DAILY NEWS

Rheumatologists Want FDA Studies On Biosimilar Cost, Access As Part Of BsUFA II

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The American College of Rheumatology (ACR) says as part of the second iteration of the Biosimilar User Fee Act (BsUFA) it would like FDA to analyze the cost and access for patients and providers as biosimilars come on the market, review how the program has been working so far and ask the agency promptly and carefully review how naming and labeling policies are working. Angus Worthing, member of ACR's Government Affairs Committee, said at an FDA public hearing on the BsUFA reauthorization process Friday (Dec. 18) that rheumatologists want to be able to use lower-priced biosimilars for their patients, but want policies that ensure a level of transparency that will make physicians comfortable using the products in lieu of innovator biologics.

Worthing said biologics have been a “miracle treatment” for the field of rheumatology, but noted that biologics are some of the highest cost medications on the market, putting them out of reach for many patients. While ACR sees biosimilars as a promising lower-cost treatment option, he said, the group believes the complex nature of biologics and biosimilars, as opposed to small-molecule generic drugs, requires a higher level of scrutiny and transparency.

“In rheumatologists’ experience, biologics are different from other pharmaceuticals in three ways that are pertinent to our discussion today: they are highly complex, highly efficacious, and very expensive. The ACR supports the reauthorization of the BsUFA because it allows the FDA to continue its vital and important work to evaluate emerging complex biopharmaceuticals to ensure safety and efficacy of biopharmaceuticals whose approval as biosimilars could help reduce treatment costs,” Worthing said during a panel. ACR was the only physicians group to participate in the panel discussions at the public meeting.

He said BsUFA plays a critical role in ensuring FDA is able to do important analyses as biosimilars come to market.

As part of BsUFA II, Worthing said ACR would like FDA to study the cost and access to biosimilars, as the price of biologics have increased “faster than any other component of the health care system.” He said one in six patients with rheumatoid arthritis reduce their medication due to cost. Additionally, because of the high cost, payers often use restrictive formularies, tiering schemes and coinsurance that further restricts access to biologics.

“We physicians are extremely frustrated when we see our patients suffer because they can’t obtain or use the medicines as we have prescribed or as recommended by the FDA. We hope the anticipated decrease in cost resulting from the introduction of safe

and effective biosimilars will increase access to these agents and improve the health of all who use them," Worthing said.

While manufacturers working with payers to make sure their biosimilars make it onto formularies and tiering schemes may be the ultimate driver of market uptake of biosimilars, Worthing told *Inside Health Policy* that this is not a very transparent process and often limits what treatments physicians can use for certain patients.

"It's frustrating when other entities, a third-party payer, try to make the prescribing decisions and essentially practice medicine," Worthing told *IHP*. "It puts an onus physicians to communicate with them via letters and phone calls to peers to try to make sure they know the rational for why we're prescribing a certain agent for a certain patient."

Worthing said at the meeting that ACR wants FDA to do a through review of BsUFA to date in order to generate an appropriate amount of fees to make sure the agency has the resources it needs to run the program effectively.

"[I]t is appropriate that the fees are structured based on FDA analysis of the complexity of review required for innovator biologics and are sufficient for the FDA to perform the critical tasks required to ensure the safety of our patients," Worthing said.

Additionally, Worthing said as part of the next iteration of BsUFA ACR would like FDA to do a prompt and careful review of its naming and labeling policies around biosimilars. FDA proposed a draft naming scheme in August that would apply four-letter nonmeaningful suffixes to the nonproprietary names of biosimilars and their reference biologics. FDA has yet to unveil labeling guidance, but with the first U.S. biosimilar approved in March, Sandoz's filgrastim-sndz, the agency gave the product the same label as its reference product, Amgen's Nuelasta.

Worthing told *IHP* that he and many other physicians were surprised that FDA went with a shared label for the first biosimilar, and was hoping for at the very least statements on the label indicating that Sandoz's product is a biosimilar and whether or not it's interchangeable and the analytics or clinical trial data that was used to approve the product. Sandoz's Zarxio is not interchangeable with its reference product, and FDA has yet to issue guidance on the requirements for interchangeability.

He said interchangeable biosimilars may have the advantage with physicians over biosimilars that aren't interchangeable because the standards for approval will be tougher for interchangeable products. Worthing said physicians need clarity about biosimilars and the basis for their approval so "we be confident and then project that confidence to our patients."

Janet Woodcock , director of FDA's Center for Drug Evaluation and Research, said at the meeting that the agency understands there are still considerable concerns among clinicians about biosimilars. She noted that this was the case with generics as FDA

ramped up that program in the 1980s following the passage of the Hatch-Waxman Act. She noted that generics now constitute 88 percent of prescriptions.
She said that as part of its education program around biosimilars the agency plans targeted outreach to specific physician specialties as biosimilars for use in their field are approved.

“We're going to try and educate the relevant specialties that use the reference molecules amalgamed by the biosimilars in a timely manner as the biosimilar is becoming available so that they can understand,”

The current iteration of BsUFA expires Sept. 30, 2017, and Congress must reauthorize the program by that date. -- *Todd Allen Wilson* (twilson@iwpnews.com)