# Additional Notes to Accompany the FDASIA Workgroup's Presentation to the HITPC on September 4, 2013

## Slide 30

The benefits of the Medical Device regulation are:

- Process control. The Medical Device law is primarily a process control describing how to create the product. That is beneficial from, first, the standpoint of flexibility. By not dictating the end product, it meets the innovation need to have flexibility in product functionality.
- The Good Manufacturing Process supported by the FDA regulation has had a positive impact on the quality of the products and resulting confidence in the products produced through it.
- Post-marketing surveillance. The current FDA regulations already support gathering data about products post marketing. This has been a key desirable element in the discussions of this workgroup; in fact, the discussions have been around expanding it and making it more transparent – an open exchange or information rather than product policing

The cons or issues with the application of the Medical Device regulation to HIT are:

- Clarity. What software is subject to the Medical Device regulation? What class will be used for HIT software? If subject to the law, what are specific requirements to be in compliance?
- Geared to physical devices. As noted on the previous slide, the turnaround time, configuration, and extensibility of software complicates the application of this regulation to HIT.
- Blood bank example. The full application of the Medical Device regulation had a significant negative impact on the Blood Bank software vendors or at least has had a perceived significant negative impact.
  (See http://www.fda.gov/downloads/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/UCM051540.pdf ). This example has been sited multiple times as an undesirable endpoint of this regulation. It would merit a more in-depth review for lessons learned.

Entry impedance. There are two cases. First, there is the learning and implementation curve for manufacturers or other trying to get into this market space. A large component of this may be education, but is also having the implementation and enforcement commiserate with the scope and size of the product. The second use case is where software is developed, tested, and implemented, but without FDA regulated process. The product is then deemed to be subject to the FDA regulation. How then can a past process be re-structured into be FDA compliant? There is no defined ability to bring current software into current FDA compliance as the FDA regulation define the process to create the software in the first place.

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## Slide 31

The motivation for the ONC certification is that the government is effecting an infrastructure change on the medical sector. There is then some obligation to insure that the products purchased in this infrastructure change are good products and meet the overall goals of the infrastructure change.

The resulting certification regulation has been implemented as a series of specific software behaviors which are reinforced by specific test case behaviors. This has changed software and narrowed the differences between software. For example, order entry systems existed, were implemented, and demonstrated positive results before ONC Certification required re-work of those same systems to meet different, but not better, specific requirements. The end result is significant "compliance innovation" or working to the test.

Sometimes, this approach is justified when there is an overriding societal benefit to specifying specific functional requirements and behaviors. Examples of these are interoperability standards and specific patient safety requirements. In the specific case of interoperability standards, there is actually a direct innovation benefit, making it easier for small vendors to compete by supplying solution that links into other solutions from other sources. These specific cases are limited, however.

## Slide 32

**ONC Certification Recommendations**. Legislation does mandate a certification process. The issue then is the nature of the certification program. The recommendations are as follows:

- **Judicious use of specific functional requirements.** The ONC is encouraged to limit specific functional requirements unless there is a specific public health or patient safety issue. The regulatory description of other features should be in higher level descriptive, not functional design, terms.
- **Flexible compliance measures.** The ONC is encouraged to show flexibility in the certifying session itself to allow for multiple approaches to the desired feature. The ONC Certification process exhibits some of this approach; e.g., the certification standards for user centered design leave open the specific implementation.
- **Avoid requirements that empower a single, external certification body.** When there is a single body, the usual issues that occur when a monopoly is present become an issue.
- **Increase predictability.** Finally, the ONC is encouraged to increase predictability. The staging process of the requirements does give an opportunity to re-adjust the requirements, but it has resulted in less long-term predictability. The re-certification based upon software change really should be better defined and very limited.

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## Slide 33

Comparing the two approaches of current regulation.

- Process versus product definition. Of these two, process control have less negative effects on innovation. Product definition significantly reduces the flexibility. This is noted in the impact statements listed under each regulatory method.
    - For the certification approach, how the software was developed does not matter; it only matters if it can run the test scripts at the certification point.

## Slide 34

In some of the slides, we classify a given issue using an A, B or C. Here is what we mean by that. A refers to ambiguous in the same sense that section 618 asks us to look for things that are ambiguous that need to be clarified. So while not all ambiguity is bad, the ambiguities that we highlight here are indeed things that need to be clarified. B means broken, which means that the actual law as written, whether codified in statute, regulation or guidance, does not fit HIT. Thus, in these cases the law needs to be changed. And finally C refers to capabilities that may be underutilized, things we want to see the agency make more use of because it's an effective approach.

## Slide 35

The issues on this slide all fundamentally deal with areas where the scope of FDA regulation is uncertain. To be specific, there are four areas related to HIT where FDA could help industry by clarifying the exact contours of its regulation. Those four areas include:

1. The borderline between disease-related claim on the one hand, and a wellness related claim on the other hand. FDA has jurisdiction over disease-related claims, but not wellness related claims. Unfortunately, simple rules in this space sometimes lead to overregulation. For example, a very simple approach would be to say that if any advertising or labeling mentions a disease, as defined in some authoritative compendium of diseases, the product would be regulated. But the mere mention of a disease such as obesity would likely cause very low risk software used to manage weight as FDA regulated. Further, there are many different types of claims and some might make veiled references to the diseases, but not specific. In which such circumstances would FDA regulate the associated HIT?

2. The scope of what constitutes an accessory to a medical device. FDA's had a long-standing rule which says that anything intended to be used as an accessory to a medical device is itself a medical device and regulated to the same level as the device it accessorizes. But there are many generic accessories that are very low risk that should not take on the regulatory classification of a product it is intended to accessorize. More specifically, we need new accessory classifications that down classified these accessories in much the same manner that FDA created the MDDS classification.

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3. The scope of clinical decision support software that FDA regulates. FDA has long regulated certain forms of clinical decision support software, such as computer-assisted diagnosis software used with medical imaging. Unfortunately, FDA has never been very clear on the contours of its regulation for this broad category of software. Much of it is low risk, and indeed much of it is used in a manner that makes it highly unlikely that the patient could ever be hurt. FDA needs to clarify the scope of CDS regulation.

The scope of FDA regulation over software modules. The development of software involves a high degree of incorporating existing modules into larger software programs that might have a medical purpose. But many of the individual modules are very generic and not particularly intended for medical software. Does FDA regulate the modules? What about for medical device software that is used on a platform where it incorporates other existing modules already available on that platform. Are any of those incorporated modules also regulated?

## Slide 36

On this slide, we focus on the areas where FDA regulation can be improved for devices that fall within FDA regulation. There are three principal areas:

1. The vast majority of devices subject to FDA jurisdiction must meet the requirements of the quality system. Unfortunately, though, understanding how to meet those requirements can be very difficult for standalone software. The regulation was written with physical products in mind. While the basic regulation is written broadly and can be interpreted, industry needs official guidance from FDA on how it should be interpreted for standalone software. Private standards groups such as AAMI are working on this issue and so this might be as simple as FDA officially recognizing that work.

2. Typically, when a medical device manufacturer goes to FDA seeking clearance, they are presenting a device with a very defined intended use typically as a solo product. If, instead, the manufacturer goes to FDA with what is essentially a complement of the future, unspecified network of devices, the agency is uncertain how to gauge risk and what kind of data to expect. We simply need FDA to come up with a paradigm that informs developers of these network components how to demonstrate their claim of substantial equivalence.

3. When something goes wrong with a network of medical devices, it is often unclear where the problem resides. Indeed, the problem may in fact reside as between two devices at their interface, as opposed to being the responsibility of one single component. But the laws that FDA were written with accountability in mind, so there are post-market obligations such as adverse event reporting and field corrective actions that are written as though it should be clear whose responsibility it is.

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## Slide 37

**FDA should actively establish a policy of "Enforcement Discretion" for lowest-risk HIT, where enforcement of regulations is inappropriate**

- ❑ Enforcement Discretion is deregulatory and immediate
- ❑ Enforcement Discretion would quickly provide transparency and minimze regulatory ambiguity and industry fear
- ❑ Concept of "lowest-risk" is something FDA has begun to define in HIT through Enforcement Discretion of EHR and EMR related software (e.g., Product Code NSX "Software, transmission and storage, patient data") which are not classified and not subject to regulation (including no registration of manufacturer/developer or listing of product with FDA)

**FDA should assess exemption from GMP for lower-risk HIT**

- ❑ Most Class I devices are exempt from pre-market notification and/or good manufacturing practices (GMP) regulation; lower-risk HIT should similarly be exempt from GMP

**FDA should expedite guidance on HIT software, mobile medical apps and related matters**

- ❑ There is a lack of timely guidance or informational documents about HIT or final guidance on mobile medical apps (final guidance on 2011 Mobile Medical Apps continues to be delayed; draft guidance on home use medical devices including wireless was promised but never issued)
- ❑ Guidance updates on matters that affect HIT are not delivered in a timely fashion: e.g., 2007 Draft RF Wireless Tech; 1997 Deciding When to Submit Change (510(K) Modification)

**FDA lacks internal coordination on HIT software, and mobile medical apps policies and regulatory treatment**

- ❑ Inconsistent regulatory treatment and information dissemination by FDA officials, reviewers and staff to inquiries by industry and publicabout HIT, mobile medical apps
- ❑ FDA should coordinate internal understanding of policy positions and regulations to maximize consistency and help eliminate ambiguity and misinformation

**FDA should utilize external facing resources to proactively educate the public about how policies and regulation impact HIT and MMA**

- ❑ CDRH Learn, Device Advice, DSMICA should be updated with information about HIT/mobile medical apps and utilized to help raise public and industry understanding in this space

**There may exist a need for additional funding to appropriately staff and build FDA expertise in HIT and mobile medical apps**

- ❑ FDA lacks adequate staffing resources and funding to adequately oversee HIT and mobile medical apps

## Slide 44

**Measurement of Regulatory Impact on Innovation**

The IOM report *Health IT and Patient Safety: Building Safer Systems for Better Care* includes a study on the impact of regulation upon innovation (see *Appendix D* of the IOM report, which is an abstract of an article, and the full article). The referenced article is a study of regulation in multiple industries and the effect of that regulation on innovation. The appendix discusses the Innovation Dimensions of regulation. These measurements are useful in evaluation of current regulation and developing requirements for innovation into a new framework for HIT regulation. These factors are:

- **Stringency**. The more stringent the regulation the
  - Less degrees of freedom for innovation
  - Increased risk of disruptive radical innovation to meet compliance
  - Divergence of resources – missed opportunities
- **Flexibility**. The number of implementation paths to meet compliance.
  - The more paths to accomplish compliance the more degrees on innovation
  - The more prescriptive the regulation in describing, or even moving from describing to specification, the desired behavior, the less innovation. In extreme, the software is designed by regulation.
- **Information**. This is defined as the effect of increasing or decreasing the amount of information in the system.
  - Increasing the amount of information in the system increases the innovation in the system.