**Health IT Policy Committee**

**Comments on FDASIA Workgroup Presentation**

**August 7, 2013**

**Policy Committee Observations, Questions, and Requests**

1. Provide more clarity on HIT that is out of scope
   * HIT that is not a medical device and out of scope for even enforcement discretion
2. Delineation of gray areas – can taxonomy subgroup or the full workgroup take this on?
   * Outline characteristics that lend HIT to one regulatory scheme or another (FDA/ONC) or otherwise
   * What is really high-risk software?
   * Claims-data for clinical purposes – where does it fall?
3. Objective certification has benefits, particularly versus subjective. The federal government should always use an objective process.
4. How can the free flow of safety information be ensured? For a publicly available database, how does the information get there?
   * Possibly outline suggestions about how to organize this process (e.g., from current reporting mechanisms, new mechanisms, etc.)
   * Just spontaneous vendor reporting? Or from front-line users?
   * FDA mentioned one set of mechanisms (medical device reports, hospital networks, registries, pilots, use of the unique device identifier, a national surveillance system in the future). Possibly comment on these mechanisms.

* Are they sufficient?
  + - Is this the right path/approach for the future?

1. How can safety reporting be strengthened?
   * Expand on local approach recommendation – outcome-based?
   * What specific current mechanisms can be used/strengthened?
2. Coordination of agencies – consider potentially commenting on:
   * How agencies could do this
   * For what areas/topics would this be a priority
3. Liability concerns
   * Can the workgroup consider liability concerns and ways to possibly address them?
   * As an example: possibly recommend exemptions/safe harbors for vendors taking certain actions such as voluntary reporting
4. Labeling—as an example, there are the FDA requirements for drug labeling (intended use)
   * Could such a process work for HIT/medical devices?
5. Self-developed and open source HIT – how best to address these types of HIT, especially regarding listing?
6. Patent issues related to medical devices/HIT – software is business methods/practices (probably out of scope unless the U.S. Supreme Court weighs in differently than what is current law)
7. Goal setting can limit innovation. For example, vendors focus on MU goals which takes time and resources away from other innovative efforts.
8. To improve both safety and innovation, consider what options within a potential framework could enhance:
   * Interoperability
   * “Trial-ability” – small scale trials of HIT products/applications in a protected and studied environment