Dear Sir/Madam:

The Advanced Medical Technology Association (AdvaMed) provides these comments in response to a request regarding the Food and Drug Administration (FDA or “Agency”) Center for Devices and Radiological Health Federal Register notice “Immunology Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments”; Federal Register Volume 84, Number 190 (Tuesday, October 1, 2019).

AdvaMed is the world’s largest trade association representing medical device and diagnostics manufacturers. AdvaMed member companies produce the innovations that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed has more than 400 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, efficient product approvals, appropriate reimbursement, and access to international markets.

Medical technology provides incredible benefits to patients; however, for some patients there will also be unanticipated risks. It is important to all of us that we understand these rare occurrences, how to identify them, how to avoid them if possible, and how to manage them when they do occur.

Product safety is a key focus of the medical device industry. Each adverse event is of concern to us, and we work diligently to identify and address the cause of each. This process often involves providing notification to doctors and patients and conducting research as necessary to address the underlying causes.
Throughout the development process of a medical device, product safety and the needs of patients are always prominent. We design devices with input from physicians that have identified a problem with the current standard care and a patient need. We select the best, well-studied materials to address the identified problem based on a number of factors: design, the stresses that will be faced by the device, duration of its use, etc. We test the devices for safety including biocompatibility in compliance with internationally recognized standards and for functionality including durability and efficacy in each specific use. This testing includes bench testing, laboratory testing when appropriate, animal testing and, where needed, human clinical trials. This testing information along with other device information is submitted to FDA prior to the Agency granting permission to market the device.

Once on the market, product use continues to be monitored by manufacturers in compliance with FDA requirements. We collect data on all adverse events, track and trend them and report them to FDA and the users. For some products like active permanent implants, we register each device and the patient that has received the implant. This allows patients and their clinicians to quickly contact the manufacturer if any issue or problem occurs. Likewise, manufacturers can efficiently notify doctors and patients when there is information they need to know about their device.

There are millions of people who have benefitted from implanted medical devices. More than a million Americans are living with pacemakers and another million with implantable cardioverter defibrillators, all of which have metal cases and leads. More than 10 million people in the U.S. are living with artificial joints, many of which have metal components. These devices and countless others are helping people live longer, healthier, more productive lives.

However, as with any medical intervention, there are risks related to these devices. Although extremely rare, some patients cannot receive the benefits of these devices due to their reaction to the materials used. Clinicians need to ask patients about metal sensitivities so they can receive an alternative therapy if available.

Laboratory tests that could reliably identify patients with metal sensitivities would help patients and their physicians make more informed decisions about the risk and benefits about any proposed treatment so that they can determine the most appropriate therapy for that individual patient. Unfortunately, currently available testing has some limitations, and it would be necessary to improve test sensitivity and availability in order for patients to fully benefit from this preferred course of action.

Medical device manufacturers will continue to choose the best available materials for use in devices as well as conduct all appropriate testing. Meanwhile clinicians and patients must communicate information about the materials used in devices and possible patient sensitivities, and laboratory test developers must meet the challenge of improving their products.
AdvaMed commends FDA efforts to learn more about materials sensitivity in patients and to work with clinicians and industry to resolve the problems. Medical device manufacturers are committed to developing the safest and most effective devices possible. We look forward to collaboration with FDA, patients and other stakeholders.

Sincerely,

/s/

Ruey C. Dempsey
Vice President
Technology & Regulatory Affairs