MDUFA Reauthorization Stakeholder Meeting
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December 18, 2015

Good morning everyone. I'd like to thank the FDA for allowing me to comment today on behalf of the Alliance for Aging Research.

I first want to acknowledge that user fees are a critical source of funding for the agency and our suggestions for the MDUFA reauthorization are not intended to alter the program's primary purpose of ensuring the effectiveness and timeliness of the device review process.

We think that many of the proposals raised by FDA and industry thus far have the potential to bring meaningful interventions to patients who need them more quickly and efficiently. My brief comments this morning are going to focus largely on two areas-resources to encourage the utilization of patient reported outcome data and striking a balance for funding of pre-market and post-market data collection.

During the September 15, 2015 and November 30, 2015 stakeholder consultation meetings FDA spoke to us about an increasing number of device applications they are receiving which include patient reported outcome (PRO) data. We were heartened to hear that industry is

embracing the inclusion of patient-centered endpoints in their development programs and the presentations signaled to us that there is growing interest to employ PROs in device trials more regularly. But, we were concerned to hear that CDRH does not have enough staff dedicated to reviewing these increasing amounts of PRO data. The Alliance supports the ability of FDA to collect user fees to properly resource these activities because we believe that it will directly impact the device approval process. In addition, we believe that CDRH should have added capacity to analyze the application information it has collected on PRO use and proactively engage with industry, patient organizations and providers to address overarching challenges with PRO utilization. Where possible, CDRH should begin identifying disease areas where fit-for-purpose tools could be developed outside of individual medical device trials by multi-representative research consortia similar to what is done by CDER.

We commend CDRH for the leadership it has shown in fostering the use of patient preference information in the medical device review and approval process. CDRH's efforts to draw patient representatives earlier into the device review process; its development of a systematic benefit-risk framework for evaluating new devices; and the recent announcement of a Patient Engagement Advisory Committee are all monumental steps. We would hate to see resource constraints holding

the Center back from making further strides. We were encouraged to see a proposal from FDA in the November 18, 2015 FDA-Industry meeting minutes requesting the addition of fees to hire and train staff in patient preference methods. We hope these discussions continue in a positive direction.

The Alliance understands that it is important for the agency to adapt to the rapid pace of technological advancement. Central to this is gaining a better sense of how approved products perform in the clinical setting and creating a feedback loop to inform future pre-market activities. During the November 18 FDA-Industry meeting, FDA put forward a proposal requesting funding for new staff and the development of a system to link health claims, electronic health records, and registry data. We agree with the FDA that there are potential benefits to de-siloing this information. These benefits include the need for fewer stand-alone clinical trials in the future; more efficient enrollment leading to shorter and quicker trials; easier patient follow-up; and harmonization with other national and international data sources.

Increased use of clinical experience information would enable an appropriate shift of data collection from the pre-market to post-market space allowing earlier patient access to devices while data is gathered in a real-world setting to validate its safety and effectiveness. This is

particularly important for the older adults who are frequently under-represented in clinical trials.

MDUFA IV provides a promising opportunity to lay the foundation for this type of system but we caution relying too heavily on user fees for its overall development. We support FDA's proposal to hire staff that would develop a framework to define how registries can be qualified and used for premarket review, link data from claims and registries, and establish registries to support premarket decision making. However, we feel that the support for infrastructure development should be achieved through a combination of user fees and appropriated funding.

Finally, I would just like to add that FDA's November proposal to support its coordinated approach to software and digital health device regulation is worth noting. We urge CDRH to continue discussions with industry on the need for policies in the area of clinical decision support and telemedicine as well as additional resources for training, oversight, and hiring of additional software experts to ensure consistency in the development and implementation of policies in these two critical areas.

Thank you again for the opportunity to comment and for your attention. It has been a pleasure to participate in the monthly stakeholder consultation meetings and we look forward to continuing to provide

feedback on proposed enhancements as the reauthorization process moves forward. If there are any questions, I would be happy to answer them.