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Life Sciences Legislation And Regulation To Watch In 2015

By **Daniel Wilson**

Law360, Washington (January 02, 2015, 2:55 PM ET) -- While some legislative changes may shake up the life sciences sector in 2015, attorneys predict regulations by a U.S. Food and Drug Administration intent on expanding its authority into areas like drug compounding and laboratory developed tests are likely to have a bigger impact.

A difficult legislative environment may make it hard for much life sciences legislation to get traction in the new Congress, but a broad federal regulatory agenda, with the FDA flexing its legal muscle by stepping into areas where it has previously been reluctant to tread will still provide plenty for industry and attorneys to chew on.

Here are some of the areas of life sciences regulation and legislation attorneys say they'll be paying attention to in 2015:

Possible ACA Medical Device Tax Repeal

With November's midterm elections flipping the Senate to a GOP majority, incoming Senate Majority Leader Mitch McConnell, R-Ky., has flagged a repeal of the 2.3 percent excise on sales of taxable medical devices, imposed as part of the Affordable Care Act, as one of his immediate priorities.

The tax, levied on the manufacturer or importer of medical devices, covers about half of all medical devices made or sold in the U.S., with exceptions for exports or standard retail goods such as contact lenses and hearing aids. It has drawn the ire not only of Republicans but also a sizeable number of Democratic lawmakers, including in a symbolic 79-20 Senate vote in support of ditching the tax in March 2013.

Crowell & Moring LLP partner John Fuson noted that finding any agreement between Republican lawmakers and the Democratic administration on an issue related to the ACA may be "difficult to imagine," no matter how tangential to the core of the law.

But although politically "tricky," a repeal of the medical device tax may be one of the few issues involving the ACA to get bipartisan traction in the new Congress, Moore & Van Allen PLLC partner Carol Bowen argued, saying she expected to see some movement on the unpopular tax in the new Congress.

"It seems to be a matter of agreement across party lines," she said.

Arnold & Porter LLP partner Daniel Kracov noted that filling the economic hole left by the repeal of the tax — worth about $30 billion to the federal government over a decade — may be the toughest selling point for rolling back the tax.

Nevertheless, a repeal is certainly possible, Kracov said, given the level of political support the medical device industry had attracted regarding the issue. Among other arguments, device makers claim that they have been stuck disproportionately with part of the bill for the ACA, despite failing to benefit from the law to the same extent as drugmakers or hospitals, and that the cost of the tax will ultimately be passed onto consumers.

“The medical device industry has done a very good job in making the case as to why it’s counterproductive,” he said.

Although he has not come out directly in support of scrapping the tax, President Barack Obama has **recently signaled** that he may be open to discussing the issue as part of broader talks with Republican lawmakers in the new Congress.

The 21st Century Cures Legislation

After a series of white papers, hearings and other public discussion over the course of 2014, following a call to action in May, the House Energy and Commerce Committee is expected to introduce a discussion draft regarding its proposed 21st Century Cures legislation, possibly as soon as January, Kracov said.

The effort is aimed at accelerating the path to market for new treatments, especially in emerging areas such as personalized and digital medicine, and if the committee’s previous papers and public hearings on the issue are any guide, the draft bill or bills may suggest overhauls to many aspects of the drug and device development and approval processes, Kracov noted.

This could include changes to basic research, the streamlining of clinical trials and expediting of biomarker development for those trials, introducing more real world evidence and patient perspectives into the process, and potentially offering new avenues for drug exclusivity.

This pending overhaul effort is one of a number of recent moves by lawmakers designed to broaden patient access to drugs outside of the traditional approval process, Kracov noted, pointing also to the recently introduced H.R. 5805, the Andrea Sloan Compassionate Use Reform and Enhancement Act, which seeks to broaden access to experimental drugs outside of clinical trials.

“I think members of Congress are hearing a lot about about [the issue],” Kracov said. “There’s a perception on the Hill that something needs to be done to try and make compassionate use processes … more accessible to patients, while preserving [the clinical trial process].”

The FDA Takes On LDTs ...

One of the areas the 21st Century Cures legislation is expected to tackle is the regulation of so-called laboratory developed tests, an area the FDA has recently waded into with the release of two guidance documents in October, with public comment closing just inside the new year.

In the guidance documents, the FDA indicated its intention to regulate LDTs, also known as “in-house”

tests, which had traditionally been designed and used in one laboratory. That could subject thousands of tests, particularly those deemed to be high risk, to new oversight such as premarket review and adverse event reporting.

The agency already polices so-called in vitro companion diagnostics, which are similar tests made by medical device firms and sold to labs, but has traditionally taken a hands-off approach to LDTs, leaving them under the purview of the Centers for Medicare and Medicaid Services.

But this is no longer sufficient in the new LDT landscape, the regulator has claimed, while arguing that it has the legal authority to oversee LDTs and has merely chosen previously not to regulate them as a matter of discretion.

Instead of being used by laboratories to meet the needs of local patient populations, with results interpreted by doctors and other professionals in the facility, many are now sophisticated tests used outside of a health care provider context to detect a wide variety of ailments, with results interpreted not by medical professionals but by technological devices, leaving out important context that may affect significant health care decisions by patients, as well as posing privacy issues, the FDA claims.

These guidance documents are aimed particularly at LDTs used in personalized medicine, such as Myriad Genetics Inc.'s assessments of cancer risk and aggressiveness, or 23andMe's personal genetic tests, and the move has drawn significant pushback from industry, which has questioned the FDA's jurisdiction and argued that further regulation could stifle innovation and limit or cut off patient access to useful treatments.

The extent of industry resistance will likely come down to the final scope of the FDA's oversight and whether or not the agency appears to attempt to regulate the practice of medicine — which is largely out of its jurisdiction — as well as how assertive enforcement will be, according to Fuson.

"This is a segment of the health care industry that has resisted oversight from the FDA," he said. "I'm sure that the agency is going to get a lot of feedback."

... And Compounding Pharmacies

LDTs aren't the only area traditionally ignored by the FDA where the regulator has taken an interest, having recently issued guidance on drug compounding, which is expected to result in further rulemaking in the new year, attorneys claimed.

Oversight of drug compounding has traditionally been left almost exclusively to the states, but after a series of scandals involving deaths and serious injuries to patients from contaminated compounded drugs, and the subsequent passage of the Drug Quality and Security Act in 2013, the agency has stepped up its oversight role.

Among other attempts to exercise its oversight, the FDA has recently indicated that it would treat compounders required to register with the agency in the same manner as other drugmakers when it comes to its authority under the FDA Safety and Innovation Act, such as blocking the sales of drugs if a company resists requests to interview employees or scour internal records during inspections.

This could create flashpoints between the regulator and compounders, who have often resisted any effort to bring them under federal oversight, Fuson noted.

“The industry has not always accepted FDA oversight, and will likely continue to resist it,” he said. “At the same time, the agency certainly wants to assert its control over this space.”

FDA's Control Over Manufacturers’ Speech

The broad issue of FDA controls on what drug and device companies can say — and how they can say it — also looks likely to be something the agency will have to consider in 2015, according to Kracov.

Among other recent efforts in the area, the agency released long-awaited guidance documents regarding prescription drug promotion via social media and search engine advertisements that are continuing to generate discussion.

And the evergreen issue of off-label promotion is also likely rear its head again, following guidance issued in early 2014 regarding drugmakers distributing scientific data related to off-label usage, possibly as one of the areas touched on under the 21st Century Cures legislation, Kracov claimed.

“The FDA may or may not be too happy [with potential legislation in the area], but I think it’s something they’re going to have to address,” Kracov said. “It’s going to be very important legislation.”

What Else Does the FDA Have in Store?

The regulator may also weigh in on a number of other areas as it seeks to further assert its authority and fill gaps where lawmakers are unwilling, or unable, to pass legislation, attorneys claimed.

“The [Obama] administration is in its home stretch and is looking to fulfill its own policy goals,” Fuson said.

Among a range of pending regulations, it is set to finalize in late 2015 a contentious rule, first proposed in 2012, that would give generic-drug manufacturers the authority to unilaterally change their drug warning labels.

The industry has pushed back against the rule, which would, among other consequences, open generic-drug companies to failure to warn claims and undercut an earlier U.S. Supreme Court decision that had freed them from design defect liability.

“This is a hugely controversial issue,” Kracov noted.

Further, the FDA is likely to continue to poke around the over-the-counter drug review and approval processes and similar regulatory areas, which will also likely draw a lot of attention from industry and attorneys alike, according to Fuson.

--Editing by John Quinn and Chris Yates.
