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Republican Congress, Trump Policies May Seek To 'Undo' FDA Device Safety Guidances; LDT Plan First To Go

by Sue Darcey

Emboldened by a Republican victory in the White House, GOP members of Congress are already putting the screws on federal agencies to back off on health and safety regulations and guidances for products, with some success – for example, FDA's Nov. 18 decision to shelve its proposed laboratory developed test guidance in final form seems to be a response to the new political reality in DC.

Industry attorneys and health consultants are predicting a new policy climate in Washington for health care regulations following the Nov. 8 elections and the choice of Donald Trump as president; one of the first policies to be impacted by the new approach, is a pending laboratory-developed test oversight framework from FDA.

"Certainly a focus of the Trump campaign was reducing regulation on industry, so I do believe there will be a new FDA, overall affecting the medical device industry, but also affecting all the medical industries that FDA regulates," said Chad Landmon, partner with Axinn, Veltrop & Harkrider, said in a Nov. 16 interview.

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says.

The proposed framework for LDTs – tests that are developed and performed by the same lab as a service – would have required a phased-in, risk-based approach targeting those that those diagnose the most serious and deadly diseases first, with FDA holding them to stricter standards now reserved for consumer test kits.

FDA had promised to issue final guidance documents establishing a regulatory framework for LDTs this year after decades of deferring to CMS oversight of labs under the Clinical Laboratory Improvement Amendments (CLIA). (Also see "*Shuren In The Lion's Den: Device Center Chief Defends LDT Plan At Clinical Lab Meeting, Fields Wide Array Of Questions*" - Medtech Insight, 14 Mar, 2016.) The guidance and framework now appears to be dead in the water, with a Nov. 18 suggestion by the agency that it would back off finalizing the LDT guidance and work with stakeholders, the new Trump administration and Congress to gets its approach "right." (Also see "*FDA Puts Lab-Developed Test Oversight Plans On Hold*" - Medtech Insight, 18 Nov, 2016.)

New Guidances To Trump Old Ones?

Landmon, along with other industry attorneys and consultants making predictions about how a new Trump Administration will impact health care legislation and regulations, observed that the easiest way to ease device and drug firms' obligations to comply with FDA and HHS standards would be by using new federal agency guidances, to reverse old ones, or to stop in-progress documents that are objectionable to Republicans from proceeding.

"Any executive order that was done to implement the Affordable Care Act, can obviously be 'undone' or changed ... with a guidance," Gail Wilensky, a consultant with Project Hope, said at a Nov. 16 Alliance for Health Reform briefing on election impacts on health care.

"Yes, the [executive branch] does have the power to do that," observed Landmon. "Focusing on the FDA piece, and less on the Affordable Care Act pieces, the chief executive has the power to work with an agency to change guidances; you don't even need an executive order, as much as you need to just work with whoever's going to be the new FDA commissioner, and then move down [the various staff levels] within FDA," Landmon remarked.

"The only caveat to it is that it can't be inconsistent with any statute, and, then, not inconsistent with any regulations promulgated by the agency."

Among those guidances that might become candidates for the new Republican administration's to reverse or restructure might be FDA's final 510(k) modification guidance (Also see "*Industry Urges FDA To Distinguish Between 510(k) Modification Factors*" - Medtech Insight, 15 Nov, 2016.), and any guidances issued by the Internal Revenue Service that would maintain high taxes against profits made by multinational companies overseas and brought back into the US, Landmon said.

Freeze On LDT Guidance Unpopular Among Some Industry Sectors

However, some moves by the new administration to weaken device or diagnostic regulations may actually backfire, and not serve some sectors of the diagnostic industry very well, according to Landmon.

"You know it's interesting, because there are some in industry who want those [lab-developed] tests to be regulated, because it helps with marketing them to patients, and helps with marketing them to doctors and to payers," Landmon told *Medtech Insight*.

> *"AdvaMedDx is disappointed that FDA final guidance on LDT oversight is not forthcoming at this time." – AdvaMedDx executive director Andrew Fish*

For example, the industry attorney said, "the bigger diagnostic companies are particularly in favor of having an obtainable approval pathway – they want to be able to say they are FDA approved or sanctioned."

Making Landmon's point, AdvaMedDx executive director Andrew Fish stated Nov. 21, "AdvaMedDx is disappointed that FDA final guidance on LDT oversight is not forthcoming at this time, but we are encouraged by congressional interest in addressing longstanding questions about LDT regulation in the context of broader diagnostics reform legislation."

Senate Panel Chair Alexander Favors LDT Regulatory Overhaul

Also, Sen. Lamar Alexander, R-Tenn., chair of the Senate Health, Education, Labor and Pensions Committee may have provided some foreshadowing for the LDT guidance's doom in September, when he held a hearing on LDTs and declared he wanted to "start all over" with a regulatory scheme for handling the diagnostics.

Alexander's primary argument against the proposed LDT framework is that FDA regulation of the

tests would be too slow and expensive.

"I'm glad that the FDA has listened and will delay making final its current draft guidance that could have halted more than 60,000 lab-developed tests in their tracks, and will work with Congress and the new administration on next steps," Alexander said late Friday, Nov. 18.

Other members of Congress have also begun to make their move against promulgation of new health and safety regulations by agency, and on Nov. 15, a group of 16 Republican House leaders including House Majority Leader Kevin McCarthy, R-Calif., Appropriations Committee Chair Hal Rogers, R-Ky., Energy and Commerce Committee Chair Fred Upton, R-Mich. cautioned agency chiefs "against finalizing pending rules or regulations in the [Obama] Administration's last days."

The move was based on a perception by the House leaders that the Obama administration "might do audacious executive action throughout the course of the rest of the year."

This article was updated on Nov. 21, 2016 to include addition quotes, from AdvaMed and Sen. Alexander. From the editors of The Gray Sheet