



August 3, 2020

The Honorable Mike Enzi (R-WY)
United States Senate
379A Russell Senate Office Building
Washington, D.C. 20510

The Honorable Maggie Hassan (D-NH)
United States Senate
324 Hart Senate Office Building
Washington, D.C. 20510

Dear Senator Enzi and Senator Hassan:

On behalf of the Partnership for Safe Medicines (PSM), I am writing to express our strong support for S. 4225 – the Safeguarding Therapeutics Act.

Comprised of more than 45 non-profit groups, PSM is a public health group committed to the safety of prescription drugs and to the protection of consumers against counterfeit, substandard or otherwise unsafe medicines. Our mission includes the fight against counterfeit drugs, securing and protecting the pharmaceutical supply chain and the regulation of online sellers of medicines.

Counterfeit medicines and medical supplies are not a new phenomenon. Over the years, we have seen individuals and criminal groups traffic not only a wide array of counterfeit prescription medicines, but also counterfeit medical supplies and devices, including counterfeit glucose tests, blood pressure cuffs and substandard syringes. While the United States Food and Drug Administration (FDA) may deny and/or destroy counterfeit medicines attempting to enter into the United States, they lack the authority to do so with counterfeit medical devices.

S. 4225 remedies this situation by amending the federal Food, Drug and Cosmetic Act to add “counterfeit device” to the list of items that can be refused entry into the United States. Additionally, the bill provides the FDA the authority to destroy medical devices, worth \$2,500 or less, they deemed counterfeit.

The COVID-19 pandemic highlights the importance of this issue. Since the onset of the pandemic, U.S. law enforcement has been reporting a proliferation of shipments of fake cures, vaccines and testing kits. In this environment, the passage of S. 4225 is especially urgent and it is more important than ever the FDA has the ability to prevent the entry of and destroy fake COVID-19 testing kits and other counterfeit supplies before they get into the hands of an unsuspecting American public.

PSM believes that counterfeit medical devices are dangerous to American patients and that the FDA and other U.S. customs authorities should have the unequivocal power to seize and destroy these dangerous products whether they are found in interstate commerce or in transit to enter America. Additionally, where the law is not clear, we support granting the FDA seizure and destruction authority to protect American patients from counterfeit medical devices in any venue it operates.

Therefore, the Partnership for Safe Medicines strongly supports S. 4225 – the Safeguarding Therapeutics Act and thanks you for working to fix a critical oversight in the FDA’s authority to combat counterfeit medical devices. We stand ready to assist your office in the passage of this bill.

Sincerely,

Shabbir Imber Safdar
Executive Director