Wait Time for Biosimilar Regs Drags On

It seems like Godot may arrive sooner. Seven years after the biosimilar law was enacted, stakeholders are losing patience with the FDA.

By Richard Mark Kirkner

Last year, when the FDA approved filgrastim-sndz (Zarxio) as a biosimilar to filgrastim (Neupogen), a biologic that stimulates the production of white blood cells, many in the biopharma industry thought maybe, just maybe, that the regulatory spigot was finally opening for biosimilars.

A drop does not a flow make. Since then the agency has not approved a single biosimilar, not one, although in fairness an FDA panel did recommended approval of a biosimilar form of infliximab (Remicade) in February.

The FDA’s foot-dragging on drafting regulations on biosimilars, as spelled out in the Biologics Price Competition and Innovation Act (BPCIA) of 2009, has frustrated and confounded not only the biopharma industry, but also the public, health plans, and pharmacy benefit managers because potential lower-cost competitors to expensive biological agents are stalled in the regulatory pipeline. Key senators are in that mix, too. Last year a Senate committee grilled Janet Woodcock, director of the FDA’s Center for Drug Evaluation and Research, on why, six years on, the agency hasn’t been able to come up with the regulations for biosimilars.

"Savings are difficult to project given the many uncertainties that still exist regarding market penetration and price; however, we project savings of 0.3% to 0.8% of total health care expenditures by 2019 for a typical commercial employer," says Milliman actuary Katie Holcomb. (Speaking of similarity, it’s just a coincidence that we ended up talking with two people with similar names for this column.)

But savings will only happen if the FDA gets its regulatory act together.

What’s in a name?

The naming of biosimilar agents has kicked up plenty of controversy. The core question is whether they should have the same molecule name as the branded reference product.

The FDA actually did make some headway on naming last year when it issued draft guidance. According to the guidance, a biosimilar should have a distinguishable name that includes the same active drug name as the reference biologic but would have a suffix that would allow doctors, pharmacists, and patients to know what variation of the biologic agent they’re getting.

The rationale is that this would allow the FDA to trace adverse events after the product gets approved.

That’s the position the likes of BIO and the Pharmaceutical Research and Manufacturers of America have staked out and prefer. "We believe that all biological products should have distinguishable names, so that the provider in particular, as well as the dispenser of the product, will understand clearly what’s being provided to the patient," says BIO’s Holcombe.
Unnecessary confusion

“Each side is looking to protect its own interest,” counters Jeffrey Casberg, a registered pharmacist and director of clinical pharmacy for IPD Analytics, a research firm in suburban Miami. A naming convention that does not align with the original chemical name or adds a prefix or suffix that has no meaning would create unnecessary confusion, he says.

Casberg and others favor following the World Health Organization’s International Non proprietary Name (INN) convention for naming medications with no FDA-designated suffix. The biosimilar and the branded product’s generic name would be the same. So, for example, it would be filgrastim and filgrastim, not filgrastim and filgrastim-sndz.

That position—an INN name with no “FDA-designated suffix”—is the one backed by AHIP and, no surprise, the Generic Pharmaceutical Association’s (GPhA) Biosimilars Council. The FDA draft guidance, however, makes no mention of the INN. In the United States, another group, the United States Adopted Names Council, acts as a naming gatekeeper, although it works closely with the WHO program.

Biosimilar companies and others say the FDA doesn’t need a name difference to keep track of biosimilars and any untoward effects that they might have. When the FDA unveiled its naming guidance last year, Bertrand Liang, chair of GPhA’s Biosimilars Council, acts as a naming gatekeeper, although it works closely with the WHO program.

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What additional studies will the FDA require to prove interchangeability? That’s just one of the questions that raises the stakes for companies that want to make biosimilars, says Jeffrey Casberg of IPD Analytics.