Combination Products Coalition

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VIA ELECTRONIC SUBMISSION AND FEDERAL EXPRESS

The Honorable Brian Deese
Acting Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Mr. Deese,

On behalf of the Combination Products Coalition ("CPC") we are writing today to support the release of FDA draft guidance documents that contain preliminary thoughts on potential FDA regulation of laboratory developed tests ("LDTs").

For many years, stakeholders have discussed the regulation of LDTs and its relation to *in vitro* diagnostic ("IVD") regulation. Some have called to maintain the status quo (two separate regulatory systems for LDTs and IVDs), others have called for FDA to regulate both IVDs and LDTs, and still others have asked for parity in the regulation of IVDs and LDTs, whatever the form that would take. The importance of that discussion, to ensure we have the right regulatory system(s) in place for diagnostics, continues to rise as LDTs and IVDs play an ever increasing role in critical medical decision-making.

A pivotal question the discussion always comes back to is what FDA regulation of LDTs, if it ever were to occur, might look like. We understand that FDA has outlined its initial ideas in draft guidance documents but OMB is holding up their release. We take no position on the substance of these documents because we have no visibility to their contents. However, we can say that their release is of the utmost importance to continuing the dialogue on optimal regulation of LDTs and IVDs because it will address the pivotal question and finally allow the discussion to move forward.

We are aware there are objections to the release of the draft guidance. These objections are premature. As you know, draft guidance is not law. Draft guidance is not even an official statement of FDA policy. Draft guidance is a tool that allows FDA to place its initial thinking in documents, and provide those documents to the public for comment so that all stakeholders can engage in discussion about the best course of action. The outcome of a discussion could be anything – a decision to allow the current system to remain, a move toward a single regulatory system for IVDs and LDTs, or some new and unexpected idea that benefits the public health. But we need to have that discussion with all the information, and that includes FDA's initial thinking on a framework for LDT regulation.

We request you release the draft guidance to let the dialogue on this important topic continue.

Sincerely,

Bradley Merrill Thompson
On Behalf of the Combination Products Coalition

cc: U.S. House of Representatives, Energy & Commerce Committee, Subcommittee on Health
U.S. Senate, Health Education Labor & Pension Committee, Subcommittee on Primary Health & Aging
Howard Shelanski, Administrator of Office of Information and Regulatory Affairs
Sylvia Mathews Burwell, Secretary, Department of Health and Human Services
Margaret A. Hamburg, M.D., Commissioner, U.S. Food & Drug Administration
Jeffrey E. Shuren, M.D., J.D., Director, Center for Devices and Radiological Health
Alberto Gutierrez, Ph.D., Director, Office of *In Vitro* Diagnostics and Radiological Health