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.

BLOCK, REPORT, AND SUSPEND SUSPICIOUS SHIPMENTS ACT OF 2021

Mr. PALLONE. Madam Speaker, I move to suspend the rules and pass the bill (H.R. 768) to amend the Controlled Substances Act to clarify the process for registrants to exercise due diligence upon discovering a suspicious order, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 768

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 ''Block, Report, And Suspend Suspicious Shipments Act of 2021''.

SEC. 2. CLARIFICATION OF PROCESS FOR REGISTRANTS TO EXERCISE DUE DILIGENCE UPON DISCOVERING A SUSPICIOUS ORDER.

(a) IN GENERAL.—Paragraph (3) of section 312(a) of the Controlled Substances Act (21 U.S.C. 832(a)) is amended to read as follows:

''(3) upon discovering a suspicious order or series of orders—

''(A) exercise due diligence;

''(B) establish and maintain (for not less than a period to be determined by the Administrator of the Drug Enforcement Administration) a record of the due diligence that was performed;

''(C) decline to fill the order or series of orders if the due diligence fails to resolve all of the indicators that gave rise to the suspicion that filling the order or series of orders would cause a violation of this title by the registrant or the prospective purchaser; and

''(D) notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business of—

''(i) each suspicious order or series of orders discovered by the registrant; and

''(ii) the indicators giving rise to the suspicion that filling the order or series of orders would cause a violation of this title by the registrant or the prospective purchaser.''.

(b) REGULATIONS.—Not later than 1 year after the date of enactment of this Act, for purposes of section 312(a)(3) of the Controlled Substances Act, as amended by subsection (a), the Attorney General of the United States shall promulgate a final regulation specifying the indicators that give rise to a suspicion that filling an order or series of orders would cause a violation of the Controlled Substances Act (21 U.S.C. 801 et seq.) by a registrant or a prospective purchaser.

(c) APPLICABILITY.—Section 312(a)(3) of the Controlled Substances Act, as amended by subsection (a), shall apply beginning on the day that is 1 year after the date of enactment of this Act. Until such day, section 312(a)(3) of the Controlled Substances Act shall apply as such section 312(a)(3) was in effect on the day before the date of enactment of this Act.

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. 768.

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.

Madam Speaker, I rise today in support of H.R. 768, the Block, Report, And Suspend Suspicious Shipments Act of 2021.

Since 1999, more than 841,000 Americans have died from a drug overdose. In the early years of this epidemic, many of these deaths involved prescription opioids. Then in 2010 we began seeing dramatic increases from heroin-involved deaths, and now we are seeing a third wave, Madam Speaker, involving synthetic opioids like illicitly manufactured fentanyl.

In those earlier years, Americans across the country became addicted to opioids. Many of those opioids were prescribed to patients to treat pain. However, throughout the years, we have discovered that many of these opioids were diverted through a system meant to prevent diversion.

The Drug Enforcement Administration requires entities that manufacture or distribute controlled substances to register and report their activities through ARCOS, a system meant to track the manufacture, distribution, and dispensing of these substances. In this system, registrants are also expected to disclose suspicious orders of controlled substances such as orders of unusual size, orders deviating from a normal pattern, or orders of an unusual frequency.

H.R. 768 will improve reporting and action on suspicious orders by clarifying the responsibilities of drug manufacturers and distributors when discovering a suspicious order. The legislation also requires that this discovery be reported to DEA, which will help all entities to better identify suspicious activity and root out bad actors.

This is a commonsense bill that will make clear the responsibilities for all entities in our supply chain, and hopefully help to deter opioid diversion and trafficking.

I commend the lead sponsors of this legislation, Representatives DINGELL and MCKINLEY, and their staff, for their work on this bill.

Madam Speaker, I urge my colleagues to support the bill, and I reserve the balance of my time.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON THE JUDICIARY,
Washington, DC, May 5, 2021.

Hon. FRANK PALLONE, JR.,
Chairman, Committee on Energy and Commerce, House of Representatives, Washington, DC.

DEAR CHAIRMAN PALLONE: This is to advise you that the Committee on the Judiciary has now had an opportunity to review the provisions in H.R. 768, the ''Block, Report, And Suspend Suspicious Shipments Act of 2021,'' that fall within our Rule X jurisdiction. I appreciate your consulting with us on those provisions. The Judiciary Committee has no objection to your including them in the bill for consideration on the House floor, and to expedite that consideration is willing to forgo action on H.R. 768, with the understanding that we do not thereby waive any future jurisdictional claim over those provisions or their subject matters.

In the event a House-Senate conference on this or similar legislation is convened, the Judiciary Committee reserves the right to request an appropriate number of conferees to address any concerns with these or similar provisions that may arise in conference.

Please place this letter into the Congressional Record during consideration of the measure on the House floor. Thank you for the cooperative spirit in which you have worked regarding this matter and others between our committees.

Sincerely,

JERROLD NADLER,
Chairman.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC, May 7, 2021.

Hon. JERROLD NADLER,
Chairman, Committee on the Judiciary, Washington, DC.

DEAR CHAIRMAN NADLER: Thank you for consulting with the Committee on Energy and Commerce and agreeing to be discharged from further consideration of H.R. 768, the ''Block, Report, And Suspend Suspicious Shipments Act of 2021,'' so that the bill may proceed expeditiously to the House floor.

I agree that your forgoing further action on this measure does not in any way diminish or alter the jurisdiction of your committee or prejudice its jurisdictional prerogatives on this measure or similar legislation in the future. I would support your effort to seek appointment of an appropriate number of conferees from your committee to any House-Senate conference on this legislation.

I will seek to place our letters on H.R. 768 into the Congressional Record during floor consideration of the bill. I appreciate your cooperation regarding this legislation and look forward to continuing to work together as this measure moves through the legislative process.

Sincerely,

FRANK PALLONE, JR.,
Chairman.

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

Madam Speaker, I rise today to express my strong support for H.R. 768, the Block, Report, And Suspend Shipments Act of 2021, which was led by my

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.

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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