mr. Speaker, I rise in support of H.R. 4712, the Fairness in Orphan Drug Exclusivity Act.

This legislation would close a current loophole that is used to block competition in the pharmaceutical marketplace. This could deny innovative treatments for opioid use disorder and limit the types of treatments for those in recovery and what they can access.

The Orphan Drug Act of 1983 has provided incentives for prescription drug manufacturers to develop products to treat rare diseases. This includes an exclusive 7-year marketing right for therapies that receive an orphan drug designation.

For a drug to qualify, it must either be a treatment for a disease or condition that affects fewer than 200,000 people in the United States;

Or a drug intended for diseases that there is no reasonable expectation to recoup research and development costs.

For the latter criterion, this legislation would require all drug manufacturers who obtain orphan drug status to prove that they have no reasonable expectation that they will recover their R&D costs. Importantly, this legislation is narrowly tailored and would not affect any product that does receive orphan drug status under the first criterion.

The scenario this legislation works to prevent, as the chairman has said, is companies continuing to use orphan drug exclusivity status for a newly approved drug with an identical ingredient to the former version without having to prove the inability to recoup costs. Closing this loophole would ensure that a product does not receive unfair market advantage and, therefore, remains consistent with the spirit and the intent of the Orphan Drug Act.

In addition, H.R. 4712 clears barriers for innovative medication-assisted treatments, or MATs, coming to market that will help treat those with substance use disorder. Substance use disorder is by no means a rare disease and should not be treated as such. Medication-assisted treatments can and do save lives.

According to the National Institute on Drug Abuse, in 2016 more than 2.1 million Americans were living with opioid use disorder, but just over 17 percent of people received specialty treatment. Medication-assisted treatment is one of those personalized options. We must work to ensure more people can gain access to newer therapies and MAT treatments that are currently blocked due to an orphan designation.

Mr. Speaker, I thank the bipartisan group of legislators who introduced this bill with me: Congressmen BUDDY CARTER, MARC VEASEY, and DAVID MCKINLEY, as well as Chairman PALLONE and Ranking Member BURGESS, for supporting the bill, and passing it unanimously out of the Energy and Commerce Committee.

Mr. Speaker, I urge all Members to support this bill.

Mr. WALDEN. Mr. Speaker, I yield 2 minutes to the gentleman from Georgia (Mr. CARTER), who is one of the coauthors of this very important legislation and who is the only—I think still only—pharmacist in the United States House of Representatives.

Mr. CARTER of Georgia. Mr. Speaker, I thank the gentleman for yielding.

Mr. Speaker, I am grateful for the time today to let me speak on this important legislation, and I thank Congresswoman DEAN for introducing it.

I am glad to be a lead Republican on this bill, as it corrects a loophole in the Orphan Drug Act that has been and very well could be taken advantage of at the expense of the American people's health.

As you know, Mr. Speaker, the Orphan Drug Act provides incentives for drug manufacturers to invest in research to bring innovative drugs to market that may not become profitable or that treat a small portion of the population.

Unfortunately, a loophole exists that allows some drugs to obtain market exclusivity even though they can easily recoup their R&D costs and turn a profit. This exact problem took place in just the past few years when a drug treating opioid abuse disorders got FDA approval—orphan status—and a new 7-year exclusivity period, despite the active ingredient remaining the same, all based on the drug's original 1994 orphan designation. This subsequently blocked a new, innovative opioid abuse drug from coming to market during the opioid epidemic—a drug that would help save lives.

The Orphan Drug Fairness Act would stop some drugs from obtaining exclusivity, in turn allowing more competition and innovation in the marketplace, benefiting consumers' health and lowering costs.

Mr. Speaker, I urge passage of this legislation.

Mr. WALDEN. Mr. Speaker, I do not have any more speakers on my side of the aisle on this matter.

Mr. Speaker, I urge colleagues to approve the bill, and I yield back the balance of my time.

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

Ms. ESHOO. Mr. Speaker, I rise in support of H.R. 4712, the Fairness in Orphan Drug Exclusivity Act. I'm proud to have advanced this bipartisan bill through my Health Subcommittee and I'm proud to support it on the Floor today.

The Fairness in Orphan Drug Exclusivity Act was introduced by Reps. MADELINE DEAN (D–PA), MARC VEASEY (D–TX), BUDDY CARTER (R–GA), and DAVID MCKINLEY (R–WV).

The bill will close a loophole so that orphan drug exclusivity cannot be used to deny access to certain drugs, especially drugs for opioid use disorder.

This is a narrowly drawn bill to fix a technical problem without hurting the original intention of the Orphan Drug Act. It requires drug companies to show that they will not recoup costs each year in order to achieve the orphan drug designation.

I urge my colleagues to support this legislation.

Mr. MCKINLEY. Mr. Speaker, I rise in support of H.R. 4712. Understandably, our nation has focused on COVID, but the opioid epidemic still ravishes across America. During this crisis overdose rates have increased dramatically. In fact, in West Virginia more people have died from drug abuse than from COVID.

We have a duty to our constituents to ensure that all possible treatment options are available. MAT (Medication Assisted Treatment), has been proven to be effective in treating opioid addiction. Yet, drug companies are holding new treatments hostage through a

loophole in the Orphan Drug Act, which was created to encourage drug companies to research treatments for rare diseases.

It was not intended to prevent competition. With millions of Americans suffering from opioid addiction, it is vital we give them and health care providers every option available. The Fairness in Orphan Drug Exclusivity Act will help expand access for those suffering from addiction by making innovative treatments available.

I urge my colleagues to support the passage of H.R. 4712.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 4712, 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.

STATE OPIOID RESPONSE GRANT AUTHORIZATION ACT OF 2020

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 2466) to extend the State Opioid Response Grants program, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 2466

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 ''State Opioid Response Grant Authorization Act of 2020''.

SEC. 2. GRANT PROGRAM FOR STATE AND TRIBAL RESPONSE TO SUBSTANCE USE DISORDERS OF SIGNIFICANCE.

(a) IN GENERAL.—Section 1003 of the 21st Century Cures Act (42 U.S.C. 290ee–3 note) is amended to read as follows:

''SEC. 1003. GRANT PROGRAM FOR STATE AND TRIBAL RESPONSE TO SUBSTANCE USE DISORDERS OF SIGNIFICANCE.

''(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall carry out the grant program described in subsection (b) for purposes of addressing substance use disorders of significance, including opioid and stimulant use disorders, within States, Indian Tribes, and populations served by Tribal organizations and Urban Indian organizations.

''(b) GRANTS PROGRAM.—

''(1) IN GENERAL.—The Secretary shall award grants to States, Indian Tribes, Tribal organizations, and Urban Indian organizations for the purpose of addressing substance use disorders of significance, including opioid and stimulant use disorders, within such States, such Indian Tribes, and populations served by such Tribal organizations and Urban Indian organizations, in accordance with paragraph (2).

''(2) MINIMUM ALLOCATIONS; PREFERENCE.—In awarding grants under paragraph (1), the Secretary shall—

''(A) ensure that each State and the District of Columbia receives not less than $4,000,000; and

''(B) give preference to States, Indian Tribes, Tribal organizations, and Urban Indian organizations whose populations have an incidence or prevalence of opioid use disorders that is substantially higher relative to the populations of other States, Indian Tribes, Tribal organizations, or Urban Indian organizations, as applicable.

''(3) FORMULA METHODOLOGY.—Not less than 15 days before publishing a funding opportunity announcement with respect to grants under this section, the Secretary shall—

''(A) develop a formula methodology to be followed in allocating grant funds awarded under this section among grantees, which includes performance assessments for continuation awards; and

''(B) submit the formula methodology to—

''(I) the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives; and

''(ii) the Committee on Health, Education, Labor and Pensions and the Committee on Appropriations of the Senate.

''(4) USE OF FUNDS.—Grants awarded under this subsection shall be used for carrying out activities that supplement activities pertaining to substance use disorders of significance, including opioid and stimulant use disorders, undertaken by the State agency responsible for administering the substance abuse prevention and treatment block grant under subpart II of part B of title XIX of the Public Health Service Act (42 U.S.C. 300x–21 et seq.), which may include public health-related activities such as the following:

''(A) Implementing prevention activities, and evaluating such activities to identify effective strategies to prevent substance use disorders.

''(B) Establishing or improving prescription drug monitoring programs.

''(C) Training for health care practitioners, such as best practices for prescribing opioids, pain management, recognizing potential cases of substance abuse, referral of patients to treatment programs, preventing diversion of controlled substances, and overdose prevention.

''(D) Supporting access to health care services, including—

''(i) services provided by federally certified opioid treatment programs;

''(ii) outpatient and residential substance use disorder treatment services that utilize medication-assisted treatment, as appropriate; or

''(iii) other appropriate health care providers to treat substance use disorders.

''(E) Recovery support services, including community-based services that include peer supports, address housing needs, and address family issues.

''(F) Other public health-related activities, as the State, Indian Tribe, Tribal organization, or Urban Indian organization determines appropriate, related to addressing substance use disorders within the State, Indian Tribe, Tribal organization, or Urban Tribal organization, including directing resources in accordance with local needs related to substance use disorders.

''(c) ACCOUNTABILITY AND OVERSIGHT.—A State receiving a grant under subsection (b) shall include in reporting related to substance abuse submitted to the Secretary pursuant to section 1942 of the Public Health Service Act (42 U.S.C. 300x–52), a description of—

''(1) the purposes for which the grant funds received by the State under such subsection for the preceding fiscal year were expended and a description of the activities of the State under the grant; and

''(2) the ultimate recipients of amounts provided to the State through the grant.

''(d) LIMITATIONS.—Any funds made available pursuant to subsection (i) shall be subject to the same requirements as substance abuse prevention and treatment programs under titles V and XIX of the Public Health Service Act (42 U.S.C. 290aa et seq., 300w et seq.).

''(e) INDIAN TRIBES, TRIBAL ORGANIZATIONS, AND URBAN INDIAN ORGANIZATIONS.—The Secretary, in consultation with Indian Tribes, Tribal organizations, and Urban Indian organizations, shall identify and establish appropriate mechanisms for Indian Tribes, Tribal organizations, and Urban Indian organizations to demonstrate or report the information as required under subsections (b), (c), and (d).

''(f) REPORT TO CONGRESS.—Not later than September 30, 2022, and biennially thereafter, the Secretary 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, and the Committees on Appropriations of the House of Representatives and the Senate, a report summarizing the information provided to the Secretary in reports made pursuant to subsections (c) and (e), including the purposes for which grant funds are awarded under this section and the activities of such grant recipients.

''(g) TECHNICAL ASSISTANCE.—The Secretary, including through the Tribal Training and Technical Assistance Center of the Substance Abuse and Mental Health Services Administration, shall provide States, Indian Tribes, Tribal organizations, and Urban Indian organizations, as applicable, with technical assistance concerning grant application and submission procedures under this section, award management activities, and enhancing outreach and direct support to rural and underserved communities and providers in addressing substance use disorders.

''(h) DEFINITIONS.—In this section:

''(1) INDIAN TRIBE.—The term 'Indian Tribe' has the meaning given the term 'Indian tribe' in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

''(2) TRIBAL ORGANIZATION.—The term 'Tribal organization' has the meaning given the term 'tribal organization' in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

''(3) URBAN INDIAN ORGANIZATION.—The term 'Urban Indian organization' has the meaning given to that term in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

''(4) STATE.—The term 'State' has the meaning given such term in section 1954(b) of the Public Health Service Act (42 U.S.C. 300x–64(b)).

''(i) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—For purposes of carrying out the grant program under subsection (b), there is authorized to be appropriated $1,585,000,000 for each of fiscal years 2021 through 2026, to remain available until expended.

''(2) FEDERAL ADMINISTRATIVE EXPENSES.—Of the amounts made available for each fiscal year to award grants under subsection (b), the Secretary shall not use more than 2 percent for Federal administrative expenses, training, technical assistance, and evaluation.

''(3) SET ASIDE.—Of the amounts made available for each fiscal year to award grants under subsection (b) for a fiscal year, the Secretary shall—

''(A) award 5 percent to Indian Tribes, Tribal organizations, and Urban Indian organizations; and

''(B) of the remaining amount, set aside up to 15 percent for States with the highest age-adjusted rate of drug overdose death based on the ordinal ranking of States according to the Director of the Centers for Disease Control and Prevention.''.