

A Sense of Déjà Vu: The Debate Surrounding State Biosimilar Substitution Laws

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The Affordable Care Act created an approval pathway for less expensive generic versions of biologic drugs, known as biosimilars, or follow-on biologics. However, new state legislation that could greatly limit the savings from biosimilars has ignited a debate similar to the one that followed the passage of federal legislation that encouraged the development of traditional generic drugs.

Biologic drugs are medicines derived from living organisms that are often used to treat conditions that commonly affect older populations, such as cancer, multiple sclerosis, and rheumatoid arthritis. Biologic drugs differ from traditional, chemically derived prescription drugs in a number of ways, but perhaps the most obvious difference is their price. On average, biologic drugs are 22 times more expensive than traditional brand name drugs.¹ Some biologic drugs have annual costs of \$200,000 or more.²

In 2010, the Food and Drug Administration (FDA) was granted the authority to approve less expensive generic versions of biologics, known as biosimilars, or follow-on biologics,³ with the expectation that such products could help reduce the costs associated with biologic drugs. However, recent state legislative activity could negatively impact these savings.⁴

What's at Stake

In the United States, spending on biologic drugs is growing more

than 10 times faster than spending on traditional, chemically derived prescription drugs.⁵ This trend is expected to continue as biologics capture more of the pharmaceutical market: there are reportedly more than 900 biologic drug products in various stages of development.⁶ Meanwhile, biologic drugs with a combined market value of \$50 billion are expected to be off-patent by 2019.⁷

The costs associated with biologic drugs impact everyone in the health care system. Individuals, employers, and taxpayers all shoulder a portion of the costs in their health premiums and through taxpayer-funded programs like Medicare and Medicaid.^{8,9}

Patients who are prescribed a biologic drug also face the possibility of high out-of-pocket costs, particularly if their insurer requires them to pay a percentage of their prescription drug cost instead of a flat copayment. These high costs could lead patients to forgo needed medications and eventually result in expensive hospitalizations and adverse health outcomes.

States Debate Regulation of Biosimilar Substitution

Some aspects of the FDA's new biosimilar approval pathway have not been finalized, raising expectations that it will be years before it is used to approve a biosimilar.¹⁰ Nevertheless, several states are already considering legislation that would regulate the substitution of biologics with biosimilars.

State biosimilar substitution legislation generally seeks to restrict the ability of pharmacists to substitute biosimilars for brand-name biologic products.¹¹ The bills' provisions vary from state to state, but typically require (1) patient consent for the substitution; (2) the pharmacist to notify the prescriber of the switch; and (3) the pharmacist and prescriber to maintain written records of the switch for several years. Some bills also require the state board of pharmacy to maintain a list of interchangeable drugs.^{12,13}

Arguments for State Biosimilar Legislation

Biologic drug companies and some patient advocacy groups, whose views are often closely aligned with those of the drug industry,¹⁴ maintain that the FDA will develop appropriate standards for the approval of safe biosimilar and interchangeable biologic products. However, they also believe that additional protections are needed in state substitution policies that will “safeguard patient safety and the primacy of the physician-patient relationship,” as well as “ensure transparency and communication between patients and their treatment care teams.”¹⁵

Biologic drug companies and other state biosimilar legislation supporters also cite quality concerns to support the need for additional safeguards in state

substitution legislation. For example, the trade organization that represents biologic drug companies argues, “Even though interchangeable biologics will be ‘expected’ to produce the same clinical result, it remains the case that patients could react differently to an interchangeable biologic than if they were given the innovator product due to the complex nature of biologic products and how they work in the human body.”¹⁶

Legislation supporters have also raised the specter of adverse events, saying that, for the sake of public health, everyone should know which biologic a patient is taking so it can be used for adverse event reporting.

Arguments against State Biosimilar Legislation

In contrast, generic drug manufacturers, health payers, and some consumer groups argue that recent state biosimilar substitution legislation is designed to preemptively deter the substitution and use of biosimilars, which will drastically reduce any savings to consumers and taxpayers. These groups point to research that shows states with patient consent requirements have generic substitution rates that are 25 percent lower than states that do not.¹⁷ Similarly, pharmacy record-keeping requirements have been shown to lower generic substitution rates.¹⁸

An additional concern among opponents of state biosimilar substitution legislation is that requirements to inform patients and prescribers when biosimilar substitution takes place could serve to heighten any lingering anxiety and suspicion of generic alternatives, deterring biosimilar use.¹⁹

Opponents also argue that state biosimilar legislation is extremely premature given that the FDA is

A Sense of Déjà Vu: The Debate Surrounding State Biosimilar Substitution Laws

still in the process of developing the biosimilar approval pathway and has yet to approve a single biosimilar using its new authority. Thus, implementing state legislation now could result in unnecessary conflict between state and national standards.

Another concern raised by opponents is that state biosimilar substitution legislation could conflict with federal law governing biosimilar substitution, which specifies that biosimilars that are determined to be interchangeable with their brand-name counterparts can be substituted without the involvement of the prescribing doctor.²⁰

The FDA has also expressed concerns about the effects of state biosimilar substitution legislation on access to lower-cost treatments.²¹

A Sense of Déjà Vu

The arguments currently being raised against biosimilar substitution are similar to arguments used against traditional generic drug substitution following the passage of the Hatch-Waxman Act in 1984.²² For example, opponents of generic substitution raised concerns

regarding the interchangeability of generic drugs and whether generic drugs were safe.^{23,24} Further, the FDA criticized several brand-name drug manufacturers for their efforts to imply that generic drugs are inferior.²⁵

Thirty years later, these concerns have been proven groundless: generic prescription drugs are now broadly viewed as completely safe and an appropriate substitution for the brand-name version, and now represent 86 percent of U.S. prescriptions.²⁶ The widespread availability and acceptance of generic drugs has also resulted in substantial savings to the health care system.²⁷

Conclusion

Between the rapid rise in the number of biologic drugs and the growing use of products already on the market, biologics are becoming an increasingly common treatment option. Given their substantial costs, every effort should be made to ensure that savings from less expensive biosimilars are not unnecessarily constrained.

Endnotes

¹ A.D. So and S.L. Katz, “Biologics Boondoggle,” *New York Times*, March 7, 2010.

² F. Megerlin, R. Lopert, K. Taymor, and J.-H. Trouvin, “Biosimilars and the European Experience: Implications for the United States,” *Health Affairs* 32(10): 1803–1810.

³ 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. Biosimilars have been defined by the FDA as “highly similar to an already approved biological product ... for which there are no clinically meaningful differences from the approved biological product in terms of safety, purity, and potency.” U.S. Food and Drug Administration (FDA), “FDA Issues Draft Guidance on Biosimilar Product Development,” Press Release, February 9, 2012.

⁴ A. Pollack, “Biotech Firms, Billions at Risk, Lobby States to Limit Generics,” *New York Times*, January 28, 2013.

⁵ IMS Institute for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2010* (Parsippany, NJ, April 2011).

⁶ PhRMA, *Medicines in Development: Biologics* (Washington, DC, 2013).

A Sense of Déjà Vu: The Debate Surrounding State Biosimilar Substitution Laws

⁷ G. Thornton, *Bio-dynamism: Insights into the Biosimilars Market: An Overall Perspective* (Grant Thornton India LLP, New Delhi, 2013).

⁸ The five highest expenditure Medicare Part B drugs were all biologics and accounted for over \$6.5 billion in spending in 2010. Government Accountability Office, “Medicare: Information on Highest-Expenditure Part B Drugs,” Testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives, Statement of James Cosgrove, Director Health Care, June 28, 2013.

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¹⁰ S. Rickwood and S. Di Biase, *Searching for Terra Firma in the Biosimilars and Non-Original Biologics Market: Insights for the Coming Decade of Change* (Parsippany, NJ: IMS Health, 2013).

¹¹ A. Pollack, “Biotech Firms, Billions at Risk, Lobby States to Limit Generics,” *New York Times*, January 28, 2013.

¹² In 2013, 28 biosimilar substitution bills were introduced in 18 states. The bills were rejected in 10 states, enacted in 5 states, and carried over in 3 states. J.S. Mazer, “Introduction to State Biosimilar Substitution Laws,” Pharmaceutical Care Management Association Presentation at Federal Trade Commission Follow-on Biologic Workshop, February 4, 2014.

¹³ The FDA has defined interchangeability as “the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.” U.S. Food and Drug Administration (FDA), “FDA Issues Draft Guidance on Biosimilar Product Development,” Press Release, February 9, 2012.

¹⁴ Patient advocacy groups have recently faced scrutiny for their financial ties to drug companies. S.M. Rothman, V.H. Raveis, A. Friedman, and D.J. Rothman, “Health Advocacy Organizations and the Pharmaceutical Industry: An Analysis of Disclosure Practices,” *American Journal of Public Health*, Advance Access: e1-e8. C. Ornstein and T. Weber, “Patient Advocacy Group Funded by Success of Painkiller Drugs, Probe Finds,” *Washington Post*, December 23, 2011. A. Schwarz, “The Selling of Attention Deficit Disorder,” *New York Times*, December 14, 2013.

¹⁵ Biotechnology Industry Organization, “BIO Principles on the Substitution of Biologic Products,” January 24, 2013. Available online at: <http://www.bio.org/advocacy/letters/bio-principles-patient-safety-substitution-biologic-products>.

¹⁶ Biotechnology Industry Organization, “BIO Principles on the Substitution of Biologic Products,” January 24, 2013. Available online at: <http://www.bio.org/advocacy/letters/bio-principles-patient-safety-substitution-biologic-products>.

¹⁷ W. H. Shrank et al., “State Generic Substitution Laws Can Lower Drug Outlays under Medicaid,” *Health Affairs* 29(7): 1383–1390.

¹⁸ A. Kesselheim, “Lessons for Follow-On Biologics from Small Molecule Drugs,” Presentation at FTC Follow-on Biologic Workshop, February 4, 2014.

¹⁹ A.L. Benedict, “State-Level Legislation on Follow-On Biologic Substitution,” *Journal of Law and the Biosciences*, Advance Access: 1–12.

²⁰ A. Pollack, “Biotech Firms, Billions at Risk, Lobby States to Limit Generics,” *New York Times*, January 28, 2013.

²¹ FDA, Statement from FDA Commissioner Margaret Hamburg to GPhA, August 29, 2013. Available online at: http://www.gphaonline.org/media/cms/fda_statement_biosimilars.pdf.

²² The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, was enacted to make it easier for traditional generic drugs to enter the market.

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²⁴ K.K. Midha and G. McKay, “Bioequivalence; Its History, Practice, and Future,” *AAPS Journal* 11(4): 664–670.

²⁵ T. Lewing, “Drugmakers Fighting Back against Advance of Generics,” *New York Times*, July 28, 1987.

A Sense of Déjà Vu: The Debate Surrounding State Biosimilar Substitution Laws

²⁶ IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013* (Parsippany, NJ, April 2014).

²⁷ Generic prescription drug use has generated more than \$1.2 trillion in savings to the U.S. health care system between 2003 and 2012. Generic Pharmaceutical Association, *Generic Drug Savings in the U.S., Fifth Annual Edition: 2013* (Washington, DC, 2013).

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