The House Forwards Legislation Expanding the FDA's Authority to Manage Counterfeit Medical Devices

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A bill expanding the authority of the Food and Drug Administration (FDA) may provide safer medical devices to the American public amid the Covid-19 pandemic, as well as support manufacturers of legitimate medical devices, by addressing a loophole in the Food, Drug, and Cosmetic Act. Counterfeit medical devices have been a danger in the U.S. supply chain for years, but their presence has been especially of concern during the current pandemic, when there have been shortages of products considered to be medical devices by the FDA, such as medical masks, surgical gowns and gloves, respirators, and other products. Counterfeit medical devices may include various products like those mentioned above, but often depend on the intended use and labeling.

Background

Many products used during the Covid-19 pandemic are considered to be medical devices by the FDA. The FDA has issued special guidance concerning medical masks, distinguishing those that are regulated by the FDA where they are intended for medical uses versus industrial uses. The FDA has also issued a number of guidance documents concerning various types of masks that may be considered medical devices.[i]

The FDA has already identified numerous hand sanitizers from China that were found to be packaged in a way that could be confused with drinks and cause serious injury.[ii] The FDA has also recalled many hand sanitizers due to methanol contamination as well.

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The FDA has had the power to seize and destroy counterfeit medicines, ensuring that they will not end up in American homes and endangering public health. The FDA does not, currently, however, have this same authority when regulating counterfeit medical devices. Additionally, drugs attached to medical devices, like a syringe, are technically considered "medical devices," creating a large loophole. In response, Republican Congressman Brett Guthrie and Democratic Congressman Eliot Engel introduced the bipartisan bill known as the Safeguarding Therapeutics Act of 2020 ("the Act") in January of this year.

While counterfeit medical devices have been problematic for years, the Act is especially relevant this year in light of the ongoing pandemic that has increased demand for many of these products. Manufacturers of counterfeit devices have certainly taken advantage of the Covid-19 pandemic by seizing the opportunity to sell counterfeit devices amidst shortages and fearful consumers. Manufacturers of counterfeit devices have been producing and shipping fake Covid-19 tests, products that claim to cure Covid-19, and counterfeit medical supplies to the U.S. For example, in March, U.S. Customs and Border Protection at the Los Angeles International Airport and Chicago O'Hare International Airport confiscated counterfeit Covid-19 tests. In September, over 500,000 counterfeit N-95 masks were seized at the Chicago O'Hare International Airport. These counterfeit devices would only contribute to misleading and improperly protecting consumers, a significant threat during a pandemic. Although the FDA has the power to store items or send them back, it has been unable to *destroy* counterfeit devices to ensure that they do not reach medical providers and consumers. The Safeguarding Therapeutics Act aims to change that.

On September 21, 2020, the U.S. House of Representatives passed the bill, allowing it to move along in the legislative process to the Senate. It was received in the Senate, read twice, and was referred to the Committee on Health, Education, Labor, and Pensions on September 22, 2020. From there, little or no activity appears to have occurred in the Committee. There has not been a reference to a subcommittee nor has there been a markup session.

There is, however, a Senate companion bill (S4225), titled "Safeguarding Therapeutics Act of 2020." S4225 was introduced in July 2020 and was referred to the Committee on Health, Education, Labor, and Pensions. It has three sponsors: Maggie Hassan (D) from New Hampshire, Rick Scott (R) from Florida, and Mike Enzi (R) from Wyoming.

The legislation seeks to amend the Food, Drug, and Cosmetic Act and address the loophole that has limited the FDA's power to target and regulate the increasing number of counterfeit medical devices in the U.S. supply chain. The bill defines "counterfeit medical devices" as:

> 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.

Although the proposed changes are few, they would have significant impacts on the FDA's authority and effectiveness in regulating counterfeit medical devices. The Act would add the phrase "or counterfeit device" to 28 U.S.C. 381(a), which currently gives the FDA the authority to refuse admission of a counterfeit drug. The Act also includes an amendment that would give the FDA the authority to destroy counterfeit devices valued at $2,500 or less, which the FDA has been able to do with counterfeit drugs. Currently, the FDA may refuse admission of the devices, but cannot seize or destroy devices deemed as counterfeit because owners must first be provided the opportunity to export the product. The FDA is thus left with the choice of storing or returning the counterfeit medical devices. This results in the FDA often returning the counterfeit medical devices to their senders, who often repackage the devices and send them back to the U.S. If they are not caught, the counterfeit devices enter the supply chain. Thus, counterfeit devices are often not fully intercepted and prevented from entering the market and endangering the health of consumers.

Lastly, besides protecting the public from counterfeit devices, increased regulation may support manufacturers of legitimate medical devices by helping curb the counterfeit medical devices on the market. Manufacturers of legitimate medical devices may benefit from a decreased need for spending and by being able to invest less in anti-counterfeiting measures, such as tracking devices and having systems in place that allow for reporting counterfeits. These measures may still be needed to different extents depending on each manufacturer's situation, but the enactment of the Safeguarding Therapeutics Act would likely assist manufacturers in their anti-counterfeiting efforts. Lastly, while the law would not provide a cause of action for manufacturers of genuine devices, it would offer support for their position against manufacturers of counterfeit devices in litigation.

Counterfeiting is a major problem that affects many U.S. businesses. Fortunately, the U.S. Customs and Border Protection (CBP) also provide protection against counterfeiting by allowing U.S. companies that hold registered trademarks and copyrights to record them with CBP, and suspected counterfeits are detained at the border.[iii] This would be in addition to the remedies set out in the proposed Safeguarding Therapeutics Act. Butzel Long attorneys have extensive experience in assisting clients against counterfeit imports.

It is yet to be seen whether this Act will get signed into law and—if it does—whether it will be in its current version. But Butzel Long will continue to monitor this Act and report back to our clients on how this may impact you and your businesses.

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[i]https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-and-face-masks.

[ii] https://www.fda.gov/news-events/press-announcements/covid-19-update-fda-warns-consumers-about-hand-sanitizer-packaged-food-and-drink-containers.

[iii] 19 CFR §133.21.