Combination Products Coalition

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September 8, 2014

VIA ELECTRONIC DELIVERY

The Honorable Joe Pitts, Chairman
Subcommittee on Health
Committee on Energy and Commerce
2125 Rayburn House Office Building.
Washington, D.C. 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
237 Cannon House Office Building
Washington, D.C. 20515

Re: September 9, 2014 LDT Hearing;
Statement for the Record

Dear Congressmen Pitts and Pallone:

The Combination Products Coalition ("CPC") offers the following statement into the record for the Subcommittee on Health's September 9, 2014 hearing entitled "21st Century Cures: Examining the Regulation of Laboratory Developed Tests."

The CPC believes that FDA's decision to submit its framework for LDT regulation to Congress is a significant step forward in continuing the conversation regarding the best regulation for diagnostic tests. A single, optimized regulatory framework will spur the kind of innovation that is crucial to advancing personalized medicine by ensuring that all test developers – whether working at a clinical laboratory or at a traditional manufacturer – can bring much-needed companion diagnostic tests to patients quickly and safely. The better the tests we have, the better the chances we have of getting patients the right drug at the right dose, which makes finalizing the framework crucial to advancing the public health.

Although FDA would regulate certain LDTs under its proposed framework, CMS would still have a significant role to play. CMS would still regulate laboratory services, continue to inspect labs, and impose its own requirements under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). There are legitimate concerns about the potential confusion the overlay of two sets of regulatory requirements from two separate agencies could cause. Thus, to form a single risk-based system for diagnostics that avoids duplication and averts confusion, it is imperative that FDA, CMS, and other stakeholders work together closely on developing a final framework.

Through the 21st Century Cures Initiative, Congress could facilitate the regulatory policy process through legislation that requires relevant federal agencies (e.g., FDA and CMS), and other stakeholders, to work together to develop a final regulatory framework within a reasonable timetable. More specifically, Congress could enact legislation similar to that used in FDASIA Section 618, which brought together relevant agencies to develop the framework for health information technology regulation, and authorized a federal advisory committee/working group to offer input into that federal strategy. We encourage you and your colleagues to consider a similar approach in this case.

In addition, as the conversation about LDT regulation proceeds, the other side of the diagnostics equation – tests produced by traditional manufacturers – must be taken into account. Whatever the final system is, it must offer equal flexibility to both laboratories and traditional diagnostic test manufacturers. Elements of FDA's proposed framework for LDTs, such as the use of literature to establish clinical validity of diagnostics – as opposed to costly and time consuming trials manufacturers are often required to perform – would be equally valuable for traditional manufacturers to use to secure FDA clearance for new diagnostics. Here, too, the 21st Century Cures Initiative could help by mandating that agencies consider not just LDT regulation, but the entirety of diagnostics regulation, to create a single, and optimal, regulatory system that treats all parties and products equally.

We believe that increasing regulatory flexibility (to accelerate innovations that help patients), and decreasing regulatory burdens on lower-risk diagnostics (to allow greater dedication of limited FDA and industry resources to higher-risk tests), should be hallmarks of the final regulatory system. Further, flexibility and regulatory burdens should be based on what the diagnostic is as opposed to *who* the manufacturer is; whether a diagnostic is made by a traditional manufacturer or a clinical lab, it must meet the same standards of safety and effectiveness, and follow the same regulatory path to patients.

We stand ready to assist you in developing this approach. Please let us know if there is anything we can do to be helpful.

Sincerely,

Bradley Merrill Thompson
On Behalf of the Combination Products Coalition