Research

Primer on the Biosimilars User Fee Act

FEBRUARY 9, 2012

The Patient Protection and Affordable Care Act (PPACA), signed into law by President Obama on March 23, 2010, amends the Public Health Service Act (PHS Act) to create an abbreviated licensure pathway for biologic products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biologic product. This pathway is provided in the part of the law known as the Biologics Price Competition and Innovation Act (BPCI Act).

Under the BPCI Act, a biologic product may be demonstrated to be "biosimilar" if data show that, among other things, the product is "highly similar" to an already-approved biologic product. Until President Obama signed the PPACA in March of 2010, there was no FDA approval process for biosimilars. In efforts to implement the BPIA, FDA and industry stakeholders have conducted meetings to develop a user fee system for the review of biosimilars and interchangeable products for fiscal years 2013 to 2017, to be named the 351(k) program. As such, this primer will provide an introduction to biosimilars and discuss the implications of the 351(k) program for the healthcare system and industry.

Click here to read the rest of the primer.