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Generic Biologics? After FDA Approves First Biosimilar Drug, Education, Clearer Policies Needed, Experts Say

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Last year, when Mariah Leach was pregnant with her son, her rheumatoid arthritis flared up again. She had stopped medication during pregnancy, but when the autoimmune disease, which causes painful and damaging inflammation in joints and elsewhere, resurged, she and her doctors made the difficult decision for her to restart during her third trimester, based on a very limited set of data that suggested a medication she had used previously could be taken safely during pregnancy.

Her son, now 7 months old, is “healthy and developing normally,” Leach, a 32-year-old patient advocate for the Global Healthy Living Foundation, said. But for others in the future, certain medical developments -- like the advent of a new class of complex medications known as biosimilar drugs -- could jeopardize the kind of careful, informed decision that she and her doctors had made.

Biosimilars are close copies of medicines known as biologics, complex medical products that are derived from organic matter. Last week, the U.S. Food and Drug Administration announced its approval of the very first biosimilar for use in the United States. The news was met with great fanfare as many predicted that biosimilars would improve access to drugs for patients and save tens of billions of dollars in health care spending.

But without downplaying these new drugs’ potential, experts have also advocated caution, arguing that the drugs will need to be integrated carefully into patient treatment plans and voicing concerns that state and federal policies are not necessarily robust enough to do so.

“Prescribers and consumers must be educated on the safety and efficacy of biosimilars,” Mary Jo Carden, senior director of regulatory affairs at the Academy of Managed Care Pharmacy, wrote in an email. Carden was citing a recent survey of pharmacists, conducted by the academy, that found that before biosimilars become commercially available, pharmacists would need "substantial education" on the drugs and how to dispense them, according to a news release.

As patents on biologics begin to run out, pharmaceutical companies are experimenting with new ways to copy those drugs as closely as possible, creating what are known as biosimilars. But because biologics are large, complex molecules, biosimilars aren’t perfect copies. Rather, to gain approval in the U.S., biosimilars must use the same mechanism as the original drug, and be just as safe and effective.

Although just one biosimilar has been approved in the United States so far, experts fear that as more are cleared for patient use, new biosimilar drugs could be substituted for their biologic originals without patients' or doctors’ clearance; or, conversely, that pharmacists won’t make those substitutions even when they are allowed to.

“They’re very volatile substances, and they have the potential to hurt people,” Steve Marmaras, manager of state and national advocacy for the Global Healthy Living Foundation, said. He echoed Carden's call for more education regarding biosimilars, noting that the frequent description of biosimilars as generic versions of biologics was inaccurate, yet many policy discussions at both the state and federal levels operate on the false belief that biosimilars are to biologics what ibuprofen is to Advil.

“There needs to be a new framework applied to state governments across the country to appropriately substitute” biosimilars for the original biologic, Marmaras said. “If a patient experiences a serious adverse event to a biosimilar, we want their physician, their pharmacist to very quickly be able to pinpoint what product that patient had taken." Tracing that medical product to its source would be crucial as well for preventing problems from occurring with other patients.

Not all experts’ concerns about biosimilars dovetail, however. Whether biosimilars and biologics should share the same scientific name is a source of contentious debate. Some researchers have pointed out that by sharing a name, the fact that biologics and biosimilars are not the same can go overlooked. Marmaras said that biosimilars and biologics should not be allowed to share the same nonproprietary name, while the Academy of Managed Care Pharmacy

has come out in support of the opposite. Not sharing names, Carden said, "could create confusion among consumers and prescribers" about how similar the products really are, potentially hurting the practice of substituting cheaper biosimilars for the original biologic.

The FDA has yet to issue official guidelines on naming biosimilars. If it did, it could perhaps help quell the debate. But such guidelines are not required in order for applications for biosimilars to be approved or rejected, Sandy Walsh, an FDA spokeswoman, wrote in an email. When asked when the FDA would issue draft guidance regarding its naming policy, she said: “We expect to issue draft guidance in 2015 and are working expeditiously to issue them.”

Marmaras said his foundation also wanted states to pass clear laws as to how and when a drug could be substituted and who would have to be notified, he explained. “We want patients to have access to them [biosimilars]. We just want them to be done in a transparent and a safe way, and in a logical and efficient way,” he said.

For now, a pharmacist cannot substitute a biosimilar for the original drug without consulting the doctor who prescribed it, unless the biosimilar has been designated as interchangeable, which none have been in the U.S. thus far. Still, more applications for biosimilar approval are in the FDA pipeline, like Basaglar, which earned tentative approval in August 2014, or a biosimilar of the drug Remicade, which was scheduled for review March 17 by the FDA’s Arthritis Advisory Committee, although that date has been postponed. The latter was proposed to treat several chronic diseases, among them Crohn’s disease and rheumatoid arthritis.

For Leach, the prospect of biosimilars is attractive for many reasons, even though she also voiced concerns about approval standards and requirements that pharmacists notify both patient and doctor if they swap out a biologic for a biosimilar. “I wouldn’t want to be in a situation where the pharmacist switched me to a biosimilar without telling me or my doctor,” she said. “They could potentially have different effects.”

But for someone who is now trying her third biologic in six or seven years (others she tried either weren’t effective or ceased to be), biosimilars are also exciting. They tend to be less expensive than their biologic counterparts -- at times, even with cost-sharing programs, Leach has paid more than $1,000 every month for biologic drugs.

Plus, “there’s a limited number of biologic treatments approved for RA [rheumatoid arthritis],” Leach said. “Biosimilars represent more treatment options,” she said, although a biosimilar has yet to be approved in the U.S. to treat rheumatoid arthritis. Given the finite number of biologic drugs that exist for rheumatoid arthritis, at least until new biologics or biosimilars are approved, “I’m always reluctant to move on to the next [drug],” Leach said. For now, of the remaining drugs available to Leach, she said she can see that “there’s an end in sight.”