

# U.S. Sen. Baldwin: Introduces bipartisan legislation to increase pandemic preparedness and support Made in America medical supplies

Posted on Tuesday, Dec 14, 2021

>> **WisPolitics is now on the State Affairs network. Get custom keyword notifications, bill tracking and all WisPolitics content. [Get the app or access via desktop.](#)**

*The Medical Device Integrity Act will help promote the manufacturing of high-quality medical devices to keep communities and frontline workers safe*

Washington, D.C. – As COVID-19 has exposed gaps in the United States' ability to respond to a pandemic effectively, U.S. Senator Tammy Baldwin is introducing bipartisan legislation alongside Senator Bill Cassidy, M.D. (R-LA) to better prepare the U.S. for future pandemics and support Made in America medical supplies. *The Medical Device Integrity Act* would help ensure our communities and frontline workers have high-quality medical devices, such as personal protective equipment (PPE), and help address counterfeit devices by giving the Food and Drug Administration (FDA) the authority to request records and require that device manufacturers comply with these requests.

“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,” **said Senator Tammy Baldwin.** “The bipartisan *Medical Device Integrity Act* will ensure that the medical equipment – like masks, gloves, PPE, and more – we rely on are of the highest quality. By rooting out poor quality medical equipment that is often made abroad, this legislation will also support our Made in America economy, supporting jobs across Wisconsin and the country.”

“When the pandemic broke, China embargoed PPE manufactured by U.S. companies that was supposed to be sent to the U.S. This endangered Americans,” **said Dr. Cassidy**. “This legislation supports production back home and strengthens our defense against future outbreaks.”

The *Medical Device Integrity Act* would ensure that the FDA has better insights into device manufacturers in the post-approval period, help the agency be better prepared for future pandemics, and promote the manufacturing of higher quality medical devices, including N95 masks and other critical PPE. Furthermore, remote records authority would better enable FDA to confront the public health risks associated with counterfeit devices, the vast majority of which come from abroad.

During the pandemic, FDA relied on its existing authority to request records in advance of or in lieu of inspections of establishments that manufacture, prepare, propagate, compound, or process drug products. This authority to request records however does not extend to manufacturers of medical devices. Medical devices are an incredibly broad category, ranging from Band-Aids to ventilators. Importantly, most PPE is also a medical device, including gloves and masks. The FDA can request 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 not an expectation of compliance. From February to May of this year, approximately 40 percent of medical device manufacturing facilities did not submit records when requested.

“Senator Baldwin has been a huge proponent in securing the United States’ domestic PPE supply chain as we continue to face surges from the COVID-19 pandemic,” **said Andrew Wegner, Managing Director of US Medical Nonwovens Co.** “Her bill will ensure that the medical devices and PPE that U.S. health care workers use on the job everyday meet the stringent quality standards set forth by the FDA. In practical terms, this means our frontline workers will have the protection they need, and jobs will be created here in America, especially in Wisconsin.”

The full text of the Medical Device Integrity Act can be found [here](#).