Earlier this year, Democrats and Republicans on the House Energy and Commerce Committee worked together to develop the 21st Century Cures legislation. I was proud to work with my colleagues on that landmark initiative in order to reduce regulation, inspire innovation, improve outcomes for patients and move our country towards precision medicine. Further, that legislation helped highlight the increased importance of diagnostics in modern health care.

Today, diagnostics play a critical role in the rapid detection and diagnosis of diseases. Diagnostics help identify targeted, effective and often less invasive treatments–ultimately leading to reduced costs to both patients and the government.

The Committee's current discussion draft legislation follows the work of 21st Century Cures and focuses on the future of diagnostics. It would advance innovation, protect patients, provide a predictable and timely path to market and avoid duplicative regulation. It does this by tailoring an appropriate role for the FDA (outside of the medical device framework) to oversee diagnostic test development activities, while modernizing CLIA oversight of separate and distinct laboratory operation activities.

Without this legislation, I am concerned that the FDA would finalize guidance to regulate laboratory developed tests as medical devices, which could impact many stakeholders. This guidance may lead to costly litigation and uncertainty or could hamper innovation and patient access to critical diagnostic tests.

Also, I am deeply concerned that this guidance would result in the medical device tax being imposed on laboratories. Dr. Shuren confirmed during the hearing in September 2014, that under the FDA's guidance, labs would ultimately be directly subject to this medical device tax. Labs already pay the tax indirectly when they purchase test kits from manufacturers, so under the guidance they would unfairly pay the same tax twice.

I have many stakeholders in my district, so this discussion draft legislation represents a good compromise between the CLIA-centric approach and the medical device framework laid out in the FDA guidance. In addition, my district is home to many veterans and military families who rely on TRICARE for their health care, so ensuring market stability and access to these crucial tests directly affects my constituents.

I am thankful for stakeholder engagement in finding a legislative solution that provides a feasible alternative to FDA's draft guidance. I stand prepared to work with the Chairman and Ranking Member in order to accomplish this goal.