



AdvaMed

Advanced Medical Technology Association

AdvaMed Response to the Department of Commerce's Request for Public Comments on Incentives, Infrastructure, and Research and Development Needs To Support a Strong Domestic Semiconductor Industry

Docket Number: DOC-2021-0010

March 25, 2022

AdvaMed would like to thank the Department of Commerce (DOC) and the National Institute of Standards and Technology (NIST) for its leadership on policies and programs to support the expansion of America's domestic industrial base for semiconductor chips. As DOC and NIST move forward to plan and design programs to incentivize investment, accelerate R&D and ensure a robust domestic semiconductor industry, we are grateful for this opportunity to provide the perspective of the U.S. medical devices industry which is heavily reliant on semiconductor chips to ensure critical life-saving equipment is readily available to meet the needs of patients and medical facilities.

About AdvaMed – Our Industry's Workers and Technologies

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 industry directly employs 397,000 people, at an average annual salary of \$88,096—49% higher than the average across all industries and 18% higher than the corresponding premium of all manufacturing jobs. Every 5 medtech industry jobs creates an additional 7 jobs. Of the nearly 15,000 medtech establishments, 94% were small businesses that employed fewer than 100 employees.

AdvaMed members 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 and life-saving 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.

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 but are not limited to capital equipment such as imaging systems, diagnostic assay systems, instrument sterilization equipment, 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. It is also worth noting that there is a vast ecosystem of technologies including



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automation and molding that directly support the manufacture of medical technologies. This equipment also relies on semiconductor chips.

Over the past year, the chips shortage has become an acute industry-wide issue for the hundreds of diagnostics, therapeutics, and capital equipment companies that produce essential medical technologies that support patient health. As the semiconductor supply chain challenges continue, shortages stemming from allocations and commitments by chips manufacturers, suppliers and brokers have disrupted medical technology manufacturing and the delivery of patient care. In the short term, AdvaMed is calling for the federal government and chips supply chain partners to prioritize the delivery of patient care by ensuring that medical device manufacturers receive the comparatively small number of chips they need to continue operations. Failure to do so could result in further production disruptions and the inability to repair the existing healthcare infrastructure, directly impacting the ability to provide patient care. Overtime, pervasive shortages could also begin to drive up healthcare prices and restrict innovation as companies are forced to pay even higher prices for scarce chips or redesign and recertify technologies to accommodate their limited inventory of chips.

Recommendations

As DOC and NIST contemplate mechanisms to promote a more robust domestic semiconductor industry, we recommend that the agencies assess the healthcare industry's requirements for mature and advanced semiconductor chips. Currently, the medical devices industry is largely reliant on mature chips to operate their technologies. While that may change over time, it is critical that the U.S. government supports R&D and growth in this sector, and, most importantly, that it has a clear picture of our nation's health technology needs, with particular focus on essential semiconductor chips and their market allocations.

In addition to the proposed programs outlined in the RFI, AdvaMed recommends that Commerce establish a program or office in partnership with key agencies including FDA (i.e., FDA's Resilient Supply Chain and Shortage Prevention Program) and HHS/ASPR that evaluates financial assistance, R&D, supply chain transparency, workforce, and other needs as it relates to the evolving infrastructure requirements of the U.S. healthcare system. This program or office could provide input into the overall process from the perspective of addressing our nation's public health and the well-being of patients. As a key part of this effort and for the reasons outlined above, we also strongly recommend a formal mechanism for regular high-level industry consultations to ensure the U.S. government receives timely information on the semiconductor needs of the medical device industry and can act appropriately to stave off future, unnecessary shortages that could impact patient care.

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