On Thursday, August 14, 2014, several physicians wrote a letter to Commissioner Hamburg of the U.S. Food and Drug Administration (FDA) expressing their concerns regarding the naming of biosimilar products in light of the implementation of the Biologics Price Competition and Innovation Act (BPCIA).

Unlike traditional small-molecule prescription drugs, most biologics are complex and are typically made from human or animal materials. The BPCIA provides an abbreviated licensure pathway for biologics that are demonstrated to be “biosimilar” to or “interchangeable” with an FDA-licensed biologic. A biologic may be demonstrated to be “biosimilar” if data show that, among other things, the product is “highly similar” to an already-approved biologic. Unlike “generic” versions of small-molecule prescription drugs, biosimilars are not bioequivalent to their reference biologics. To date, the FDA has not approved any biosimilar products.

The licensure pathway contemplated by the BPCIA is meant to reduce the time and cost of bringing competing biosimilar products to consumers. As the FDA begins evaluating the first U.S. applications for the licensing of biosimilars, concerns have arisen as to how approved biosimilars will be named. In their letter to
Commissioner Hamburg, the physicians argued that biosimilars “must have distinguishable nonproprietary names” from their reference biologics. The physicians wrote that distinct names are needed to avoid confusion: if a biologic and its biosimilars share a common name, physicians may incorrectly assume that the products are approved for all of the same indications, even if the FDA disagrees. The physicians also argued that unique names for biosimilars will help doctors track adverse events by allowing them to correctly identify what product caused the event.

However, not everyone agrees with the physicians’ position. On July 1, 2014, a group of pharmacies, insurers and unions wrote a letter to Commission Hamburg asking the FDA to require that biologics and biosimilars share the same name. This group argued, among other things, that requiring distinct names for biosimilars may slow the uptake of biosimilar products as substitutes for brand-name biologics, thereby limiting significant potential cost savings.

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