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3 Must-Watch Issues For Drug Cos. In 2013's Final Stretch

By **Jeff Overley**

Law360, New York (September 06, 2013, 5:06 PM ET) -- The rest of 2013 could reshape the pharmaceutical industry as regulators potentially issue guidance on biosimilars and Congress weighs bills related to drug tracking and compounding pharmacies.

On the legislative side, rare bipartisan cooperation is driving pushes for a track-and-trace system and stronger oversight of compounders, and passage of reform measures seems probable. The likelihood of new regulation emerging from the U.S. Food and Drug Administration is harder to gauge, as regulators have been tight-lipped about their timetable for issuing long-awaited guidance on copycat biologics.

Here are three issues for drugmakers to watch closely in the coming months.

Track-and-Trace Finally in the Cards

Industry-backed legislation intended to greatly boost supply-chain management, after just missing out on being included in last year's user-fee law, appears likely to pass this year with broad support in both parties.

The U.S. House of Representatives pushed through H.R. 1919 in June, and the Senate version, S. 959, has made it through committee. Both bills aim to prevent counterfeit products from entering the market and enable easier recalls, and they would impose new mandates on drug manufacturers, distributors and pharmacies.

One sticking point has been whether and how soon to mandate that companies be capable of so-called unit-level tracking that would allow them to keep tabs on every bottle of pills.

Stephen Paul Mahinka, head of the life sciences practice at Morgan Lewis & Bockius LLP, said that while important wrinkles must still be ironed out, the lack of a "great philosophical divide" on the issue makes it seem likely that lawmakers will eventually find common ground.

"That is the issue here: Can they get over some of these relatively minor policy objections?" he said.

A major reason for optimism is the desire by drug firms to nullify a tough California law set to take effect in 2015. Corporations have warned that the Golden State's law is too stringent and that it would set the stage for a patchwork of different laws across the country.

"There's a risk that, at some point, the California law is going to be implemented, and if they aren't able to preempt it through federal legislation, all these entities are going to incur costs," said Charles M. Clapton, a partner at Hogan Lovells.

Tough Rules for Compounding Pharmacies

The Senate has been taking the lead on legislation that would provide the FDA with clear authority to regulate compounding pharmacies, which over the past year have been subjected to historic scrutiny after a deadly outbreak linked to the now-defunct New England Compounding Center.

While many House Republicans have have argued that the FDA simply needs to make better use of existing powers, experts have generally predicted that some sort of bill will eventually reach the president's desk because nonsterile compounded drugs have been blamed for dozens of deaths and hundreds of serious illnesses.

Mahinka said lawmakers would have to work out some remaining areas of disagreement, such as how large a compounder must be before it’s forced to comply with federal quality standards. Also, the definition of what turns a traditional compounder into a manufacturer has cropped up as a point of contention.

But as with track-and-trace — which is combined with the compounding bill in the Senate — there doesn't appear to be any deeply controversial issue dividing Democrats and Republicans, he said.

"Again, I haven't heard any of any real philosophical policy objections to the idea," Mahinka said.

Long-Awaited Biosimilars Guidance

Although the FDA early last year issued three draft guidance documents related to biosimilars — generic versions of biologics — drugmakers complained that key questions were left unanswered.

Specifically, the FDA acknowledged receiving requests to explain how the drugs will be named and labeled, which could be complicated because biosimilars won't be exact copies of their brand-name counterparts. Also unclear is how developers can have their biosimilars be deemed interchangeable with original biologics, clearing them for substitution in the same manner as traditional generics.

"FDA has been very, very slow," Mahinka said, adding that the caution makes sense because of the "extremely contentious" debate surrounding biosimilars' safety and effectiveness.

Clapton added that the unexpected concerns about drug compounding, which have triggered a wave of FDA inspections across the nation, also have probably contributed to delays by sapping some of the agency’s resources.

Through a spokeswoman, FDA regulators declined to discuss their progress on drafting additional guidance.

Mahinka suggested that while guidance could come out soon, it's also possible that the FDA will stay silent for some time to come, and that drugmakers will have to simply forge ahead and draw conclusions from how the approval process plays out.

As of early August, the FDA had received 56 meeting requests regarding 12 different biosimilars, and it reported receiving 17 so-called investigational new drug applications that allow clinical trials of unapproved drugs.

"The fact is, biosimilars are being developed," Mahinka said. "You don't have to have final regulations to have biosimilars developed or even approved."

--Editing by Elizabeth Bowen and Katherine Rautenberg.