July 3, 2018

Via Electronic Mail Only
Eric D. Hargan
Immediate Office of the Secretary
Office of the Deputy Secretary
U.S. Department of Health and Human Services
Attn: RFI Regarding Healthcare Sector Innovation and Investment Workgroup
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: RFI on Facilitation of Public-Private Dialogue to Increase Innovation and Investment in the Healthcare Sector

Dear Deputy Secretary Hargan:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to respond to the Agency’s request for information on facilitating improved dialogue on promoting health innovation and increased investment in the healthcare sector. This initiative, as presented by the Department of Health and Human Services (HHS), represents a positive step towards improving patient access to innovative medical technologies to treat and resolve their health concerns and we appreciate your leadership on this important matter and in ensuring that the U.S. continues to be a leader in the provision of cutting edge healthcare.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming healthcare through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies.

Rapid innovation in medical technology has delivered huge gains to patients and the U.S. healthcare system, but coverage, coding, and payment reforms are needed to more fully realize the promise of modern medical technologies. Uncertainty in these areas has severely impacted the level of investment in the healthcare sector and has compromised the ability of device companies to innovate and bring new treatments to the market. The proportion of venture capital investment in medical technology companies declined from 13 percent in 1992 to 4 percent in 2016. The proportion of funding that goes into Series A investment, the first round of venture capital funds raised by startups, has experienced an even greater decrease. Series A investments...
in medical technology as a percent of total venture investments declined from 19 percent in 2006 to 10 percent in 2016.

AdvaMed is encouraged by HHS’s publication of the RFI request and views it as a positive step towards the development and promotion of policy changes that strengthen the medtech innovation ecosystem and directly benefit patients, the health care system, and the U.S. economy. We offer the following comments in response to the questions presented in the RFI:

**Question 1:**
In recent years AdvaMed members have experienced, firsthand, reductions in funding by venture capitalists and other investors due to uncertainty related to coding, coverage, and reimbursement for new medical technologies. We think it is imperative that the group convened by HHS examine the decline in funding innovation in this sector and the reasons underlying this trend. AdvaMed also recommends that the workgroup focus on eliminating and/or reducing regulatory barriers to innovation and engage stakeholders who can offer first-hand accounts regarding their experience procuring investment, including venture capitalists and others who make funding decisions.

HHS’s workgroup should also address patient access challenges created by the regulatory complexity of CMS’s coverage, coding, and reimbursement processes. Being able to identify and bill for a technology as well as having a clear and reasonable pathway for coverage and reimbursement is crucial in providing investors assurances of a product’s success. Failure to have these elements in place often impacts the confidence that investors might otherwise have regarding the likely success of a device. Many medical technology companies, especially small companies, and investors have tremendous difficulty understanding the evidence and outcomes expected by CMS to deem a technology “reasonable and necessary” for Medicare coverage. This lack of certainty, which is also problematic in the private payer environment, is one of the key challenges in the industry.

At the same time, the shift to value-based payment models provides important opportunities for medical technologies companies to help drive improved outcomes at lower cost. Yet new approaches that would allow risk-based or outcomes-based arrangements between manufacturers and providers and payers are hindered or prevented by outdated, fee-for-service-based rules like the Anti-Kickback Statute.

We recommend that HHS workgroup discussions include private and public payer issues related to policy and other constraints that interfere with patient access to and adoption of innovative new technologies. Additionally, the group should evaluate the impact of current FDA and NIH policies which impact the ability of medical technology manufacturers to receive clearance and approvals in a timely fashion or which limit the ability to access grant funding that can spur development of new innovations. We believe that the workgroup’s role should also include identifying and evaluating challenges, offering and vetting solutions, and seeking stakeholder input for improving the innovation ecosystem and the regulations affecting the ecosystem.


**Question 2:**
AdvaMed believes that the workgroup should be structured in a way that allows broad participation by as many stakeholders from the innovation and life sciences ecosystem as possible and that accounts for the wide variation of persons and factors which impact the medical technology industry. Investment in and development of new innovations happens in large multinational corporations, midsize corporations, and small start-up ventures – all of which should be represented. The workgroup also should capture the diversity of medical technology services. Medical technology spans all of healthcare, across all settings of care and all therapeutic areas, including surgical tools, implantable technologies, diagnostic tests, imaging and radiation therapies, durable medical products, collaborative technologies that utilize algorithmic data, and new digital and solutions-based technologies. Having representation on the workgroup from the associations which represent and interact with the medical technology industry will also be important. We believe AdvaMed should be included as one such representative.

This group might also include representatives from other government agencies whose policy making can directly impact the ability to innovate through the imposition of tariffs, taxes, and fees that limit device development and production (i.e. Department of Treasury) as well as other agencies who may be able to lend insights into their strategies for procuring and paying for innovative devices (i.e. Veterans Affairs or Department of Defense).

We recommend that the group meet publicly and consider convening meeting in hubs for medical technology manufacturing (i.e. California, Minnesota, Massachusetts) or at industry or investor meetings. Hosting meetings across the country in a town hall type of format will allow diverse attendance and more targeted discussions. We also recommend that meetings accommodate attendance via web-based technology or other means and that all meeting materials be made public on an easily accessible website.

In addition to the broad public meetings, AdvaMed also recommends that HHS consider hosting meetings with a more limited sub-group of stakeholders to facilitate more targeted discussions. For instance, it may be beneficial to hear from small, pre-revenue companies and venture capitalists (from different areas of the country) regarding challenges that they face in securing and sustaining investment in their technologies for a long enough period to get to market. Similarly, it may be helpful to engage a sector of the industry, for example digital or diagnostics, to allow the workgroup to focus on a specific subsector of innovation.

While we understand that the type of dialogue in which HHS wishes to engage may not be conducive to a very large group we would recommend that any recommendations or suggestions coming out of these dialogues be distributed to interested stakeholders for feedback and comment by set deadlines and/or that specific topics be considered for presentation and discussion via public meetings. Recommendations that are developed as a part of these discussions should be circulated for public comment in a timely manner (possibly within 45 days) following the conclusion of each meeting and should be subject to a public comment period (minimum of 30 days). AdvaMed further recommends that HHS act on recommendations coming out of the workgroup, through either follow-up action, incorporation of new policies by
the appropriate agency, and/or the development of legislative proposals to address the concerns within six months following the conclusion of the applicable public comment periods.

**Question 3:**
AdvaMed recommends utilizing the workgroup in a way that promotes ongoing interaction and dialogue between industry and HHS on healthcare investment and innovation issues. Hosting listening sessions where HHS seeks input on ideas it is developing could be beneficial in maintaining this dialogue and in providing recommendations and feedback from industry stakeholders on an ongoing basis. Additionally, HHS could also host annual or bi-annual dialogues on these issues into the foreseeable future – similar to the Learning Action Network meetings.

**Conclusion**

AdvaMed appreciates the opportunity to provide input on the questions raised in the RFI and looks forward to being engaged in this important dialogue going forward. We encourage you to consider and act upon our recommendations as we all, collectively, strive to improve the healthcare ecosystem.

Please contact me (202-434-7202 or swhitaker@advamed.org and cc my assistant, Lyndee Rose at lrose@advamed.org) or Don May (202-434-7203 or dmay@advamed.org) if you have any questions or if we can be of further assistance.

Sincerely,

Scott Whitaker
President and CEO