Thank you for the opportunity to provide input to HHS as the Department examines ways to accelerate the clinical innovation process in the United States. I am Andrew Fish, chief strategy officer with AdvaMed, the Advanced Medical Technology Association (AdvaMed).

AdvaMed’s 400 member companies produce the life-saving and life-enhancing medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed member companies range from the largest to the smallest medical technology innovators. In addition to our U.S. headquarters, the association maintains a presence in China, India, Japan, and Brazil, and, through collaboration with over twenty-five medical technology associations worldwide, represents about 85 percent of the medical technology purchased and used around the globe.

The medical technology industry has made vital contributions to the two-year gain in life expectancy realized in the most recent decade. It employs nearly 519,000 people at wages almost 40 percent higher than average, indirectly generates over 1.44 million additional jobs and generates a favorable balance of trade. Policy changes that strengthen the medtech innovation ecosystem will have direct benefits for patients, the health care system, and the entire U.S. economy.

Today, medical technologies are poised to drive unprecedented value for patients and the health care system, through exponential advances in scientific knowledge and powerful convergences across engineering, materials, sensors, diagnostics, biomechanical interfaces, communications, data collection and analytics, machine learning, robotics, and more.

The potential rewards ahead for patients are tremendous, but the medtech ecosystem in the U.S. has been stressed. The 2.3 percent medical device excise tax, while currently
suspended by Congress, represents a major drag on medical technology innovation and even the uncertainty inherent in repeated, temporary suspensions of the tax casts a pall over the industry and constrains investment decisions. FDA has made notable progress over a number of years in its regulatory processes and performance metrics, but we continue to work with that agency and Congress on improvements while maintaining a high bar for safety and efficacy. Following FDA clearance and approval, a potentially years-long gap until coverage and payment policies are in place can mean long delays in getting new technologies to patients and extended stretches of retrenchment in medical device investment have been attributed in large part to the uncertainties and lag associated with coverage and payment.

These challenges fall on an industry whose products not only represent the most cutting-edge and transformative innovations in health care, but also make up a relatively small and constant share of national health expenditures. Device spending as a share of total national health expenditures was about 6 percent from 1992-2013, and then declined over several years to 5.2 percent. Over those several decades, medical device prices have increased at an average annual rate of only 0.8 percent, compared to 2.5 percent for the Consumer Price Index and 4.3 percent for the Medical Consumer Price Index.

This relatively very slow rate of price increase indicates that the medical technology industry is highly price competitive and suggests that the impact of public policies therefore may be more pronounced on the industry.

For many years, AdvaMed has advocated for improved processes to speed clinician and patient access to new and innovative medical and we applaud the Administration for undertaking its clinical innovation initiative.

We recognize that the scope of the current inquiry is intended to exclude policies, procedures, and review processes, but policy improvements in those areas can be the most meaningful for reducing unnecessary regulatory burdens and speeding patient access to clinical innovations. I would be remiss if I didn’t mention briefly our proposals to make significant improvements to how CMS covers and pays for FDA-designated breakthrough devices, and thank CMS for its recent proposals in response.

FDA’s Breakthrough Device Program is intended to provide patients more timely access to a limited set of the most innovative and disruptive medical technologies by expediting their development, assessment, and review while still meeting statutory standards for safety and effectiveness. Yet the medical technologies that FDA determines are most important for patients can languish at CMS without Medicare coverage – defeating the purpose of accelerating their FDA approval. Two key administrative changes can
dramatically improve patient access to these technologies and remove unnecessary regulatory red tape that currently slows the process. First, we have advocated that breakthrough technologies should be automatically covered for 3-5 years for Medicare patients and, secondly, as breakthrough technologies represent new and substantial improvements over existing care options, they also should receive automatic approval for inpatient New Technology Add-on Payments (NTAP) and hospital Outpatient Passthrough payments.

We applaud CMS’s recent proposal, in the Fiscal Year 2020 Inpatient hospital rule, to consider new medical technologies that are designated as breakthroughs by the FDA to be deemed to meet the “new” and “substantial clinical improvements” criteria for the purposes of receiving the NTAP under Medicare, and we are developing our comments to CMS in support of that proposal.

Second, we propose that for technologies that do not receive automatic access to Medicare coverage or have an established payment pathway, a new evidence development process should be created to provide coverage certainty by detailing up front CMS’s desired evidence expectations for a specific medical technology, including study outcomes and metrics.

Under our proposal, Medicare coverage should be available to help support the post-FDA evidence development process for at least three years. This can be done by a new, voluntary process that would provide certainty on the type of evidence and outcomes CMS wants for determining whether a new technology meets the agency’s definition of “reasonable and necessary” and provides coverage and reimbursement for a limited time to develop the evidence.

Our proposal, to better clarify CMS’ decision-making criteria and improve medical technology manufacturers’ ability secure positive coverage and payment decisions, seems right in line with today’s inquiry.

Within the scope of the Clinical Innovation Initiative inquiry, we would like to recommend several additional areas for further examination.

First, we endorse continued initiatives to better support product development and commercialization, especially for small companies. The NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, for example, have provided critical support for small medical technology companies to advance their product development and commercialization. These programs are vital to the research and development necessary to support companies that are on the cutting edge.
of medical technology and have the potential to create the next generation of lifesaving treatments for patients. We encourage HHS to fully leverage existing programs and explore potentially expanded efforts to help connect the fruits of NIH’s formidable research portfolio with innovators seeking commercialization opportunities.

Second, as suggested in the Notice associated with this public hearing, HHS should explore ways to make its massive health data resources more accessible and usable to medical technology innovators seeking to better understand clinical needs and opportunities for improved patient care. It is possible that analysis of those aggregated data resources could help redirect research and development investments, point to new indications for existing technologies, or provide additional data to demonstrate the value propositions of specific technologies. These data resources also may offer evidence to help medical technology manufacturers more easily demonstrate to CMS that a specific technology meets the “reasonable and necessary” test for Medicare coverage.

Third, HHS data resources potentially could be brought to bear on product development specifically in the digital health arena. In digital health, emerging and converging technologies are enabling collection of novel kinds of data, aggregation of ever-larger data sets, increasingly sophisticated data analysis, and augmented intelligence. Current and emerging elements of health care powered or enhanced by these data capabilities include new insights into individual and population health; real-time, continuous, remote patient monitoring; distributed care outside of traditional settings; advanced diagnoses through wearable, implantable and ingestible technologies; more effective management of population health; autonomous and/or remote interventions; enhanced clinical decision support; product research and development; and more.

These advances in digital health will be transformative and are building tremendous value with respect to improved patient outcomes and the quality and efficiency of health care delivery. Augmenting these efforts with the data resident within HHS agencies could provide substantial benefits along the continuum of research and development, regulatory approval, coverage, payment, commercialization and adoption. Training artificial intelligence algorithms, for example, can be data intensive and there are challenges associated with gathering enough of the right types of data, including consented data as necessary.

Fourth, the increased use of outcome-based care arrangements among medical technology manufacturers, hospitals, and payers is a laudable trend in which higher quality care is prioritized and rewarded over volume. HHS may be holding data that could point the way toward new areas amenable to these types of arrangements and
support the development and validation of outcome-based care models for different clinical pathways.

Finally, we also want to underscore a cautionary note that HHS itself raised in the Notice for this public hearing, regarding promoting competition and maintaining commercial confidential information. This is a critical consideration, because much of the data generated in health care, especially as new data-generating technologies come online, is the product of substantial commercial investment and we presume this is true for a significant amount of the information held in HHS data resources. A systematic effort to unlock value from HHS data resources still must preserve the confidentiality of commercial, proprietary data, not just to protect the rights of the data holders in specific instances but also to help ensure more generally that our digital health ecosystem continues to incentivize and reward investment in data and data-driven innovations.

Again, we applaud this HHS initiative on clinical innovation and look forward to working with the Department as it continues this effort. Thank you for providing this opportunity to share our input.