Portfolio Media. Inc. | 111 West 19th Street, 5th floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Life Sciences Regulation To Watch In 2018

By **John Kennedy**

Law360, New York (January 1, 2018, 3:04 PM EST) -- Although prescription drug pricing and opioid abuse have held prominent positions in public discourse over the past year, experts say the future is uncertain for legislation and regulation in those areas in 2018.

But like someone whose favorite TV series just became available for streaming, the life sciences community isn't going to stop watching. Here are a few of the plotlines it's got queued up for the coming year.

Will There Be Federal Action on Drug Pricing?

"Drug pricing remains at the forefront of everyone's thinking — from Congress, to the White House, to state legislatures and the media," said Seth H. Lundy, a King & Spalding LLP partner.

The price the public generally sees — the average wholesale price, or "sticker price" — often isn't what's ultimately paid, and Lundy said some stakeholders are pushing for more transparency regarding rebates, discounts and other pricing concessions provided by manufacturers.

"On the federal level, Congress is ramping up their efforts to better understand those aspects of the industry with an eye to potential increased oversight or legislation," Lundy said.

That's already happening outside the federal sphere, with states such as California and Maryland having **developed their own** "price-gouging" laws. They were quickly **challenged in court**, and any federal regulations might be subject to the same type of litigation, Lundy said.

Congress can also focus on how much federal health care programs, such as Medicare and Medicaid, will pay. Lundy is confident there will be congressional investigations and hearings on this issue, but he isn't so sure that this "turbulent" Congress will be able to work out such a complex piece of legislation, especially with midterm elections approaching.

There's also the subplot starring the executive branch, led by President Donald Trump, who has repeatedly promised to lower drug prices. The president may push on his own for the U.S. Food and Drug Administration and Centers for Medicare & Medicaid Services to act on pricing, Lundy said.

Others, including Mayer Brown LLP's Mark Mansour, also believe Trump could factor into any action on drug prices. But Mansour doesn't yet see a concrete plan in place to change the status quo.

"That's something that Trump has been all over, and I think that FDA feels like it has a mandate to try to find some way to work with industry on drug pricing," Mansour said.

The agency's Trump-appointed commissioner, Dr. Scott Gottlieb, **has promised to work toward lower drug prices** by making the FDA's own review process more efficient — which would result in more generic options — and by taking action against anti-competitive activity in the drug market. In doing so, Gottlieb is showing he seems to understand the public health and economic benefits of getting more safe and effective treatments to the public, said James Boiani of Epstein Becker & Green PC.

"There are lots of ways you can prove whether something's safe and effective, and sometimes manufacturers are having to take the long road instead of the shorter road," Boiani said. "That's been a concern that I think he's been trying to address internally."

What Will Be Done to Combat the Opioid Epidemic?

Like drug pricing, any federal action on curtailing opioid abuse could be stymied by politics and the midterm elections, experts say.

So far, the federal solutions that have been discussed are unlikely to work out, according to Ed Dougherty, a principal in Dentons' health care practice. Dougherty instead predicts that much of the fight against opioid addiction will take place at the state level because the states recognize the problem and some state attorneys general are actively seeking solutions.

While the FDA has arguably been trying to take a strong stance on opioids for years, the agency's attempts have either been too burdensome for the industry or not gained any traction, he said.

"In many ways, at a very high level, everyone agrees this is a huge problem," Dougherty said. "So how do we fix the problem? And that's where I think the politics for the midterm election very quickly take over."

At the federal level, there are powerful competing interests that will make the issue impossible to meaningfully address in a divided Congress, he said, as some will blame the pharmaceuticals industry, some will seek more regulations requiring drugmakers to report sales and distribution, and others will look to increase funding for social service programs that are often viewed as ineffective.

Will There Finally Be Clarification on Off-Label Promotions?

Experts were watching for possible FDA regulation regarding the promotion of off-label uses for FDA-approved products **this time last year**, and they are still waiting. Lundy described "violent disagreement" about what appropriate policies might look like, both within the FDA and between the agency and Congress.

On the one hand, there are interpretations like those **espoused by several courts**, which would allow drugmakers to disclose truthful, nonmisleading information about their products regardless of their FDA-approved use. On the other hand, there are those who seek stricter regulations that would require companies to stick to only talking about what's on an FDA-approved label, Lundy said.

Adding to the confusion are numerous other opinions between the two extremes, the sum of which is a drug industry that's unsure about best practices and how to balance its desire to provide more information to customers with the need to appease regulators. This uncertainty leaves companies vulnerable to investigations, prosecutions and allegations for

following rules that aren't clear, Lundy said.

Mansour described the FDA as being in "a holding pattern" as it tries to find middle ground between what the courts might do and what the industry wants.

"I think they run the risk that if the courts decide, the off-label regime will be gutted," Mansour said. "I think they'd rather come up with some sort of regulation or regulatory paradigm that actually gives industry part of what it wants without having to have the courts take off-label away from them completely."

Some, like Dougherty, see off-label promotion as a smaller issue. He said that the more the FDA thinks about it, the more the agency will become concerned with how to regulate the safe use of drugs when they're being used or promoted for things that aren't specifically approved by the agency.

"My view is that the agency will continue to take a very conservative view on that because the risks to the public health and public safety of having products used for indications that FDA has not explicitly approved or cleared presents tremendous risk and liability," Dougherty said.

How Will 21st Century Cures Be Implemented?

Although some aspects of the Obama administration's 21st Century Cures Act — including a requirement that the government evaluate the possible use of real-world evidence in approving drugs — have begun to be implemented, there's still more to be done, experts say.

One area of interest for Boiani is the Clinical Laboratory Improvement Amendments program, which regulates medical tests developed by laboratories. The act calls for improvements in the process for tests seeking CLIA waivers, which aid in getting lab-developed tests into doctors' offices.

The FDA published draft guidance on the subject at the end of November, but Boiani said more discussion could be coming. The agency is supposed to finalize the guidance by the end of November 2018.

CLIA waivers may not be on everyone's radar, but they're shaping up to be an active subject area that could pick up speed, Boiani said.

For years, the FDA held that the accuracy of a test shouldn't be affected when it changes hands from experts to untrained providers; if a lab worker can use the test with 80 percent accuracy, a doctor should be able to do the same, Boiani said. In that environment, a number of tests, including the first HIV test, quickly received CLIA waivers.

Then, in the early 2000s, the FDA changed its mind, saying that instead of focusing on trained and untrained practitioners receiving the same results, nonexperts must be even more accurate. That causes problems when a test that's FDA-approved to be 85 percent accurate in the hands of experts is denied a CLIA waiver because the agency says it has to be 95 percent accurate when used by nonexperts, Boiani said.

The FDA's recent draft guidance appears to have reiterated that position, he explained.

"The legislative history is extremely clear on this point," Boiani said. "Congress wasn't telling them that these CLIA-waived tests need to be more accurate in the hands of physicians than they do in lab techs', they're just saying it needs to be equally accurate."

--Editing by Jeremy Barker and Edrienne Su.