STATEMENT

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Good afternoon and thank you for the opportunity to participate in this public meeting.

The Food and Drug Administration (FDA) believes that Health Information Technology (HIT) offers tremendous health benefits to the American public. HIT also poses potential risks that can and should be mitigated.

I will divide my presentation into four parts to address the questions asked of the FDA by the Committee.

I will first discuss information available to the FDA about the adverse effects of HIT.

Second, I will review FDA involvement to date in HIT.

Third, I will discuss core principles applied to other information technologies that may be applicable for HIT.

Fourth, I will close by reviewing the tools available to the FDA that, in concert with actions by others, may help address the patient safety challenges posed by HIT.

Information Available to the FDA

From January 2008 to December 2010, the FDA received approximately 370 reports of adverse events or near misses purportedly associated with different types of HIT, including electronic health records (EHRs). They likely reflect a small percentage of the actual events that do occur. Most of the causes involve the failure to adequately address interoperability with other technologies, user error, inadequate workplace practices, design flaws, failure to properly test the technology prior to distribution, upon installation or during maintenance (such as validation testing), or failure to adequately address human factors, which is the design of a technology to address problems that can arise when people interface with machines.

The takeaway from this limited snapshot is that safety problems related to HIT are highly varied and protean. Any approach that is adopted should assure that problems are prevented to the extent practical by building in safety and quality into the design, manufacture, distribution, monitoring, and maintenance of the technology, develop safe

use practices, and have the capability to quickly identify and correct safety problems when they do occur.

FDA Regulation of HIT to Date

The FDA regulates several forms of HIT as medical devices, including technology used for collecting, storing and transferring laboratory results or radiological images, technology for patient monitoring in hospitals, systems for automating and documenting anesthesia-related information, and decision support software such as drug dose calculators and ovulation calculators. HIT that provides other types of functionality (such as patient scheduling and billing management) are not medical devices.

For some types of HIT that are medical devices, including EHRs, the FDA has exercised enforcement discretion; meaning it has not enforced existing requirements. We are interested in the IOM's recommendations on potential uses of the FDA's regulatory tools for these products.

Core Principles

To assure patient safety any approach that is adopted should incorporate four core safety principles that have been applied to information technology used in other fields including aviation.

First, Use a Risk-Based Approach
By applying a risk-based, rather than one-size-fits-all approach, a regulatory framework can be implemented that strikes the right balance between protecting patient safety and facilitating innovation.

This may have relevance for HIT, which can include components of varying risk to patients based on its functionalities and its interconnectedness with other technologies. For example, an HIT that incorporates automated decision making capabilities would likely present greater risks if it malfunctioned or was not properly designed and validated than an HIT that only stores patient information.

Second, Expect Operational Quality
Systems in healthcare should be designed and built using a quality management system, which focuses on achieving and maintaining product and service quality through quality planning, quality control, quality assurance, and quality improvement.

Third, Develop Clear Standards for Interoperability
Sophisticated and complex interconnected HIT systems are interfacing with an increasing variety of other software technologies and traditional medical devices, such as imaging machines, patient monitoring systems, ventilators, and infusion pumps. This concept of "system of systems" can provide tremendous benefits for patient care but also can increase risks because a problem with one component or interface of the system can affect the performance of other components. To reduce these risks standards for

interoperability should be developed and adopted that allow for safe interfaces between all components.

Fourth, Establish a Robust Learning Infrastructure

Surveillance systems of different types should be used as part of a national system to monitor the performance during actual use of interconnected systems. Coupled with analytical capabilities and feedback loops, these surveillance systems should be specifically tailored to HIT, allow for real-time collection, aggregation and analysis across systems, and performed using appropriate tools at different levels within the healthcare system (such as at the facility, regional, and national levels) to allow for the rapid identification and correction of problems. These surveillance systems should have effective security measures and protect patient privacy, confidential information, and reporter identity while providing as much granular information publicly as appropriate and feasible to allow assessment and learning by many entities.

Tools Available to the FDA

The fundamental strengths of the FDA's authority are the flexibility provided in the law to tailor an appropriate level of oversight to technologies based on their level of risk and that can be employed across the total product lifecycle. This allows the FDA to strike the right balance between protecting public health by assuring patient safety and promoting public health by facilitating innovation.

The FDA can require manufactures to register and list – namely tell us who they are and what they make – and thereby be able to identify all manufacturers and all technologies of a particular type.

The FDA can obtain, aggregate, and analyze information from all device manufacturers, providers, patients, and others on the performance and safety of medical devices through several interconnected mandatory and voluntary postmarket surveillance systems. Manufacturers are required to report to the FDA device-related deaths and serious injuries, and malfunctions that may, if they were to recur, result in death or serious injury. Through the Medical Product Safety Network (MedSun), which includes roughly 350 participating healthcare facilities, the agency conducts proactive surveillance of adverse events and near misses associated with medical devices at these facilities. Additionally, through the MedWatch voluntary adverse event reporting system all providers, patients, and caregivers can report adverse events and near misses to the FDA. Reports submitted to the FDA are de-identified and made available to the public.

We plan to use the Common Format for HIT – developed by the Agency for Healthcare Research and Quality and the FDA and reviewed by the National Quality Forum – as part of our MedWatch and MedSun systems to allow for information collected by the FDA and by Patient Safety Organizations to be more readily shared and aggregated.

The agency is also developing an active surveillance system, called the Sentinel System, that would use analytical tools on information collected through EHRs, insurance claims, and other data sources to better understand the risk-benefit profile of medical products.

The FDA can require that device manufacturers have a quality management system. Quality system requirements for medical devices mirror established practices of other industries for ensuring safe and reliable products by building quality into their design and manufacture. Manufacturers retain flexibility to tailor quality system requirements to their specific products, manufacturing processes, and business model. The FDA's device quality system requirements do not prescribe specific performance measures, but establish flexible requirements for appropriate processes to verify and validate product design, monitor performance trends and correct problems before they can cause harm to patients, and validate the installation and maintenance of systems at user facilities, which may include appropriate training. Failure to implement a robust quality system is a leading cause of device recalls. The FDA's approach to Quality Systems is consistent with international standards such as those by ISO.

The FDA can require the submission of data prior to the marketing of higher-risk devices. The agency can tailor the data needs based on the risks of the product.

The agency actively engages in standards development, including participation in national and international standards development organizations. Given the agency's authority to enforce compliance with standards, adoption of a standard by the FDA tends to assure adoption of that standard by the applicable industry sector. The FDA has already taken steps to facilitate the development of standards for medical device interoperability, including a two-day public workshop held earlier this year.

There are several actions the FDA plans to take in 2011 that do not pertain to EHRs but could be helpful if the FDA applied some or all of its tools to EHRs and related functionalities.

In 2011, the agency intends to issue draft guidance on the application of its Quality Systems regulation and premarket review authorities to stand-alone software to better tailor our advice to more recent changes in software development practices. We recognize that in many cases assuring that a manufacturer has implemented an effective quality management system and appropriately validated its software before distribution, after installation, after maintenance, and after subsequent upgrades may be sufficient to assure patient safety without the need for submitting clinical data to the agency. Such an approach could allow for continuous upgrades of software without new premarket applications while dramatically simplifying premarket applications when they are warranted. The FDA is exploring not requiring the submission of premarket applications in some cases of stand-alone software where it traditionally would. The draft guidance will take these considerations into account.

In 2011 the FDA also intends to issue a draft guidance on its approach to mobile applications to strike the right balance between innovation and patient safety as well as a

final guidance on safety considerations for wireless technologies used in medical devices. In addition the agency is developing a regulation on clinical decision support systems.

Thank you and I look forward to addressing any questions the Committee may have.