Comment of athenahealth, Inc.' s Dan Haley to FDASIA Health IT Report Public Workshop, May 13, 2014, National Institute of Standards and Technology:

Throughout this process, kicked off in 2012 by the FDASIA legislation, a common theme heard from the agencies and industry alike is the need to provide regulatory certainty to foster innovation (and investment). That is particularly important for a cloud-based company like ours, because we iterate our EHR service at a pace that is simply incompatible with the medical devices framework--we literally iterate on a daily basis. In that we are currently an outlier, but we do not expect to be for long.

We are gratified to see a proposed risk-based framework reflecting regulatory forbearance and appropriate incorporation of private sector expertise and experience. But the draft FDASIA report, in the end, is a statement of present regulatory intent that relies for its greatest specificity on illustrative examples.

The FDA's Dr. Shuren referred several times in his introductory remarks this morning to the "recommendations" set forth in the draft. My understanding from previous presentations since the draft was released is that the agencies do not believe they need, nor do they necessarily want, Congressional action to implement the recommended framework. So the question arises: "recommendations" to whom? This goes, obviously, to Mike Marchlik's point on the last panel about the need for legislation.

Simply put, a statement of present regulatory intent does not and cannot provide regulatory certainty. For all of the excellent and encouraging language in the draft, in the end absent Congressional action to codify its recommendations what the agencies are asking of industry is that we trust not only that the human beings currently making regulatory policy will stick to their own recommendations over time, but that their successors will share their perspective and perpetuate their policies as well. That isn't certainty. It is closer to the opposite - a leap of faith.

I heard the response that Mr Patel gave to Mike about the need for flexibility, but statutory certainty does not preclude regulatory flexibility. Congress can draw broad lines to establish the outer parameters of agency authority and discretion without micromanaging the finer lines that FDA and the other agencies should properly be charged with drawing within those parameters. That is a challenge. But statutory certainty and regulatory flexibility need not be mutually-exclusive.