United States Senate
WASHINGTON, DC 20510

October 11, 2019

Norman Sharpless, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless:

We write today to express our continued interest in the Food and Drug Administration's regulation of entities that refurbish, repair, recondition, rebuild, remarket, or remanufacture medical devices and to request information on forthcoming guidance clarifying the distinction between the "servicing" and "remanufacturing" of medical devices. We are pleased that FDA plans to issue guidance on this topic and are particularly interested in how the agency will address the issues raised below in the guidance it publishes.

As part of its mission to "protect … public health," the Food and Drug Administration (FDA) regulates the safety and efficacy of thousands of medical devices, ranging from cotton swabs to powered wheelchairs to heart catheters.[1] While some medical devices—such as patient examination gloves—are disposable or designed to be used only once, other devices—such as endoscopes—are used repeatedly and on multiple patients.[2] Original equipment manufacturers (OEMs) and third party entities often refurbish, repair, recondition, rebuild, remarket, or remanufacture these devices to ensure that they continue to operate safely and effectively after entering the market.[3]

Entities that perform maintenance activities face different regulatory requirements depending on the type of maintenance being performed. Activities that "significantly change" the performance, safety specifications, or intended use of a finished device are considered "remanufacturing."[4] Remanufacturers, which can include OEMs and third party entities, must comply with numerous FDA requirements to ensure the safety of remanufactured devices.[5] Activities that do *not* "significantly change" the performance, safety specifications, or intended use of a device—but instead provide "preventive or routine maintenance…for the purpose of returning [a finished device] to the safety and performance specifications established by the

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[1] U.S. Food and Drug Administration, "What We Do," https://www.fda.gov/about-fda/what-we-do.
[2] U.S. Food and Drug Administration, *FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices*, May 2018, https://www.fda.gov/media/113431/download, pg. 1.
[3] *Id.*, pg. 1-2.
[4] *Id.*, pg. 3.
[5] *Id.*, pg. 1-2.

OEM and to meet its original intended use"—are considered "servicing." Third-party servicers are not subject to the same safety and reporting requirements as remanufacturers.[6]

Stakeholders have expressed interest in a variety of issues regarding the servicing of medical devices and in the authority of the FDA to regulate servicing activities.[7] In May 2018, in response to Section 710 of the FDA Reauthorization Act of 2017 (Public Law No. 115-42), the FDA issued a report on the continued quality, safety, and effectiveness of medical devices with respect to servicing.[8] The report noted significant stakeholder confusion over the difference between "servicing" and "remanufacturing." In response, the FDA announced that it would publish guidance clarifying the difference between "servicing" and remanufacturing" to "allow more consistent interpretation and clarification."[9] In December 2018, the FDA held a public workshop on "Medical Device Servicing and Manufacturing Activities" and published a white paper to help "better inform the development of a future draft and final guidance."[10] The FDA is expected to issue draft guidance on the topic.[11]

We applaud the agency's commitment to clarifying the distinction between servicing and remanufacturing, particularly in light of significant discussion within the medical device industry about the difference between the two activities. According to the FDA, "a majority of" the "comments, complaints, and adverse event reports alleging…inadequate 'servicing'" that the agency reviewed to develop its May 2018 report "actually pertain[ed] to 'remanufacturing' and not 'servicing.'"[12] This assessment raises questions about how the FDA, once it issues final guidance, will clarify, communicate, and enforce the distinction between "servicing" and "remanufacturing" to entities that believe themselves to be "servicers," but who may in fact be "remanufacturers" subject to more stringent regulation. The FDA does not require servicers to register with the agency and has not made public any plans to require such registration. As a result, the "precise number of entities that perform servicing of medical devices in the U.S. is not

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[6] *Id.*, pg. 2-3.; *See also* the testimony of Dr. Jeff Shuren during a May 2, 2017, Energy and Commerce Health Subcommittee hearing, during which he stated, "So, in [the FDA's] regulation on quality systems, we had made clear that third-party servicers are manufacturers but that they have been subject to enforcement discretion. We have not enforced those requirements." House Committee on Energy and Commerce, Subcommittee on Health, "Examining Improvements to the Regulation of Medical Technologies (transcript)." May 2, 2017, https://docs.house.gov/meetings/IF/IF14/20170502/105908/HHRG-115-IF14-Transcript-20170502.pdf.

[7] *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, https://www.federalregister.gov/documents/2016/03/04/2016-04700/refurbishing-reconditioning-rebuilding-remarketing-remanufacturing-and-servicing-of-medical-devices.

[8] U.S. Food and Drug Administration, *FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices*, May 2018, https://www.fda.gov/media/113431/download.

[9] *Id.*, pg. 24.

[10] U.S. Food and Drug Administration, "Public Workshop—Medical Device Servicing and Remanufacturing Activities, December 10-11, 2018," October 23, 2018, https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-medical-device-servicing-and-remanufacturing-activities-december-10-11-2018-12102018#whitepaper.

[11] U.S. Food and Drug Administration, "CDRH Fiscal Year 2019 (FY 2019) Proposed Guidance Development," October 22, 2018, https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-fiscal-year-2019-fy-2019-proposed-guidance-development.

[12] U.S. Food and Drug Administration, *FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices*, May 2018, https://www.fda.gov/media/113431/download, pg. 1.

known," though the FDA estimates that "the total number of firms" is between 16,520 and 20,830.[13]

To help us better understand the FDA's consideration of this matter, as well as how it plans to address the issues raised in this letter in its forthcoming guidance, we request answers to the following questions no later than November 1, 2019:

1. In its May 2018 report, the FDA stated that "[a] majority of comments, complaints, and adverse event reports alleging that inadequate "servicing" caused or contributed to clinical adverse events and deaths actually pertain to "remanufacturing" and not "servicing."

    a. If so many entities believed to be involved in "servicing" are actually "remanufacturing" devices, and FDA has said "the precise number of entities that perform servicing of medical devices in the U.S. is not known,"[14] how does FDA intend to identify the universe of actors to whom its upcoming guidance will apply?

    b. How does the FDA intend to educate those entities who are unknowingly involved in remanufacturing activities about their obligations when the upcoming guidance is released?

2. The FDA has estimated approximately 16,000 to 20,000 entities are engaged in servicing activities. How will the FDA promote compliance with the guidance by those entities who consider themselves as only servicers but who may in fact also be involved in remanufacturing?

3. What surveillance mechanisms are available to the FDA to detect servicers who are also performing remanufacturing?

4. What actions does the FDA currently take if it identifies unregistered entities engaged in remanufacturing? What, if any, new options for action are under consideration?

Sincerely,

Elizabeth Warren
United States Senator

Bill Cassidy, M.D.
United States Senator

[13] *Id.*, pg. 19.
[14] *Id.*, pg. 19.