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Sens. Baldwin And Cassidy Want Medical Devices Made In The USA

by Brian Bossetta

US Senators Tammy Baldwin and Bill Cassidy have introduced legislation to ensure frontline workers have the supplies they need for the next health emergency.

The *Medical Device Integrity Act*, introduced in the US Senate by Tammy Baldwin, D-WI, and Bill Cassidy, R-LA, aims to promote domestic manufacturing of medical devices and essential supplies so those on the front lines won't be left empty handed should another pandemic hit.

The senators say that the emergence of COVID-19 has exposed vulnerabilities in the country's ability to respond effectively to a national health emergency, and these failures have only been heightened by the latest supply chain woes.

Along with better preparing the US for future pandemics, the legislation seeks to boost domestic production of medical supplies. The bill, according to a *press release* from Baldwin's office, would help ensure Americans that frontline health care workers have the medical equipment they need, including devices and PPE. The legislation also addresses the proliferation of counterfeit devices by providing the Food and Drug Administration with the authority to request records from device and supply makers, and requires manufacturers to comply with those requests.

The legislation, however, is not the only government action seeking to deal with fraudulent devices. The FDA recently issued draft guidance clarifying the definition of medical devices to put an end to counterfeits. (Also see "*A Device or A Counterfeit Device, That Is The Question*" - Medtech Insight, 15 Dec, 2021.)

The expanded authority, the senators say, would better enable the FDA to confront the public health risks associated with counterfeit devices, the vast majority of which come from abroad.

Rooting out poor-quality medical equipment will not only ensure Americans have products that

are safe and effective, but will produce jobs at home, according to Baldwin.

> *"This legislation supports production back home and strengthens our defense against future outbreaks." – Sen. Bill Cassidy*

During the pandemic, the FDA relied on its existing authority to request records before or instead of conducting inspections of drug manufacturers. However, such authority does not extend to manufacturers of medical devices. As it stands now, the FDA can request records from medical device manufacturers, but there's no expectation or requirement that facilities respond, even in a pandemic.

During the pandemic, many of the FDA's inspections were halted, and the agency relied heavily on remote records requests. But for medical device manufacturers, there is simply not an expectation of compliance. From February to May 2021, approximately 40% of medical device manufacturing facilities did not submit records when asked, say the senators.

The Baldwin/Cassidy bill would change that.

"Unfortunately, it is not 'if,' but rather 'when' the world will face another pandemic, and as a country, we must be better prepared to keep our friends, neighbors, and frontline workers safe," Baldwin said.

This is not the first bipartisan effort to address the supply chain crisis and foster more domestic manufacturing. Earlier this month, Sens. Bob Menendez, D-NJ, and Marsha Blackburn, R-TN, and US Reps. Norma Torres, D-CA, and Chuck Fleischmann, R-TN, introduced the National Manufacturing Extension Partnership (MEP) Supply Chain Database Act in both houses of Congress, which would create a national database to streamline the country's supply chain. (Also see "*Bipartisan Bill Seeks To Address US Supply Chain Issues, Prevent Further Crises*" - Medtech Insight, 2 Dec, 2021.)

Cassidy, who is also a physician, notes that at the onset of the pandemic China embargoed PPE manufactured by US companies. "This endangered Americans," Cassidy said. "This legislation supports production back home and strengthens our defense against future outbreaks."