# United States Senate

WASHINGTON, DC 20510

May 7, 2018

Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb,

We write today regarding the regulation of entities that refurbish, rebuild, recondition, and remanufacture medical devices and to express our interest in a forthcoming Food and Drug Administration (FDA) report on medical device servicing.

As part of its mission to "protect [. . .] the public health," the Food and Drug Administration regulates the safety, efficacy, and substantial equivalence of thousands of medical devices, ranging from powered wheelchairs to heart catheters.[1]

After medical devices enter the market, various types of these devices may be refurbished, repaired, reconditioned, rebuilt, remarketed, and remanufactured by both the original equipment manufacturers and third-party servicers. Stakeholders have expressed interest in a variety of issues regarding the servicing of medical devices, and in the authority of the FDA to regulate these activities.[2] Section 710 of the FDA Reauthorization Act of 2017 (Public Law No. 115-52) requires the FDA to submit a report to Congress that provides an overview of its statutory and regulatory authority related to the regulating of medical device servicers, as well as information on its current efforts to track and prevent adverse events stemming from medical device servicing.[3]

We appreciate the FDA's continued attention to this critical patient safety issue. We look forward to the timely completion of the FDA's report on medical device servicing and hope to continue to work with you moving forward on initiatives to protect the public health.

Sincerely,

Elizabeth Warren
United States Senator

Bill Cassidy, M.D.
United States Senator

[1] U.S. Food & Drug Administration, "What We Do" (online at https://www.fda.gov/AboutFDA/WhatWeDo/).
[2] *See* U.S. Food and Drug Administration, "Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments" (81 FR 1147) (March 4, 2016) (online at https://www.federalregister.gov/documents/2016/03/04/2016-04700/refurbishing-reconditioning-rebuilding-remarketing-remanufacturing-and-servicing-of-medical-devices).
[3] *See* H.R. 2430—FDA Reauthorization Act of 2017 (online at https://www.congress.gov/bill/115th-congress/house-bill/2430).