PhRMA

June 30, 2013

Office of the National Coordinator
for Health Information Technology
Attention: FDASIA Report
Hubert Humphrey Building
Suite 729D
200 Independence Ave. SW.
Washington, DC 20201

Re: Docket No. HHS-OS-2013-0003:

Food and Drug Administration Safety and Innovation Act (FDASIA): Request for Comments on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology; 78 Fed. Reg. 104, 32390 (May 30, 2013)

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments and recommendations in response to the Office of the National Coordinator (ONC) for Health Information Technology (HIT), Department of Health and Human Services' (HHS) request for comments on the development of a risk-based framework for the regulation of HIT. PhRMA is a voluntary, nonprofit association that represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. In 2012, PhRMA member companies invested an estimated $48.5 billion in the discovery and development of medicines, representing the majority of all biopharmaceutical R&D spending in the United States. PhRMA believes that HIT is an important enabler of research and development and that, when properly implemented, it improves the efficiency of care delivery and supports improvements in the quality of care provided to patients. We encourage the Agencies to develop a regulatory framework that promotes innovation, protects patient safety, and avoids regulatory duplication. With these specific goals in mind, PhRMA provides some general comments below for consideration by the FDASIA Workgroup.

PhRMA believes that the report to be published by the ONC, the Food and Drug Administration (FDA), and the Federal Communications Commission (FCC) (together,

"Agencies") offers an important opportunity to develop an appropriate regulatory framework for HIT that improves the quality and efficiency of patient care and encourages innovation. The first important step towards achieving this goal will be for the Agencies to provide a clear definition of the types of HIT it will cover in the report. PhRMA encourages the Agencies to include in the report comprehensive and definitive detail around the types of HIT that are included in the scope of the report, and how different types of HIT will or will not be subject to various regulatory requirements. As HHS considers patient safety in the context of developing this report, it should consider several factors, including the extent to which patient safety issues with a type of HIT are or are not well-defined, and whether there is a reasonable and quantifiable likelihood of a risk to patient safety. PhRMA believes it will be important that the development of a regulatory framework does not hinder innovation in areas that rely on HIT for which the benefits outweigh the risks.

As HHS develops the report, it is important for the Agencies to ensure that its regulatory framework not hinder the development and adoption of important new HIT capabilities. Important aspects of HIT related to ONC's Federal EHR incentive program, for example, hold significant potential to improve patient safety: the use of electronic prescribing and computerized physician order entry; maintenance of active medication and medication allergy lists; coding of drug-drug and drug-allergy interactions; use of electronic medication administration record technology; and reconciling medications at transitions of care. Further, PhRMA believes that well-executed and appropriately regulated HIT can improve the timeliness and accuracy of medical safety adverse event reporting and improve the efficiency of drug development and clinical trials.

With respect to potential risk-based approaches to regulation of HIT, PhRMA suggests the report aim to achieve the following:

- **Alignment of Activities with Current Mission and Roles of the FDA, ONC and FCC.** As per the stated goals of this workgroup, PhRMA believes it is essential to delineate the specific regulatory obligations of each agency and to avoid regulatory redundancy across the Agencies. This will be more straightforward if the current missions of these agencies are preserved without expansion of scope. For example, PhRMA suggests the FDA focus upon HIT aspects that are directly related to protecting the public health by assuring the safety, efficacy and security of medical products for human use. The ONC should continue to focus on privacy and security of patient data as well as improving the quality of care through HIT infrastructure. And, the FCC should maintain the focus on communication for the purposes of promoting safety of life and property.

- **Minimization of Redundancy within Each Federal Agency.** As stated above, HIT presents regulatory challenges and opportunities that cross boundaries within government agencies. Specifically, in the case of FDA, there is need for clear communication of regulatory policies between the FDA Center for Drug

Evaluation and Research, the FDA Center or Devices and Radiological Health and, potentially, the FDA Center for Biologics Evaluation and Research. It is very important for an overall FDA-level approach be taken to eliminate the possibility of redundant and possibly conflicting guidance from these different centers within the Agency. PhRMA encourages all three Agencies to identify areas of redundant or conflicting guidance within each Agency, then seek to compare across Agencies for potential overlap or redundancy.

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PhRMA appreciates the opportunity to submit these comments, and we hope that the FDA, ONC and FCC will find them helpful as the FDA develops plans for implementation of a risk-based strategy for the regulation of HIT. We look forward to opportunities to work collaboratively with this workgroup and the Agencies as needed to ensure the success of this important initiative.

Sincerely,

Sarah A. Spurgeon, Assistant General Counsel

Michelle Drozd, Senior Director, Policy & Research

Kristen Van Goor, Senior Director
Scientific and Regulatory Affairs