Congress of the United States
Washington, DC 20515

August 9, 2013

The Honorable Sylvia Mathews Burwell
Director
Office of Management and Budget
Executive Office of the President
725 17th Street, NW
Washington, DC, 20503

Dear Ms. Burwell:

We are writing to urge the release of the Food and Drug Administration's (FDA) draft guidance on the regulation of laboratory developed diagnostic tests (LDTs). We have reached a critical point in the development of advanced diagnostics at which it has become essential that FDA move this guidance forward to ensure appropriate and efficient oversight of safe and effective diagnostics.

The field of diagnostics has changed fundamentally and rapidly in recent years. A new generation of advanced molecular diagnostics—widely developed as LDTs—is increasingly determinative of critical treatment decisions for patients with life-threatening conditions. These advanced diagnostics, the cornerstone of personalized medicine, provide unprecedented insights into the presence and course of diseases and other health conditions. The insights that these tests provide help to make therapeutic decisions that increasingly are tailored to the individual patient. The result is that patients receive more effective care, and avoid the substantial costs and treatment delays associated with use of ineffective therapies.

The growing reliance of doctors and patients on diagnostics to make treatment decisions, however, means that the risks to patients are much higher if these tests do not perform as expected. False results mean that patients either will not receive the therapy they need, or will be subject to the costs and adverse effects of a therapy that will not work for them.

Currently, a diagnostic test produced by a manufacturer and sold to a laboratory must first obtain pre-market clearance or approval from FDA to support the safety and effectiveness of the test, and these tests are subject to a total quality system from design through distribution as well as post-market oversight, including mandatory adverse event reporting and FDA's recall authority.

Laboratories that develop and use the same kind of test, however, do not need to obtain pre-market approval for tests offered and are also not subject to a post-market surveillance system. Yet these LDTs are widely used as interchangeable with FDA-approved or cleared diagnostics, with little transparency for patients or even doctors regarding what test has been used.

The FDA currently has regulatory authority under the Food, Drug and Cosmetic Act to provide oversight of LDTs. The FDA has not exercised its regulatory authority because LDTs have been regarded as established and well-understood tests that pose relatively low risk to

patients. However, the widespread development and use of a new generation of advanced molecular diagnostics by clinical laboratories without FDA oversight has exposed a significant gap in the regulatory system. Patients and consumers depend on FDA for assurance that the diagnostics, medical devices, and therapies used for their care are safe and effective.

Recently, the New York Times editorial board expressed its concern that many LDTs have never been tested for safety and accuracy. The editorial also states that the time is right for appropriate regulation and that "the draft guidelines should be released for public comment."[1] We agree.

The time has come for the Administration to address this regulatory gap and resolve the uncertainty hanging over this critical area of medicine by affirming FDA's oversight of diagnostics. The promise that advanced diagnostics hold for patients is tremendous, but, at the same time, the increasingly pivotal role of these diagnostics in patient care makes it imperative that their safety and effectiveness is assured by the FDA prior to use.

Sincerely,

Louise M. Slaughter
Member of Congress

Ami Bera, M.D.
Member of Congress

John Delaney
Member of Congress

Rosa DeLauro
Member of Congress

Steve Israel
Member of Congress

Barbara Lee
Member of Congress

1 "The Gap in Medical Testing." Editorial. *The New York Times* 7 July 2013

Carolyn Maloney
Member of Congress

Jan Schakowsky
Member of Congress

Debbie Wasserman Schultz
Member of Congress