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Biosimilar names may affect pharmacist dispensing habits

Joe Raedle/Getty Images

By Ed Silverman @Pharmalot

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What's in a name? An awful lot when it comes to biosimilars.

A newly released survey suggests variations in how biosimilars are named may affect the willingness of pharmacists to substitute a so-called interchangeable biosimilar for a more expensive biologic. While a biosimilar is supposed to be highly similar to a biologic, interchangeability confers a higher threshold — it's a distinct regulatory description for a biosimilar producing the very same clinical result as a biologic.

So far, the US Food and Drug Administration has approved just two biosimilars, although neither is deemed interchangeable with a brand-name biologic. There is ongoing debate, meanwhile, about the extent to which the names given to any and all biosimilars will make it harder to track side effects, or confuse doctors and pharmacists, some of whom may regard these new drugs with skepticism.

Much is at stake because biosimilars are forecast to save billions of dollars in US health care costs. But finding the best approach for naming biosimilars has perplexed regulators and divided the pharmaceutical industry as manufacturers scramble for ensuing profits.

The survey may shed light on what to expect.

A key finding: nearly 63 percent of pharmacists reported they would feel more confident dispensing an interchangeable biosimilar when it shared the same underlying chemical name — as opposed to a commercial name — as the brand-name biologic. The survey was published last week in the Journal of Managed Care & Specialty Pharmacy.

This is potentially significant. Despite the lack of an interchangeable biosimilar in the United States, nearly 20 states have so far passed laws that allow pharmacists to substitute an interchangeable biosimilar for a brand-name biologic without the prescribing physician intervening, according to the National Conference of State Legislatures.

“Pharmacists are a last line of defense — they either recommend a product or discourage its use,” said Daniel Tomaszewski, the study author, who is a pharmacist and an assistant professor at the Chapman University School of Pharmacy. “If pharmacists are less confident or uncomfortable, it could reduce the use or uptake of a product, because they can affect the view the general public has toward a product.”

Indeed, comfort levels are believed to be an issue, and not only with pharmacists. A study released earlier this month found that a group of biosimilar drugs, which are used to treat such afflictions as rheumatoid arthritis, psoriasis, and inflammatory bowel disease, appear as safe and effective as the comparable brand-name biologics. The study authors suggested the findings should put physicians at ease as they consider whether to prescribe these biosimilars.

We should note that the pharmacist survey, which canvassed 781 pharmacists, took place last year. Since then, the FDA has released draft guidelines that suggest both biologics and biosimilars can use the same name. But the agency also proposed that both types of medicines should have a four-letter suffix tacked on to their names, but that these suffixes should be different.

The survey points out that nearly half of the pharmacists preferred the approach that was eventually suggested by the FDA. Whether the agency ultimately adopts its own proposal remains to be seen. In April, the agency approved a biosimilar version of Remicade, which is

used to treat rheumatoid arthritis and other ailments. The biosimilar has its own commercial name, Inflectra, but also a chemical name with a random suffix, infliximab-dyyb.

Brand-name and biosimilar drug makers have staked out different positions on product naming as they jockey for profits. Brand-name drug makers supported unique names to make it easier to track side effects in patient records and in reports that are filed with regulators. Biosimilar makers wanted different names to allay confusion among doctors and pharmacists.

By suggesting the use of different suffixes attached to product names, however, the FDA appears to be mimicking the Solomon-like approach taken by the World Health Organization, which has also proposed adding a random four-letter suffix at the end of each biosimilar. Each country, however, is free to adopt its own system.

Ed Silverman can be reached at ed.silverman@statnews.com
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- **pharmvet1** says:

  August 16, 2016 at 2:25 pm

  There should be absolutely no confusion for the educated pharmacist. All druggists know what the FDA Orange Book is for generic drugs. Likewise they should all keep a copy of the Purple Book on their desks. It is a listing of approved biologics with the brand name and the name of the interchangeable biosimilar. There are two: one for CBER and one for CDER.

  http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm411418.htm

  Reply

- **Observer079** says:

  August 15, 2016 at 9:07 pm

  Based on previous legal battles going back some years, isn't it already held that there is a biosimilar with a unique and different name from Remicade – wasn't it called Humira? Or was JNJ holding it was a patent-infringing bioidentical?

  Reply