

The legislation also creates a SAMHSA grant program to fund self-harm and suicide prevention services in hospital emergency departments. This includes screening at-risk patients, providing services as needed, and referring patients for follow-up care for long-term self-harm and suicide prevention.

Hospital emergency departments are on the front lines of providing critical behavior health services, and these resources will help identify and treat individuals at the highest risk for suicide and self-harm.

Madam Speaker, I appreciate my colleagues, Congressman STEWART and Congresswoman MATSUI, for leading this important legislation, and I urge my colleagues to support its passage.

Madam Speaker, I reserve the balance of my time.

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

Madam Speaker, I rise today in support of H.R. 5619, the Suicide Prevention Act, by Representatives STEWART and MATSUI.

This legislation establishes two grant programs to prevent self-harm and suicide. One would be to help train emergency room personnel in suicide prevention strategies and screening. The bill also establishes a grant program to enhance data collection and sharing to help save lives.

My home State of Montana, unfortunately, has one of the highest suicide rates in the country. I thank my colleagues for bringing forward this important legislation.

Madam Speaker, this is an important piece of legislation. I urge my colleagues to support it, and I yield back the balance of my time.

Mrs. DINGELL. Madam Speaker, the gentleman is absolutely correct at how important a piece of legislation this is. I urge my colleagues to support this legislation, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentlewoman from Michigan (Mrs. DINGELL) that the House suspend the rules and pass the bill, H.R. 5619, 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.

#### SAFEGUARDING THERAPEUTICS ACT

Mrs. DINGELL. Madam Speaker, I move to suspend the rules and pass the bill (H.R. 5663) to amend the Federal Food, Drug, and Cosmetic Act to give authority to the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to destroy counterfeit devices, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5663

*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 “Safeguarding Therapeutics Act”.

#### SEC. 2. AUTHORITY TO DESTROY COUNTERFEIT DEVICES.

(a) IN GENERAL.—Section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended—

(1) in the fourth sentence, by inserting “or counterfeit device” after “counterfeit drug”; and

(2) by striking “The Secretary of the Treasury shall cause the destruction of” and all that follows through “liable for costs pursuant to subsection (c).” and inserting the following: “The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations, except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug or device refused admission under this section, if such drug or device is 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 (19 U.S.C. 1498(a)(1))) and was not brought into compliance as described under subsection (b). The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity to appear before the Secretary of Health and Human Services and introduce testimony, as described in the first sentence of this subsection, on destruction of a drug or device under the seventh sentence of this subsection. The regulations shall provide that prior to destruction, appropriate due process is available to the owner or consignee seeking to challenge the decision to destroy the drug or device. Where the Secretary of Health and Human Services provides notice and an opportunity to appear and introduce testimony on the destruction of a drug or device, the Secretary of Health and Human Services shall store and, as applicable, dispose of the drug or device after the issuance of the notice, except that the owner and consignee shall remain liable for costs pursuant to subsection (c).”

(b) DEFINITION.—Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended—

(1) by redesignating subparagraphs (1), (2), and (3) as clauses (A), (B), and (C), respectively; and

(2) after making such redesignations—

(A) by striking “(h) The term” and inserting “(h)(1) The term”; and

(B) by adding at the end the following:

“(2) The term ‘counterfeit device’ means a device which, or the container, packaging, or labeling of which, without authorization, bears a trademark, trade name, or other identifying mark, imprint, or symbol, or any likeness thereof, or is manufactured using a design, of a device manufacturer, packer, or distributor other than the person or persons who in fact manufactured, packed, or distributed such device and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other device manufacturer, packer, or distributor.

“(3) For purposes of subparagraph (2)—

“(A) the term ‘manufactured’ refers to any of the following activities: manufacture, preparation, propagation, compounding, assembly, or processing; and

“(B) the term ‘manufacturer’ means a person who is engaged in any of the activities listed in clause (A).”

#### 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 gentlewoman from Michigan (Mrs. DINGELL) and the gentleman from Montana (Mr. GIANFORTE) each will control 20 minutes.

The Chair recognizes the gentlewoman from Michigan.

#### GENERAL LEAVE

Mrs. DINGELL. 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. 5663.

The SPEAKER pro tempore. Is there objection to the request of the gentlewoman from Michigan?

There was no objection.

Mrs. DINGELL. Madam Speaker, I yield myself such time as I may consume.

Madam Speaker, I rise in strong support of H.R. 5663, the Safeguarding Therapeutics Act.

Madam Speaker, this legislation provides FDA additional authority to take action to protect public health and safety by extending the agency’s administrative destruction authority for counterfeit medical devices, including diagnostic tests and surgical masks, as well as combination products, like vaccines, that may pose a threat to public health.

Given the global marketplace and extended supply chains for complex medical products, counterfeit medical devices are becoming increasingly common, both in the United States and abroad. These counterfeit products pose a significant risk to patient health and safety, and ensuring that FDA has the appropriate authority to take action by seizing and destroying counterfeit medical devices will help safeguard America’s health.

Under current law, counterfeit medical devices and combination products are typically shipped back to the sender because of the limitations in FDA’s existing authority. This allows dangerous counterfeit devices to remain in the supply chain, continuing to represent a significant risk to consumers. The Safeguarding Therapeutics Act is a straightforward, commonsense approach to this issue with bipartisan support that will provide FDA with authority it already possesses with respect to counterfeit drugs.

Given the deficiencies highlighted with certain aspects of the healthcare supply chain throughout the current pandemic, taking action to further

safeguard the supply chain from potentially dangerous products is more important than ever.

Madam Speaker, I thank my colleagues on the Committee on Energy and Commerce, Representatives GUTHRIE and ENGEL, for their work on this legislation, and I urge my colleagues to support its passage.

Madam Speaker, I reserve the balance of my time.

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

Madam Speaker, I rise today in support of H.R. 5663, the Safeguarding Therapeutics Act, introduced by Representatives GUTHRIE and ENGEL. This legislation would extend FDA's administrative destruction authority to counterfeit and other illegal medical devices.

Under current law, the FDA is authorized to destroy certain imported drugs that may pose a threat to public health; however, this authority does not extend to medical devices.

The passage of this legislation during the coronavirus pandemic is especially timely, as we have seen a surge in counterfeit COVID-19 test kits imported to the United States.

But it is not only counterfeit COVID-19 test kits entering our borders and posing risks to U.S. consumers. International mail facilities have also intercepted shipments of illegal contact lenses and combination products in recent years.

This additional authority will prevent shippers from trying to send illegal products back to the United States and may deter future illegal shipments of medical devices.

Madam Speaker, I thank my colleagues, Representatives GUTHRIE and ENGEL, for working together in a bipartisan manner to advance this legislation to provide the FDA with the additional tool to protect American consumers against potentially dangerous medical products.

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

Mrs. DINGELL. Madam Speaker, I reserve the balance of my time.

Mr. GIANFORTE. Madam Speaker, I yield 3 minutes to the gentleman from Kentucky (Mr. GUTHRIE).

Mr. GUTHRIE. Madam Speaker, I rise today in support of my bill, the Safeguarding Therapeutics Act.

Last year, I had the opportunity to visit the international mail facility at JFK Airport in New York.

When counterfeit drugs come through the mail facilities, the FDA has the authority to destroy it. However, if that counterfeit drug is attached to a syringe, it therefore constitutes a medical device, and the FDA does not currently have the authority to destroy counterfeit medical devices. Instead, in most cases, they are mailed back to where they came from, where they are repackaged and sent right back to the United States.

After visiting the mail facility, I joined with my colleague, Representative ELIOT ENGEL, to fix this, introducing the Safeguarding Therapeutics Act. This commonsense, bipartisan bill will give the FDA the authority to destroy counterfeit medical devices at entry points into our country. These include items such as combination products, like injections and vaccines. If allowed into the country, these products could end up on the black market and harm American patients.

The Safeguarding Therapeutics Act has become especially important now that the country is facing the COVID-19 pandemic. We have already seen instances of counterfeit COVID-19 tests and products claiming to cure COVID being sent to the United States. Bad actors are marketing tests and treatments that have not been approved by the FDA or the CDC.

We need to give the FDA the ability to destroy these products as they enter the United States. While our Nation continues to grapple with the coronavirus pandemic, the last thing we need is fake COVID-19 tests and products in our market.

Also, in going to the JFK Airport, you are standing there with the personnel, men and women who are wearing the uniform of our country, receiving this mail moving forward. We gave them the authority: If it is a drug, they can destroy it if it is counterfeit; if it is a device, it is an interpretation, but they don't have the authority to move forward.

They even told me that sometimes they open the package, see that it is counterfeit, and they have to return it. They close the package, return it, and they will see the same package come back through the exact way that they taped it.

So we need to give them the authority. It doesn't make sense. It is a commonsense approach.

ELIOT ENGEL and I made this bipartisan. I think every American citizen says that is not the way we want to operate, and particularly in this time and this pandemic, and there are people trying to take advantage of this time and this pandemic.

Madam Speaker, I appreciate bringing this to the floor today. I appreciate the hard work of the Committee on Energy and Commerce.

I thank Representative ENGEL. I don't think he represents JFK, but he does represent the great city of New York.

Madam Speaker, I look forward to continuing to work with my colleagues on the Committee on Energy and Commerce as they respond to the coronavirus pandemic.

Mrs. DINGELL. Madam Speaker, I reserve the balance of my time.

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

Madam Speaker, I thank Mr. GUTHRIE for his leadership on this and taking the initiative to get out and under-

stand the issue on the ground and crafting bipartisan legislation to solve this problem and protect American consumers.

Madam Speaker, I urge adoption of this legislation, and I yield back the balance of my time.

Mrs. DINGELL. Madam Speaker, I also thank Mr. GUTHRIE and Mr. ENGEL for their leadership.

I think the American people understand this issue more now than ever, unfortunately. I urge my colleagues to support this legislation.

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

The SPEAKER pro tempore. The question is on the motion offered by the gentlewoman from Michigan (Mrs. DINGELL) that the House suspend the rules and pass the bill, H.R. 5663, 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.

**BLOCKING PROPERTY OF CERTAIN PERSONS WITH RESPECT TO THE CONVENTIONAL ARMS ACTIVITIES OF IRAN—MESSAGE FROM THE PRESIDENT OF THE UNITED STATES (H. DOC. NO. 116-154)**

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 Committee on the Judiciary and ordered to be printed:

*To the Congress of the United States:*

Pursuant to the Countering America's Adversaries Through Sanctions Act (Public Law 115-44), the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*), section 212(f) of the Immigration and Nationality Act of 1952 (8 U.S.C. 1182(f)), and section 301 of title 3, United States Code, I hereby report I have issued an Executive Order (the "order") that affirms that it remains the policy of the United States to counter Iran's malign influence in the Middle East, including transfers from Iran of destabilizing conventional weapons and acquisition of arms and related materiel by Iran. Transfers to and from Iran of arms or related materiel or military equipment represent a continuing threat to regional and international security. Iran benefits from engaging in the conventional arms trade by strengthening its relationships with other outlier regimes, lessening its international isolation, and deriving revenue that it uses to support terror groups and fund malign activities.

In light of these findings and in order to take additional steps with respect to the national emergency declared in Executive Order 12957 of March 15, 1995