

OVERVIEW OF STATEMENT OF

MICHAEL MARCHLIK

VICE PRESIDENT - QUALITY ASSURANCE AND REGULATORY AFFAIRS
MCKESSON TECHNOLOGY SOLUTIONS

McKesson supports HR 3303, *the Sensible Oversight for Technology Which Advances Regulatory Efficiency Act*, also known as the SOFTWARE Act. This bipartisan legislation is an important and necessary step toward establishing a new regulatory framework for health IT that recognizes the different categories of health IT solutions and focuses Food and Drug Administration (FDA) oversight on the technology that poses a potential risk to patient safety. It is a logical step forward to help realize a safer, more modern healthcare system.

Applying a four decade old approach to mobile and cloud based technologies that did not exist even four years ago is ill advised. Under the current law, the FDA regulates medical software under the broader category of “medical devices,” a term that was defined by amendments enacted in 1976 to the Food, Drug and Cosmetic (FD&C) Act. There is an important distinction between the regulation of traditional medical devices and the regulation of rapidly evolving technology.

The existing FDA regulatory framework is not well suited for regulating clinical software. Medical devices and the medical software that operates these devices act directly on a patient, and potential harm stems from how the device or software is designed and manufactured. In contrast, the risks to patients from clinical software are associated with how the software is customized, implemented and used by providers (hospitals and physicians). Clinical software requires a new risk-based regulatory framework that reflects the shared responsibility among health IT developers, providers who are implementing and customizing the systems, and, ultimately, the clinical and administrative personnel who use these systems in the delivery of healthcare.

The FDA’s expertise is in overseeing quality control and manufacturing processes. The Agency has little expertise in the area of clinical software implementation and use. Additionally, the FDA does not regulate hospitals or the practice of medicine, nursing or pharmacy, and, therefore, has little, if any, involvement in healthcare operations, including use of clinical software in care delivery by hospitals and clinics.

The SOFTWARE Act establishes three distinct categories of health IT: medical software, clinical software and health software. This legislation calls for the FDA to continue to regulate the highest risk category of “medical software” and charges Congress and the Administration with collaborating in the development of a new risk-based regulatory framework for “clinical” and “health” software. These classifications recognize that the risk associated with health IT, and hence the intensity of regulatory oversight, should be based upon the severity of potential harm to the patient as well as the opportunity for a clinician to intervene between the technology and the patient.

We urge Congress to:

- 1) pass the SOFTWARE Act, a critically important step in setting the guideposts for a new policy;
- 2) provide oversight to the Administration in implementing this policy; and
- 3) continue to work with stakeholders and industry to establish an effective risk-based framework to ensure that modern-day health IT is appropriately regulated.

STATEMENT OF
MICHAEL MARCHLIK
VICE PRESIDENT - QUALITY ASSURANCE AND REGULATORY AFFAIRS
MCKESSON TECHNOLOGY SOLUTIONS

BEFORE THE
ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH
U.S. HOUSE OF REPRESENTATIVES

EXAMINING FEDERAL REGULATION OF MOBILE MEDICAL APPS AND
OTHER HEALTH SOFTWARE

November 19, 2013

Good morning Chairman Pitts, Ranking Member Pallone and distinguished members of the Subcommittee. My name is Michael Marchlik, and I currently serve as Vice President of Quality Assurance and Regulatory Affairs for McKesson Technology Solutions. I am here today on behalf of more than 15,000 McKesson employees who work every day on the development and deployment of health information technology (IT) solutions that improve the quality and safety of patient care.

I appreciate the opportunity to testify in support of HR 3303, *the Sensible Oversight for Technology Which Advances Regulatory Efficiency Act*, also known as the SOFTWARE Act. This bipartisan legislation is an important and necessary step toward establishing a new regulatory framework for health IT.

Prior to joining McKesson, I spent 30 years as a quality and regulatory professional in the medical device, nuclear and process industries at organizations such as Becton Dickinson, Duke Energy and Arthur D. Little. This experience has provided me with a unique perspective on effective risk-based regulatory frameworks and an appreciation as to how health IT software development and delivery differs from traditional medical device manufacturing.

For 180 years, McKesson has led the industry in the delivery of medicines and healthcare products. As the nation's largest distributor of pharmaceuticals, we pride ourselves on the efficiencies that we bring to the healthcare system by delivering safe medicines every day to pharmacies, hospitals, physician offices, skilled nursing facilities and government locations, including every Department of Veterans' Affairs facility, across the country.

As the largest health IT company in the world, McKesson is 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 strongly supports the SOFTWARE Act which is a logical step forward to help realize a safer, more modern healthcare system. This bipartisan legislation provides critical clarity regarding the regulation of a broad array of health IT or medical software.

As you are aware, under the current law, the Food and Drug Administration (FDA) regulates medical software under the broader category of “medical devices,” a term that was defined by amendments enacted in 1976 to the Food, Drug and Cosmetic Act. The definition of medical device in the Act is so broad that it can be, and has been, interpreted to include *all* health IT. In my role at McKesson, I recognize the important distinction between the regulation of traditional medical devices and the regulation of rapidly evolving technology. Applying a four decade old approach to mobile and cloud- based technologies that did not exist even four years ago is ill advised.

My previous twelve years of experience with a large medical device manufacturer has helped me appreciate that FDA rules are optimized for physical devices which undergo slower incremental changes subject to well defined, expensive development processes. In these circumstances, the burden of Good Manufacturing Practice (GMP) regulations makes sense because variations of one-thousandth of an inch could result in patient harm. That environment is markedly different from agile software development where patient risk is not measured by precise manufacturing standards but relies equally on the development and deployment of the technology.

The SOFTWARE Act creates a regulatory framework that recognizes the different categories of health IT solutions and focuses FDA oversight on the technology that poses potential risk to patient safety. The legislation will promote patient safety while continuing to foster innovative medical advancements so critical to the quality and efficiency of healthcare.

Government and Industry Engagement

This legislation is the culmination of numerous efforts over the past two years to address how health IT should be regulated in the 21st century.

- 1) The FDA Safety and Improvement Act of 2012 (FDASIA) includes a requirement that the FDA, the Federal Communications Commission (FCC) and the Office of the National Coordinator for Health IT (ONC) develop and submit to Congress by the end of this year recommendations for a new risk-based regulatory framework specific to health IT.
- 2) Under the auspices of the Bipartisan Policy Center (BPC), McKesson helped lead the development of consensus recommendations for a new risk-based regulatory framework for health IT in conjunction with more than 100 hospital, physician and patient organizations, IT and health IT companies. These recommendations are outlined in the BPC report: *An Oversight Framework for Assuring Patient Safety in Health Information Technology*, which was released in February 2013.
- 3) In a March 2013 hearing before this subcommittee, my colleague, Dr. Jackie Mitus, testified that health IT is foundational to improving the quality, safety and affordability of healthcare. She also emphasized that a **new** risk-based regulatory framework, **distinct** from medical device regulation and **specific** to health IT, is necessary.
- 4) Over 140 healthcare organizations signed a letter sent to the Administration in June 2013 urging it to collaborate with Congress in the development of a risk-based statutory

framework for regulation of health IT while supporting innovation and patient safety.

Signatories ran the gamut from health IT startups to large public companies, from physicians' organizations to think tanks and major hospitals.

The introduction of the SOFTWARE Act is an important bipartisan milestone recognizing that a 40 year old statute must be updated to support rapid innovation essential to improving the quality and delivery of healthcare and reducing cost.

SOFTWARE Act

The SOFTWARE Act establishes three distinct categories of health IT: medical software, clinical software and health software. This legislation calls for the FDA to continue to regulate the highest risk category of "medical software," and charges Congress and the Administration with collaborating in the development of a **new** risk-based regulatory framework for "clinical" and "health" software.

These classifications recognize that the risk associated with health IT, and hence the intensity of regulatory oversight, should be based upon the severity of potential harm to the patient as well as the opportunity for a clinician to intervene between the technology and the patient. We agree that it is appropriate to regulate technology that directly acts on a patient ("medical software") differently from software that merely aggregates information and renders a recommendation to a clinician ("clinical software"). Administrative software ("health software") that supports the administrative and operational aspects of healthcare but is not

used in direct delivery of clinical care should not be subject to any regulatory oversight. These categories of medical, clinical and health software are consistent with the logic and principles described in the BPC Report and provide a sound basis for distinguishing amongst the broad array of health IT solutions.

The existing FDA regulatory framework is not well-suited for regulating clinical software.

Medical devices and the medical software that operates these devices act directly on a patient, and potential harm stems from how the device or software is designed and manufactured. In contrast, the potential risks to patients from clinical software are associated with how the software is customized, implemented and used by providers (hospitals and physicians). Clinical software requires a new risk-based regulatory framework that reflects the shared responsibility among health IT developers, providers who are implementing and customizing the systems, and, ultimately, the clinical and administrative personnel who use these systems in the delivery of healthcare.

The FDA's expertise is in overseeing quality control and manufacturing processes. The Agency has little expertise in the area of clinical software implementation and use. Additionally, the FDA does not regulate hospitals or the practice of medicine, nursing or pharmacy, and, therefore, has little, if any, involvement in healthcare operations, including use of clinical software in care delivery by hospitals and clinics.

Finally, the distinctions between the categories of health IT defined in the SOFTWARE Act are consistent with historic FDA guidance on software regulation. Specifically, the FDA issued a draft guidance document in 1989 that exempted from regulation administrative software, including patient administration and accounting software. Diagnostic and clinical decision support software were also exempted, if the program required “competent human intervention before any impact on health occurs.” While this guidance was later withdrawn in 2005, FDA acknowledged that direct interaction with the patient and the opportunity for clinical intervention are significant factors in determining risk.

Clear Congressional Policy Needed

Mr. Chairman, throughout the course of the debate on the SOFTWARE Act, you may hear testimony that current regulation of health IT by the FDA is working successfully. It is true that the guidance set forth by the FDA on mobile medical applications, the Agency’s approach to enforcement discretion, and its participation in the FDASIA working group have been thoughtful and productive.

But, as my colleague, Dr. Mitus, said last March: “We are using a 40 year old law to regulate rapidly changing and dynamic technology.” Non-binding guidance and enforcement discretion do not provide the clarity that a highly innovative industry like health IT requires.

The SOFTWARE Act updates the current Food, Drug & Cosmetic Act to provide clarity to the Administration and industry on how best to ensure patient safety while promoting innovation and broad adoption of health IT.

We urge Congress to:

- 1) pass the SOFTWARE Act, a critically important step in setting the guideposts for a new policy;
- 2) provide oversight to the Administration in implementing this policy; and
- 3) continue to work with stakeholders and industry to establish an effective risk-based framework to ensure that modern-day health IT is appropriately regulated.

Mr. Chairman, health IT is imperative to the successful transformation of healthcare. It improves quality and patient safety, enables payment and delivery reform, promotes efficiency, lowers cost and drives patient satisfaction. It is an essential building block of everything we are trying to accomplish in healthcare reform. That is why it is so important that we regulate it thoughtfully.

The SOFTWARE Act establishes different categories of health IT, meters oversight appropriately according to relative risk, and sets the stage for a new regulatory framework that reflects the shared responsibility for patient safety. We appreciate the opportunity to testify in support of this important legislation and commend the sponsors for their leadership on this significant issue.

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