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**Request for Comments on FDASIA Health IT Report: Proposed Risk-Based Regulatory Framework  
Docket ID: FDA-2014-N-0339-0001**

On behalf of the American Medical Informatics Association (AMIA), I am pleased to submit these comments in response to the above-referenced request. AMIA is the professional home for biomedical and health informatics and is dedicated to the development and application of informatics in support of patient care, public health, teaching, research, administration, and related policy.

AMIA's goals work to enhance health and healthcare delivery through the transformative use of information and communications technology. AMIA's 4,000 members work throughout the health system in various clinical care, research, academic, government, and commercial organizations. Through their work, our members advance the use of health information and communications technology in clinical care and clinical research, personal health management, public and population health, and translational science with the ultimate objective of improving health.

AMIA commends the Department of Health and Human Services and the Office of the National Coordinator for Health Information Technology for their engagement with the stakeholder community, and for issuing this request for comment. AMIA has put forth a number of suggestions as HHS, ONC, FDA, and FCC have worked to implement FDASIA, including weighing in on the creation of a risk-based regulatory framework and the creation of a strategy for HIT.

In issuing this comment, AMIA will focus solely on the agencies proposed HIT Safety Center, and discuss AMIA's thoughts on how best to use this new entity to improve patient safety.

Health information technology has provided improvements to our delivery system, but enhancing patient protections from the current weaknesses in and the unintended consequences of the application of information technology and informatics interventions is critical. Unintended consequences can arise due to a number of problems within our health IT systems, causing inefficient care, data loss, and even patient harm. AMIA is strongly of the belief that health IT safety is a responsibility shared among developers, health care organizations, and federal and state authorities. Through the creation of a single body focused on health IT safety housed within the ONC and empowered to collect information on, evaluate, and report on the overall safety of health IT, we believe that event reporting, education, data aggregation, and the creation of best practices can improve patient safety and the effective use of health IT.

With the creation of the Health IT Safety Center should come extensive outreach to stakeholders from clinical, academic, government and industry settings. Patients and patient groups should also be given a voice with regards to setting the Center's agenda, as engagement and education must extend beyond clinical professionals and policymakers. AMIA agrees with one of the core strategies of the Center being "providing education on health IT safety, including best practices regarding risks, mitigation strategies, usability, workflow, etc." This is an area where the Health IT Safety Center could leverage data and best practices from its stakeholder agencies to promote improvements in patient safety.

We agree that, in creating the Health IT Safety Center, a public-private entity is the best mechanism for ensuring that the appropriate resources and level of stakeholder engagement is achieved to materially improve safety outcomes within health IT systems. Continuous feedback and engagement is essential as health IT system safety will require effective monitoring, analysis, strategy and best practice implementation. We believe the operating principles for an HIT Safety Center should include:

- A system of IT safety reporting that is non-punitive and includes liability protections
- An approach to issue identification that encourages the reporting of "near-misses" as well as actual errors – including both errors in software design and use as well as care delivery errors
- A well-defined system of feedback to users of health information technologies that includes recommendations for remediating identified safety issues
- A well-reasoned approach to balancing transparency and disclosure with appropriate levels of de-identification of report submitters and vendors

We believe that the Health IT Safety Center as imagined in the FDASIA health IT report – a convener of stakeholders rather than an additional regulatory body – is the best approach to achieving the intended goals. Innovation in the health IT sector is an integral part of advancing new patient therapies and treatment options, as well as the promotion of data sharing across the delivery system. It is important that the Health IT Safety Center does not play a direct role in regulation, but rather serves as a source of data, analysis and recommended best practices for the safe use of health IT. Adding an additional regulatory oversight body could lead to the stifling of innovation and discourage increased use of health IT technologies.

Finally, AMIA is prepared to be of assistance in any capacity related to the creation of the Health IT Safety Center as our membership has expertise that spans across the healthcare continuum. AMIA looks forward to continued opportunities to engage with your agencies in the near future.

Sincerely,

A handwritten signature in black ink, reading "Blackford Middleton". The signature is fluid and cursive, with a long horizontal stroke at the end.

Blackford Middleton, MD, MPH, MSc, FACMI  
Chair, AMIA Board of Directors