Alliance FOR AGING RESEARCH
Catalyzing Innovation for Healthy Aging

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Comments as delivered

Good afternoon, my name is Michael Ward. I am the Director of Public Policy for the Alliance for Aging Research.

The Alliance for Aging Research is the leading non-profit dedicated to accelerating the pace of scientific discoveries and their application to improving the experience of aging and health. We are happy to have a longstanding partnership with the FDA to advance its important work on medical devices, including user fee agreements.

Investment in Digital Health Infrastructure

I will begin by discussing investment in digital health infrastructure. Digital technologies, mobile applications, remote monitoring devices, and artificial intelligence serve a key role in the advancement of healthcare. The development of these tools has been brisk – the FDA reports 4,200 submissions with digital health considerations during MDUFA IV. The role of digital-based technologies has been reinforced and strengthened as a result of the COVID-19 pandemic, as consumers have experienced heightened hesitancy to receiving in-person services.

The Alliance has a long-standing interest in these concerns. As individuals age, they often have elevated care needs and face increased obstacles to receiving in-person care, such as frailty and limited transportation options. Older adults also have a higher probability of having one or more chronic conditions. Monitoring key metrics, such as weight and glucose levels are vital, as sudden changes or fluctuations may provide an early notice that an adverse event is likely to occur.

At the same time, these tools require specialized expertise in technology and communications, while also elevating cybersecurity concerns. The FDA and the Center for Devices and Radiological Health (CDRH) have made admirable efforts to adjust and accommodate the evaluation of these digital technologies. Staff have gone above and beyond to expand expertise in digital health, often in areas outside the scope of their current role.

In response to this need, we applaud the FDA's establishment of the Digital Health Center of Excellence this year. The need to support additional infrastructure is critical – for example, CDRH is currently responding to over six hundred inquiries related to digital health per year, with requests exceeding two thousand per year since fiscal year 2018. The digital health market size is expected to grow 25 percent year over year through 2025.

In the next round of MDUFA, the Alliance encourages the FDA to prioritize investment in appropriate infrastructure to accommodate both reviews and the ongoing surveillance of digital health and artificial intelligence technologies.

Patient Access to Device Benefit-Risk Reduction

Next, we'll look at patient access to device benefit-risk statements and labeling. Manufacturers are required to include information in product packaging to ensure the safe and effective use of devices and pharmaceuticals. However, this insert is generally less accessible for implantable medical devices. For example, a patient may require a stent or a pacemaker in the course of their care. However, the surgeon and care team would physically handle the implant during the procedure – including unpackaging the device from a sterile package. It is reasonable to expect that the patient information would then be discarded with the other packaging for the device, without the patient having the opportunity to review.

An additional issue is that patients may not be aware of the existence of alternative devices, let alone their availability or accessibility for their medical indication. Physicians and hospitals often, and understandably, focus on the implementation of a specific device to ensure maximum faculty and to standardize their supply chain. However, if patients are made fully aware of risks and benefits among suitable options, they may – in conjunction with their doctor – decide they are more comfortable with an alternate device and care plan. From the patient perspective, this represents a lost opportunity to learn as much as possible about their device before implantation.

The Alliance for Aging Research is interested in exploring strategies for patients to have greater access to labeling information for implantable devices. We have appreciated the opportunity to work with the Medical Device Innovation Consortium's (MDIC) Virtual Patient Engagement Forum to provide interactive opportunities to engage with relevant stakeholders

to learn and share challenges about best practices for communicating benefit, risk, and uncertainty for medical devices to patients. CDRH is actively participating in that effort, and the next virtual meeting is on November 18. The MDIC's communications report, which will be discussed at this meeting, will serve as a guide for the next steps in efforts to provide relevant patient labeling.

We encourage the FDA to utilize the MDUFA process to explore options that ensure patients have access to label information before a procedure to facilitate shared decision-making between patients and their providers. We anticipate this effort would be patient-centered, with focus groups and data collection to support evaluation. As part of this process, we also anticipate that the FDA would work with provider trade associations and clinicians to determine how to incorporate enhanced patient communication about device benefit-risk and labeling into their workflows.

Data Transparency in Patient Registries

We encourage the FDA to utilize its policy authority to ensure appropriate access to device registry data. Patient registries collect post-approval information on outcomes, efficacy, and safety. In many cases, CMS has instituted provider reporting to registries as a requirement when the device is approved under coverage with evidence development status. Registries can also support manufacturers in meeting FDA post-approval data collection requirements. Registries are often hosted and operated by specialty medical societies.

However, we currently face a problem with registries, as a lack of transparency and ongoing inconsistent availability of registry data provides barriers to evaluating outcomes. For example, the TVT Registry collects data on transcatheter valve replacement and repair procedures. However, the registry has not publicly published data on the procedures or health outcomes in over three years. Further, federal agencies do not have open access to the data, which is vital for the collection of real-world evidence. In fact, in CMS's proposed National Coverage Decision for mitral valve repair, the agency said they will continue to "assess patient outcomes through evidence published in the peer-reviewed literature." However, waiting for data published in articles in peer-reviewed journals is a lengthy process. Patients and federal agencies have the right to understand how devices are performing in a timely manner.

Addressing data blocking has been a priority in other areas of healthcare, and we ask the FDA to prioritize data access for device performance. To support this aim, the FDA should explore authority, either alone or in partnership with CMS, to ensure that registries provide regular reports – annually, at a minimum – to evaluate outcomes. Registry data can fill gaps in information that are not available through claims databases. We acknowledge that public reporting may not be appropriate for all devices if utilization is limited. However, federal

agencies should have access to registry data to support safety and efficacy monitoring efforts.

Advancing Evidence on Patient-Centered Outcomes

The Alliance encourages the FDA to explore a strategic partnership with the Patient-Centered Outcomes Research Institute, known as PCORI. Last year, PCORI was reauthorized for ten years and has an expanded scope in evaluating outcomes for patients and other stakeholders. This expanded scope includes the ability to examine burden and the economic impact of medical treatments, items, and services on patients, families, clinicians, payers, and society.

This reauthorization comes at an opportune time. The collection of real-world evidence (RWE) on clinical outcomes continues to be a priority for the FDA in both pre- and post-market analyses. Other regulatory activity also underlines the essential need to collect RWE. For example, CMS's recent proposed rule for Medicare Coverage for Innovative Technology would align Medicare coverage for four years once a device with breakthrough classification receives FDA market approval.

Given the increasing demands for RWE and PCORI's ability to investigate and develop data, it makes sense for CDRH to initiate a strategic research partnership to meet mutual goals. PCORI's mandate also allows studies to measure the relative clinical effectiveness of two or more alternative approaches, including the impact on the cost of care. Enhancing patients' understanding of the relative efficacy of devices and digital health tools will empower patients in their healthcare choices.

Support for MDUFA Reauthorization

I want to emphasize the Alliance for Aging Research's support for the reauthorization of MDUFA. We encourage the FDA to prioritize infrastructure and expand access to outcomes data in the next round of negotiations. We look forward to partnering with the agency in this important effort.

In closing, I want to share a quote from Winston Churchill: "Every day you may make progress. Every step may be fruitful. Yet there will stretch out before you an ever-lengthening, ever-ascending, ever-improving path. You know you will never get to the end of the journey. But this, so far from discouraging, only adds to the joy and glory of the climb."

Thank you.

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