

Congress Must Improve “No Generics” Proposal for Biologics

Healthcare Reform Offers Only the Illusion of Generic Competition for Biotech

Drugs: Patient Access To Expensive New Medicines at Stake

U.S. Congress is considering proposals to establish a process for regulatory approval of generic versions of biotech drugs (“biologics”). The Food and Drug Administration (FDA) approval process available for conventional pharmaceuticals does not apply to biologics, which are drugs engineered from human or animal cells using biotechnology. New and different procedures are required to demonstrate the safety and efficacy of comparable and interchangeable biologic pharmaceuticals (called “biosimilars” or “biogenerics”).

Proposals passed by the Senate and House health committees as part of healthcare reform in July 2009, however, will establish prolonged delays before permitting price-lowering generic competition. Even worse, they will facilitate brand-name companies’ ability to renew their monopolies, potentially keeping generic firms out of the market for biologics altogether and creating only the illusion of generic competition. Either result will torpedo the objective of healthcare cost containment so crucial to current reform efforts, and severely limit patient access to these important and exceptionally high-priced medicines for conditions like cancer, arthritis and diabetes.

The bottom line is this: Under these proposals, Medicare and other federal programs will find their budgets increasingly strained by growing biologic drug costs. Employers will continue to struggle to provide affordable health insurance to their employees. Americans with insurance will find it even more difficult to pay for their already sky-high prescription drug co-payments. And the uninsured may have to go without crucial lifesaving biologics.

High Stakes in Biogenerics Debate

There is a lot at stake in the biogenerics debate. Key biologics include most new cancer drugs, all vaccines and key treatments for arthritis, diabetes, MS and many other conditions. Biologic drugs are currently a quarter of all new drug approvals in the United States, and half of all important new drugs on the market. Biologics already make up 15% of U.S. prescription sales. They are also the fastest growing part of the nation’s prescription drug bill, with sales consistently increasing at nearly double the rate of growth for traditional pharmaceuticals.

Table 1: Cost of Selected Biologic Pharmaceuticalsⁱ

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

Brand-name biologics are also priced very high -- much higher than conventional chemical drugs, heightening the need for low-cost generics. 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.ⁱⁱ

Generic competition is the most important means to reduce the price of medicines. A Congressional Budget Office (CBO) study shows that after generic versions of conventional drugs enter the U.S. market, prices fall on average between 40 and 80 percent.ⁱⁱⁱ Generic competition will also lead to major cost savings for biologics, bringing down prices 20-40 percent, according to very conservative estimates^{iv}. There is good reason to believe price reductions will be greater than that. But even the more modest estimates like those calculated by the CBO find that the introduction of biogenerics could result in cost savings of many tens of billions of dollars for American consumers.^v As a result, a well-designed biogenerics regulatory pathway could play an important role in achieving significant cost savings, a critical objective of U.S. healthcare reform.

The Legislative Landscape

Unfortunately, the biogenerics proposals now included in the healthcare reform bills approved by the House Energy and Commerce Committee and the Senate Health, Education, Labor and Pensions (HELP) Committee, include very extensive obstacles to price-lowering generic competition. The biopharmaceutical industry-backed proposals are being championed by Representatives Eshoo and Barton in the House of Representatives, and Senators Hatch, Enzi and Hagan. There are several problems with these proposals, but the two most troubling issues are discussed below.

Problem One: Inappropriately Long Marketing Monopolies (Data Exclusivity)

The proposals passed by Senate and House committees would establish a 12-year marketing monopoly (known as “data exclusivity”) for brand-name biologics, a monopoly that is separate and distinct from (although sometimes overlapping with) the patent monopolies biologic drugs already have. 12 years is

Case Study: The High Cost of Cancer Blockbusters Avastin and Herceptin

Jeanne Sather from Seattle Washington, a woman who blogs about her struggles with metastatic breast cancer, typifies the challenges faced by Americans struggling with the high cost of biologics, as well as healthcare costs in general. When she was taking Roche-Genentech’s blockbuster biologic cancer drugs Avastin and Herceptin in 2006, the price was more than \$300,000 a year.

Covered by a state insurance plan for those who are turned down by private insurance, Jeanne did not have to pay the entire price tag, but she did have large co-payments to make. And because of her need for these high-priced biologics, she also came dangerously close to hitting the plan’s lifetime cap of \$1 million. She and others in the same predicament successfully lobbied for the cap to be raised to \$2million.

Still very sick, Jeanne is now struggling to pay her mortgage because of her medical bills, and is at risk of losing her home to foreclosure. Genentech reported Herceptin sales of \$1.38 billion in 2008 alone (and \$1.28 billion in 2007), meaning revenues far exceed the inflated industry estimate of its risk-adjusted average cost of developing a new biologic, which they claim is \$1.3 billion dollars.

Sources: Barbara Basler, “Million Dollar Medicines,” AARP Bulletin, October 1, 2008; Jeanne Sather, “Medical Bills and Bankruptcy,” *The Assertive Cancer Patient (blog)*, June 8, 2009; Jeanne Sather, “The True Cost of Herceptin,” *The Assertive Cancer Patient (blog)*, March 13, 2007;

an excessively long period of extra monopoly protection; conventional drug makers receive only three or five years of data exclusivity under the 1984 Hatch-Waxman Act.

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.

The Federal Trade Commission (FTC) did a major study, released in June 2009, which recommended zero years of data exclusivity for biologics^{vi}. The brand-named biopharmaceutical industry has sought 14 years of data exclusivity. The Obama Administration took the position after the FTC report was released that they wished to limit the amount of data exclusivity to a "generous compromise" of 7 years extra protection, in order to promote the objective of cost savings for U.S. consumers. Essential Action believes that biologic patents provide sufficient reward to the drug companies that own them, and that zero years of additional protection in the form of data exclusivity is required. But if Congress decides to give additional protection biologics, newly approved brand-name products should be granted no more than five (5) years of data exclusivity, the same amount traditional drugs receive under Hatch-Waxman.^{vii}

Problem Two: The Evergreening of Data Exclusivity and the Creation of Perpetual Monopolies

Even worse than the unprecedented and unjustified amount of data exclusivity being proposed for biologics, the recently approved proposals would enable brand-name biopharmaceutical companies to do relatively cheap and minor tweaks to the drugs, and obtain an additional 12 years of monopoly protection. The minor modifications that would receive brand new monopolies include creating a once-a-day injection where the original product was a thrice-a-day injection.^{viii} These modifications of the original biologic product may offer small or significant patient benefits. But they are typically easy to design. Brand-name firms do not need the lure of protracted monopolies to make these minor modifications.

Based on the experience with conventional drugs, there is very strong reason to believe that brand-name companies will be able to exert their marketing acumen to transition patients (and doctors) to the modified product, and away from cheaper, generic versions of the old product. Indeed, it is quite likely that in many or most cases this prospect will deter generic manufacturers from entering the biogenerics market at all.^{ix}

This kind of "evergreening" strategy is common and very problematic for conventional drugs, even where there is no possibility of sequential 12 -year monopolies. There is reason to believe evergreening will be much easier and more effective for biologics under the existing proposals.^x This means Big Pharma will be able to game the system to obtain near perpetual monopolies on biologics, extending several decades beyond patent and original exclusivity expiration.

Debunking Big Pharma's Justification for Extended Monopolies, High Prices

Brand-name biopharmaceutical companies argue that they need these special monopoly protections and the right to charge very high prices because it is so difficult and expensive to produce new biologics. But even the industry's most cited studies show biologic research and development (R&D) costs to be relatively equivalent to costs for conventional drugs (\$1.3 billion versus \$1.2 billion) and that it takes roughly the same amount of time on average to develop them.^{xi}

The brand-name companies also conveniently overlook the massive public investment that undergirds their work. In the area of cancer, all private sector research occurs on a public foundation constructed with billions of dollars of public money. And, many or most of the cancer biologics received direct funding support from the government through the National Cancer Institute (NCI) -- a fact conveniently ignored by the brand-name companies when they talk about the cost of innovation.

Big Pharma Not "Little" Biotech

The biotech drug industry likes to portray itself as composed of tiny entrepreneurial firms that struggle to raise venture capital for R&D when it justifies the need for special monopoly protections for its products. And, while there are certainly many small firms, the industry is increasingly dominated by a small number of major players -- and it is increasingly integrated into Big Pharma, which biotech relies upon for capital, collaborations, technology and, when they have success, licensing deals. Moreover, traditional pharma giants like Merck, Pfizer-Wyeth, Roche and Eli Lilly all are now among the leading biotech firms.^{xii}

How Did We Get Here? Follow the Money

Big Pharma and the biotech industry have hired legions of lobbyists to work this issue on Capitol Hill. They have spent tens of millions of dollars this year alone -- Pharma is spending more than a million dollars a day on lobbyists. It is this massive investment, plus other leveraging of money and power that has resulted in a bill that is so tilted against consumers and the public interest.^{xiii}

Avoidable Problems: Waxman-Deal and Schumer-Brown Proposals Offer Superior Approach

The biologic data exclusivity evergreening problem is solvable. The Waxman-Deal and Schumer-Brown-Collins-Martinez-Vitter biogenerics legislation (H.R. 1427/ S.726) offers new biologics five (5) years of data exclusivity and three (3) years for modified products, mirroring what is offered to traditional drugs under the 1984 Hatch-Waxman Act. These proposals also establish clear and precise standards for obtaining data exclusivity, and specifies categorically and by example that minor modifications are not eligible for subsequent full exclusivity periods. Legislators can alter the current proposals in draft healthcare reform legislation using the Waxman-Schumer model as a guide to better promote cost savings and patient access to biologics.

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ⁱ AARP Public Policy Institute, *Top 20 Biologics (2006 Ranking) and Approximate Annual Treatment Costs*, May 2007.

ⁱⁱ 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.

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

^{iv} Federal Trade Commission (FTC), *Emerging Health Care Issues: Follow-on Biologic Drug Competition*, June 2009.

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

^{vi} FTC, *Ibid.*

^{vii} Essential Action, “Ensuring Effective Biogenerics Legislation: Avoid Inappropriate Marketing Monopolies (Data Exclusivity),” available at <http://www.essentialaction.org/access/index.php?/archives/179-Ensuring-Effective-U.S.-Biogenerics-Legislation-Avoid-Inappropriate-Marketing-Monopolies-Data-Exclusivity.html>

^{viii} Essential Action, “Congress Should not Adopt “No Generics” Proposals for Biologics: The Eshoo-Barton-Inslee and Hatch-Enzi-Hagan Approach to Biogenerics: Evergreening and the Creation of Perpetual Monopolies,” July 2009, p.1, available at <http://www.essentialaction.org/access/index.php?/archives/202-Congress-Should-Not-Adopt-No-Generics-Proposals-for-Biologics-Evergreening-and-the-Creation-of-Perpetual-Monopolies.html>

^{ix} *Ibid.*, p.2.

^x *Ibid.*

^{xi} JA DiMasi JA and HG Grabowski. “The cost of biopharmaceutical R&D: Is biotech different.” *Managerial & Decision Economics*. 2007 28:469-479.

^{xii} Essential Action, *The Marriage of Big Pharma and BIO: Collaborations and Combinations of the Top 20 Brand-Name Pharmaceutical Companies with Small- and Medium-Size Biotechnology Firms and Implications for the U.S. Biogenerics Debate*, forthcoming, September 2009.

^{xiii} Michael Beckel, “Will \$1.2 Million a Day Convince Congress to Buy Big Pharma’s Rx for Change?” *Center for Responsive Politics*, June 25, 2009; Timothy Noah, “An Amgen Payoff? Why is Ted Kennedy being so nice to the biotech industry?” *Slate Magazine*, July 13, 2009; Fredreka Schouten, “Industry Donates to Drug Plan Foes,” *USA Today*, July 28, 2009; Lisa Wangsness, “Biotech firms lobby for say on healthcare,” *Boston Globe*, July 21, 2009.