THE COMMITTEE ON ENERGY AND COMMERCE

MEMORANDUM

September 5, 2014

To: Members, Subcommittee on Health

From: Majority Committee Staff

Re: Hearing Entitled "21st Century Cures: Examining the Regulation of Laboratory Developed Tests"

On Tuesday, September 9, 2014, at 9:30 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled "21st Century Cures: Examining the Regulation of Laboratory Tests." The hearing will allow the Subcommittee to gain a better understanding of how laboratory developed tests (LDTs) are performed in clinical practice, what their impact has been on personalized medicine, and how we can continue to foster innovation in this space. In addition, it will provide an opportunity to hear from the Food and Drug Administration (FDA) and a variety of stakeholders about the agency's recently proposed regulatory framework for the review and oversight of such tests.

I. WITNESSES

Panel One

- Jeffrey Shuren, M.D., J.D., Director, Center for Devices and Radiological Health, Food and Drug Administration.

Panel Two

- Christopher Newton-Cheh, M.D., Assistant Professor of Medicine, Harvard Medical School, Cardiologist, Massachusetts General Hospital, *On behalf of American Heart Association;*
- Andrew Fish, Executive Director, AdvaMed Diagnostics;
- Alan Mertz, President, American Clinical Laboratory Association;
- Charles Sawyers, M.D., Immediate-Past President, American Association for Cancer Research; and,
- Kathleen Wilsey, M.D., Co-Founder, Coalition for 21st Century Medicine;

II. BACKGROUND

Section 1143 of the Food and Drug Administration Safety and Innovation Act required that, if FDA plans to issue guidance relating to the regulation of LDTs, the agency must notify the Committee at least 60 days prior to taking such action and include the anticipated details of any such documents as part of the notification. On July 31, 2014, FDA notified the Committee of its intent to issue two draft guidance documents regarding oversight of LDTs and provided the anticipated details in guidance format.[1] Currently, the Centers for Medicare and Medicaid Services regulate LDTs under the Clinical Laboratory Improvement Amendments of 1988.[2]

III. STAFF CONTACTS

Should you have any questions regarding the hearing, please contact John Stone, Robert Horne, or Carly McWilliams at (202) 225-2927.

[1] Additional background on the notifications is available at: www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm407409.pdf.
[2] For additional background, please see Sarta & Johnson: *Regulation of Clinical Tests: In Vitro Diagnostic (IVD) Devices, Laboratory Developed Tests (LDTs), and Genetic Tests*, Congressional Research Service, March 2014, http://www.crs.gov/pdfloader/R43438.