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July 7, 2014

Leslie Kux,
Assistant Commissioner for Policy
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted electronically via www.regulations.gov

Re: Docket No. FDA-2014-N-0339
Comments on the FDASIA Health IT Report's Proposed Strategy and Recommendations for a Risk-Based Framework

Dear Ms. Kux:

ECRI Institute is pleased to provide comments to the Office of the National Coordinator for Health Information Technology (ONC), the Food and Drug Administration (FDA), and the Federal Communications Commission (FCC) on the proposed strategy and recommendations for a risk-based framework described in the FDASIA Health IT Report. True to its promise, the FDASIA report does a balanced job of creating a national framework that addresses safety and innovation. We appreciate the efforts of all three agencies to seek out comment through public workshops, task forces, and meetings.

Like other technologies, health IT plays a multifaceted role in patient safety. It holds extraordinary promise as a tool for achieving higher quality, safer and more reliable care. However, it also creates new risks that contribute to adverse patient safety events. The healthcare community must engage in effective efforts to both foster innovation as well as protect patients from accidental harm. To ensure patient safety, there must be thorough understanding of potential harms and preventive interventions shared across stakeholders – from policymakers to product developers to providers to patients.

In this letter, we provide comments on the proposed Health IT Safety Center (the "Center"). Our comments are based on several decades of experience operating patient safety programs, including ones with a deep focus on healthcare technology. In addition, we recently convened a multi-stakeholder collaborative, the *Partnership for Promoting Health IT Safety*. We believe that as the *Partnership* unfolds, it will provide valuable lessons for how to set up a Center that deserves the public trust and supports a national framework for safety.

By way of background, ECRI Institute is an independent, nonprofit healthcare improvement organization whose mission is to benefit patient care by promoting the highest standards of safety, quality, and cost-effectiveness in healthcare. Since 1971, we have served as a trusted third party working on programs that improve the safety, effectiveness, and implementation of healthcare technologies and safe practices. We conduct independent analysis of patient safety

data and disseminate safe practices. We operate patient safety systems, conduct hands-on testing of products, investigate adverse events, research evidence-based approaches to care, and serve as contractor to numerous federal and state agencies on safety projects, including several projects on health IT safety. ECRI Institute is designated an Evidence-based Practice Center by the U.S. Agency for Healthcare Research and Quality (AHRQ), and ECRI Institute PSO is listed as a federally-certified Patient Safety Organization (PSO) by the U.S. Department of Health and Human Services. The latter serves over 1,000 US hospitals.

In April 2013, ECRI Institute PSO began convening the *Partnership for Promoting Health IT Patient Safety,* a multi-stakeholder learning collaborative that aims to make healthcare safer by understanding and mitigating health IT hazards and safety events. The *Partnership* is a data-driven program that aggregates health IT safety data from many organizations. It seeks to test a collaborative model for collecting and analyzing health IT hazards and safety events, evaluate the use of two existing electronic reporting systems (the AHRQ Common Formats and the AHRQ-funded Health IT Hazard Manager), and allow policymakers and the broader healthcare community to learn more about the barriers and challenges associated with building a safety reporting system for health IT and an eventual center for health IT safety. The *Partnership* provides a non-punitive, collaborative forum for data aggregation and analysis and, equally important, for dialogue on safety among providers, product developers, safety scientists, professional societies, and other stakeholders – a dialogue that has been sorely missing. It advances many of the stated functions of the Center, thus presenting a fertile opportunity for providing real life "lessons learned" for next steps that should be taken to establish an effective national program.

We previously provided information on the *Partnership* to ONC's Health IT Policy Committee, which can be accessed on the web at http://www.healthit.gov/facas/calendar/2014/06/13/policy-safety-task-force, and would be pleased to provide briefings to agency workgroups on the *Partnership's* progress.

ECRI Institute supports the premise of a Health IT Safety Center. For it to be a success, it should align existing efforts and refrain from increasing burdens on providers or unnecessary duplication of efforts. The Center does not need to overbuild for the mission. The sad fact is that, unlike aviation or other high reliability industries, healthcare has "crashes" every day: there are actual events to study and learn from. Rather than set up particularly elaborate instrumentation to detect unsafe conditions and unsafe practices, we need trusted partners with whom to collaborate in a meaningful and protected space. The Patient Safety and Quality Improvement Act of 2005, which created PSOs, establishes a framework for healthcare providers to voluntarily and confidentially report sensitive patient safety data for the purpose of learning from mistakes. This law provides an infrastructure for candid sharing of health IT related safety data that would otherwise not be shared.

The Center should not create new reporting mandates for healthcare providers. They already exist, and it would be more productive to work with organizations that already capture and make sense of this type of data. Our experience shows that patient safety reports submitted by providers often fail to classify health IT as a factor contributing to a patient safety mishap. It is usually only after analysis by the PSO that health IT is discerned as a factor. Thus, creating a

silo for health IT reporting will likely be far less effective that culling out health IT events from existing "all cause" sources.

The Center should collaborate closely with AHRQ and not build another Network of Patient Safety Databases (NPSD). AHRQ has already built it.

The Center should work with and encourage participation in private sector initiatives related to health IT and patient safety, such as the *Partnership for Promoting Health IT Patient Safety*. The results of the *Partnership* pilot can help to inform the best governance structure and functions for the Center, and how to engage successful private sector participation.

The Center should engage in research that vets interventions, provides education, and supports the development of tools like the SAFER Guides that can be used by providers, vendors, and other stakeholders. It can do more: For example, it could support development of and make available tools for mining qualitative data using natural language processing, thus accelerating effective safety analytics in the public and private sector. By making such tools available, which are often too expensive for any single organization to develop, the Center would broaden engagement, make data more consistent, and draw from other federally-funded and private sector initiatives. Healthcare providers, vendors, PSOs and other stakeholders all want tools to help make healthcare safer, and the Center should support and encourage their creation.

We would be pleased to provide information about the *Partnership* and other important safety initiatives. Please do not hesitate to contact me (jlerner@ecri.org) or my colleague, Ronni Solomon (rsolomon@ecri.org).

Thank you for the opportunity to present our comments.

Sincerely,

Jeffrey Lerner, PhD
President and Chief Executive Officer