Dear Commissioner Gottlieb:

Over the past two years, the maintenance and repair of medical devices have become subject to increased attention at the U.S. Food and Drug Administration (FDA) and on Capitol Hill, due to patient safety concerns raised by inappropriate servicing. Currently, only servicing activities undertaken by the original equipment manufacturer (OEM) are regulated by the FDA. By contrast, similar servicing activities performed by third parties lack FDA quality, safety, or regulatory controls. This lack of oversight has resulted in devices being improperly serviced or repaired, including instances involving the use of non-qualified parts, which present a significant threat to patient safety.

As you may recall, the FDA Reauthorization Act (FDARA; P.L. 115-52), which was signed into law in August 2017, included a provision requiring the FDA to issue a report with respect to servicing of medical devices (Section 710). This report, among other provisions, asks the FDA to present its findings from the comment period and public workshop it held over a year ago and make recommendations as to next steps.

We respectfully request that you give this patient safety issue your full attention, and we look forward to the FDA’s report and responses.

As Dr. Jeff Shuren, Director of the Center for Devices and Radiological Health, stated during his testimony to the House Energy and Commerce Committee on May 2, 2017, the FDA has the legal authority to regulate third party servicers, but has elected not to do so. This authority allows the FDA to take regulatory action to protect the safety of patients and the integrity of medical devices.

In order to protect patient safety and device performance, we respectfully request the FDA require all entities engaged in medical device servicing activities to:

- Register with the FDA;
- Report to the FDA on adverse events such as deaths or serious injuries; and
- Establish a quality management system, such as outlined in 21 CFR 820.

This basic level of regulation would be a significant step forward in protecting patients. Currently, all OEMs are held to these requirements, whether they are large multi-national conglomerates or small “mom-and-pop” operations.

Patients rely on the safe, effective, and reliable operation of medical devices. Improper servicing of medical devices challenges patient trust and has serious implications for patient safety. We look forward to the FDA’s timely and full completion of this FDARA-required report and continuing our work together to ensure patient safety.

Sincerely,

RYAN A. COSTELLO  
Member of Congress

SCOTT PETERS  
Member of Congress
BILLY LONG  
Member of Congress

RICHARD HUDSON  
Member of Congress

LEONARD LANCE  
Member of Congress

MICHAEL C. BURGESS M.D.  
Member of Congress

GENE GREEN  
Member of Congress

ANNA G. ESHOO  
Member of Congress

TONY CARDENAS  
Member of Congress

DORIS MATSUI  
Member of Congress

G.K. BUTTERFIELD  
Member of Congress

MIMI WALTERS  
Member of Congress

MIKE DOYLE  
Member of Congress

DIANA DEGETTE  
Member of Congress
GUS BILIRAKIS
Member of Congress

ROB WOODALL
Member of Congress

RAUL RUIZ M.D.
Member of Congress

KEITH ROTHFUS
Member of Congress