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Pharma Cos. Smell Victory In Push For Drug-Tracking System

By **Rachel Slajda**

Law360, New York (May 02, 2013, 9:08 PM ET) -- With gathering momentum in Congress this year, experts say the pharmaceutical industry — including drugmakers, wholesalers and pharmacies — could win its push for a nationwide system to trace drugs through the supply chain, protecting brands from counterfeiters and preempting a stricter California law set to take effect in 2015.

The industry has been lobbying for a nationwide drug-tracing system, in which each step of the supply chain logs where drug shipments came from and where they are going. Companies say such a system would make it easier to track down recalled drugs and prevent adulterated or counterfeit drugs from making their way into the legitimate supply chain.

It could also protect a company from the risk of losing major business if a counterfeit or adulterated version of one of its products causes injuries.

“Brand protection is key,” said Joseph Slota, a director of the life sciences strategy and operations practice at Deloitte LLP. “You could have a going concern that's been successful for 50 years, but it only takes one breakdown” to tarnish the brand, he said.

Regulators tend to support a tracing system, saying it is critical to protect public safety, but legislation creating such a system has faced obstacles. Tracing legislation failed to make it through Congress last year, when it was dropped from the U.S. Food and Drug Administration user fee bill after negotiations fell apart.

This year could be different. Experts say the user fee bill was moving too quickly to give lawmakers time to sort out the major issues, but this year, many of the details have been worked out and there is consensus among the leading lawmakers of both parties as well as the industry on the ultimate goals of the bill.

“There aren't a lot of things where there are bipartisan support. This is an issue that doesn't necessarily seem to slant along political lines,” said Nathan Beaver, a partner at Foley & Lardner LLP. “This has a pretty good chance of getting some movement. ... In a Congress that doesn't get much done because of political differences, there's sometimes an incentive to say, let's do the things we can do. This is one of those areas.”

Both houses of Congress released draft bills in April. The Senate Health, Education, Labor and Pensions Committee and the House Energy and Commerce Committee each plan to hold votes on the bills in May, according to industry lobbyists. Committee leaders have said they want to send a final bill to the president before August recess.

The bills are still under revision and have some differences from one another. But the industry group lobbying for the system, the Pharmaceutical Distribution Security Alliance, says the differences are "bridgeable." And they are so far both acceptable enough that the PDSA plans not to get involved in eventual conference negotiations to bring the bills in line.

Last year, the legislation got hung up on some major issues, such as whether companies would have to track drugs down to the lot level or all the way down to the unit level – that is, individual bottles or vials. The FDA and public health groups say the system is useless without unit-level tracking, while industry says the technology just doesn't exist yet for that level of surveillance.

This year, the PDSA has accepted that unit-level tracking is the ultimate goal. In the Senate version of the bill, lot-level tracking would be phased in over the next several years, and unit-level tracking would have to be in place in a decade.

The House version is less prescriptive, requiring the FDA to administer pilot projects testing unit-level tracking and reporting to Congress on the projects in 10 years.

"We have a high degree of confidence that our approach lands somewhere in the middle of the two different approaches," said Vince Ventimiglia of Faegre Baker Daniels, a spokesman for the PDSA.

"I think the proposals are a lot stronger now," said Stephen Mahinka, chair of Morgan Lewis & Bockius LLP's life sciences and health care interdisciplinary group. "With some good will and compromise, this could be a real positive for the life sciences industry for the year."

The industry also has a keen interest in preempting state laws. Complying with multiple variants of tracking laws would be extremely difficult, if not impossible, experts say. One of the few state laws currently on the books, in California, is much more stringent than the congressional proposals, requiring an electronic, interoperable system that will track drugs at the unit-level from manufacturer to pharmacy.

The industry hopes to preempt that law before the bulk of it goes into effect in 2015.

"It's not helpful to end up with multiple distribution systems," Mahinka said. "That would prove to be at a minimum unwieldy and at a maximum impossible. … [The preemption provisions] can't be watered down."

Both the House and Senate versions would preempt state laws on tracing, including e-pedigree laws like California's. The Senate version, however, would allow stricter state laws when it comes to licensing wholesalers and third-party logistics providers.

But at the end of the day, a system that could help prevent counterfeit drugs from entering the legitimate market is in the business interests of the industry, Slota said.

"If I know as a CEO that I can seal that material leak of counterfeiting or diversion and the risks that come with that ... then I'm going to want to have my teams working on that," he said. "I think it's a win-win for a lot of folks."

--Editing by Elizabeth Bowen and Chris Yates