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Stakeholders Gear Up For Biosimilar Substitution Battle In 2013

FDA's first biosimilar approval is not expected this year, but debate is anticipated at the federal and state level over substitution policies, including naming, interchangeability and automatic substitution standards, according to industry sources following the new pathway. Sources also said 2013 will be a critical year for smoothing out kinks in the biosimilar review process to determine whether the health reform-created pathway will prove lucrative to drug makers and provide health care savings.

Nearly a year ago, FDA released a trio of biosimilar guidance documents, giving highly anticipated direction to industry. Later in the year, Congress cleared a new user fee program to fund meetings with sponsors and product reviews. The agency and industry are transitioning into the new program, albeit with some kinks as the agency has canceled meetings with sponsors for lack of analytical data, an agency official recently said.

Still, industry sources said there are uncertainties about the program that will have to be sorted out before companies start using the pathway

"There's a lot that's still unknown about what kind of journey one might have if they go down 351(k)," an industry source said. This year the agency will likely continue to roll out the new process to make it "useable," the source said.

While naming and interchangeability are big-ticket items, interchangeability is likely to be addressed by the agency later in the process, the source said. The agency said interchangeability determinations will be made separate from and subsequent to biosimilarity, therefore it could occur later in the review process. However, the agency could address naming, hopefully through guidance, earlier, the industry source said.

"I think substitution — big picture — is a theme for 2013," the source said, including naming and interchangeability. A handful of bills on substitution have been introduced at the state level and the legislative activity will likely increase, the source said.

Pharmacy groups are also monitoring activity at the state level. "For us the issue is how hard they make it for us to interchange a drug," said John Coster, senior vice president of government affairs at the National Community Pharmacists Association. Limiting pharmacists' ability to substitute drugs also hinders their ability to help patients control costs, he said.

Still, groups like the Alliance for Safe Biologic Medicines, which has a broad membership of patient groups and innovator biologic companies, are pressing for a unique naming scheme, saying it is pertinent for ensuring safety and tracking adverse events.

"[I]t is important to understand that biosimilar and interchangeable biological products will be only similar to, but not the same as, an original reference product. From a patient and provider perspective, it would be inappropriate, unsafe, and misleading to allow biosimilar products to use the same name for biological products that are not exactly the same," Richard Dolinar, the group's chairman wrote in a recent Food and Drug Law Institute Policy Forum. Tracking products by National Drug Codes, as some pharmacy groups have suggested, has limitations because the numbers are not uniformly used in medical billing, and doctors and patients associate products by name, not a number, the group says.

An FDA official recently said the agency is addressing interchangeability and naming, per direction from stakeholders at public meetings on the biosimilar pathway.

"We heard loud and clear that naming and interchangeability were the things people wanted us to work on next," Leah Christl, associate director for biosimilars in FDA's Office of New Drugs, said at an event last month.

Christl said FDA is also in the process of finalizing the three guidances and releasing another draft guide on clinical pharmacology. Another industry source said this document could provide more details on reference products, such as how to bridge foreign data. "All the way through they've said, 'We don't want to require unnecessary clinical trials'," the source said.

The agency and industry are transitioning to the biosimilar user fee program, which has yet to be appropriated. Christl said the agency has turned away a handful of biosimilar sponsors seeking meetings because the sponsors had little or no analytical data, making it difficult for the agency to provide direction, such as whether clinical trials would be necessary.

The agency must weigh its limited resources, she said, noting that the agency provided written comments in the instances where sponsors were turned away. However, she clarified that the biosimilar development meetings are different than pre-investigational new drug meetings under prescription drug user fees, a misunderstanding that is part of the

transition into the biosimilar user fee program.

As of last month, the agency received 50 requests for initial meetings and held 34 meetings, with several others scheduled, Christl said. The agency has received 12 INDS for 12 reference products, she said.

The industry source noted that it is unlikely FDA will approve a biosimilar in 2013, given the fact that the agency had not received an application as of late 2012 and there is a ten month review timeline under the biosimilar user fee program. Further, sponsors are likely to have major amendments, adding to the review timeline, the source said.

The next couple of years will tell whether companies use the biosimilar pathway, but a citizen petition more immediately comes into play and offers cues into potential legal challenges, said George Yu, counsel at Schiff Hardin. Abbott last year petitioned FDA to refuse biosimilar applications, meetings with companies developing them and approvals for products that reference a biologic license application submitted to FDA before the Affordable Care Act was signed into law, citing Fifth Amendment protections for company trade secrets.

It will be interesting to see FDA's final position or whether the petition starts litigation around the pathway, Yu said. "If rejected, Abbott will certainly seek to challenge in district court," he said. FDA provided an interim response in October, saying it was still analyzing the complex issues raised by the petition.

However, the issue was already discussed when legislators debated the pathway and FDA has been holding meetings with potential sponsors, industry sources said. "To me (the petition is) constructively denied because it was so all encompassing," an industry source said, noting that the agency continues to hold meetings. — *Alaina Busch*