

essential action

Access to Medicines Project

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Saving Billions: The Case for Effective Biogenerics Legislation

There is currently no regulatory means for generic substitutes for biologic pharmaceuticals (also known as “biotech drugs”) to gain marketing approval in the United States. The approval process available for traditional pharmaceuticals does not apply to biologics, which are sometimes more complex than conventional “small molecule” drugs both in their make-up and method of manufacture. New and different procedures are required to demonstrate the safety and efficacy of comparable and interchangeable biologic pharmaceuticals (“biogenerics”).

Generic competition is the most important means to reduce the price of medicines. A Congressional Budget Office study shows that after generic versions of conventional drugs enter the U.S. market, prices fall on average between 40 and 80 percent, depending on the number of firms entering the market.¹ Brand-name biologic drugs cost significantly more on average than brand-name conventional pharmaceuticals, heightening the need for generics. But while growing numbers of patents on biologic drugs are set to expire over the next decade, American consumers will continue to pay extremely high monopoly prices for this important class of drugs, unless a regulatory process for granting marketing approval to safe and effective generic substitutes for biologic drugs is adopted.

Authorizing sales of generic biologics will save U.S. consumers and government purchasers of drugs tens of billions of dollars every year. How much consumers will save, however, depends crucially on the details of the new Food and Drug Administration (FDA) regulatory approval process. A streamlined approach would ensure that safe generics reach market – and deliver savings to consumers – as soon as possible. An overly bureaucratic approach, or one that confers new monopolies, will needlessly delay and reduce generic savings.

High Stakes in Biogenerics Debate

There is a lot at stake in the biogenerics debate. More than 250 biologic products -- used to treat more than 800 million patients globally -- have been brought to market since the industry originated in the 1970s. The FDA reports that biologics “often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available.”² Several vaccines as well as key treatments for cancer, diabetes, heart disease and autoimmune disorders represent the majority of the biologic market globally. Approximately 25% of the current new drug pipeline is biotech drug products and vaccines targeting more than 200 diseases, such as Alzheimer's, arthritis, various cancers, HIV/AIDS and multiple sclerosis.

Table 1: Cost of Selected Biologic Pharmaceuticals³

Trade Name	Company	Generic Name	Uses	Approximate Annual Cost Per Patient (USD)
Avastin	Genentech	bevacizumab	Colon, Lung and Breast Cancer	Up to \$185,250
Avonex	Biogen	interferon beta-1a	Multiple sclerosis	\$19,900
Enbrel	Amgen/Wyeth	etanercept	Autoimmune Disorders such as Rheumatoid Arthritis and Psoriasis	\$15,000-20,000
Rituxan	Genentech	rituximab	Non-Hodgkin's Lymphoma and Rheumatoid Arthritis	\$211,250

U.S. spending on biologics -- drugs made from living human or animal proteins -- increased by 127% between 2001-2005. By 2006, they made up 15% of U.S. prescription sales. Worldwide sales of biologic medicines increased by 12.5% in 2007 to more than \$75 billion, nearly double the 6.7% rate of growth for traditional pharmaceuticals, a consistent pattern over the past decade. The United States is the largest single market for biotech products, representing 56 percent of worldwide biologics sales in 2007.

Biologics are exceptionally expensive. In some cases, prices approach or exceed \$100,000 per patient, per year. Biologics priced at tens of thousands of dollars per patient per year are commonplace. The five top-selling biologic drugs in 2006 constituted 30 percent of Medicare Part B spending.⁴

The Legislative Landscape

Since early 2007, Members of Congress have introduced six bills that aim to create a pathway for FDA approval of lower-cost comparable and interchangeable biopharmaceuticals. These proposals build on the framework of the 1984 Hatch-Waxman Act, which created regulatory pathways for generic versions of conventional pharmaceuticals.

As a result of the abbreviated procedures for generic drug approval in Hatch-Waxman, conventional generic medicines grew from 12 percent of the prescription drug market to 65 percent in 2007, saving consumers an estimated \$8 to \$10 billion annually in pharmacies alone. At the same time, the brand-name pharmaceutical industry has continued to innovate new products and earn significant profits. In fact, after Hatch-Waxman was adopted, the amount of money invested in R&D increased significantly.⁵

Major Cost Savings from Biogenerics

If adopted, well-crafted biogenerics legislation in the United States will result in significant cost savings for all purchasers, including individual patients, insurance providers and state and federal government programs. A June 2008 Congressional Budget Office report estimates that enacting the procedures proposed by Senate Bill 1695, *Biologics Price Competition and Innovation Act of 2007*, would reduce spending on one key subset of biologics by all U.S. purchasers by \$25 billion between 2009-2018.⁶ Federal Programs would save about \$6.6 billion. The CBO estimates are particularly remarkable because S. 1695 includes a proposal for an unprecedented 12 years of data exclusivity, which would likely result in significant delays to biogeneric market entry compared to the procedures available for conventional pharmaceuticals under Hatch-Waxman. A 2007 study by a pharmaceutical benefit management firm that assessed cost savings for a broader range of drugs estimated much greater potential savings to all U.S. consumers (public and private) of \$71 billion over ten years.⁷

Key Principles for Effective Biogenerics Legislation

Providing timely access to affordable, safe and effective products is the central purpose of U.S. biogenerics legislation. Provisions that extend the monopoly protection period of brand-name companies, or otherwise make it unreasonably difficult to sell affordable biogenerics to patients as soon as possible after patent expiration, would therefore defeat the purpose of the new biogenerics rules. To ensure that this purpose is met, new biogenerics rules should address the following (non-exhaustive) list of issues.

❖ *Workable Pathway for Marketing Approval*

There is consensus that the science exists to permit the FDA to approve safe and comparable interchangeable biopharmaceuticals despite the relative complexity of making such determinations as compared to conventional drugs. A workable pathway for the approval of biogenerics would give the FDA the flexibility to determine on a case-by-case basis the data necessary for marketing approval.

However, several biogenerics proposals would impose administrative hurdles that would impede the FDA's scientific judgment. The FDA should be given the required flexibility to ensure quality without being subjected needless obstacles to generic approval.

❖ ***Avoiding Inappropriate Marketing Monopolies***

All but one of the legislative proposals currently under consideration call for significant and unprecedented periods of data exclusivity prior to marketing approval (for periods ranging between 8 to 15 years, plus extensions in some cases). When a generic company seeks approval for a generic drug, it shows that its product is the same as, or essentially similar to, a brand-name product. It then relies on, but does not repeat, the clinical tests performed by the brand-name maker. Data exclusivity prohibits the generic firm from relying on the brand-name test data, effectively barring the generic from the market for a set period of time. Data exclusivity can delay the introduction of generic competition -- keeping prices high longer -- for drugs that are not able to obtain patent protection, or for which the patent term has expired. It also overcompensates data originators, enabling them to earn many times the cost of their investment. Provisions requiring data exclusivity should not be included in biogenerics legislation.

If policymakers wish to create an additional incentive specifically for the cost of clinical trials, there are approaches -- such as sharing the cost of clinical trials -- that satisfy the public policy rationale for providing data exclusivity to innovators, at a much lower cost and while avoiding data exclusivity-conferred marketing monopolies that undermine access to medicines and other public health objectives. If a policy decision were made that innovator companies need investment protections beyond those afforded by the patent system, the cost-sharing approach would be an efficient and pro-public health alternative to the data exclusivity approach. This approach gives generic firms an automatic right to use originators' data, but requires them to pay a share of the documented costs of generating the data, proportionate to the size of the markets in which they are selling their product.

A cost-sharing system would be administratively manageable. A version is already in effect for U.S. approval of agricultural chemicals, although the agrichemical cost-sharing scheme follows only after grant of an initial marketing monopoly.⁸

❖ ***Timely Patent Dispute Resolutions and Patent Disclosure***

Biogenerics legislation should include provisions that would allow for clear and timely resolution of patent disputes, prohibiting frivolous suits that could delay the market entry of biogenerics. Requiring brand name companies to disclose all relevant patents is one key element to ensure potential generic competitors have sufficient information to make an informed assessment of the potential barriers to competition. Several of the biogenerics proposals under consideration do not require such disclosure as part of the proposed patent dispute resolution system, or do not contain any provisions governing patent dispute resolution related to biogenerics.

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¹ Congressional Budget Office, *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998, p.32.

² Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) website, “Frequently Asked Questions,” available at <http://www.fda.gov/cber/faq.htm#2>.

³ C.D. Monroe et al., “Kaiser Permanente’s Evaluation and Management of Biotech Drugs: Assessing, Measuring and Affecting Use,” *Health Affairs*, September/October 2006, Vol. 25(5), p.1340-1346; Biogen Idec, “New One-Year Pharmacoeconomic Study Shows Avonex Is Cost-Effective Relative to Other Interferon Therapies for Multiple Sclerosis,” Press Release, April 13, 2007.

⁴ Engel & Novitt LLP, *Potential Savings that Might be Realized by the Medicare Program from Enactment of Legislation Such As the Access to Lifesaving Medicine Act (H.R. 6257/S. 4016) That Establishes a New cBLA Pathway for Follow-on Biologics*, Report to Pharmaceutical Care Management Associates, January 2007.

⁵ Congressional Research Service (CRS), *Follow-on Biologics: Intellectual Property and Innovation Issues*, June 4, 2007, p. 4.

⁶ Congressional Budget Office, *Cost Estimate, S. 1695, Biologics Price Competition and Innovation Act of 2007*, June 25, 2008.

⁷ Jonah Houts and Steve Miller, M.D., *Potential Savings of Biogenerics in the United States*, Express Scripts Inc., 2007.

⁸ Section 3(c)(2)(b), 7 U.S.C. 136(a)(c) (2) (B), of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y.