On July 28, 2021, the Food and Drug Administration (FDA) announced the approval of the first “interchangeable biosimilar”—in this case Mylan Pharmaceuticals Inc.’s Semglee® (insulin glargine-yfgn), which is both biosimilar to, and interchangeable with, its reference product Lantus® (insulin glargine), a long-acting insulin analog. Acting FDA Commissioner Janet Woodcock, M.D. called it a “momentous day.”

FDA has for years approved biosimilars—and there have been biosimilar launches—for numerous reference products, including Neupogen®, Remicade®, and Avastin®.

The key here is “interchangeable.” Interchangeable biosimilars require information demonstrating that the product “is expected to produce the same clinical result as
the reference product in any given patient.’’

As a practical matter, there is another important result of obtaining an “interchangeable” designation:

An interchangeable biosimilar product may be substituted for the reference product without the intervention of the prescriber. The substitution may occur at the pharmacy, a practice commonly called “pharmacy-level substitution”—much like how generic drugs are substituted for brand name drugs, subject to state pharmacy laws, which vary by state.

According to FDA, “[b]iosimilars marketed in the U.S. typically have launched with initial list prices 15% to 35% lower than comparative list prices of the reference products.”

FDA appears excited, as it simultaneously published new materials for prescribing physicians explaining the concept of interchangeable biosimilars and FDA’s “rigorous research and evaluation” before granting that designation. Given the public relations effort, practitioners should expect FDA to continue to press for interchangeable biosimilar status where possible.

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