FDA: Rethink how diagnostics are regulated

Feb. 6, 2018—U.S. Food and Drug Administration commissioner Scott Gottlieb, MD, said we need to think differently about how we regulate diagnostics.

“It’s been a little bit more challenging to define a pathway on how to get regulatory approval for the diagnostic at the same time you get regulatory approval for the drug, in part because a lot of these diagnostic tests have been promulgated as laboratory-developed tests, so they haven’t been brought through a traditional regulatory process,” Dr. Gottlieb said at a panel session at the World Economic Forum in Davos, Switzerland.

The FDA should work with Congress and stakeholders to develop specific, targeted legislation that would give the agency a unique set of authorities to regulate diagnostics properly, he said.

“My view is that the old 510(k) PMA pathway . . . for approving medical devices doesn’t really fit well with modern diagnostics, and we need very well-fashioned authorities when it comes to diagnostics.”

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