November 2, 2016

Division of Dockets Management (HFA-305)
Food & Drug Administration
5630 Fishers Ln., Room 1061
Rockville, MD 20852
Attention: FDA-2016-N-2872
Submitted electronically at http://www.regulations.gov

RE: "Medical Device User Fee Amendments; Public Meeting; Request for Comments; Docket No. FDA-2016-N-2872"

The American Medical Informatics Association (AMIA) appreciates the opportunity to provide comments on the reauthorization of the Medical Device User Fee Amendments (MDUFA IV). Notice of a public meeting and request for comments was published by the Food & Drug Administration (FDA) in the October 7, 2016 issue of the *Federal Register*.

AMIA is the professional home for more than 5,000 informatics professionals, representing front-line clinicians, researchers, educators and public health experts who bring meaning to data, through the systematic collection, analysis and application of data across the health and research enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from the bench to the bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

Historically, AMIA has not engaged with FDA over its priorities for medical device review. However, recent FDA musings on evidence generation[1], along with several recent guidance documents,[2,3] signal clear interest by the Administration to leverage informatics tools and methodologies to augment regulatory decision-making. We fully support these efforts and believe AMIA members are well-positioned to help FDA realize the tremendous value of real world data to inform medical device reviews and surveillance.

Several aspects of the MDUFA IV commitment letter have garnered our members' attention, and are aligned with our Policy Principles & Positions, including:

- Enhanced Use of Consensus Standards (pg. 13)

[1] Sherman, R., Califf, R., "What We Mean When We Talk About EvGen Part II: Building Out a National System for Evidence Generation," FDAVoice, May 3, 2016
[2] Use of Electronic Health Record Data in Clinical Investigations; Draft Guidance for Industry
[3] Use of Real-World Evidence to Support Regulatory Decisionmaking for Medical Devices; Draft Guidance for Industry

  - AMIA is a strong proponent of efforts to identify and promote use of consensus standards. Insofar as FDA is considering the use of data standards, we note that the HHS Office of the National Coordinator for Health IT has extensive experience with their certification program and would encourage FDA to understand lessons learned from ONC's experience. In particular, we note an important difference between conformance to a standard and the ability to interoperate using a standard. ONC's certification program did not test the capacity of systems to "send" and "receive" data, opting to focus on conformance to only the "send" function in most cases.
- Patient Engagement & the Science of Patient Input (pg. 16)
  - AMIA supports patients' efforts to design, test, and validate new technologies that help them manage their health and the health of their families.[4] As such, we are encouraged to see continued and enhanced focus on the use of patient preference information and patient reported outcomes data in medical device decision-making.
- Real World Evidence (RWE) (pg. 17)
  - AMIA is eager to help FDA realize the potential of RWE to improve regulatory decision-making and improve post-market surveillance. Further, we support FDA plans to develop the National Evaluation System for health Technology (NEST) and commend both regulated industry and FDA for embarking on such an important effort.
- Digital Health (pg. 19)
  - Digital Health, as described by FDA to include Software as a Medical Device (SaMD) and Software inside of Medical Devices (SiMD), is among the most interesting developments of MDUFA IV for AMIA and our members. It likely represents the most challenging aspect as well. The merging of software and medical devices is a truly exciting, and somewhat daunting, area for policy development. We fully support this development and offer our members' informatics expertise to help FDA supplement its competencies in this space.

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Thank you for considering our comments. AMIA strongly supports the robust agenda described in the MDUFA IV commitment letter, and we are eager to assist. Should you have questions about these comments or require additional information, please contact Jeffery Smith, Vice President of Public Policy at jsmith@amia.org or (301) 657-1291. We look forward to continued partnership and dialogue.

[4] AMIA Policy Principle 1, Position 8; Lee JM, Hirschfeld E, Wedding J. A patient-designed do-it-yourself mobile technology system for diabetes: promise and challenges for a new era in medicine. *JAMA*. 2016:315(44):1447-1448.

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Sincerely,

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