U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

April 28, 2017

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Hearing entitled "Examining Improvements to the Regulation of Medical Technologies"

I. INTRODUCTION

The Subcommittee on Health will hold a hearing on Tuesday, May 2, 2017, at 10:00 a.m. in 2123 Rayburn House Office Building. This hearing, entitled "Examining Improvements to the Regulation of Medical Technologies," will provide members an opportunity to better understand several bipartisan bills related to the regulation of various medical technologies. The Food and Drug Administration (FDA) and interested stakeholders will provide testimony.

II. WITNESSES

Panel I

- Jeffrey Shuren, M.D., J.D., Director, Center for Devices and Radiological Health, Food and Drug Administration.

Panel II

- Thomas Powers, Ph.D., Powers Consulting, LLC;
- Frank Lin, M.D., Ph.D., Associate Professor of Otolaryngology – Head and Neck Surgery, Geriatric Medicine, Mental Health, and Epidemiology, Johns Hopkins University;
- Joe Robinson, Senior Vince President, Health Systems Solutions, Philips North America;
- Robert Kerwin, General Counsel, International Association of Medical Equipment Remarketers and Servicers;
- Patricia Shrader, Vice President, Global Regulatory Affairs, Medtronic.

III. BACKGROUND

H.R. 1652, Over-the Counter Hearing Aid Act.

H.R. 1652, introduced by Reps. Joe Kennedy (D-MA), Buddy Carter, (R-GA), and Marsha Blackburn (R-TN), would require FDA to promulgate regulations to establish a category of over-the-counter hearing aids intended to be used by adults to compensate for perceived mild to moderate hearing impairment.

H.R. 2009, Fostering Innovation in Medical Imaging Act.

H.R. 2009, introduced by Reps. Ryan Costello (R-PA) and Scott Peters (D-CA), would clarify the FDA review process for medical imaging devices intended to be used in conjunction with contrast agents, which are drugs that enhance the contrast between the targeted tissue of a patient and the surrounding areas.

H.R. 2118, Medical Device Servicing and Accountability Act.

H.R. 2118, introduced by Reps. Ryan Costello (R-PA) and Scott Peters (D-CA), would require both original equipment manufacturers and third-party service providers to register to the FDA, maintain a complaint handling system, and submit adverse event reports.

H.R. 1736, to amend the Federal Food, Drug, and Cosmetic Act to improve the process for inspections of device establishments and for granting export certifications.

H.R. 1736, introduced by Reps. Larry Buschon (R-IN), Scott Peters (D-CA), Susan Brooks (R-IN), and G.K. Butterfield (D-NC), would modernize FDA's risk-based approach to inspecting medical device manufacturing facilities and improve related communications between the agency and industry.

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Carly McWilliams or John Stone of the Committee staff at (202) 225-2927.