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# PODCAST TRANSCRIPT

Health Care ▪ Life Sciences

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I'm Tom Bulleit, a partner in the Washington, D.C. office of Ropes & Gray, and a member of the firm's Healthcare practice group. Joining me today is my Washington-based Life Sciences group partner, Al Cacozza, to discuss the regulatory outlook for 2017 for healthcare and life sciences companies, especially with regard to actions by the Food & Drug Administration.

This is part of the Capital Insights podcast series we're hosting to examine the issues of potential regulatory changes emanating from Washington, D.C. as we transition to a new federal administration.

Al, one issue that has been highly contentious over the last year is prescription drug pricing. How do you see the debate on drug pricing shaping up in 2017?

***Al:*** As you know, this is a perennial issue that generates a lot of heated rhetoric, but very little in the way of concrete action. There's always talk of authorizing CMS to negotiate prices with the drug industry, or allowing for re-importation of lower-priced versions of U.S. drugs, particularly from Canada, or triggering so-called "march-in rights" that would authorize the government to issue mandatory licenses for any high-priced drug where research was funded through NIH funds. The conventional wisdom is that there is no real appetite for any of these measures with Congress, particularly a Republican-controlled Congress.

The one wild card in that equation, and it is a big wild card, is President-elect Trump. On the campaign trail, he railed against high drug prices, and vowed to use his negotiation skills to drive them down. Since the election, he has publicly chastised several large companies, so far in the defense sector, over high costs for certain government contracts. So it is possible he may use the bully pulpit to criticize certain high drug prices, and he will have support from a bipartisan group of legislators, including Iowa Republican Senator Charles Grassley, who already was on record on this issue in light of the Turing and Epipen pricing episodes.

My guess is that industry will seek to temper its high profile pricing increases in an attempt to respond to these public concerns. We have already seen several drug companies announce voluntary price restraints. In the end, I think the conventional wisdom will hold, and I would be very surprised to see any formal systemic effort to control drug prices.

But market forces may change things. There is a link between value-based healthcare and drug prices. As value-based principles become more common in this system, there is increasing demand for drug companies to justify pricing based on outcomes. If a drug company sets a premium price for a new drug, payers likely would want to be convinced the drug adds value as a therapeutic breakthrough, a safety enhancement, or even a disease cure. The bottom line is the debate over drug prices should continue to be very active in 2017.

***Tom:*** What other major developments or trends should drug and medical device companies pay attention to in 2017?

***Al:*** I think there are three major developments in 2017: changes at the FDA in light of the new Administration, implementation of the recently enacted 21st Century Cures law, and re-authorization of the user fee program, all of which are interrelated.

As you know, on December 13, 2016, President Obama signed the 21st Century Cures Act into law, and we did a podcast as part of this Capital Insight series to discuss the highlights. Perhaps the most impactful change is the law gives the FDA much needed flexible hiring authority to bring in more staff to address a resource deficit that has taxed the agency's ability to process increasingly sophisticated and complex medical technology issues. The law reinforces two trends – patient-focused drug development, and the expansion of the types of evidence the FDA should consider in assessing market approvals. The FDA will be looking to incorporate patient views in the design of clinical trials, and should be more open to patient-reported outcomes data in a drug marketing application. While the overall evidence standard remains unchanged, the law does call for the FDA to consider real world evidence in an application for a new use for an approved product. We will have to see how that affects approvals going forward.

The new Administration has not said much about the FDA either during the campaign or since the election. The general philosophy of the new Administration has been to reduce regulation. So, while there may be some pressure on the FDA in this regard, it is unclear what that will mean in practice. It could be simply an extension of the provisions of the Cures Law to open up the types of evidence that the FDA will consider in making its risk benefit assessment based on the traditional substantial evidence standard. It could be a resolution of the long standing debate about the limits on manufacturer speech shifting toward a First Amendment-friendly approach, that allows for dissemination of truthful, non-misleading information even about off-label uses. At its most radical, it could be an effort to scale back the efficacy requirement that was adopted by law in 1962. Some of this may depend on who is the next FDA commissioner, and right now that is anyone's guess.

All of this may come to a head in 2017 because there is a must-pass legislative vehicle in the coming year. The user fee law, originally enacted in 1992, must be re-authorized every five years, and 2017 just so happens to be a re-authorization year. Because user fees are now part of the fabric of the FDA budget, the re-authorization has been considered a mandatory enactment. As such, it serves as a so-called "Christmas tree" bill to hang all manner of FDA measures. So, by the time the user fee bill is up for final consideration, likely in the third quarter of the year, we will see what issues have percolated to the top of the agenda.

***Tom:*** Thanks Al. That's all the time we have for now. Thank you for listening. Please visit our newly launched Capital Insights page at www.ropesgray.com for additional news and analysis about noteworthy regulatory and enforcement issues.