House Energy & Commerce Committee Seeking Comments on Regulation of Diagnostic Tests - Congressional Update

Alan G. Minsk and Cathy Fortney

The House Energy and Commerce Committee last week released its latest White Paper in the 21st Century Cures Initiative. The Committee is soliciting comments regarding the Food and Drug Administration's regulation of in vitro diagnostic (IVD) test kits and laboratory developed tests (LDTs). The 21st Century Cures Initiative is a group that has been charged with the task of examining current trends in medicine, and assessing how regulations are keeping up with constantly-changing technologies. As the 21st Century Cures initiative proceeds, with preparation for a discussion draft early in 2015, the Committee is seeking all interested stakeholders' feedback on a list of 11 specific questions contained in the White Paper, in addition to advice on what role Congress should play in addressing any other related issues. To ensure consideration, comments are due no later than January 5, 2015, and should be directed to: cures@mail.house.gov.

The White Paper follows FDA draft guidance, issued on September 30, with a 120-day comment period (expires on February 2, 2015). Comments are being solicited on all aspects, but specifically, feedback regarding specific issues for the oversight framework draft guidance. AGG prepared a bulletin on the LDT guidance available here[1].

The White Paper and Congressional Committee efforts also follow testimony on September 9, 2014, by Dr. Jeffrey Shuren, the Director of FDA's Center for Devices and Radiological Health, before the Subcommittee on Health, House Committee on Energy and Commerce. In his testimony, Dr. Shuren said that FDA believes that oversight for those LDTs that pose greater risk to patients is critical to preventing physicians from failing to provide beneficial treatments, ordering unnecessary tests, and delivering unnecessary or harmful medical treatments. In addition, FDA does not want to delay or impede access to potentially important tests if there is no approved test on the market; the Agency does not believe that FDA oversight is necessary for low-risk tests. For these reasons, rather than draft a framework that proposes the same level of oversight for all LDTs, FDA intends to propose a risk-based oversight framework, which is discussed in the aforementioned AGG bulletin.

1 http://www.agg.com/Latest-Developments-on-FDA-Regulation-of-Laboratory-Developed-Tests-10-28-2014/

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