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The Honorable Frank Pallone
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20510

The Honorable Cathy McMorris Rodgers
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20510

Dear Chairman Pallone and Ranking Member Rodgers:

On behalf of the Advanced Medical Technology Association (AdvaMed) and the 400-plus medical technology companies we represent, allow me first to thank you for your leadership in Congress throughout the Covid-19 crisis, and particularly for the work you and your staff have done with our organization and member companies to help improve the health of the patients we serve. I am writing today to express our concerns as an industry with H.R. 2467, the PFAS Action Act.

Medical devices manufactured by AdvaMed members help patients stay healthier longer, expedite recovery, allow earlier detection of disease, and improve the effectiveness and efficiency of treatment. As the largest global organization representing innovators and providers of the most critical life-saving and life-enhancing medical devices, diagnostic products, digital health technologies, and health information systems, we oppose legislative efforts that do not recognize the significant importance of medical devices that use fluoropolymers.

In its current form, the legislation would circumvent existing, well-established regulatory processes and predetermine outcomes using inadequate scientific data by regulating all per- and polyfluoroalkyl substances ("PFAS") as a single class of chemicals. We strongly encourage you to oppose the bill. Here is why:

PFAS have a wide variety of chemical and physical properties, with more than nine thousand different compounds used in various ways. Given such variation, we believe it would be 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 exposure profiles. H.R. 2467 fails to make those regulatory distinctions.

Medical devices made with fluoropolymers, a compound of PFAS, have been available to patients for more than 50 years, with tens of millions of devices used without demonstrating adverse health effects (such as 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 PFAS Action Act's regulatory requirements set forth in section 2, section 8, and section 9 – among others – would regulate PFAS, including fluoropolymers used in medical devices, as a class. Thus, for example, all PFAS could be regulated as a "hazardous substance" under the Comprehensive Environmental Response, Compensation, and Liability Act or as a "hazardous air pollutant" under the Clean Air Act. Further, all PFAS-containing "waste" – no matter how innocuous – would be regulated as a "hazardous waste" under the Solid Waste Disposal Act. Circumventing the existing 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 healthcare 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. We recommend that Congress instead allow EPA to retain its statutory authority to assess the array of PFAS and determine which should be designated under the environmental laws based on risk, using the best available science.

We look forward to working with you on this important matter as the legislative process continues, and we welcome the opportunity to speak directly with you or your staff about it.

Sincerely,

Scott Whitaker