



AdvaMed

Advanced Medical Technology Association

AdvaMed Response to the Department of Commerce's Request for Public Comments on Risks in the Semiconductor Supply Chain

Docket Number: 210915-0189

November 8, 2021

AdvaMed would like to thank the Department of Commerce and Bureau of Industry for leading the 100-day supply chain review of semiconductors and advanced packaging mandated by Executive Order 14017. We appreciate the Administration's resolve to strengthen the resilience of U.S. supply chains, including the availability of semiconductor chips, and address near-term shortages and bottlenecks. We likewise support the Administration's goal of improving transparency and facilitating information flow across the various segments of the supply chain.

About AdvaMed

AdvaMed is the world's largest medical technology association, with over 400 members ranging from the largest to the smallest medical technology innovators and companies. Our member companies manufacture products that support our national defense by preventing, detecting and treating COVID-19. These products include personal protective equipment (PPE), testing supplies and equipment, ventilators and vaccine ancillary devices – as well as other life-changing technologies ranging from cardiovascular and orthopedic implants to cancer diagnostics, surgical instruments and digital health products. These technologies help save and improve millions of lives every day. As the collective voice of the medical devices industry, AdvaMed appreciates the opportunity to respond to the Department of Commerce's Request for Public Comments on Risks in the Semiconductor Supply Chain. We respectfully submit the following comments:

MedTech Industry and Semiconductor Chips

Despite being less than 1% of the overall semiconductor chip market, manufacturers of medical devices and diagnostics rely on semiconductor chips for a vast array of technologies. These include capital equipment such as imaging systems, diagnostic systems, and robotic surgical systems, patient monitoring systems (glucose, oxygen levels, blood pressure, etc.), cardiovascular care such as EKG, pacemakers and defibrillators, respiratory care such as ventilators and CPAP, orthopedic implants and a broad spectrum of technology enabled systems and applications in the healthcare delivery system.

To better understand the extent to which the medical devices industry manufactures technologies that utilize chips and the impact of the chips shortages on our sector, AdvaMed commissioned a study by Deloitte. Researchers at Deloitte found that the chips shortage is not confined to one organization or one technology, rather it's becoming an acute, industry-wide issue for the hundreds of diagnostics, therapeutics, and capital equipment companies that produce essential medical technologies. Combining insights from a survey and interviews with members of AdvaMed, Deloitte revealed the following findings:



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- Two-thirds of companies have semiconductors and firmware/embedded software in over half of their products. In addition, 50 percent of respondents report that connected devices, which also require semiconductors, comprise half of their products.
- The medical device industry's primary needs are 2nd or 3rd generation chips, placing it in competition with automotive, industrial, and consumer industries for critical chips rather than high tech.
- All respondents have experienced some disruption to their chip supply chain. The most common disruptions are delays, order cancellations and short orders. Delays vary significantly, from two to 52+ weeks.

Challenges for MedTech Industry

As the Deloitte study reflects, the pervasive shortage of chips has greatly impacted our sector and is significant cause for concern as the trajectory of the pandemic remains uncertain and more and more citizens are seeking much needed medical care that was delayed or postponed during the early days of the pandemic.

The Deloitte study found hoarding practices and dramatic price increases to be prevalent. AdvaMed also members consistently observe that they are unable to compete in the chips market with larger players such as the automotive and home appliances industries. In addition, AdvaMed members have encountered an uptick in scams or other unethical players taking advantage of the chip crisis. These kinds of practices waste critical time and resources as companies scramble to find reliable alternative sources.

Finally, a unique challenge to the medical device industry is the FDA regulatory requirements that must be met should a manufacturer find a substitute or replacement chip. In these cases, the manufacturer is required to conduct validation and verification testing to ensure compatibility of the component with the medical device, and in many cases will need to submit the information to FDA for a new regulatory review. This new regulatory review must be completed by FDA before the manufacturer can legally market the device with the substitute or replacement chip.

MedTech Solutions

Ensuring the continuity of patient care is our members' top priority. Our Supply Chain Task Force members have highlighted several best practices that have emerged during the pandemic amidst supply shortages such as activating dual sources, building redundancy into their operations (i.e., qualifying alternative parts), redesigning and requalifying product configurations and expanding inventory and factory capacity. In addition, our member companies have gone to extreme lengths to communicate deep into their supply chain, often reaching out to their suppliers' suppliers about the nature and criticality of the technologies the chips are destined for. These efforts reflect the Deloitte study findings that poor visibility into supplier risk is a top concern for 60% of companies.



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Recommendations

Even as the medical devices industry has proven nimble and adaptive, avoiding disruptions in the delivery of patient care, the ongoing shortages which are predicted to go on well into next year present an unsustainable situation for our industry. As we noted at the outset, medical devices is only a sliver of the overall chips market, but it is undeniably a critical sector that supports our national security. While the expansion of the domestic industrial base for chips is a welcome initiative that AdvaMed fully supports for long term supply chain resilience, it is critical that policy makers and chips supply chain partners work together to ensure that delivery of healthcare in America is not disrupted in the near term. Accordingly, we look forward to working with the Department of Commerce, the interagency and key private sector partners to raise awareness about the unique and critical needs of our sector and explore ways that chips for medical uses are prioritized over non-essential uses.

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