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The Honorable Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework [Docket No. FDA–2014–N–0339]

Dear Dr. Hamburg:

On behalf of McKesson Corporation ("McKesson"), I am pleased to submit comments to the Food and Drug Administration (FDA) on the *FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework* (FDASIA Report), which was released in April 2014.

For more than 180 years, McKesson has led the industry in the delivery of medicines and healthcare products. As the largest health information technology (IT) company in the world, we are actively engaged in the transformation of healthcare from a system burdened by paper to one empowered by interoperable electronic solutions that improve patient safety, reduce the cost and variability of care and advance healthcare efficiency.

McKesson has decades of experience serving the health IT needs of the largest and most diverse provider base in the industry, including 52 percent of our nation's hospitals, 20 percent of all physician practices and 16 percent of home care agencies, which support more than 50,000 home care visits annually. We process billions of financial healthcare transactions annually among physicians, hospitals, pharmacies, insurers and financial institutions, and provide care and claims management solutions to most of America's health insurance companies. We also manage millions of aggregated personal health records, connecting patients online with their physicians, hospitals, reference laboratories and health plans.

McKesson has a long history of leadership and collaboration with the industry in the area of patient safety. Our comments on the FDASIA Report are based on our extensive experience and informed by our belief in the power of health IT to improve the quality, safety and efficiency of healthcare.

We continue to engage in dialogue with Congress, the Administration and industry partners on the appropriate oversight of health IT and offer the following comments and recommendations:

- McKesson generally supports the recommendations made in the FDASIA Report and its goal of establishing a new risk-based framework for health IT.

- We further agree that FDA oversight of health IT should be limited to only the highest risk forms of software, and that the vast majority of health IT is not appropriate for FDA regulation.

- Finally, the Food, Drug, and Cosmetic Act (FD&C Act) should be updated to codify the framework outlined in the FDASIA Report and clearly define the various categories of health IT.

A Risk-Based Framework

McKesson is a strong advocate for a new risk-based regulatory framework that is *specific* to health IT. We have endorsed the regulatory framework recommended in the Bipartisan Policy Center 2013 report: *An Oversight Framework for Assuring Patient Safety in Health Information Technology*, which establishes three categories of health IT according to potential risk to the patient and the opportunity for clinical intervention. We are pleased that the FDASIA Report closely mirrors these recommendations.

FDA Regulation of Highest Risk Software

As recommended in the FDASIA Report, software that potentially poses the highest risk to patients should be regulated by the FDA. Users of this software rely heavily on the information derived from this technology and have little or no opportunity or time to validate the results or recommendations. A clinician's inability to intervene with experience and judgment to validate results should define software appropriate for FDA regulation.

We do not believe that specific functionality (e.g., order entry versus documentation), specific disease states or settings of care are useful in defining high or medium risk software. For example, the fact that clinical decision support (CDS) software is used to manage a patient with cancer does not, in and of itself, render that software to be potentially riskier than if it is used to manage a patient with diabetes. The critical distinction between high and medium risk software is the degree to which the clinician relies on the application.

In identifying a category of "medical device health IT" that should be regulated by the FDA, the FDASIA Report lists examples of the types of health IT which should be included. While we may agree with many of the examples, simply listing examples is insufficient for distinguishing high and medium risk health IT. Instead, we suggest that this high risk group be defined by **absolute reliance on the software by the clinician.**

Oversight of Other Health IT

McKesson agrees that the vast majority of health IT should not be subject to FDA regulation. This heterogeneous "medium risk" group of "health management health IT software," which includes CDS software, encompasses thousands of health IT solutions used by clinicians and consumers in a variety of settings. The information and results from this software *supplement* a clinician, payer or consumer's expertise and judgment.

Oversight of software that could potentially be considered medium risk to patients could be provided by a public-private partnership where industry is involved. McKesson recommends that such a partnership or other non-governmental entities participate in standards setting organizations to identify, develop and certify adherence to standards.

McKesson supports the promotion of an environment of learning and continual improvement through the creation of a Health IT Safety Center within an existing organization such as the National Patient Safety Foundation (NPSF). The Center should be a public-private partnership that would serve as a trusted convener of health IT stakeholders and a forum for the exchange of ideas and information to promote health IT as an integral part of patient safety. Based on our participation on the Patient Safety Task Force of the ONC Health IT Policy Committee, we offer these specific recommendations regarding the function of a Health IT Safety Center under the auspices of the NPSF:

1. The governance structure of a Health IT Safety Center should include representation from all interested stakeholders.

2. A culture of safety and trust should be established for all participants; a safe environment to share and discuss information will be critical to increased reporting and analysis of health IT events, near misses and hazards.

3. The focus of the Center should be to study aggregated and de-identified safety-related information across the industry to better understand trends, causes and remedies to improve health IT safety. We do not believe that the Health IT Safety Center should include comparative user experience of health IT in its charter. Comparative user experience should remain a market-driven activity.

Appropriate oversight through a public-private partnership, involving all stakeholders and leveraging existing infrastructure and standards, will provide a flexible learning environment to promote and accelerate innovation in this complex and rapidly evolving industry.

Amend the FD&C Act to Define Health IT

McKesson has long noted that regulation of all health IT as a medical device is not appropriate and will not improve patient safety. Just as the FD&C Act was updated in the 1970s to define medical devices, it should be updated once again to define health IT or medical software and provide clear, predictable guidelines for its oversight.

While the FDASIA Report calls for FDA jurisdiction to be focused *only* on the highest risk health IT, it is silent on whether changes to the FD&C Act are required. As a result, the Report leaves all health IT subject to potential regulation as a medical device by the FDA.

We believe Congress should amend the FD&C Act to establish broad guidelines to define each of these categories of health IT in an appropriate risk-based regulatory framework, and then charge the Administration with implementing these guidelines. FDA regulation should be limited only to those health IT solutions with the highest potential patient risk.

Conclusion

McKesson appreciates the opportunity to comment on the FDASIA Report and to recommend ways to create a risk-based framework that is specific to health IT. We are pleased that the FDA, FCC, and ONC concur that FDA regulation should be limited to the technology with the highest potential risk to patients.

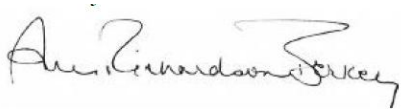
While we support many of the recommendations in the FDASIA Report, we urge specific changes as noted below:

- Establish a risk-based framework for health IT;
- Focus FDA oversight on the highest risk health IT; and
- Amend the FD&C Act to define health IT categories and codify the risk-based framework.

McKesson supports a regulatory approach to health IT that promotes quality, assures patient safety and fosters innovation. We believe health IT is essential to the successful transformation of healthcare and we stand ready to partner with the Administration, Congress, and the industry to determine the most appropriate oversight of health IT to improve the quality and efficiency of care.

Should you have questions or need further information, please contact me at (415) 983-8494 or ann.berkey@mckesson.com.

Sincerely,



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