Provisions in the Affordable Care Act created an approval pathway for generic versions of biologic drugs, or biosimilars, but ensured that brand name biologic manufacturers are protected from this new competition for at least 12 years. However, drug manufacturer sales data show that most top-selling biologics can recoup their manufacturer's development costs in a single year.

In the United States, spending on expensive biologic drugs is growing more than ten times faster than spending on traditionally-developed “small molecule” drugs. Global biologic drug sales are expected to reach nearly $200 billion by 2015, up from $138 billion in 2010. Currently, just under half of biologic drug spending is concentrated in the United States.

One factor driving biologic spending is that the U.S. Food and Drug Administration (FDA) only recently acquired the authority to approve less-expensive generic versions of biologic drugs, known as biosimilars. Conventional drug products fall under the purview of the Federal Food, Drug, and Cosmetic Act, which has a streamlined process to approve generic drug products. However, the majority of biologics fall under the Public Health Service Act, which did not have an equivalent approval pathway until the passage of the Affordable Care Act in 2010. The new biosimilar approval pathway is expected to result in biosimilars entering the market by 2014.

While the need for a biosimilar approval pathway was widely accepted, the newly created pathway is a source of considerable debate. One of the most prominent issues is the 12-year market exclusivity period, or the amount of time that brand name biologic manufacturers are protected from generic competition. Brand name biologic manufacturers maintain that a 12-year exclusivity period is needed to recover the costs associated with biologic drug development and support continued innovation. However, the U.S. Federal Trade Commission (FTC) concluded that 12 years of exclusivity was unnecessary and could negatively impact innovation.

Based on drug manufacturers’ U.S. sales data alone, most top-selling biologic drugs are able to recoup their manufacturer’s development costs within a single year (see figure 1). The FTC also concluded that the costs associated with biosimilar development, manufacturing, and marketing will likely limit biosimilar entry to biologic drug markets with more than $250 million in annual sales. Thus, only biologic drugs that can quickly recoup their development costs are likely to face competition.
In addition, unlike traditional generic drugs, a variety of factors are expected to prevent biosimilars from rapidly gaining market share. Consequently, brand name biologic manufacturers will likely continue to earn substantial profits even after biosimilar versions of their products enter the market.8

Between the rapid rise in the number of biologic drugs9 and regularly expanding indications for the products that are already on the market,10 biologics are becoming an increasingly common treatment option for conditions that primarily affect older populations, such as cancer, rheumatoid arthritis, and multiple sclerosis. Allowing the FDA to approve less-expensive biosimilars should help patients facing the substantial out-of-pocket costs that can be associated with biologic drugs.11

However, an unnecessarily lengthy market exclusivity period will impede access to biosimilars and increase costs for consumers, employers, and publicly-funded programs like Medicare and Medicaid.
Endnotes


7 The average cost to develop a new biologic drug is $1.2 billion. This figure includes the costs associated with compounds that fail to reach the market. J.A. DiMasi and H.G. Grabowski, “The Cost of Biopharmaceutical R&D: Is Biotech Different?” Managerial and Decision Economics, 28, no. 4-5: 469-479.


10 For example, Avastin, which was approved in 2004, is currently involved in more than 1,000 clinical trials investigating its use in over 50 tumor types and different settings. Roche, 2010 Roche Annual Report, 2011.