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Life Sciences Legislation And Regulation To Watch In 2017

By **John Kennedy**

Law360, New York (January 2, 2017, 1:03 PM EST) -- The impending administration change has life sciences experts wondering what sort of regulatory environment to expect in 2017, and amid the uncertainty, they'll be closely watching the implementation of the 21st Century Cures Act and looking for possible U.S. Food and Drug Administration guidance on interchangeable biologics and off-label promotion.

Of course, with regulations somewhat dependent on whom President-elect Donald Trump names to head the FDA, his choice will set the agency's tone, experts say.

"This could be a very interesting year in the sense that people don't really know what's coming up," said Albert F. Cacozza Jr., a partner at Ropes & Gray LLP. "Things might get a little clearer in a month or two."

Here's a roundup of the legislation and regulation life sciences attorneys will be keeping an eye on in the new year.

How Will 21st Century Cures Work?

What's clear already is that the 21st Century Cures Act, signed by President Barack Obama on Dec. 13 after it received broad bipartisan support in both houses of the legislature, must be implemented. H.R. 34, as it's formally known, includes a number of potential changes, many of which fall along the path the Trump administration appears to want to take.

One such provision involves requiring the U.S. Department of Health and Human Services to evaluate the potential use of real-world evidence in approving drugs. This directive, and others like it, could result in more drug and device approvals and less red tape, which seems to jibe with Trump's goals, according to Christopher M. Mikson, a partner at Mayer Brown LLP.

"It's interesting timing," Mikson says. "Symbiotic timing in a lot of ways."

But it's still not a done deal. Because the use of real-world evidence remains controversial due to the

vast array of information that could be covered by its definition, we should expect ongoing clarifications regarding what, exactly, the term means, says Edward Dougherty, a principal in Dentons' global health care practice.

Opponents of using real-world evidence argue that it could weaken approval standards, but proponents simply see it as taking into account more evidence. The law itself is clear that nothing within its text should be construed to change the current standard of approval from requiring "substantial evidence"; it just allows new types of evidence to be accepted.

"[Clinical] trials can give you good data in some cases but can be real impediments to bringing a product to market," said James A. Boiani of Epstein Becker Green. "Now with the cloud and web-based computing, there's just a lot more information out there."

Given that the draft guidance for real-world evidence relating to medical devices has included database studies and pragmatic clinical trials, experts say it's likely that the FDA will similarly balance all available information with its goals of keeping consumers safe and approving effective products.

"We can expect it’s going to have a similar emphasis on reliability and relevance," Patricia A. Carson, a partner at Kirkland & Ellis LLP, said of what possible guidance could look like.

Will Off-Label Promotion Stay Off-Limits?

The FDA is also looking to provide direction regarding what, if anything, companies are allowed to say about off-label uses for FDA-approved products. The agency held two days of hearings on this long-standing issue in November, and it's one area experts say the Trump administration could push the agency on.

"A new commissioner in a supposed deregulatory environment might be more aggressive in getting that sort of guidance out," Cacozza says.

Historically, any statement that doesn't match what's on a product's label has been considered false and misleading, even if the statement is true, simply because it hasn't been blessed by the FDA, Cacozza says. However, the U.S. Supreme Court has deemed commercial speech protected by the First Amendment, and a number of recent cases, including Amarin Pharma Inc. v. FDA, have successfully challenged the FDA's ability to prohibit such speech.

In August 2015, U.S. District Judge Paul A. Engelmayer granted Amarin's preliminary injunction motion, ruling that the company is allowed to talk truthfully about off-label uses of omega-3 drug Vascepa for patients with "persistently high triglycerides," without fear of prosecution. Amarin and the FDA settled the dispute in March.

Under Trump's administration, this issue could garner more attention. Mikson says that whoever

becomes FDA commissioner is likely to relax enforcement in general and potentially also to push for guidance on off-label promotion.

Dougherty, however, doubts the agency will be quick to allow companies to promote off-label uses even if the promotions are true and not misleading. Such a decision may be viewed as a slippery slope, given the agency's mission of protecting public safety, he says, adding that if the FDA does move to resolve this dispute, it may happen slowly.

This topic is of particular interest in the diagnostics industry, where companies sell instruments and chemicals to laboratories that make their own test procedures. Because of the FDA's restrictions on off-label promotion, manufacturers can't talk to labs about how to use their products in lab-developed tests, Boiani says.

The idea that one manufacturer can't talk to another about how tests should be developed using its products is hard to justify, he says.

What Does an Interchangeable Biologic Look Like?

Interchangeability for biologics is another area that has seen much discussion but no FDA action yet, experts say.

"The industry is very interested in seeing the FDA’s thoughts on that," says Scott Lassman, a partner at Goodwin Procter LLP.

The FDA currently has two standards for nonbranded biologics: similar and interchangeable. Unlike a generic drug, a biosimilar cannot be substituted for the branded biologic because it isn't exactly the same or close enough to be interchangeable.

The agency has suggested that biologic approvals may be done sequentially — first for a biosimilar and then, if the company wants to go further and submit another application, for an interchangeable product. But the FDA has so far been silent about what the requirements for interchangeability will be, Lassman says.

Trump's administration could see interchangeability as an enticing subject for further guidance. Obama has viewed biosimilars as a path to lower drug prices, and given the amount of attention drug prices drew during the campaign, it wouldn't be surprising for Trump to see them the same way, Mikson says.

How Easily Will FDA User Fees Be Reauthorized?

The FDA's user fee acts expire during 2017, and these fees, which form the fabric of the agency's budget, will have to be reauthorized before the end of the fiscal year. User fees are typically a bipartisan issue, and they have been reauthorized every five years since the 1990s. But because they're seen as must-pass legislation, lawmakers may try to attach sought-after FDA reforms to the proposals, Cacozza says.

The fees themselves tend to be agreed-upon, so the intensity of any dispute over them will depend on how controversial any of these add-ons are, he says.

Some of this could be influenced by Trump's pick to head the FDA, but the fee negotiations are typically driven more by the industry and the career staff at the agency than they are by the commissioner, says Brian J. Malkin of McGuireWoods LLP.

User fees also contribute to a bit of a "vicious cycle," Malkin says, explaining that fees are necessary to improve certain programs, so programs attached to fees tend to get priority and those without associated fees get pushed aside.

--Editing by Kat Laskowski and Mark Lebetkin.