Energy and Commerce Committee colleagues, MCKINLEY and DINGELL.

This bill addresses an alarming problem that was identified in the Energy and Commerce Committee's 2018 bipartisan investigation into the distribution of prescription opioids by wholesale drug distributors.

The committee found that when millions of prescription opioids were dumped into communities large and small across the country, the distributors flagged the orders for the DEA, but shipped the orders anyway—even after notifying the authorities that the orders were suspicious.

□ 1600

This bill places additional obligations on drug manufacturers and distributors that discover a controlled substance suspicious order.

In addition to reporting the suspicious order to the DEA, H.R. 768 requires the manufacturer or distributor to exercise due diligence, decline to fill the order, and provide information to the DEA on the indicators that led to the belief that filling the order would violate the Controlled Substances Act.

All stakeholders have important roles to play in preventing substance use disorders, and it is critical that our pharmaceutical manufacturers and distributors step up in stopping pill dumping.

I urge a ''yes'' vote, and I reserve the balance of my time.

Mr. PALLONE. Madam Speaker, I yield such time as she may consume to the gentlewoman from Michigan (Mrs. DINGELL), who is the author of this bill and oftentimes presents to the House commonsense action plans on important issues.

Mrs. DINGELL. Madam Speaker, I thank the gentleman for being a very good and fair chairman.

I rise in support of the Block, Report, And Suspend Suspicious Shipments Act. This bipartisan legislation would implement safeguards against pill dumping and other abusive practices to address the ongoing opioid epidemic, which remains one of the most pressing public health threats facing our country.

Last year, over 88,000 Americans lost their lives as a result of the opioid crisis, including 2,650 individuals in my home State of Michigan. Communities across the country are hurting, and new tools to address pill dumping and other dodgy practices that have exacerbated the opioid crisis are needed now more than ever.

The Block, Report, And Suspend Suspicious Shipments Act will strengthen oversight and integrity of the opioid supply chain by requiring that drug manufacturers and distributors exercise due diligence when they receive a suspicious order for controlled substances. This includes blocking or declining to fill the suspicious order and providing DEA additional data and background on the indicators of the order in question.

This legislation's commonsense protection will save lives in Michigan and all around this country by making distributors and manufacturers active partners in curbing these abuses.

I would like to recognize my colleague, Congressman MCKINLEY, for his record of leadership, concern, empathy, compassion, and working to address this longstanding issue that has helped perpetuate the opioid crisis.

I would also like to thank Chairman PALLONE and Ranking Member RODGERS, as well as the Democratic and Republican committee staff, for their hard work to build consensus and advance this important bipartisan priority.

I urge my colleagues to support this legislation.

Mr. GUTHRIE. Madam Speaker, I yield myself the balance of my time.

My good friend from Michigan thanked the Republican and Democratic staff. We have gone through a series of bills and have another one to go, most dealing with substance use disorders, mental health, and suicide prevention, and all of them brought to the floor in a bipartisan way. That happens with Members working together, but it also happens with staff working long hours together. We certainly appreciate all of them who are here with us on the floor or not on the floor this afternoon.

This is important. We did an oversight investigation. We did a committee investigation and saw what seemed to us obvious quantities of pills being distributed that should be raised to the attention of people.

I think my friend from Michigan said it best when she said this is common sense, so we want to make sure we clarify the role of pharmaceutical manufacturers and distributors.

This is a good bill, and I urge its support.

Madam Speaker, I yield back the balance of my time.

Mr. PALLONE. Madam Speaker, I yield myself the balance of my time.

I appreciate my colleague from Kentucky referencing the investigation that was done that led to this bill and other legislation. Many times, I think the public doesn't realize that our committees do a lot of investigative work that leads to important legislation. This is certainly an example.

Again, I thank Mrs. DINGELL, in particular, because this is something that I think will help us with the supply chain and, hopefully, deter opioid diversion and trafficking.

Madam Speaker, I urge bipartisan support, and I yield back the balance of my time.

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. 768.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. ROY. Madam Speaker, on that I demand the yeas and nays.

The SPEAKER pro tempore. Pursuant to section 3(s) of House Resolution 8, the yeas and nays are ordered.

Pursuant to clause 8 of rule XX, further proceedings on this motion are postponed.

FAIRNESS IN ORPHAN DRUG EXCLUSIVITY ACT

Mr. PALLONE. Madam Speaker, I move to suspend the rules and pass the bill (H.R. 1629) 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.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 1629

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 Kentucky (Mr. GUTHRIE) each will control 20 minutes.

The Chair recognizes the gentleman from New Jersey.

GENERAL LEAVE

Mr. PALLONE. Madam Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on H.R. 1629.

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

There was no objection.

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

I rise in support of H.R. 1629, the Fairness in Orphan Drug Exclusivity Act. The legislation will close a loophole in the orphan drug program to ensure generic drugs can come to market and are not unfairly blocked by their brand competitors.

This bill, which passed the House by a voice vote last Congress, takes steps to address two crises: one, the soaring cost of prescription drugs; and, two, the ongoing opioid crisis. It deserves our bipartisan support once again today.

The Orphan Drug Act has been successful in driving research and discovery of new therapies to treat and even cure rare diseases. The law incentivizes the development of these therapies, including by awarding 7 years of market exclusivity and two pathways for manufacturers to receive these incentives.

Under the first pathway, orphan drug status may be awarded when manufacturers develop drugs approved to treat diseases with patient populations of 200,000 or fewer. Under the second pathway, through the rarely used cost recovery pathway, they may receive orphan drug status if 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 get additional rounds of exclusivity for additional drugs in their portfolio if they treat the same condition 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 the creation of novel drugs for small populations.

Because of this loophole, some manufacturers have been able to market widely used drugs to large populations, all while retaining exclusivity and blocking generic competition from coming to market.

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

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

Clearly, we knew in 2017 that bupe was not an orphan drug. Nevertheless, the drug was granted orphan drug status and exclusivity, and that delayed additional forms of generic competition.

While the FDA 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, Madam Speaker, every tool available to us to combat the opioid epidemic, including low-cost, affordable medication treatments, and loopholes like this one should not be allowed to limit access to low-cost drugs.

H.R. 1629 would stop this from happening again in the future. It requires 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. The legislation would also ensure that these rules apply to drugs already on the market.

This bill is a narrowly tailored fix for a narrow but very real loophole in the law. I thank Representative DEAN from Pennsylvania for introducing this bill. It passed the House on a bipartisan basis, by voice vote, and without opposition last Congress. I look forward to it passing with bipartisan support again today and getting it through the Senate and to President Biden's desk so it can become law. I urge all of my colleagues to support the bill.

Madam Speaker, I reserve the balance of my time.

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

Madam Speaker, I rise today in support of the Fairness in Orphan Drug Exclusivity Act.

The Orphan Drug Act was enacted to incentivize the development of drugs for rare diseases by giving products that receive an orphan drug designation 7 years of market exclusivity, meaning 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.

One way a drug can receive an orphan designation and, subsequently, market 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 the market, have tried to take advantage of a loophole in the law. Existing law allows an orphan drug designation and market exclusivity to carry forward to future versions of the same drug without requiring the manufacturer to demonstrate that the drug has not been, and remains unlikely to be, profitable.

This legislation will close that loophole, requiring manufacturers to show there is no reasonable expectation that the cost of research and development will be covered for each successor drug, while still preserving incentives for orphan drug development.

We must preserve incentives to innovate while preventing bad actors from exploiting those incentives to benefit from a national crisis, as we saw during the opioid epidemic.

While no drug currently benefits from market exclusivity awarded through this mechanism, I remain concerned about including language that allows for the retroactive revocation of an incentive through legislation.

Legislation that sets a precedent of revoking a benefit awarded prior to enactment creates a slippery slope and could chill innovation if adopted elsewhere in statute. While this bill itself is narrowly tailored, we do not want uncertainty caused by Congress retroactively legislating to discourage truly innovative drugs from coming to the

market, especially for the rare disease community.

However, I will support this bill as it moves forward today as I believe it is important to prevent the abuse of this program in the future. I look forward to continuing discussions to come to a resolution on this outstanding concern as we work with the Senate to get this bill to the President's desk.

Madam Speaker, I reserve the balance of my time.

Mr. PALLONE. Madam Speaker, I yield such time as she may consume to the gentlewoman from Pennsylvania (Ms. DEAN), the author of this legislation, which is important because whenever we can encourage generics and make drugs more affordable, it is certainly to the benefit of the American people.

□ 1615

Ms. DEAN. Madam Speaker, I thank Representative GUTHRIE and Chairman PALLONE for their support of this critical legislation.

Madam Speaker, I rise in support of H.R. 1629, the Fairness in Orphan Drug Exclusivity Act.

This crucial legislation would close a loophole in the current law that can be used to block competition in the pharmaceutical marketplace.

The Orphan Drug Act of 1983 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 a condition that affects fewer than 200,000 people in the United States, or is a drug intended for diseases that there is no reasonable expectation to recoup research and development costs.

This legislation focuses on the drugs intended for diseases that there is no reasonable expectation to recoup research and development costs. It would require all drug manufacturers who obtain orphan drug status to prove that they have no reasonable expectation that they will recover their research and development costs and efforts.

This legislation works to prevent companies from 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.

This exact circumstance happened when a manufacturer of a buprenorphine product updated an older product that received orphan drug status and subsequently was given a renewed orphan drug exclusivity. Buprenorphine is used as a treatment for opioid use disorder to help those recovering from addiction. Unfortunately, at the time, the opioid epidemic was raging. It was, by no means, a rare disease, and the drug was not a market loser.

Closing this loophole will ensure that products do not receive an unfair market advantage and, therefore, remains consistent with the spirit and intent of the Orphan Drug Act. We must work to ensure people can gain access to newer therapies and medically assisted treatments that are potentially blocked due to orphan designation.

Madam Speaker, I thank Representative MARC VEASEY for introducing this legislation along with me. I thank my colleagues in the House for passing this bill without objection on a voice vote just 6 months ago in the 116th Congress.

Again, I thank Chairman PALLONE for bringing this bill forward and for his leadership on substance use disorder and behavioral health issues more broadly.

Madam Speaker, I urge Members to support this bill.

Mr. GUTHRIE. Madam Speaker, I yield myself such time as I may consume for the purpose of closing.

Madam Speaker, it is so important that we have the Orphan Drug Act. We have so many people who have rare diseases come to our offices and visit us on Capitol Hill, as they should. Hopefully we will be able to do that again soon. It just touches your heart. Many of these diseases have so few people affected by it; but if it is you or your child or somebody in your family, it is devastating.

We have all seen the power of the private marketplace to come in and produce these pharmaceuticals that make a difference. So we have to have provisions to allow these drugs to come into the marketplace and incentivize that private innovation moving forward.

But when people use that in order to move forward, this loophole has to be closed. I am glad that it is here, and it is these things that we need to work on. It is really not specifically here; it is just maybe a slippery slope in other places as we move forward.

I thank my friend from Pennsylvania for bringing this forward, and the Energy and Commerce Committee for addressing this, because we have to preserve orphan drug status for those afflicted by the rarest and the most devastating diseases. We also need to bring lower drug prices to Americans, and we can do that working together.

Madam Speaker, I appreciate this being brought forward. I urge my colleagues to support this piece of legislation, and I yield back the balance of my time.

Mr. PALLONE. Madam Speaker, I yield myself such time as I may consume for the purpose of closing.

Madam Speaker, I thank Representative GUTHRIE for his remarks about trying to work together to lower the cost of prescription drugs. I thank Congresswoman DEAN because this is a part of that effort.

As you will note, today, we had a whole package dealing with mental health, behavioral health, and other drug activities. It is very important that we move this whole package and try to get it passed in the Senate as quickly as possible.

Madam Speaker, I urge support for this legislation on a bipartisan basis, and I yield back the balance of my time.

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. 1629.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. GUTHRIE. Madam Speaker, on that I demand the yeas and nays.

The SPEAKER pro tempore. Pursuant to section 3(s) of House Resolution 8, the yeas and nays are ordered.

Pursuant to clause 8 of rule XX, further proceedings on this motion are postponed.

CONTINUATION OF THE NATIONAL EMERGENCY WITH RESPECT TO YEMEN—MESSAGE FROM THE PRESIDENT OF THE UNITED STATES (H. DOC. NO. 117–37)

The SPEAKER pro tempore laid before the House the following message from the President of the United States; which was read and, together with the accompanying papers, referred to the Committee on Foreign Affairs and ordered to be printed:

To the Congress of the United States:

Section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)) provides for the automatic termination of a national emergency unless, within 90 days prior to the anniversary date of its declaration, the President publishes in the *Federal Register* and transmits to the Congress a notice stating that the emergency is to continue in effect beyond the anniversary date. In accordance with this provision, I have sent to the *Federal Register* for publication the enclosed notice stating that the national emergency declared in Executive Order 13611 of May 16, 2012, with respect to Yemen is to continue in effect beyond May 16, 2021.

The actions and policies of certain former members of the Government of Yemen and others continue to threaten Yemen's peace, security, and stability. These actions include obstructing the political process in Yemen and the implementation of the agreement of November 23, 2011, between the, Government of Yemen and those in opposition to it, which provided for a peaceful transition of power that meets the legitimate demands and aspirations of the Yemeni people. For this reason, I have determined that it is necessary to continue the national emergency declared in Executive Order 13611 with respect to Yemen.

JOSEPH R. BIDEN, Jr.

THE WHITE HOUSE, *May 11, 2021.*