STATEMENT OF

A. JACQUELINE MITUS, MD
SENIOR VICE PRESIDENT, CLINICAL DEVELOPMENT AND STRATEGY
MCKESSON HEALTH SOLUTIONS

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HEALTH INFORMATION TECHNOLOGIES: HOW INNOVATION BENEFITS PATIENTS

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Good morning Chairman Pitts, Ranking Member Pallone and distinguished members of the Subcommittee. My name is Jackie Mitus, and I currently serve as Senior Vice President of Clinical Development and Strategy for McKesson Health Solutions. I appreciate the opportunity to appear before you today.

My background as a practicing hematologist/oncologist at the Brigham and Women's Hospital in Boston, and faculty member of Harvard Medical School, as well as my responsibilities at McKesson, have provided me with a unique perspective on health information technology (IT). I have seen first-hand the value that health IT brings to patient care as well as the overriding importance of protecting patient safety.

I work every day on the development and deployment of health information technology solutions that improve the quality and safety of patient care. I am pleased to share with you McKesson's perspective on the benefits and value of health IT and to discuss the need to establish a new regulatory framework for medical software.

For 180 years, McKesson has led the industry in the delivery of medicines and healthcare products. McKesson is the nation's largest distributor of pharmaceuticals, and 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 has decades of experience serving the health IT needs of the largest and most diverse provider base in the industry, including 50 percent of all health systems, 77 percent of health systems with more than 200 beds, 20 percent of all physician practices and 25 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. In short, 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.

Based on this breadth of experience, I would like to make two key points to you and members of the subcommittee.

First, health IT is foundational to improving the quality, safety and affordability of healthcare.

Second, to ensure continued innovation in the development of health IT solutions and leverage the power of those solutions to transform healthcare, we need a new risk-based regulatory framework that is <u>specific</u> to health IT.

Let me touch briefly on each of these points.

HEALTH IT: THE FOUNDATION FOR CHANGE AND IMPROVEMENT

Healthcare in our country is undergoing fundamental changes. Each day, clinicians and others critical to providing healthcare services strive to find safer, better, more efficient and increasingly patient centric ways to deliver care. Health IT is the foundation of these efforts.

First and foremost, health IT underpins our ability to dramatically improve quality and safety. Physicians, nurses, pharmacists, paramedics and all health professionals increasingly rely on health IT systems in virtually all care settings. In order to provide safe, effective care, physicians must have timely access to current, accurate patient information, including medical history, medication lists, laboratory and x-ray results, regardless of location. Automating paper records and enabling electronic connectivity is critical to communicating and coordinating across disparate healthcare systems.

Medical software can also help to inform physicians and other clinicians as they assess and treat patients. New advances in clinical care and other important information from text books and medical journals are made readily available through health IT. Additionally, automated clinical systems can help prevent medication errors, identify gaps in care, and suggest appropriate diagnostic and treatment paths.

It is important to note that health IT does not replace physician judgment. Rather, it provides guidance and support by making patient data more readily available, and by automating clinical recommendations. The ultimate responsibility for patient treatment decisions and clinical care rests with the prescribing physician and his or her experience and expertise, along with other

involved clinicians. I will come back to this in a moment when we talk about the differences between medical devices and health IT.

Beyond improving quality and safety, health IT is also critical to transforming the way we deliver and pay for healthcare: transitioning from a volume system that rewards the number of tests or procedures performed to a value system that measures the quality of patient outcomes.

Through data and analytics, transaction processing and cost transparency, health IT provides efficiency and support for delivery and payment reforms. With the adoption of Electronic Health Records (EHRs) and other health IT solutions by both physicians and hospitals, the market has now reached a tipping point where widespread interoperability could make possible the meaningful exchange of information to lower costs and support outcome-based health initiatives.

Clearly, there is still much work to be done to improve health IT. In particular, the health IT industry is engaged in a new alliance to dramatically improve interoperability so that different health IT systems will be able to communicate with one another seamlessly. Earlier this month, McKesson and four other health IT developers announced their intent to form The CommonWell Health Alliance and their plans for CommonWell to be an independent not-for-profit organization open to all health information technology vendors. The Alliance plans to promote and certify a national infrastructure with common standards and policies, which enable patient matching and linking services, HIPAA-compliant patient consent and access management, and a patient record locator and query service. These capabilities will allow care

providers to more easily track and manage patients across disparate locations and to share critical information in an industry standard way.

This effort and many others are ongoing. In the coming weeks, months and years, the pace of innovation in health IT will only increase, and, with it, the promise of improved care.

A New Risk-Based Regulatory Framework for Health IT

Now let me turn my attention to the need for a new risk-based regulatory framework for health IT. Given that health IT is critical to improving healthcare, and ever mindful of the incredible pace of innovation in technology development, it is imperative that health IT is regulated in a way that improves quality, assures patient safety and fosters innovation.

Today, the Food and Drug Administration (FDA) has the authority to regulate medical devices under amendments to the Food, Drug and Cosmetic Act that were made in 1976. The definition of medical device in the Act is broad and can be interpreted to include all health IT, including medical software.

The current regulatory approach for medical devices is generally not well-suited for health IT for three specific reasons.

First, the drafters of the law defined medical devices based on the technology available at the time. No one could have envisioned the progress we would make in the development and implementation of technology in the almost 40 years since that definition was enacted.

For example, does an iPad application to help track the number of steps walked per day, or a reminder that it's time to refill a prescription, render this apparatus a traditional "medical device"? Should each application upgrade require a regulatory review?

Should the software that allows a physician to search a medical textbook or review x-rays on-line be subject to FDA regulation? That software merely provides access to medical data; it does not interpret or act upon the information that is transmitted.

Should clinical decision support software that simply aggregates existing protocols and standards of care be regulated differently than those same standards that appear in printed form and sit on a shelf in the doctor's office? The information is exactly the same; the only difference is that the paper information is now automated and relayed to the physician in a different, more efficient format.

The second reason for a new framework is that there are fundamental differences between medical devices and health IT. For example, safety of medical devices is almost entirely dependent on how they are manufactured. The FDA oversees the manufacturing, production and quality control processes of medical devices where problems might develop.

Safety of health IT systems, on the other hand, is dependent on how they are designed and developed, and, perhaps more importantly, how they are customized, implemented and used. Safety in health IT, therefore, cannot be ensured simply through good manufacturing practices. Instead, it must be a shared responsibility among those who develop the technology, those who implement it, and ultimately those who use it.

Finally, medical devices, ***unlike health IT***, are directly involved in the treatment of a patient, with little if any opportunity for the clinician to intervene. Heart stents, implantable defibrillators and pacemakers all connect to the heart and function automatically without clinician involvement.

Some forms of health IT are inextricably linked to medical devices, such as the software that interprets fetal heart monitors or automatically doses certain medications. In these cases, regulation of the medical software as a device is probably appropriate. However, the majority of medical software, including clinical decision support and EHRs, does not directly treat the patient, but rather provides data and guidance to the clinician in the assessment or treatment of a patient.

The ability of the physician to utilize professional judgment when interacting with these forms of health IT makes these types of technology fundamentally different from traditional medical devices.

Mr. Chairman, we are using a 40 year old law to regulate rapidly changing and dynamic technology. We are regulating manufacturing instead of use, and we are marginalizing the role of clinicians. Simply put, we must not impede medical advances with medical device regulation that is ill-suited for health IT.

The FDA Safety and Innovation Act that was enacted last summer requires the FDA, the Office of the National Coordinator (ONC) of Health IT and the Federal Communications Commission (FCC) to provide Congress with recommendations on a new risk-based regulatory framework for health IT.

To assist these agencies in better understanding the stakeholder perspective, the Bipartisan Policy Center (BPC) convened nearly 100 organizations and companies throughout the healthcare system over the past five months to develop a set of principles to guide the establishment of a risk-based regulatory framework for health IT. The results of this extraordinary collaborative effort were announced last month.

The BPC recommendations are best reflected in the chart on page 13 of the BPC report that has been submitted with my testimony. This chart represents a new regulatory framework for health IT—one that protects patient safety, is risk-based, promotes innovation, is flexible, leverages existing quality and patient safety-related systems and processes, avoids regulatory duplication, and has the support of experts and stakeholders across every sector of health care.

Most importantly, the BPC recommendations divide health IT into three categories according to the relative risk to patients and the opportunity for clinical intervention.

The first category includes technology linked to or used to operate a medical device; again, technology that directly touches the patient. This technology would continue to be regulated by the FDA as a "medical device".

The second category includes technology that informs the treatment of a patient, such as clinical decision support software or EHRs. This software would be subject to a rigorous process of accreditation by an independent third-party, or perhaps ONC.

Finally, the third category, non-clinical technology such as billing and scheduling software, would not be subject to any regulatory oversight.

This proposed framework recognizes the fundamental difference between traditional medical devices that are directly involved in the treatment of a patient, and medical software that helps *guide* the physician in the diagnosis or treatment of a patient.

Mr. Chairman, health IT is imperative to the successful transformation of healthcare. It improves quality and patient safety, enables payment and delivery reform and promotes efficiency and lower costs. It is an essential building block of everything we are trying to accomplish in healthcare. That is why it is so important that we regulate it thoughtfully. That is why we cannot have a one size fits all approach which stifles innovation and delays advances in medical knowledge and care. That is why we need a new risk-based regulatory framework.

McKesson appreciates the opportunity to share our views on health IT with the members of the Subcommittee, and we look forward to continuing to promote the development and use of this important technology that is so vital to patient care.

I am happy to answer your questions.