Fact Sheet

Biologics in Perspective: The New Biosimilar Approval Pathway

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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[1] is growing more than ten times faster than spending on traditionally-developed "small molecule" drugs.[2]

Global biologic drug sales are expected to reach nearly $200 billion by 2015, up from $138 billion in 2010.[3] Currently, just under half of biologic drug spending is concentrated in the United States.[4]

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.[5]

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.[6]

Based on drug manufacturers' U.S. sales data alone, most top-selling biologic drugs are able to recoup their manufacturer's development costs[7] 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.

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Endnotes

[1] Biologic drug prices are an average of 22 times higher than traditional drug prices. A.D. So and S.L. Katz, "Biologics Boondoggle," *New York Times*, March 7, 2010.

[2] IMS Institute for Healthcare Informatics, "The Use of Medicines in the United States: Review of 2010," April 2011.

[3] IMS Institute for Healthcare Informatics, "The Global Use of Medicines: Outlook Through 2015," May 2011.

[4] IMS Institute for Healthcare Informatics, "The Use of Medicines in the United States: Review of 2010," April 2011.

[5] IMS Institute for Healthcare Informatics, "The Global Use of Medicines: Outlook Through 2015," May 2011.

[6] U.S. Federal Trade Commission, "Emerging Health Care Issues: Follow-on Biologic Drug Competition," June 2009.

[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.

[8] U.S. Federal Trade Commission, "Emerging Health Care Issues: Follow-on Biologic Drug Competition," June 2009.

[9] W.H. Schacht and J.R. Thomas, "P.L. 111-148: Intellectual Property Provisions for Follow-On Biologics," Congressional Research Service Report, May 25, 2010.

[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.

[11] Median cost sharing for biologic drugs under Medicare Part D is around 30 percent. MedPAC, *Health Care Spending and the Medicare Program: A Data Book*, June 2011. J. Appleby, "Workers Squeezed As Employers Pass Along High Costs Of Specialty Drugs," *Kaiser Health News*, August 22, 2011.

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