Opening Statement of Chairman Fred Upton

Health Subcommittee Hearing on "Examining the Regulation of Diagnostic Tests and Laboratory Operations"

November 17, 2014

The 21st Century Cures Act passed this committee 51-0 and was through the House in July with 344 votes. It was the product of over a year's worth of ideas members received at hearings, roundtables in DC and across the country. Provisions were proposed and fleshed out with the help of a wide variety of stakeholders, in and out of government, of all political stripes. It goes without saying that for any piece of comprehensive legislation to garner these vote totals, compromise is critical and the perfect can't become the enemy of the good. It also goes without saying that some important pieces of the puzzle didn't get included because the timing just wasn't right. Modernizing our regulatory framework for the review and oversight of diagnostics is one of those pieces.

As I said at our first forum on this topic in July 2014, these increasingly important and complex tests are providing researchers and clinicians with valuable tools to match the right patients with the right treatments. We must ensure that our laws and regulations keep pace so that innovation in this space continues and patients benefit from accurate and reliable tests.

I saw Cures as a unique opportunity to elicit feedback on what such a framework should look like and what role Congress could play in developing it. We issued a white paper asking targeted questions and were overwhelmed with the scope and thoroughness of the responses we received. We realized early on that the traditional medical device framework was not ideally suited for these unique tests, which provide clinicians with critical information but do not actually provide therapy to a patient.

It was also apparent that there was quite a difference of opinion about what the roles and responsibilities of FDA and CMS should be. Developing legislative language with broad support on an abbreviated timeframe was not achievable. I told my staff to table these discussions until we got Cures through the House but to urge stakeholders to use the time to forge ahead and find as much common ground as possible.

I was very encouraged to hear that a diverse group of stakeholders with different points of view came together and, in the spirit of finding consensus, developed a draft framework that answered a lot of our questions in a responsible, balanced manner. Of course there is room for

improvement, but folks need to be realistic in their approach and pragmatic with their suggestions if the ultimate goal is a bill signed into law any time soon. We must get this right and we need everyone's help in order to do so.