



November 13, 2015

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Hearing entitled “Examining the Regulation of Diagnostic Tests and Laboratory Operations”

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## I. INTRODUCTION

On November 17, 2015, at 10:00 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled “Examining the Regulation of Diagnostic Tests and Laboratory Operations.”

## II. WITNESSES

- Dr. Jeffrey Shuren, Director, Center for Devices and Radiological Health, Food and Drug Administration, Department of Health and Human Services
- Dr. Patrick Conway, Deputy Administrator for Innovation and Quality & Chief Medical Officer, Office of the Administrator, Centers for Medicare and Medicaid Services, Department of Health and Human Services

## III. BACKGROUND

Throughout the 21st Century Cures initiative, the Committee heard from a wide range of stakeholders about the important role diagnostic tests already play in the advancement of precision medicine. One week after a July 2014 roundtable on this topic, the Food and Drug Administration (FDA) notified Congress of the agency’s intent to issue draft guidance documents that would fundamentally alter the regulatory landscape for the review and oversight of laboratory developed tests (LDTs). While there are significant differences of opinion about FDA’s proposed approach, the [draft guidance](#) has clearly served as a catalyst for broader conversations about what a modern regulatory framework for these unique and evolving tests and services should entail.

In December 2014, the Committee issued a [white paper](#) seeking feedback and asking what roles FDA and the Centers for Medicare and Medicaid Services (CMS), under its Clinical Laboratory Improvement Amendments (CLIA) authority, should play in such a framework. This hearing will be the first time FDA and CMS have testified together about their respective areas of expertise as well as their current responsibilities and what they should be going forward.

**IV. STAFF CONTACTS**

If you have any questions regarding this hearing, please contact John Stone or Carly McWilliams at (202) 225-2927.