Comer

AdvaMed
Advanced Medical Technology Association

August 27, 2019

The Honorable Jim Inhofe
Chairman
Armed Services Committee
United States Senate
Washington, DC 20510

The Honorable Jack Reed
Ranking Member
Armed Services Committee
United States Senate
Washington, DC 20510

The Honorable Adam Smith
Chairman
Armed Services Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Mac Thornberry
Ranking Member
Armed Services Committee
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Inhofe, Ranking Member Reed, Chairman Smith, and Ranking Member Thornberry:

The Advanced Medical Technology Association (AdvaMed) is deeply concerned about provisions in S. 1790 and H.R. 2500, the "National Defense Authorization Act for Fiscal Year 2020" (NDAA), related to the regulation of per- and polyfluoroalkyl substances ("PFAS"). AdvaMed strongly urges you to oppose those provisions in the legislation that circumvent existing, well-established regulatory processes and predetermine outcomes using inadequate scientific data by seeking to regulate PFAS as a single class of chemicals.

AdvaMed is a trade association that represents over 400 of the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. Medical devices made by AdvaMed members help patients stay healthier longer, expedite recovery, allow earlier detection of disease, and improve effectiveness and efficiency of treatment. As innovators and providers of the most critical life-saving and life-enhancing equipment purchased in the United States and globally, we oppose legislative efforts that fail to recognize the significant importance of medical devices that use fluoropolymers.

PFAS have a wide variety of chemical and physical properties, with over one thousand different compounds used in various ways. Given such variations, it is inappropriate to circumvent existing regulatory authorities by grouping all PFAS as a single class, as not all PFAS maintain the same potential risk, as proven by fluoropolymers used in many medical devices. Federal agencies with relevant expertise should identify potential avenues for prioritizing individual groups of PFAS with similar

properties that may otherwise require greater scrutiny based on hazard and exposer profiles.

Medical devices made with fluoropolymers, a compound of PFAS, have been available to patients for over 50 years, with tens of millions of devices used without demonstrating adverse health effects like carcinogenicity and reproductive, developmental, or endocrine toxicity. The health risks of these medical devices are thoroughly assessed by the U.S. Food and Drug Administration ("FDA") before being placed on the market and must undergo multiple tests to prove biocompatibility in compliance with international biocompatibility standard ISO 10993. Furthermore, manufacturers and the FDA, in compliance with the FDA Quality System Regulation, continue to monitor the safety of these products even after they are marketed.

The regulatory requirements imposed by Section 330A, 330D and 330O of H.R. 2500 that group together all PFAS would incorporate those fluoropolymers used in medical devices. Therefore, we urge you to reject sections 330A, 330D and 330O of H.R. 2500 that would require EPA to add all PFAS to the list of toxic pollutants regulated by the Clean Water Act; require all PFAS-containing "waste" to comply with Subtitle C of the Resource Conservation and Recovery Act; and finally, would require that EPA designate **all** PFAS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act. Circumventing the exiting regulatory process for determining hazardous substances and wastes could threaten the ability of our members to continue to provide patients with life-saving devices.

Finally, the regulatory determination of "hazardous" and "toxic" in the legislation would suggest to patients and health care providers that use of medical devices made from fluoropolymers is not safe, although decades of use and FDA's thorough assessment through clinical trials illustrate otherwise. Congress should instead allow EPA to retain its statutory authority to assess the array of PFAS and determine which should be designated under CERCLA, the CWA or the RCRA based on risk using the best available science.

We look forward to working with you on this important matter as the legislative process continues.

Sincerely,

Scott Whitaker
President and CEO