

Rx Watchdog Report

Shining a light on the cost and quality of prescription drugs

Biologic Drugs and Market Exclusivity: The Federal Trade Commission's Recommendations

A recent report by the Federal Trade Commission (FTC) disputes the contention that the makers of biologic drugs need a long period of market exclusivity on those drugs as a means of promoting innovation within the industry. Indeed, the FTC concluded that the 12- to 14-year period of market exclusivity supported by the drug industry actually *negatively* impacts innovation.

The report is particularly relevant to the current debate in Congress over how to bring generic versions of biologic drugs—also known as “biosimilars”—to the market. One particularly controversial element is market exclusivity, or how long biotech pharmaceutical companies can keep their brand name products on the market without threat of competition (market exclusivity is separate from patent protection—generic drug manufacturers have to wait for both to expire before their products can enter the market). Finding the right balance between encouraging competition and maintaining incentives for the future development of biologic drugs is not an easy task for policy makers. It is particularly difficult when billions of dollars are at stake.

AARP, along with many consumer, business, labor, and health groups, supports the “Promoting Innovation and Access to Life-Saving Medicine Act” (H.R. 1427/S. 726), which provides five years of market exclusivity (for more information on this legislation and generic biologics, see our May 2009 *Rx Watchdog* at www.aarp.org/watchdog). In contrast, the pharmaceutical and biotechnology industries support a 12- to 14-year market exclusivity period. President Obama has proposed

what he calls a “generous compromise” of seven years of market exclusivity.

The FTC report, entitled *Emerging Health Care Issues: Follow-on Biologic Drug Competition* is the first objective, third-party report that addresses the balance between competition and innovation in the biologics market. The FTC has decades of experience examining pharmaceutical and biotechnology mergers and likely models of competition, and has conducted numerous investigations and enforcement actions involving the conduct of branded and generic drug manufacturers arising in the context of the Hatch-Waxman Act, which regulates traditional prescription drugs.

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Federal Trade Commission's Findings

The FTC report addresses competition and innovation, and its conclusions directly refute many of the arguments used to support a long period of market exclusivity, instead making the case that brand name manufacturers do not need any exclusivity.

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Developing an FDA Approval Process for Generic Biologic Drugs: Myth vs. Fact

AARP believes that any final health care reform package should include an FDA approval process for generic versions of biologic drugs so Americans can get these life-saving medicines at a price they can afford. As the largest organization representing Americans age 50 and older, AARP knows our members are especially burdened by the high costs of biologic drugs. Older Americans use more prescription drugs than any other age group, and also have the highest prevalence of the chronic conditions that can be treated using biologic drugs.

AARP supports provisions consistent with the “Promoting Innovation and Access to Life-Saving Medicine Act” (H.R.1427/S.726), which provides a workable, science-based FDA approval pathway and appropriate exclusivity for brand name products. In contrast, the pharmaceutical and biotechnology industries support proposals that would provide them with greater profits and needlessly delay consumers' access to lower-cost versions of these life-saving medications.

Below are many of the myths that have been used by the pharmaceutical and biotechnology industries to support their position, as well as the facts that refute them.

Myth #1: Biologic drug manufacturers need a long period of market exclusivity in order to continue to innovate.

FACT: According to the Federal Trade Commission (FTC), brand name manufacturers do not need special incentives to support continued innovation, and the unreasonable 12 to 14 years of market exclusivity supported by the drug industry actually negatively impacts innovation. As

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Biologic Drugs

Biologic drugs are different from chemically derived drugs, in that they are made from living organisms and have a more complex molecular structure. Biologics are typically expensive. For example, breast cancer treatment with Herceptin, a biologic, can cost \$48,000/year. Biologics are often used to treat serious, chronic illnesses that can affect older populations, such as cancer and multiple sclerosis.

For more information on costs and exclusivity read “Biologics in Perspective: The Case for Generic Biologic Drugs,” by AARP Public Policy Institute, at www.aarp.org/research/ppi/health-care/medicare/articles/fs155_biologics.htm.

Among the FTC findings are:

- **the economic model that is commonly used to support a 12- to 14-year period of market exclusivity contains numerous methodological and conceptual weaknesses** that render its results too imprecise and nonrobust to inform discussions on exclusivity periods;
- **competition between a biologic drug and a biosimilar is much more likely to resemble brand-to-brand competition than the dynamics of brand-to-generic competition:** the costs to enter the generic biologics market are much higher, and the biosimilar products will take much longer to produce. Given the steep costs, the only companies able and willing to produce generic biologics will be the larger companies with substantial resources;
- **lack of automatic substitution between a generic biologic and a brand name biologic will reduce the rate at which generics penetrate the market:** a pharmacist can usually substitute a generic drug for a brand unless the prescriber states otherwise. This is unlikely to occur when the first biosimilar products enter the market, as they will not be considered interchangeable;
- **biologic drugs currently are not reimbursed in such a way that payers can incentivize the use of lower-priced**

drugs: biologic drug products are usually delivered to patients as part of medical treatments (e.g., oncology) and reimbursed by health insurers as part of a medical benefit. Therefore, traditional incentives to increase generic utilization (e.g., tiered formularies) will not be effective.

Biotechnology Industry Corporation (BIO), the world's largest biotechnology organization, has heavily criticized the FTC's conclusions, stating that any legislation based on the report would be flawed and unsound, “eroding the incentives for developing new biological products or conducting clinical research.” However, BIO has thus far been unable to present objective evidence that supports its criticisms.

“There is a public policy trade off: a restriction on competition is provided in return for the development of a new drug product or new use of an existing product. A 12 to 14 exclusivity period departs sharply from this basic trade-off, because it does not spur the creation of a new biologic drug or indication. The drug has already been incentivized through patent protection and market-based pricing.”

–From the “Emerging Health Care Issues: Follow-on Biologic Drug Competition, Federal Trade Commission Report,” June, 2009. For the full report go to www.ftc.gov/os/2009/06/P083901biologicsreport.pdf ■

MedPAC: Generic Biologics Would Provide Much-Needed Savings for Medicare

The outcome of the biosimilar drug debate has important implications for the Medicare program, according to a report recently released by the Medicare Payment Advisory Commission (MedPAC). MedPAC is an independent congressional agency that advises Congress on issues affecting the Medicare program.

“Biologics play a substantial role in Medicare Part B, with the top six biologics accounting for more than \$7 billion of nearly \$17 billion in total Medicare Part B spending on prescription drugs in 2007.”

MedPAC's report noted that the Medicare program spent about \$12 billion on biologic drugs in 2007. Biologics play a substantial role in Medicare Part B, with the top six biologics accounting for more than \$7 billion of nearly \$17 billion in total Medicare Part B spending on prescription drugs in 2007. In the same year, Medicare Part D spending on biologics totaled approximately \$3.9 billion, or about 6 percent of Part D spending. Spending on Part D biologics has increased more rapidly than overall drug spending: between 2006 and 2007, Part D spending on biologics grew by about 36 percent, whereas total Part D spending grew by 22 percent.

Given Medicare's substantial spending on biologic drugs and the expectation that such spending will grow significantly in the future, MedPAC concluded that the establishment of a process to approve biosimilar drugs has important implications for the program, and will generate much-needed savings.

To read the entire report, go to: www.medpac.gov/documents/Jun09_EntireReport.pdf ■

Myth vs. Fact continued

noted by the Medicare Payment Advisory Commission (MedPAC), brand name companies have little incentive to improve their products without the threat of imminent competition.

Myth #2: Biologic drugs need a long period of exclusivity because the costs associated with drug development are so high.

FACT: The FTC concluded that generic entry is only likely in biologic drug markets with more than \$250 million in annual sales. Thus, only biologic drugs that can quickly recoup the \$1.2 billion cost of development will face generic competition. Further, brand name manufacturers are likely to retain 70 to 90 percent of their market share and will continue to reap substantial profits even after generic versions of their product enter the market.

Myth #3: Biologic drugs need a long period of market exclusivity because their patents are less effective.

FACT: According to the FTC, there is no evidence that patents claiming a biologic drug product have been, or are likely to be, designed around more frequently than those claiming non-biologic drug products. In fact, biologic drugs are covered by more and varied patents than non-biologic brand name drug products.

Myth #4: Legislation that regulates generic versions of biologic drugs must

mandate clinical trials in order to ensure patient safety.

FACT: Clinical trials are not mandated in the legislation that regulates brand name biologic drugs; there is no reason for generic biologic drugs to be handled differently. In addition, the FTC has said that requiring generic manufacturers to duplicate existing knowledge about safety and efficacy through clinical trials represents an inefficient use of limited research and development resources and raises ethical concerns associated with unnecessary human testing.

Myth #5: Biologic drug manufacturers need a long period of exclusivity in order to continue to attract venture capital funding for research and development.

FACT: According to the FTC, much of the funding of basic medical research comes from the National Institutes of Health or other government sources, angel investors and corporations—not venture capitalists.

Myth #6: Biologic drug manufacturers need a long period of exclusivity because the FDA will have wide latitude in approving generic versions that may be similar to the innovator reference product but different enough to avoid patent infringement.

FACT: A recent FDA review found that the average difference between the more than 270 traditional generic drugs approved in

1997 and their brand name counterparts was 3.5 percent—about the same as the differences found between batches of brand name products. There has been no indication that they will relax these standards for generic biologic drugs. Further, as noted by the FTC, efforts to attempt to design around a pioneer manufacturer's patent should be expected and encouraged, as the development of non-infringing products to compete with the patented discovery spurs greater innovation.

Myth #7: Generic versions of biologic drugs are not going to benefit consumers.

FACT: According to the FTC, generic versions of biologic drugs would provide millions of dollars in consumer savings for these very expensive products. Further, brand name manufacturers are expected to respond to generic competition by offering discounts to maintain their market share, increasing consumer access and further expanding the market.

In addition to consumer savings, MedPAC has concluded that generic biologics would generate much-needed savings for the Medicare program. Medicare spent \$13 billion on biologic drugs in 2007, and six biologic drugs alone accounted for 43 percent of Medicare Part B spending on prescription drugs in that same year.

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