The Coalition for
21st
centurymedicine

October 3, 2014

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairman Pitts:

I am pleased to respond to your request of September 30, 2014 regarding my testimony before the Subcommittee on Health on Tuesday, September 9, 2014 at the hearing entitled "21st Century Cures: Examining the Regulation of Laboratory Developed Tests." This letter provides my response to the additional question for the record from Dr. Burgess that I received:

The Honorable Michael C. Burgess

1. **The FDA has cleared a few LDTs with labeling statements that include limitations against use of the tests for treatment selection or even to make a diagnosis. With a manufacturer-distributed kit, a laboratory can use the kit "off label" in practice of laboratory medicine, without running afoul of FDA's promotional rules. With an LDT, however, if FDA considers the laboratory to be a "manufacturer" and considers the LDT service to be a "device" subject to FDA's labeling rules, this could raise concerns that the laboratory is "promoting" off-label use if it performs a test with labeling restricting the use for treatment or diagnostic purposes when the laboratory knows that the treating physician does not intend to use the test for such purposes. From your perspective as an investor in laboratories performing LDTs, how would this risk impact your decision to invest in these innovative companies?**

Thank you, Dr. Burgess, for raising this important issue. The Coalition for 21st Century Medicine identified this concern a number of years ago, and has raised this with FDA on a number of occasions. Laboratories have a longstanding practice whereby they provide consultation to treating physicians to help them understand how to use their tests in patient management, which is required under CLIA regulations. However, FDA labeling rules for devices restrict communication between manufacturers and physicians to prevent "promoting" off-label use. Unfortunately, we have not received any assurances that routine communications between laboratories and treating physicians would be protected from challenge as off-label promotion. In the absence of clear, written rules addressing this concern in a way that recognizes that laboratories are medical service providers

involved with provider-to-provider communications and that reconciles this conflict between CLIA regulations and FDA promotional rules, laboratories who offer LDTs will be at significant risk of potentially serious and onerous penalties. In my view, this risk would definitely chill investment in innovative biotechnology companies developing personalized diagnostics as LDTs.

Sincerely,

M. Kathleen Behrens Wilsey

M. Kathleen Behrens Wilsey, Ph.D.
Co-founder, Coalition for Twenty-first Century Medicine