

Follow-on biologics: Time for action

The United States needs a pathway for follow-on biologics, or biosimilars, to reach consumers. No one, including innovator companies, argues that point. Congress is currently engaged in legislative debate that may establish such a pathway for therapeutically equivalent generic versions of biologic drug products. Issues include exclusivity—Rep. Henry Waxman (D-CA) wants 5 years while Sen. Ted Kennedy (D-MA) wants 12.5 years; scope of coverage—proteins or all substances; and data requirements, interchangeability, and naming issues related to substitution and postmarketing surveillance.

Drugs are approved by FDA under the Federal Food, Drug, and Cosmetic Act using standards and processes that are quite familiar to pharmacists. As was explained well by Farley and coauthors in the March/April 2006 issue of the *Journal of the American Pharmacists Association* (available online at www.japha.org), biologics are licensed under a separate statute, the Public Health Safety Act. This was and is appropriate for biologics derived from animal and plant sources; the recent experience with heparin reminded us of the difficulties in ensuring the quality of such products. However, follow-on biologics are produced through industrial processes much more similar to those for drugs. In fact, responsibility was shifted to FDA's drugs division in 2003 for approving several types of predictably synthesized biologics, including monoclonal antibodies, proteins, immunomodulators, and growth factors.



Thomas E. Menighan, BPharm, MBA
Executive Vice President and CEO

Little has happened in the intervening years, despite this recognition by FDA of the similarities between drugs and recombinant biologics some 6 years ago and testimony by FDA officials that the agency had the authority to proceed with modeling an abbreviated approval pathway after that of the Hatch–Waxman generics process. Omnitrope, a product marketed at the time by Sandoz, was approved in 2006 as a follow-on equivalent to Pfizer's Genotropin brand of growth hormone. Because of leadership changes, unfunded mandates, and politics, we've been in a dark period of little progress. An Act of Congress may give the United States needed clarity on the best

approach to follow-on biologics.

APhA went on record in support of follow-on biologics when our House of Delegates adopted policy on the issue in 2007. We encourage the development of safe, effective, and affordable therapeutically equivalent generic versions of biologic drug products, including clinical trials that assess safety. In addition, APhA encourages FDA to develop a scientific process to approve therapeutically equivalent generic versions of biologic drug products and supports legislation that hastens the development of an efficient regulatory process to approve therapeutically equivalent generic versions of biologic drug products.

As Congress considers the issue, insights can be gained from the experiences of other countries that have addressed follow-on biologics, including the science behind their production, their safety, and effects on costs and innovation. The European Union approved a process for handling biosimilar products in 2004, and we can learn much from its 5 years of experience. The Canadians are more advanced as well.

Whether the United States follows these or other models or develops one of its own, pharmacists are ready, willing, and able to provide the needed expertise to manage formularies and substitution processes once FDA begins administering the pathway that gets follow-on biologics to the U.S. market. We understand the science, and because our primary concerns are for the patient, we will work diligently to ensure that drugs and biosimilars are safe, efficacious, and cost-effective. Congress can decide the policy issues—how long intellectual property rights should be protected and how to ensure competition and innovation in the pharmaceutical industry—and pharmacists will then take the baton and work with industry partners and other stakeholders to get the right drug and the most cost-effective product to our patients, day in and day out.

Thomas E. Menighan