



Competition Inhibitors

How Biologics Makers Are Leveraging Political Power to Maintain Monopolies and Keep Prices Sky-High

Acknowledgments

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Introduction

Biologics are a rapidly growing class of medications derived from biological sources, and often produced using biotechnology methods, that provide novel therapies for a range of medical conditions.¹ Most believe that the future of the pharmaceutical industry rests with biologics.²

If that's so, that future is on a path to be extraordinarily expensive.

Protected by robust monopolies, biologics makers are charging astounding sums for their products, and biologics already make up a significant share of drug expenses. In 2012, total global spending on biologic medications amounted to \$169 billion, representing 18% of total drug spending.³ As of 2011, the U.S. market accounted for just under half of that spending on biologics.⁴ In 2010, eight of the top 10 most costly Medicare Part B drugs were biologics, with the most expensive drug claiming \$2 billion in Medicare funds.⁵

On a per patient basis, many biologics have staggering price tags.⁶ For example, the annual cost of an important biologic used to treat breast cancer, Herceptin, amounts to \$37,000

¹ “Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources — human, animal, or microorganism — and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available.” Food and Drug Administration, “What Are ‘Biologics’ Questions and Answers,” available at: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm>

² John Carroll, “Tufts: Big Pharma Bets Its Future on a Swelling Pipeline of Biologics,” FierceBiotech, November 18, 2013, available at: <http://www.fiercebiotech.com/story/tufts-big-pharma-bets-its-future-swelling-pipeline-biologics/2013-11-18>.

³ IMS Institute for Healthcare Informatics, “The Global Use of Medicines: Outlook Through 2017” November 2013, p.9, available at http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Global_Use_of_Meds_Outlook_2017/IIHI_Global_Use_of_Meds_Report_2013.pdf.

⁴ Leigh Purvis, “Biologics in Perspective: The New Biosimilar Approval Pathway,” AARP Public Policy Institute, October 2011, available at <http://www.aarp.org/health/drugs-supplements/info-10-2011/Biologics-in-Perspective-The-New-Biosimilar-Approval-Pathway.html>.

⁵ U.S. Government Accountability Office, “Medicare: High-Expenditure Part B Drugs,” GAO-13-46R 7, 2012, available at <http://www.gao.gov/assets/650/649459.pdf>.

⁶ See Alfred B. Engelberg, Aaron S. Kesselheim & Jerry Avorn, “Balancing Innovation, Access, and Profits — Market Exclusivity for Biologics,” 361 New England Journal of Medicine 1917, pp. 1917–19 2009; Anthony D. So & Samuel L. Katz, “Biologics Boondoggle,” New York Times, March 8, 2010, available at: < http://www.nytimes.com/2010/03/08/opinion/08so.html?_r=0>.

per person.⁷ The cost to treat patients with rheumatoid arthritis or Crohn's disease with another biologic, Humira, is \$50,000 per year per person.⁸ And most astonishingly, the cost of the biologic Cerezyme, a treatment for Gaucher disease, a rare inherited enzyme deficiency, is \$200,000 a year.⁹

Biologics are more complicated to manufacture than traditional, small-molecule pharmaceuticals. But the super-high cost of biologics is a result not of research-and-development or manufacturing costs, but government-granted monopolies.

For traditional, small-molecule drugs, generic competition typically reduces prices by 80 percent or more, when a sufficient number of competitors are present; and there is every reason to anticipate steep price reductions for biologics with robust generic competition.¹⁰

Even conservative estimates suggest that generic competition for biologics can save enormous sums. Express Scripts has estimated that increased substitution of generic versions of biologics (often called "biosimilars") for their reference products can save around \$250 billion in healthcare costs from 2014 to 2024.¹¹

It is precisely for this reason that brand-name biologics makers have ardently resisted generic competition. For years, the biologics industry argued that generic competition should be prevented altogether, because of the purported insuperable challenges in copying biologics and making safe and effective generic versions. Eventually, this position became untenable, and the industry shifted to supporting a legislative framework that would formally authorize generic competition — but simultaneously impose enormous barriers to generic entry.

In 2010, the U.S. Congress passed the Biologic Price Competition and Innovation Act (BPCIA) as part of the Affordable Care Act eventually signed into law by President Obama.

⁷ Anthony D. So & Samuel L. Katz, "Biologics Boondoggle," New York Times, March 8, 2010, available at: < http://www.nytimes.com/2010/03/08/opinion/08so.html?_r=0>.

⁸ Anthony D. So & Samuel L. Katz, "Biologics Boondoggle," New York Times, March 8, 2010, available at: < http://www.nytimes.com/2010/03/08/opinion/08so.html?_r=0>.

⁹ See Alfred B. Engelberg, Aaron S. Kesselheim & Jerry Avorn, "Balancing Innovation, Access, and Profits—Market Exclusivity for Biologics," 361 New England Journal of Medicine 1917, pp. 1917–19 2009; Anthony D. So & Samuel L. Katz, "Biologics Boondoggle," New York Times, March 8, 2010, available at: < http://www.nytimes.com/2010/03/08/opinion/08so.html?_r=0>.

¹⁰ Food and Drug Administration, "Generic Competition and Drug Prices," available at: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>.

¹¹ Joseph P. Fuhr Jr., "Lower Price, Greater Access to Life-Saving Drug," The Hill, July 30, 2014, available at: <http://thehill.com/blogs/congress-blog/healthcare/213702-lower-price-greater-access-to-life-saving-drugs>.

Legislative proposals floated during the previous few years to give the Food and Drug Administration (FDA) authority to license generic versions of biologics for sale were incorporated into the overall health care debate, and the Affordable Care Act does include a “regulatory pathway” for biosimilars. However, a strong lobbying effort led by the industry trade associations — the Biotechnology Industry Organization (BIO) and the Pharmaceutical Researchers and Manufacturers Association (PhRMA) — successfully thwarted efforts to devise a system that would enable a robust market for biosimilars. Market entry for biosimilars is proceeding excruciatingly slowly.

Meanwhile, the brand-name biologics companies continue to advocate for still more barriers to competition, focusing major efforts at state, federal and international levels.

Existing barriers to competition and those for which the industry is still advocating are costing patients and taxpayers untold billions of dollars, and threaten even greater costs long into the future. They are also, inevitably, denying patients access to needed medicines.

None of this has anything to do with science, assuring fair returns on investment for brand-name companies or patient safety. The barriers to competition are entirely a result of the leveraging of the political power of the biologics pharmaceutical industry.

This report examines how the industry has deployed and is deploying that political power. Part I provides background on biologic medications and their differences from traditional, small-molecule drugs. Part II recounts how the brand-name biologics industry managed to turn legislation intended to introduce competition in the biologics market into a law that impedes generic entry; and briefly contrasts the American with the European experience, where biosimilar competition is leading to major cost savings. Part III explains how the industry is now working at the federal level for policies intended to deter biosimilar prescription and patient uptake, and at the state level to interfere with pharmacist dispensation of biosimilars. Part IV explains how the brand-name industry is advocating for trade agreement provisions that would both lock in monopoly protections in the United States and force other countries to adopt similar, anti-competitive measures. Part V looks at the industry’s federal political and lobbying expenditures. Part VI reports on the industry funding behind patient groups allied with biotech companies in the Alliance for Safe Biologic Medicines.

Existing biologics offer some important medical therapies, and biologics offer the promise of even more important treatments and cures in the future. But the promise of biologics will be denied to many if the industry is able to leverage its political power to obtain and maintain monopolies that leave key products priced out of range of many.

I. Background on Biologics and Biosimilars

Biopharmaceuticals, or biologics, are medical products derived from living cells or organisms, such as animal or human blood.¹² They can take many different forms, including vaccines, cells, and gene therapies, and can be used to both treat disease as well as diagnose it.¹³ Since 1982, the U.S. Food and Drug Administration (FDA) has approved over 250 biologics,¹⁴ and, in 2013, there were approximately 125 different approved prescription biologic products available on the U.S. market (not counting separate approvals for new doses).¹⁵ Biologics have become especially important in the fields of oncology, rheumatology and endocrinology.¹⁶

Biologics differ from traditional, small-molecule drugs in that they tend to be much larger with more complex structures, due to the fact they are based on proteins and not chemically active molecules. They are generally manufactured in living systems, such as a microorganism or animal or plant cells. In contrast, small molecule drugs are typically produced through chemical synthesis.¹⁷ Due to the inherent variability of the biologic system and the manufacturing process, biological medications will display a certain degree of variability (microheterogeneity) even between different batches of the same product.¹⁸ This variability can result in small alterations to the drug's chemical structure,¹⁹ which can, in turn, affect the biologic's efficacy. In contrast, the size of chemically

¹² See Martina Weise, et al., "Biosimilars: What Clinicians Should Know," 120 *Blood* 5111, 2012, available at: <http://www.bloodjournal.org/content/120/26/5111.long?sso-checked=true>.

¹³ See "What is a Biological Product?" U.S. Food and Drug Administration, available at: www.fda.gov/AboutFDA/Transparency/Basics/ucm194516.htm.

¹⁴ Thijs J. Giezen et al., "Safety-Related Regulatory Actions for Biologics Approved in the United States and the European Union," 300 *Journal of the American Medical Association*, 1887, (2008).

¹⁵ "User Fee Billable Biologic Products and Potencies Approved Under Section 351 of the PHS Act," U.S. Food and Drug Administration, December 2013, available at: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm122936.htm>.

¹⁶ Stacy Lawrence and Riku Lahteenmaki, "Public Biotech 2013 — The Numbers," *Nature Biotechnology* 32,626–632, available at: <http://www.nature.com/nbt/journal/v32/n7/full/nbt.2949.html>; Pharmaceutical Researchers and Manufacturers of America, "Biologics Overview," available at: <http://www.phrma.org/sites/default/files/pdf/biologicsoverview2013.pdf>.

¹⁷ See U.S. Food and Drug Administration, Guidance for Industry: Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009, 2012, available at: <http://www.fda.gov/downloads/Drugs/Guidances/UCM273001.pdf>.

¹⁸ See Martina Weise, et al., "Biosimilars: What Clinicians Should Know," 120 *Blood* 5111, 2012, available at: <http://www.bloodjournal.org/content/120/26/5111.long?sso-checked=true>.

¹⁹ See, e.g., Shawn Glidden, "The Generic Industry Going Biologic," 20 *Biotechnology Law Report* 172, pp. 172-73, 2001.

synthesized, small-molecule drugs enables traditional, small-molecule drug manufacturers to produce highly uniform products.²⁰

Generic versions of biologic medications are commonly referred to as biosimilars. As with generic versions of traditional, small-molecule drugs, biosimilar drugs are intended to be used at the same doses and dosing regimens to treat the same medical conditions as their reference products. Several biosimilars have been licensed and become available in the European Union, and many other biosimilars are currently in the development process.²¹ There are at least four key biologic medicines — used to in treatments for cancer, growth disorders and auto-immune diseases — for which biosimilars are currently available to European patients. Recent data compiled by IMS Institute for Healthcare Informatics show that the introduction of these biosimilars to European markets in 2006 has led to substantial price savings.²²

The public health concern with biosimilars is ensuring sufficient comparability to their brand-name reference products. “Because of unavoidable differences in the manufacturing processes, a biosimilar and the respective originator product, the reference product, will not be entirely identical,”²³ although the same point applies even to different batches of a biologic from a single, brand-name manufacturer. As with different batches, it is possible to manufacture a biosimilar that possesses the same amino acid sequence as its reference product and only slight microheterogeneity between products.²⁴ The differing nature of the process for replicating biologics as compared to traditional, small-molecule drugs means that extra care must be taken to ensure the copies are sufficiently similar, making it reasonable to adopt different tests for biosimilars than generic drugs.²⁵ However, as one regulator underscores, it “should be emphasized” that the scientific principles underlying the comparability of reference and follow-on biologic products are the same as those used

²⁰ See U.S. Food and Drug Administration, “What Are “Biologics” Questions and Answers” available at: www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm.

²¹ See Martina Weise, et al., “Biosimilars: What Clinicians Should Know,” 120 Blood 5111, 2012, available at: <http://www.bloodjournal.org/content/120/26/5111.long?sso-checked=true>.

²² IMS Institute for Healthcare Informatics, “Assessing Biosimilar Uptake and Competition in European Markets,” October 2014, available at: http://www.imshealth.com/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Insights/Assessing_biosimilar_uptake_and_competition_in_european_markets.pdf.

²³ Martina Weise, et al., “Biosimilars: What Clinicians Should Know,” 120 Blood 5111, 2012, available at: <http://www.bloodjournal.org/content/120/26/5111.long?sso-checked=true>.

²⁴ See Martina Weise, et al., “Biosimilars: What Clinicians Should Know,” 120 Blood 5111, 2012, available at: <http://www.bloodjournal.org/content/120/26/5111.long?sso-checked=true>.

²⁵ See, e.g., Martina Weise, et al., “Biosimilars: What Clinicians Should Know,” 120 Blood 5111, 2012, available at: <http://www.bloodjournal.org/content/120/26/5111.long?sso-checked=true>.

to assess changes in the manufacturing process of a given reference biologic drug, “for which guidance and experience already exist.”²⁶

Until 2010, U.S. law did not provide a clear pathway for the entry of generic biologic drugs onto the U.S. market. The debate over how to create a pathway might have focused only on the public health issue of ensuring the safety, effectiveness, and comparability of generic products. However, BIO managed to frame the debate primarily over how to protect the profitability of the brand-name industry, arguing for the creation of new government monopolies beyond those afforded by standard patent protection, on the grounds that these were needed to spur innovation. The industry would eventually be able to leverage its political power to overcome pro-consumer measures proposed by the primary shepherd of the House of Representative’s healthcare legislation, Rep. Henry Waxman, and the preferred approach of the Obama administration.

Having won in Congress, the brand-name biologics makers have focused their recent efforts at maintaining their extremely profitable monopolies on state laws, federal rules and international trade agreements. Over time, the industry has shifted messaging away from “protecting innovation” to “ensuring safety” — but its overriding goal of preserving its monopolies continues unabated.

²⁶ Martina Weise, et al., “Biosimilars: What Clinicians Should Know,” 120 Blood 5111, 2012, available at: <http://www.bloodjournal.org/content/120/26/5111.long?sso-checked=true>.

II. History of the Biologics Price Competition and Innovation Act

On March 23, 2010, Congress passed the Biologics Price Competition and Innovation Act (BPCIA) as part of the Affordable Care Act.²⁷

The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, had created an abbreviated pathway for the entry of generic versions of traditional, small-molecule drugs. Under Hatch-Waxman, when a company seeks approval from the FDA to sell a generic version of an already approved 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 to show safety and efficacy.

But Hatch-Waxman did not address biosimilar market entry.²⁸

The BPCIA would create that pathway for biosimilar market entry — but, as it turned out, on terms very favorable to the brand-name industry.

As the biotechnology industry began to deliver an increasing number of important biologics to the market, and with those products' price tags increasingly shocking, generic manufacturers, drug purchasers and consumer advocates started advocating in the 2000s for clarification of a pathway for biosimilar entry onto the U.S. pharmaceutical market.²⁹ While some argued that the FDA already possessed the authority to approve biosimilars under the Federal Food, Drug, and Cosmetic Act (FDCA) or the Public Health Services Act, others contended the FDA held no such power.³⁰ The question was mooted by 2007, when bipartisan agreement emerged to legislate to create a biosimilars pathway.³¹

A. The Pathway to Biosimilar Approval

At the outset of the debate, BIO and PhRMA basically argued that there could be no pathway for biosimilars; that making safe and effective copies of biologics was impossible;

²⁷ Biologics Price Competition and Innovation Act of 2009 § 7002, 42 U.S.C. § 262 (Supp. V 2012).

²⁸ Erwin A. Blackstone & Joseph P. Fuhr, Jr., "Generic Biopharmaceutical Drugs: An Economic and Policy Analysis," 4 *Biotechnology Healthcare* 43, p. 44, 2007.

²⁹ Parker Tresemer, "FDA Regulations under the Biologics Price Competition and Innovation Act," 16 *UCLA Journal of Law and Technology* 1, p. 7, 2012.

³⁰ Krista Hessler Carver et al., "An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009," 65 *Food and Drug Law Journal* 671, pp. 698-99, 2010, available at: <http://www.lawtechjournal.com/home/articles/340>.

³¹ Krista Hessler Carver et al., "An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009," 65 *Food and Drug Law Journal* 671, p. 699, 2010, available at: <http://www.lawtechjournal.com/home/articles/340>.

and that generic versions of biologics should be required to undergo the same testing requirements as new drugs.³² The industry groups took the position that differences in the manufacturing processes of brand-name and biosimilar producers would be so significant that “both preclinical safety and clinical studies are expected to be necessary for follow-on protein products in order to protect patients.”³³ Moreover, BIO contended that use of the term “comparability” to describe the relationship between certain brand-name and generic biologic products was “misleading.”³⁴ Accordingly, BIO suggested that to “avoid confusion,” the term “comparability” should “not be used in the discussion of follow-on protein products.”³⁵ Many brand-name manufacturers, such as Amgen and Genentech,³⁶ contended as well that biosimilars could not be shown to be pharmaceutically equivalent to their reference products³⁷ and a “full complement of critical animal and clinical studies”³⁸ must be required to justify approval of biosimilars.

When the generics industry pointed out that the same logic could be used to argue that changes to intra-manufacturer production processes result in different, and non-interchangeable products, PhRMA asserted that the brand-name manufacturers’ “complete knowledge of the entire manufacturing process ..., as well as significant historical experience with manufacturing the product and validating manufacturing changes,”³⁹

³² Krista Hessler Carver et al., “An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009,” 65 Food and Drug Law Journal 671, pp. 708-709, 2010, available at: <http://www.lawtechjournal.com/home/articles/340>.

³³ Letter from Sara Radcliffe, BIO, to FDA, Comments, Docket No. FDA-20040N-0059 (formerly 2004N-0355), at 25 (December 13, 2004), available at: <http://www.bio.org/sites/default/files/20041213.pdf>.

³⁴ Letter from Sara Radcliffe, BIO, to FDA, Comments, Docket No. FDA-20040N-0059 (formerly 2004N-0355), at 13 (December 13, 2004), available at: <http://www.bio.org/sites/default/files/20041213.pdf>.

³⁵ Letter from Sara Radcliffe, BIO, to FDA, Comments, Docket No. FDA-20040N-0059 (formerly 2004N-0355), at 13 (December 13, 2004), available at: <http://www.bio.org/sites/default/files/20041213.pdf>.

³⁶ Genentech is a subsidiary of Roche.

³⁷ Krista Hessler Carver et al., “An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009,” 65 Food and Drug Law Journal 671, p. 712, 2010, available at: <http://www.lawtechjournal.com/home/articles/340>. (citing Letter from Kenneth Seamon, Amgen, Inc., to FDA, Docket No. FDA-2004-N-0059 (formerly 2004N-0355), at 9-10 (November 12, 2004) (“Amgen took the position, for example, that the concept of ‘therapeutic equivalence’ could not apply, because ‘proteins cannot be characterized and duplicated in the same way as small molecule drugs.’”).

³⁸ Krista Hessler Carver et al., “An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009,” 65 Food and Drug Law Journal 671, p. 712, 2010, available at: <http://www.lawtechjournal.com/home/articles/340>. (citing Letter from Robert L. Garnick, Genentech, Inc. to Steven Galson, M.D., FDA, Docket No. FDA-2004-N-0059 (formerly 2004N-0355), at 3 (November 11, 2004).

³⁹ Krista Hessler Carver et al., “An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009,” 65 Food and Drug Law Journal 671, p. 712, 2010, available at:

insulated changes to their internal manufacturing processes from the issues associated with generic biologic products.

The battle over biosimilars was fought from 2006-2010 through a series of bills introduced by proponents of generic competition and those favored by the brand-name industry. The brand-name industry eventually moved away from the position that biosimilars should be required to undergo the same kinds of testing as originator products — but it didn't concede much else.

BIO and PhRMA defeated the approach included in pro-competition bills introduced by Representative Henry Waxman (D-CA) and Senator Charles Schumer (D-NY). The Access to Life-Saving Medicine Act introduced in the House and Senate as H.R. 6257 and S.4016, on September 29, 2006⁴⁰ and an amended version of the Access to Life-Saving Medicine Act, introduced in February 2007, established two distinct regulatory pathways for the approval and licensure of biologic products. The bills would have permitted the FDA to approve comparable biologic products (close copies of biologic products) while establishing a second pathway for products not directly comparable to their reference products, so long as applicants established the products' safety, purity, and potency relative to their reference products.⁴¹ The second version would have required biosimilar applicants to submit more extensive data demonstrating product comparability and interchangeability.⁴² Waxman would later introduce a third bill, the Promoting Innovation and Access to Life-Saving Medicine Act, that maintained the dual pathway approach.

A series of brand-name industry-endorsed alternatives to the Waxman-Schumer legislation provided only for a single pathway for biosimilar approval, characterized by heavy testing burdens.

- In April 2007, Representative Jay Inslee (D-WA) introduced the Patient Protection and Innovative Biologic Medicines Act. The Inslee bill permitted the FDA only to approve generic biologic products that were close copies of their reference products. The bill set forth a number of very stringent data requirements that biosimilar companies would have to meet before the FDA

<http://www.lawtechjournal.com/home/articles/340>. (citing Letter from Caroline J. Loew, PhRMA, to FDA, Comments, Docket No. FDA-20040N-0059 (formerly 2004N-0355) (November 12, 2004).

⁴⁰ Parker Tresemer, "FDA Regulations under the Biologics Price Competition and Innovation Act," 16 UCLA Journal of Law and Technology 1, 17 (2012), available at:

<http://www.lawtechjournal.com/home/articles/340>.

⁴¹ H.R. 6257, 109th Cong. § 3(a)(2) (2006) (proposed Public Health Services Act §§ 351(k)(1), (k)(2)).

⁴² Parker Tresemer, "FDA Regulations under the Biologics Price Competition and Innovation Act," 16 UCLA Journal of Law and Technology 1, 19-20 (2012), available at:

<http://www.lawtechjournal.com/home/articles/340>.

could approve a biosimilar product.⁴³ Additionally, it only permitted the entry of therapeutic proteins, excluding other biologics, such as vaccines and blood products.⁴⁴ In the 2007-2008 election cycle, Inslee received more campaign contributions from the pharmaceutical industry than any other field.⁴⁵ Biologic maker Amgen was the second largest source of his career campaign funds after hometown company Microsoft.⁴⁶

- Senator Judd Gregg (R-NH) introduced a companion to the Inslee bill, the Affordable Biologics for Consumers Act (ABCA), into the Senate as S. 1505. Like Representative Inslee, Senator Gregg received more campaign funding from the pharmaceutical sector than any other industry and his third largest donor was Amgen.⁴⁷
- In March 2008, Representative Anna Eshoo (D-CA) introduced the Pathway for Biosimilars Act of 2008, containing many elements of the Inslee bill, and another iteration of the bill in March 2009. Over her career, Representative Eshoo has received more campaign contributions from the pharmaceutical industry than any other,⁴⁸ with Johnson & Johnson the largest source of funds over the course of her career.⁴⁹

In July 2009, the Eshoo legislation was incorporated into the House of Representatives version of the Affordable Care Act (see below), with just a single pathway for biosimilar approval authorized. Having conceded that biosimilars could exist, BIO won an overwhelming victory on the subsequent battle over creation of a regulatory pathway for approval of biosimilars.

Under Section 351(k) of the BPCIA, a competitor may obtain approval to market a biosimilar if it can show that it “highly similar” to its reference product based on analytic, animal and clinical studies. The biosimilar applicant must further establish that its product

⁴³ Krista Hessler Carver et al., “An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009,” 65 Food and Drug Law Journal 671, pp. 739-740, 2010; Parker Tresemer, “FDA Regulations under the Biologics Price Competition and Innovation Act,” 16 UCLA Journal of Law and Technology 1, 22 (2012), available at: <http://www.lawtechjournal.com/home/articles/340>.

⁴⁴ Krista Hessler Carver et al., “An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009,” 65 Food and Drug Law Journal 671, pp. 739-740, 2010, available at: <http://www.lawtechjournal.com/home/articles/340>.

⁴⁵ See data compiled by Center for Responsive Politics, available at: <https://www.opensecrets.org/politicians/industries.php?cycle=2008&cid=N00001725&type=I>.

⁴⁶ See data compiled by Center for Responsive Politics, available at: <https://www.opensecrets.org/politicians/contrib.php?cycle=Career&type=I&cid=N00001725&newMem=N&recs=20>.

⁴⁷ See data compiled by Center for Responsive Politics, available at: <https://www.opensecrets.org/politicians/industries.php?cycle=2010&cid=N00000444&type=I>.

⁴⁸ See data compiled by Center for Responsive Politics, available at: <https://www.opensecrets.org/politicians/industries.php?cycle=Career&cid=N00007335&type=I>.

⁴⁹ See data compiled by Center for Responsive Politics, available at: <https://www.opensecrets.org/politicians/contrib.php?cycle=Career&cid=N00007335&type=I>.

uses the same mechanism of action as the reference product; that the strength, dosage and route of administration are the same as for the reference product; and that the facility in which the biosimilar will be marketed meets standards to ensure the product will be safe, pure and potent.⁵⁰ Summarizing the standard for biosimilarity, the FDA explains, “A biological product may be demonstrated to be ‘biosimilar’ if data show that the product is ‘highly similar’ to the reference product notwithstanding minor differences in clinically inactive components and there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency.”⁵¹

A competitor that meets the standards of biosimilarity may also seek to have its product designated as an “interchangeable.” To be designated an interchangeable, the manufacturer must show that the biosimilar will produce the same clinical result as the reference product in any patient.⁵² An interchangeable product should be completely substitutable with the brand-name reference product. Explains the FDA: “In order to meet the higher standard of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product in any given patient and, for a biological product that is administered more than once, that the risk of alternating or switching between use of the biosimilar product and the reference product is not greater than the risk of maintaining the patient on the reference product. Interchangeable products may be substituted for the reference product by a pharmacist without the intervention of the prescribing health care provider.”⁵³

At the time of writing this report, the FDA has not yet finalized its guidance for the data that a biosimilars manufacturer should submit to obtain approval of a biosimilar product.⁵⁴

B. Marketing Exclusivity

BIO was not satisfied only with creating an obstacle-laden pathway for biosimilar approvals. The industry insisted it needed special monopoly protections known as “data and marketing exclusivity,” beyond the monopolies afforded by 20-year patents.

⁵⁰ BPCIA, Sec. 351(k)

⁵¹ Food and Drug Administration, “Implementation of the Biologics Price Competition and Innovation Act of 2009,” available at: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm215089.htm>.

⁵² BPCIA, Sec. 351(k)(4)

⁵³ Food and Drug Administration, “Implementation of the Biologics Price Competition and Innovation Act of 2009,” available at: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm215089.htm>.

⁵⁴ See U.S. Food and Drug Administration, “Guidance for Industry: Clinical Pharmacological Data to Support a Demonstration of Biosimilarity to a Reference Product,” available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM397017.pdf>.

When a generic company shows the FDA that its product is the same as, or essentially identical, to an already approved brand-name small-molecule drug product, it relies on, but does not repeat, the clinical tests performed by the brand-name maker to show safety and efficacy. These clinical tests are both time-consuming and relatively expensive (comprising the majority of brand-name companies' research and development costs). Data and marketing exclusivity prohibits the generic firm from relying on the brand-name test data, effectively barring the generic competitor from the market for a set period of time. While 20-year patent terms begin at the time a product is invented, the period of data and marketing exclusivity begin later, at the time the FDA approves a product to be sold.

Under the Hatch-Waxman scheme for authorizing generic versions of traditional, small-molecule pharmaceuticals, brand-name products are given five years of data exclusivity. In most cases, although they begin much earlier, patent terms will extend longer than the five-year marketing monopoly afforded by data exclusivity for traditional, small-molecule drugs.⁵⁵

BIO, however, demanded much more than five years data and marketing exclusivity. It demanded 12-14 years, a period that would in many cases extend monopoly protection beyond that available from patents. Expansive data and marketing exclusivity was needed because drug development is expensive and risky, the industry claimed. Exclusivity, according to its proponents, was necessary both to provide an incentive for brand-name companies to undertake research and development (R&D) and to ensure that they are not placed at unfair disadvantage as against "free-riding" generic firms.

These arguments for expansive data and marketing exclusivity are not compelling.

First, the industry already had strong patent protection. BIO insisted nonetheless that the patent system inadequately incentivized R&D. It warned that there is the "very real potential" patent protection would not provide the incentives needed for continued biologics innovation and that patent protection might be narrow for many biologics, enabling generics manufacturers to design around patent claims.

The most powerful rebuttal to this claim about the limits of patent protection for biologics came from BIO itself. In lobbying for a patent reform bill, citing accomplishments in biotechnology, the trade group stated, "All of this innovation is possible because of the certainty and predictability provided by the U.S. patent system."

⁵⁵ See Henry Grabowski et al., *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, *Managerial and Decision Economics*, 28 (2007) 491–502, available at: <http://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/6727/GenComp%26MarkaetExclusivity.pdf?sequence=1>.

And indeed, as former FTC Commissioner Pamela Jones Harbour pointed out, “patents are far more numerous and complex” for biologics than traditional drugs.⁵⁶

Second, there had been no showing that biologic products involved significantly greater R&D costs than traditional, small-molecule drugs, and therefore no rationale for why the period of exclusivity should be longer. At the time, the brand-name drug companies pointed to industry-funded academic studies purportedly showing that the R&D cost for a typical, traditional, small-molecule drug was \$1.2 billion, while the R&D cost for a biologic was \$1.3 billion.⁵⁷ While these estimates were, to say the least, highly questionable, and in the eyes of many drastically overstated, the relevant point here is the rough equivalence of the figures.

Third, even in the absence of exclusivity or patent protection, brand-name firms enjoy both the same benefits as first entrants in conventional pharmaceutical markets (including building up brand-name identity and allegiance) and advantages unique to the biologics market. Even after generics are permitted to enter the market, biologics may enjoy a period of de facto exclusivity resulting from the difficulties inherent in producing them. As with brand-name companies, it will also take generic firms several years to develop FDA-approved manufacturing processes for biologics, and even with a streamlined regulatory pathway — which today remains politically contested — this approval process will likely be considerably longer and more expensive in many cases than for conventional drugs.

Indeed, the Federal Trade Commission found in a 2009 study that very substantial hurdles may impede biosimilar makers from gaining market share, and that there will be numerous built-in delays for competition to develop for any particular product. These include:⁵⁸

- “The lack of automatic substitution between an FOB [follow-on biologic — a biosimilar] product and a pioneer biologic drug will slow the rate at which an FOB product can acquire market share and thereby increase its revenues. In small-molecule drug markets, automatic substitution erodes a branded

⁵⁶ Pamela Jones Harbour, “The Competitive Implications of Generic Biologics,” June 14, 2007, p. 16, available at: http://www.ftc.gov/sites/default/files/documents/public_statements/competitive-implications-generic-biologics/070614genbio_0.pdf.

⁵⁷ Joseph A. DiMasi and Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different? Managerial and Decision Economics* (2007) 28: 469-479, available at: <http://onlinelibrary.wiley.com/doi/10.1002/mde.1360/abstract>.

⁵⁸ Federal Trade Commission, “Emerging Healthcare Issues: Follow-On Biologic Drug Competition,” June 2009, p. iv, available at: <http://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf>.

- manufacturers' market share quickly once the first generic product enters the market. This situation is unlikely to occur in FOB markets."
- "An FOB drug also may have difficulty gaining market share due to concerns about safety and efficacy differences between a pioneer biologic drug and the competing FOB. Physicians and their patients who have been taking a pioneer biologic drug may be reluctant to switch to an FOB due to a risk that the patients will react differently to the FOB than to the pioneer drug. Concerns such as these may limit FOB market opportunities to newly diagnosed patients."
 - "The specialty pharmaceutical characteristics of FOBs also are likely to constrain the ability of an FOB entrant to obtain market share. ... Because most biologic products are delivered to patients in clinics, hospitals, doctor's offices, or other medically supervised settings, shifting to another biologic product is typically more costly because it requires restocking of inventory and retraining of nurses and healthcare providers."

The costs of expanded exclusivity were plain enough. In general, if biosimilar firms are unable to use or rely on originators' data, they will not enter the market until the period of exclusivity expires. Redoing the tests conducted by brand-name companies is not only wasteful, it is frequently too time-consuming and expensive for the relatively low-capitalized generic industry to manage, not to mention unethical in the case of testing that involves humans. Thus data and marketing exclusivity confer an effective marketing monopoly for the term of the exclusivity period, potentially delaying the onset of generic competition, keeping medicine prices high for a longer period of time.

Where patent monopolies extend beyond the period of exclusivity provided, data and marketing exclusivity may have little practical effect.⁵⁹

But with an exclusivity period of 12 years, in many cases data and marketing exclusivity will provide monopolies that last longer than those conferred by patents. With blockbuster medications commonly earning more than \$1 billion a year, every year's extension of a drug's monopoly can result in a significant transfer of income from consumers and insurers to drug makers.

Having carefully considered the detailed arguments submitted by the brand-name industry as well as proponents of competition, the Federal Trade Commission in a lengthy

⁵⁹ One important case where data exclusivity matters even when it runs concurrent with a patent term is where the relevant patents are held to be invalid. In such cases, the brand-name company is able to obtain patent-like monopolies despite not having a valid patent. In such cases, it is not clear that the brand name product contributes significantly to innovation, and it is not clear that the public should insulate the company from competition. Indeed, when a product lacks the innovative properties to qualify for patent protection, it is generally in the interest of innovation to promote competition, so that the next innovations — like another company's improvement on an existing drug — are not held up by exclusive rights.

investigation forcefully concluded that expanded exclusivity could not be justified on policy grounds. Central to each of the pharmaceutical marketing exclusivities that Congress has created, the Commission noted, “is a public policy trade-off: a restriction on competition is provided in return for a development of a new drug product or new use of an existing product. A 12- to 14-year exclusivity period, however, departs sharply from this basic trade-off, because it does not spur the creation of a new product or indication. The drug has already been incentivized through patent protection and market-based pricing.”⁶⁰ The Commission held open the possibility that some exclusivity might be merited in instances where patent protection could not be obtained for new products, though it noted that “there is no evidence about the lack of patentability of new biologic products.”⁶¹

But as with other matters, the debate on exclusivity was to be resolved not based on the evidence, but on political power. BIO was able to effectively flex its power to win the day, and the Affordable Care Act provided for 12 years of exclusivity.

C. Passage of the Affordable Care Act

As the House Energy and Commerce Committee moved to mark-up of the Affordable Care Act, industry-allied Members of the Congress insisted on incorporation of Representative Eshoo’s bill, which provided the industry-favored single pathway for regulatory approval and the industry-preferred data and marketing exclusivity period of a dozen years.

On July 13, 2009, members of the New Democrat Coalition wrote to the Speaker of the House Nancy Pelosi (D-CA), proclaiming their support for Eshoo’s biosimilar bill and “urging that this language be included in the final version of the House health care reform bill.”⁶² In response, on July 14, several House Democrats, including Representative Waxman, “unveiled their proposed health care reform legislation without biosimilars language or even a placeholder.”⁶³ Because the biologics pathway act proposed by Representative Eshoo would impede efficient biosimilar market entry and create elongated

⁶⁰ Federal Trade Commission, “Emerging Healthcare Issues: Follow-On Biologic Drug Competition,” June 2009, p. 45, available at: <http://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf>.

⁶¹ Federal Trade Commission, “Emerging Healthcare Issues: Follow-On Biologic Drug Competition,” June 2009, p. 45, available at: <http://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf>.

⁶² Krista Hessler Carver et al., “An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009,” 65 Food and Drug Law Journal 671, p. 802, 2010, available at: <http://www.lawtechjournal.com/home/articles/340>.

⁶³ Krista Hessler Carver et al., “An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009,” 65 Food and Drug Law Journal 671, p. 802, 2010, available at: <http://www.lawtechjournal.com/home/articles/340>.

marketing monopolies, Chairman Waxman preferred that the healthcare reform bill make no provision for biosimilars, rather than create an obstacle-laden path for biosimilar introduction.

Yet the BIO-backed machine ploughed over Chairman Waxman, who otherwise exerted enormous power as chairman of his committee and the primary shepherd of the Affordable Care Act legislation.

After Rep. Eshoo introduced the legislation in mark-up, Chairman Waxman made the case against it:

I know that members of this committee support creation of a biosimilar pathway. I know they believe it will bring competition and reduce the high price of biologics. I endorse that. But I strongly believe that adoption of this amendment is exactly the wrong way to achieve increased competition and lower prices, nor will it enhance innovation.

This amendment enacts a lengthy monopoly period, 12 years, and then allows those periods to be extended indefinitely, the so-called evergreening problem. The evidence is overwhelming that these open-ended monopolies will create huge obstacles to competition.⁶⁴

Waxman knew that he did not have the votes to carry the day. “I understand a large majority of this committee supports this amendment,” he said. “I do not. And I will continue to make my case that we need real competition to bring down the cost of the fastest growing segment of our Nation’s drug bill, not endless monopolies for the drug industry.”⁶⁵

After a limited debate on the amendment, Waxman called for a voice vote. There was no doubt what the result would be. “All those in favor say aye. Opposed no. The ayes have it.”

But that was not enough for Rep. Eshoo, who ignored the pleas of Waxman to gracefully accept her victory:

Ms. Eshoo. Request a roll call vote, Mr. Chairman.

⁶⁴ Transcript, Markup of H.R. 3200, America’s Affordable Health Choices Act of 2009, July 31, 2009, 31, 2009, House Of Representatives, Committee On Energy And Commerce, p. 244, available at: <http://democrats.energycommerce.house.gov/sites/default/files/documents/Transcript-HR-3200-FC-2009-7-31.pdf>

⁶⁵ Transcript, Markup of H.R. 3200, America’s Affordable Health Choices Act of 2009, July 31, 2009, 31, 2009, House Of Representatives, Committee On Energy And Commerce, p. 245, available at: <http://democrats.energycommerce.house.gov/sites/default/files/documents/Transcript-HR-3200-FC-2009-7-31.pdf>

The Chairman. The gentlelady from California requests a roll call vote?

You have won. Do you want a roll call vote?

Mr. Barton. Mr. Chairman, I will request a roll call vote if she wants it.

The Chairman. Well, if you want it, we will go with it.

Ms. Eshoo. I would like one.

Mr. Barton. I request a roll call vote.

The Chairman. Let's go to a roll call vote.

The Eshoo amendment passed 47-11.

Meanwhile, the same approach was adopted in the Senate healthcare legislation, where an amendment set forth by Senators Orrin Hatch (R-UT), Mike Enzi (R-WY), and Kay Hagan (D-NC), was added in the Health, Education and Labor and Pensions Committee in July.⁶⁶ Indeed, before it was incorporated into the House legislation, Eshoo tweaked her biologics legislation so it tracked the version in the Senate.

Subsequently, the White House, in a very late and last-minute effort, urged "significant changes to [the] biosimilars provisions in health care reform legislation," including a "a shorter exclusivity period" and changes to the language "believe[d] [to] allow drug makers to secure additional 12-year periods by making minor changes to their products."⁶⁷ However, in January 2010, Republican Scott Brown won the Massachusetts Senate seat left vacant after the death of Senator Ted Kennedy. This effectively meant that for the legislation to be adopted, the House would have to pass the version of legislation that had passed the full Senate on December 24. Mindful that Senator Brown had campaigned on an anti-Affordable Care Act platform, the White House dropped its late and last-ditch effort to address the exclusivity issue. On March 21, the House passed the Affordable Care Act, which included the BPCIA, and on March 23, 2010, the president signed this bill into law.⁶⁸

Having abandoned its claims from only a few years previous that biosimilars should be prohibited per se, the brand-name biologics industry had prevailed on its most important

⁶⁶ Parker Tresemer, "FDA Regulations under the Biologics Price Competition and Innovation Act," 16 UCLA Journal of Law and Technology 1, 26 (2012), available at: <http://www.lawtechjournal.com/home/articles/340>.

⁶⁷ "White House Pressing for New Biosimilars Policy in Reform Talks," FDA Week, January 15, 2010.

⁶⁸ Krista Hessler Carver et al., "An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009," 65 Food and Drug Law Journal 671, p. 806, 2010, available at: <http://www.lawtechjournal.com/home/articles/340>.

priorities. Biosimilars would be permitted in the United States, but only on the very difficult terms imposed by the brand-name industry. Though the industry couched its arguments in terms of public health and fair returns on investment, the final result was a reflection of the quality not of its policy arguments, but its lobbying power.

D. Lagging Behind

As subsequent sections in this report discuss, even the BPCIA's partial promise of competition for biologics products has yet to be fulfilled. The FDA has not yet established a regulatory pathway for approval of biosimilars; the brand-name industry is lobbying for biosimilar naming conventions that would significantly deter physicians from prescribing and patients from accepting biosimilars; and the brand-name industry has advocated for state rules that would burden pharmacists seeking to substitute interchangeable biosimilars.

Yet there is no doubt about the potential benefits of competition in the biologics industry. Europe has proceeded with the approval of biosimilars, and recorded very significant price savings as a result.

Because European countries in general engage in various forms of price controls or negotiated tenders, European prices for brand-name products are generally considerably cheaper than those in the United States.⁶⁹

Yet the introduction of competition in the biologics market has led to very substantial cost-savings in Europe, according to IMS. In its study of prices for four biologics for which biosimilars are now available in Europe, IMS found considerable variation between countries in biosimilar penetration and evolution of prices from 2006 to 2013, but quite dramatic price savings in many countries. Introduction of biosimilar competition for erythropoietin (EPO) — used to control red blood cell production, and commonly prescribed with dialysis and with oncology treatments — led to price declines of 36 percent in Austria, 81 percent in Croatia, 55 percent in Germany and 13 percent in Sweden. The median price reduction across European countries was 35 percent. Biosimilar competition for granulocyte colony-stimulating factor (G-CSF) — used with some cancer

⁶⁹ See J. Cohen, A. Malins, Z. Shahpurwala, “Compared to U.S. practice, Evidence-Based Reviews in Europe Appear to Lead to Lower Prices for Some Drugs,” *Health Affairs*, 2013 April;32(4):762-70, available at: <http://www.ncbi.nlm.nih.gov/pubmed/23569057>; The Economist, “Costly Cures,” June 7, 2014, available at: <http://www.economist.com/news/business/21603453-american-fight-over-expensive-new-treatments-has-global-implications-costly-cures>; Decision Resources, “**European Prices of 170 Best-Selling Drugs Averaged 40 Percent Less Than U.S. Prices in 2008,**” July 7, 2009, available at: <http://www.fiercebiotech.com/press-releases/european-prices-170-best-selling-drugs-averaged-40-percent-less-u-s-prices-2008-0>.

patients to accelerate recovery from neutropenia — has led to price drops of 79 percent in Bulgaria, 22 percent in France, 50 percent in Norway and 40 percent in Spain.⁷⁰

Additionally, while noting that many factors account for prescribing decisions and total treatment volume, IMS found that — as biosimilars became available — treatment generally became much more accessible, with product usage rates generally much increased.⁷¹

III. The Next Fight: Naming and Prescribing Rules

A. What's in a Name: Non-Proprietary Names for Biosimilars

With the federal legislative fight over biosimilars behind it, BIO has moved to other fora to deter generic competition, targeting its lobbying efforts at the World Health Organization⁷² and the FDA⁷³ over the naming of biosimilars. The dispute is whether interchangeable biosimilars should share a generic name with brand-name products, as is the case with traditional, small-molecule drugs, or whether they should be given distinct generic names. There is a legitimate patient safety issue in ensuring that identical names on products with clinically important variations could lead to inappropriate substitution. From a regulatory standpoint, however, the best way to avoid inappropriate substitution is to ensure that biosimilars designated as interchangeable can indeed be substituted without risk to patients, and this is the FDA's charge under the BPCIA. From the pro-competitive standpoint, the worry is that distinct names will massively interfere with the substitution of interchangeable biosimilars for brand-name products, as doctors and patients doubt whether the products are legitimately substitutable.

In September 2013, the Generic Pharmaceutical Association (GPhA) petitioned the FDA to implement its International Non-Proprietary Naming (INN) naming policy so as to apply

⁷⁰ IMS Institute for Healthcare Informatics, “Assessing Biosimilar Uptake and Competition in European Markets,” October 2014, p. 19, available at: http://www.imshealth.com/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Insights/Assessing_biosimilar_uptake_and_competition_in_European_markets.pdf.

⁷¹ IMS Institute for Healthcare Informatics, “Assessing Biosimilar Uptake and Competition in European Markets,” October 2014, p. 20, available at: http://www.imshealth.com/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Insights/Assessing_biosimilar_uptake_and_competition_in_European_markets.pdf.

⁷² Zachary Brennan, “WHO Proposes ‘Biological Qualifiers’ to Deal With Biosimilar Naming Issues,” Biopharma Reporter, September 4, 2014, available at: <http://www.biopharma-reporter.com/Markets-Regulations/WHO-looks-to-solve-biosimilar-naming-issues>.

⁷³ Zachary Brennan, “AbbVie, Genentech, Amgen Split from Novartis, Call for Non-Proprietary Biosimilars Names,” Biopharma Reporter, April 1, 2014, available at: <http://www.biopharma-reporter.com/Markets-Regulations/AbbVie-Genentech-Amgen-split-from-Novartis-call-for-non-proprietary-biosimilars-names>.

equally to all biologics, so that brand-name biologics and biosimilar would share the same non-proprietary name. GPhA argued that concerns about biologics pharmacovigilance — tracking, assessing and monitoring the safety of biologics — should be carried out through robust track-and-trace methods applying to all products, brand-name and biosimilar alike, not by distinguishing between names. “Unsubstantiated concerns regarding biosimilar nomenclature must not be used as an anti-competitive barrier to biosimilar development and commercialization,” contended GPhA.⁷⁴

A long list of health care payers have lent their support to this pro-competitive position. In a July 1, 2014 letter to the FDA, organizations and companies including the AFL-CIO, CVS Caremark, Express Scripts, MetLife, the National Association of Chain Drug Stores and Walgreens wrote to the FDA, echoing the GPhA position: “We believe that the legislative intent of the biosimilar approval pathway included in the Patient Protection and Affordable Care Act was to support the development of less expensive but equally effective alternatives to biologic drugs. However, requiring different INNs would create an unnecessary barrier to the benefits of FDA-determined interchangeability.”⁷⁵

The brand-name biologics industry has argued for rejection of the GPhA petition and the use of separate names for brand-name products and biosimilars. In its comment on the GPhA petition, BIO argues, “we believe that a system that assigns the same name to products that are similar, but not the same, would create confusion for physicians and patients, hinder effective pharmacovigilance, and could jeopardize patient safety.” Among BIO’s justifications for its position is that “scientifically justified manufacturing changes performed throughout the lifecycles of biological products, for both biosimilars and their reference products, may result in incremental changes to those products. Such incremental product changes, when compounded over time, are sometimes referred to as ‘drift,’ but are better characterized as ‘product evolution’ for each given product with the resulting potential for ‘product divergence’ among a set of originally related products. ... The reality of product evolution and divergence supports the need for distinguishable names.”⁷⁶

The journal Nature Biotechnology has editorialized with a powerful rebuttal of the BIO position, contending that separate non-proprietary names for biosimilars “could mean biosimilars arrive stillborn to the market.” The editorial clarified directly what is at stake:

⁷⁴ Generic Pharmaceutical Association, citizen petition to the FDA, September 17, 2013, available at: <http://www.regulations.gov/#!documentDetail;D=FDA-2013-P-1153-0001>.

⁷⁵ Academy of Managed Care Pharmacy et. al. letter to Margaret Hamburg, FDA, July 1, 2014, available at: http://www.gphaonline.org/media/cms/Ltr_to_FDA_on_biosimilars_INN_June_2014.FINAL.pdf.

⁷⁶ Tom DiLenge and Sara Radcliffe, BIO, BIO Comments to Generic Pharmaceutical Association Citizen Petition Requesting the Food and Drug Administration to Implement its INN Naming Policy Equally to all Biologics, January 31, 2014, available at: <https://www.bio.org/sites/default/files/2014-01-31%20BIO%20Naming%20Response%20GPhA%20FINAL.pdf>.

“clinicians who prescribe drugs — and the patients who receive them — will assume the naming difference indicates the biosimilar has a different mechanism of action from the brand drug. In other words, it introduces uncertainty in the mind of the prescriber and provides a disincentive to use a cheaper biosimilar.” The editorial also rebutted the BIO argument relating to minor modifications in biologic products over time, pointing out what the industry calls “product evolution” and “divergence” is equally true for brand-name products themselves as for biosimilars — that is, that brand-name biologics themselves evolve slightly over time, including because of changes in manufacturing methods — but that the brand-name industry is not suggesting these changes should lead to evolving names for brand-name products. Concludes Nature Biotechnology: “The logical inconsistency of arguing for a different INN for a biosimilar (which is deemed by regulators as comparable to an originator product) but keeping the same INN for a brand biologic produced by a different process (which is deemed by regulators as comparable to an originator product) seems to have escaped the Biotechnology Industry Organization (BIO).”⁷⁷

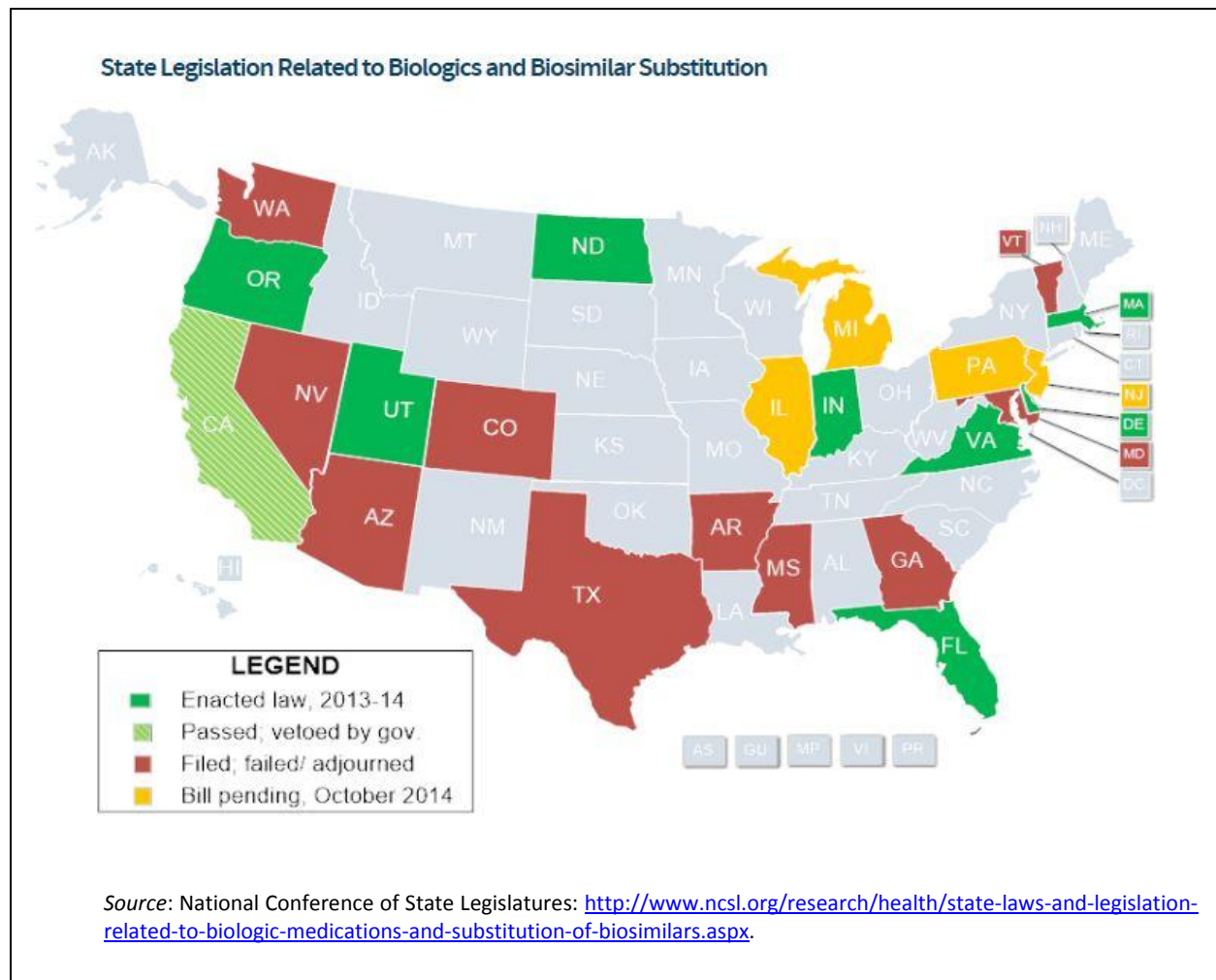
B. State Laws and Lobbying on Biologics

Meanwhile, BIO has waged a vast campaign at the state level to impose burdensome requirements on pharmacists seeking to substitute FDA-approved interchangeable biosimilars for biological products⁷⁸ — even before the FDA has established the approval pathway for biosimilars and established rules regarding interchangeability. Eight states — Delaware, Florida, Indiana, Massachusetts, North Dakota, Oregon, Utah and Virginia — have already passed legislation restricting substitution, and another 15 states have considered or are still considering similar bills, according to data maintained by the National Conference of State Legislatures.⁷⁹

⁷⁷ “The INN Crowd,” Nature Biotechnology 31, 1055 (2013), available at: <http://www.nature.com/nbt/journal/v31/n12/full/nbt.2760.html>.

⁷⁸ Richard Cauchi, “State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars,” National Conference of State Legislatures, available at: <http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx>.

⁷⁹ Richard Cauchi, “State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars,” National Conference of State Legislatures, available at: <http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx>.



Although the exact provisions of these laws vary from state to state, they frequently share the following requirements:

- Any biological product under consideration for substitution must be certified and listed as interchangeable by the FDA.
- Prescribers must be able to prevent substitution by writing “dispense as written” or “brand medically necessary” on the prescription;
- The prescriber must be notified of any allowable substitution made at a pharmacy;
- Individual patients must be notified of and consent to substitutions made in certain cases;
- Pharmacists and physicians must retain records of substituted biologic medications; and
- The state must maintain a public list of permissible interchangeable products.⁸⁰

⁸⁰ Richard Cauchi, “State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars,” National Conference of State Legislatures, available at: <http://www.ncsl.org/>

These provisions are carefully designed to seem commonsensical. However, as with the naming dispute, the intent of these provisions is to cast doubt in the minds of doctors and patients on the substitutability of interchangeable biosimilars — even though the BPCIA charges the FDA with establishing rigorous testing requirements to establish exactly this standard — as well as to impose time and cost obligations on pharmacists that will deter them from substituting biosimilars. “By imposing additional requirements on pharmacists when they dispense a biosimilar product that has been certified by the FDA as interchangeable, this bill could undermine patients and health care providers’ trust in these products,” noted the California Public Employees’ Retirement System (CalPERS) in opposing a California version of the anti-substitution language.⁸¹ CalPERS noted reasonably that the same standards for substitution as apply to traditional, small-molecule drugs should apply to biologics certified by FDA as interchangeable, and that these standards should adequately protect public health and facilitate effective competition. (Of course, it is possible that FDA will fail to establish an adequate standard of interchangeability, at which point there might be a need to impose additional state requirements; but there is no reason to expect or presume such a failure in advance of the FDA issuing its standard.)

In California in 2013, the biologics anti-substitution bill, SB 598, sailed through the legislature by a 60-4 vote in the California Assembly and a 30-2 vote in the California Senate.⁸² However, CalPERS and other insurers, pharmacists and labor unions persuaded Governor Jerry Brown to veto the bill. Brown expressed concern that certain provisions of the bill “would cast doubt on the safety and desirability of more cost-effective alternatives to biologics.”⁸³

After the California veto, BIO stated that it was disappointed in Governor Brown’s decision: “As other states continue to address issues related to biosimilars, BIO encourages policy makers to continue to put patients first.”⁸⁴

[research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx](http://www.fda.gov/oc/2013/05/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx).

⁸¹ California Public Employees Retirement System, “Senate Bill 598 (Hill) — Prescription Drugs: Biosimilar Products,” May 14, 2013, available at: <http://www.calpers.ca.gov/eip-docs/about/committee-meetings/agendas/pension/201305/item-7b.pdf>.

⁸² Jeff Overley, “California Governor Vetoes Biosimilars Substitution Bill,” Law 360, October 15, 2013, available at: <http://www.law360.com/articles/480315/calif-governor-vetoes-biosimilars-substitution-bill>.

⁸³ Andrew Pollack, “Governor Brown of California Vetoes Biotech Drug Bill,” New York Times, October 13, 2013, available at: http://www.nytimes.com/2013/10/14/us/gov-brown-of-california-vetoes-biotech-drug-bill.html?_r=0.

⁸⁴ Andrew Pollack, “Governor Brown of California Vetoes Biotech Drug Bill,” New York Times, October 13, 2013, available at: http://www.nytimes.com/2013/10/14/us/gov-brown-of-california-vetoes-biotech-drug-bill.html?_r=0.

The brand-name industry had a lot to be disappointed about; it had spent good money to push the legislation through the legislature. According to reports on file with California's Secretary of State, entities lobbying for passage of SB 598 included AbbVie, Amgen, BIO, Genentech and PhRMA. The records do not disclose how much was spent lobbying on SB 598 versus other industry priorities (and PhRMA in particular lobbied on a long list of bills), but the companies and trade groups reported spending big money in Sacramento in the 2013-2014 legislative session: \$522,000 for AbbVie, \$293,000 for Amgen, \$157,000 for BIO, \$423,000 by Genentech, and \$1.04 million by PhRMA.⁸⁵

There is no clamor from public health groups for anti-substitution legislation in states — and no good public health rationale for imposing barriers beyond the science-based standards that FDA will adopt for determining interchangeability — so it should come as little surprise that the state action on this issue appears driven by the brand-name industry's exercise of political power and insider influence.

Virginia passed an anti-substitution bill in 2013. Dr. John O'Bannon III, the Republican delegate who introduced the legislation in the Virginia House, told the New York Times that "he did so because as a practicing neurologist, he was familiar with biologicals."⁸⁶ However, he also acknowledged that "[t]he Amgen folks actually did come and talk to me."⁸⁷ According to the Virginia Public Access Project, Amgen gave \$22,000 to Virginia state legislators in both 2011 and 2012, more than double the \$11,000 it gave in 2010. Of that total, Dr. O'Bannon received \$1,500 from 2012 to 2013.

According to the Virginia Public Access Project database, companies supporting the anti-substitution legislation spent at least \$242,000 on lobbying in the 2012-2013 legislation session, led by Amgen with a \$63,000 expenditure.⁸⁸

The brand-name biologics industry also played a strong role in the passage of North Dakota's biologics substitution law. As the state senator who introduced the law in North

⁸⁵ Disclosure statements available at: <http://cal-access.sos.ca.gov/Lobbying>.

⁸⁶ Andrew Pollack, "Biotech Firms, Billions at Stake, Lobby States to Limit Generics," New York Times, January 28, 2013, available at: <http://www.nytimes.com/2013/01/29/business/battle-in-states-on-generic-copies-of-biotech-drugs.html>.

⁸⁷ Andrew Pollack, "Biotech Firms, Billions at Stake, Lobby States to Limit Generics," New York Times, January 28, 2013, available at: <http://www.nytimes.com/2013/01/29/business/battle-in-states-on-generic-copies-of-biotech-drugs.html>.

⁸⁸ Disclosure data available at: http://www.vpap.org/lobbyists/bills_display/41495?year=2013.

Dakota, Senator Dick Dever, explained to the New York Times, “Genentech was the one that brought the bill to me.”⁸⁹

Similarly, the New York Times reports that, in Indiana, Genentech and Eli Lilly brought a draft bill to the chairman of House Public Health Committee, Ed Clere. Clere asserted the bill “doesn’t do anything to prevent or discourage the use of biosimilars.”⁹⁰ Indiana passed anti-substitution legislation in 2014, including all of the key anti-substitution features. Genentech and local company Eli Lilly lobbied hard in the legislature during the year, reporting spending \$40,000 and \$181,000 respectively.⁹¹

Across the country, the story is basically the same: the brand-name companies are throwing around money and relying on insiders to pitch their preferred bills. In Illinois, for example, BIO has employed as lobbyists Julie Curry,⁹² a former state legislator and former deputy chief of staff for ex-Governor Rod Blagojevich,⁹³ and Shaw Decrember,⁹⁴ a former top staffer for powerful Illinois Speaker of the House Michael Madigan known for his take-no-prisoners approach.⁹⁵

As this report was going to press, BIO and GPhA announced an agreement to support legislation that would involve automatic pharmacist reporting to prescribers of the name of the product and manufacturer in every case where a biologic is prescribed. No reporting would be required where no interchangeable is available or for refills. How this compromise agreement is translated into state legislative action remains to be seen.⁹⁶

⁸⁹ Andrew Pollack, “Biotech Firms, Billions at Stake, Lobby States to Limit Generics,” New York Times, January 28, 2013, available at: <http://www.nytimes.com/2013/01/29/business/battle-in-states-on-generic-copies-of-biotech-drugs.html>.

⁹⁰ Andrew Pollack, “Biotech Firms, Billions at Stake, Lobby States to Limit Generics,” New York Times, January 28, 2013, available at: <http://www.nytimes.com/2013/01/29/business/battle-in-states-on-generic-copies-of-biotech-drugs.html>.

⁹¹ Disclosure data available at: <http://www.in.gov/ilrc/2335.htm>.

⁹² Disclosure data available at: <http://www.ilsos.gov/lobbyistsearch/registrationpdf?procID=REG&transType=ANNUAL&year=2014&entityID=5221&webDataXmlId=50032>.

⁹³ Michael Hawthorne, “EPA Chief Turns Coal Lobbyist,” Chicago Tribune, February 9, 2006, available at: http://articles.chicagotribune.com/2006-02-09/news/0602090094_1_mercury-pollution-coal-fired-power-plants-toxic-metal.

⁹⁴ Disclosure data available at: <http://www.ilsos.gov/lobbyistsearch/registrationpdf?procID=REG&transType=ANNUAL&year=2014&entityID=6695&webDataXmlId=51031>.

⁹⁵ John Chase, David Kidwell and Ray Long, “Madigan consolidates power by holding sway in legislative races,” Chicago Tribune, June 5, 2012, available at: http://articles.chicagotribune.com/2012-06-05/news/ct-met-madigan-campaign-operation-20120605_1_madigan-legislative-races-legislative-session.

⁹⁶ Fiona Barry, “GPhA Reaches Compromise on Thorny Biosimilars Substitution Question,” BioPharma Reporter, December 12, 2014, available at: <http://www.biopharma-reporter.com/Markets->

IV. International Trade and Investment Agreements

In addition to influencing federal and state law-making, the brand-name biologics and pharmaceutical industry expends considerable resources lobbying the Office of the U.S. Trade Representative (USTR) to ensure that its interests are further protected by U.S. trade agreements with other nations.

The industry has a structurally favored position at the agency, with representatives serving on key advisory committees that are able to review secret draft trade agreement text and comment on early versions of both U.S. and partner country draft proposals. Represented on the Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products and Services (ITAC 3)⁹⁷ are Amgen, PhRMA, Airmed Biotech and Johnson & Johnson. The Generic Pharmaceuticals Association also has a representative on this committee. Represented on the Industry Trade Advisory Committee for Intellectual Property (ITAC 15)⁹⁸ are Gilead, Johnson & Johnson, PhRMA and BIO. Also represented on this committee are the Generic Pharmaceuticals Association and Mylan. There are no consumer representatives on either of these committees, and only a single consumer representative among the hundreds of advisors in the USTR system.

Intellectual property-reliant companies have also benefited from a fast-spinning revolving door between USTR and pharmaceutical and copyright industries. In recent years, former USTR negotiators left the agency for jobs with Abbott Pharmaceuticals (Abbott has since split into two firms, one of which is the biopharmaceutical company AbbVie), Eli Lilly and BIO, among other industry landing places.⁹⁹

Since adoption of the North American Free Trade Agreement (NAFTA) and arguably before, U.S. trade agreements have included intellectual property chapters that provide monopoly guarantees for pharmaceutical manufacturers. These include requirements to provide 20-year patents, data exclusivity and prohibitions on drug regulatory agencies granting marketing approval for drug that are potentially covered by patents (a provision known as

[Regulations/GPhA-reaches-compromise-on-thorny-biosimilars-substitution-question](#). See also “New Fall 2014 Compromise Language,” available at:

http://www.gphaonline.org/media/cms/New_Fall_2014_Compromise_Language_1.pdf.

⁹⁷ Industry Trade Advisory Committee on Chemicals, Pharmaceuticals, Health/Sciences Services, member list, available at: <http://ita.doc.gov/itac/committees/itac03.asp>.

⁹⁸ Industry Trade Advisory Committee on Intellectual Property Rights, member list, available at: <http://ita.doc.gov/itac/committees/itac15.asp>.

⁹⁹ Timothy Lee, “Here’s why Obama Trade Negotiators Push the Interests of Hollywood and Drug Companies,” Washington Post, November 26, 2013, available at: <http://www.washingtonpost.com/blogs/the-switch/wp/2013/11/26/heres-why-obama-trade-negotiators-push-the-interests-of-hollywood-and-drug-companies>.

“linkage”). Mirroring U.S. law for traditional, small-molecule pharmaceuticals, most U.S. trade agreements call for five years of data exclusivity.

Most recently, industry has pushed hard for inclusion of dramatically longer data and marketing exclusivity — mirroring the win scored by BIO in the Affordable Care Act. The issue has been most heated in negotiation of a trade deal between the U.S. and 11 other countries in the Asia-Pacific region (Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam), known as the Trans-Pacific Partnership (TPP).

Towards this end, the brand-name biologics industry has published a barrage of op-eds and other news articles pushing for heightened protection of brand-name biologic drugs. For example, the presidents of BIO and PhRMA published an article in 2012, asserting “[t]he bottom-line is that the biopharmaceutical research sector is a national asset and is essential to our health and economic future. If we fail to act, including in the current TPP negotiations, there will be profound consequences — for patient access to innovative medicines as well as for our economy.”¹⁰⁰ This article, like many others, focuses on the import of the biopharmaceutical industry to the U.S.’s economy and competitive advantage over other nations.

The brand-name biologics lobby has successfully enlisted elected officials to echo its interests. In September 2011, Senators Mark Udall (D-CO) and Michael Bennet (D-CO) sent a letter to Ambassador Ron Kirk, the United State Trade Representative, in which they “stress[ed] the importance of proposing a high standard of intellectual property rights for biologics, which is consistent with the 12 years of exclusivity under U.S. law.”¹⁰¹ The letter also emphasized that “we hope that the Office of the U.S. Trade Representative finalizes its negotiations in a manner that reflects U.S. law on biologics exclusivity standards.”¹⁰² A second letter, authored by Senators Orrin Hatch (R-UT) and John Kerry (D-MA) and signed by 35 other senators, stated that “[w]hile the views of individual members of Congress may differ as to the desirability of [the TPP] negotiations, we are united in urging you to propose a strong minimum term of regulatory data protection for biologics consistent with

¹⁰⁰ James Greenwood & John J. Castellani, “U.S. Negotiators on TPP — Don’t Trade Away the Biopharmaceutical Research Sector,” Patent Docs, [September 30, 2012](http://www.patentdocs.org/2012/09/us-negotiators-on-tpp-dont-trade-away-the-biopharmaceutical-research-sector.html), available at: <http://www.patentdocs.org/2012/09/us-negotiators-on-tpp-dont-trade-away-the-biopharmaceutical-research-sector.html>.

¹⁰¹ Letter from Senators Mark Udall and Michael F. Bennet, to Ambassador Ron Kirk, United States Trade Representative, September 12, 2011, available at <http://patentdocs.typepad.com/files/udall-bennet-letter.pdf>.

¹⁰² Letter from Senators Mark Udall and Michael F. Bennet, to Ambassador Ron Kirk, United States Trade Representative, September 12, 2011, available at <http://patentdocs.typepad.com/files/udall-bennet-letter.pdf>.

U.S. law.”¹⁰³ After noting that the “U.S. law provides for a 12-year term of regulatory data protection for biologics,” the senators urged that this 12-year period “should serve as the baseline for the administration’s objectives for this aspect of the negotiation.”¹⁰⁴

The most recent version of the intellectual property chapter of the TPP, which was released by Wikileaks on October 16, 2014, demonstrates that their efforts have been successful: the U.S.’s proposal for the TPP’s provision on data and marketing exclusivity for biologic drugs would grant brand-name biologics 12 years of exclusivity.¹⁰⁵

This is a far greater achievement and exercise of political influence than is apparent at first glance. While the industry has already secured a 12-year exclusivity period in the United States, the Obama administration not only opposed this lengthy monopoly when it was adopted, it continues to do so. Each of the President Obama’s budgets has called for reducing exclusivity to seven years. The 2015 budget projects that this reduction in exclusivity, along with another measure to increase generic competition, would save the federal government \$15 billion over a 10-year period.¹⁰⁶

However, if the USTR wins the 12-year exclusivity provision it is aggressively pushing in the TPP negotiations, the United States will be foreclosed from reducing its domestic exclusivity term.

In other words, BIO and PhRMA lobbyists have convinced the USTR, a White House agency, to propose a position that directly contravenes the position officially favored by the White House, and which would preclude the White House from winning a favored policy change that it believes would save taxpayers billions of dollars!

¹⁰³ Letter from Senators Orrin G. Hatch and John F. Kerry, to Ambassador Ron Kirk, United States Trade Representative, September 12, 2011, available at <http://patentdocs.typepad.com/files/hatch-kerry-letter.pdf>.

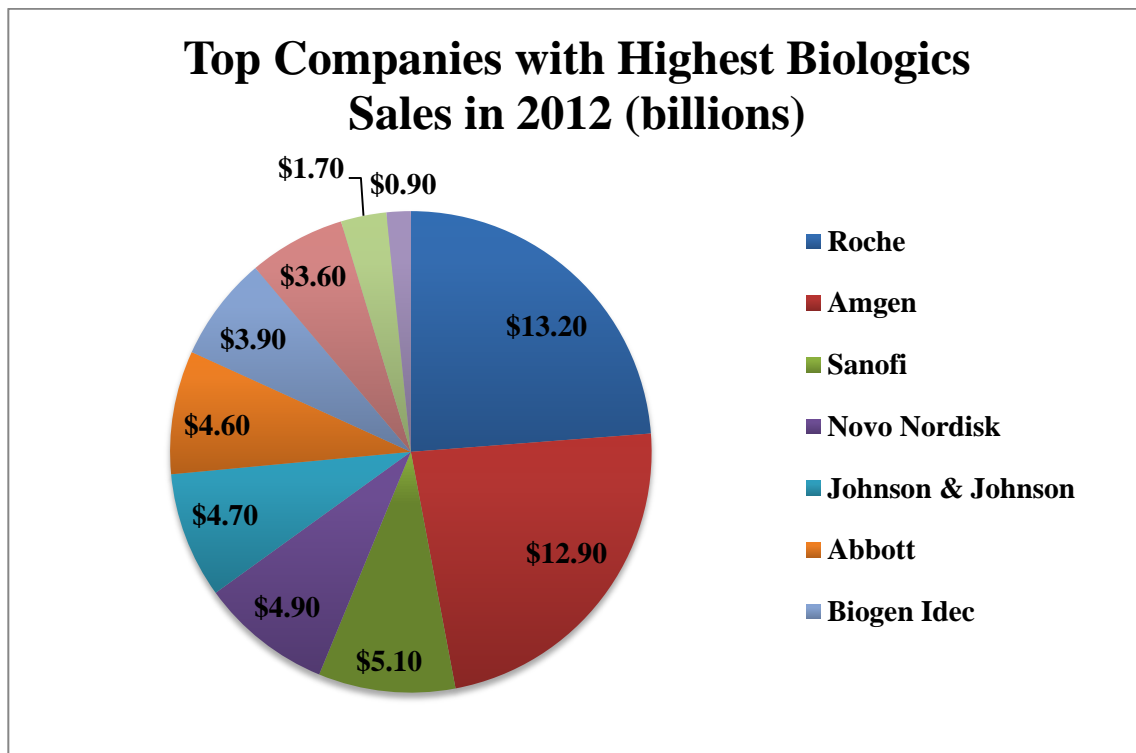
¹⁰⁴ Letter from Senators Orrin G. Hatch and John F. Kerry, to Ambassador Ron Kirk, United States Trade Representative, September 12, 2011, available at <http://patentdocs.typepad.com/files/hatch-kerry-letter.pdf>.

¹⁰⁵ “Secret Trans-Pacific Partnership Agreement (TPP) — IP Chapter,” Wikileaks, October 16, 2014, available at: <https://wikileaks.org/tpp>.

¹⁰⁶ Executive Office of the President of the United States, “Fiscal Year 2015 Budget of the U.S. Government,” p. 32, available at: <http://www.whitehouse.gov/sites/default/files/omb/budget/fy2015/assets/budget.pdf>

V. Bio/Pharma's Political Power in Profile

The biotech industry has gained political power in no small part by positioning itself as distinct from the traditional pharmaceutical industry. It has cultivated the image of little-engine-that-could start up companies, spun off from research university biology labs. In this way it has sought to position itself as innovative and progressive as distinct from stodgy Big Pharma. The image was never valid, because there has always been a deep interconnection between the biotechnology and Big Pharma. By now, while there are certainly many tiny biotech start-ups, the image of the biotech industry as separate and distinct from Big Pharma has no basis in reality: biologics are well-integrated into the portfolios of the old-line drug giants, which are the biggest biologics sellers; one of the two largest start-up biotechs, Genentech, is now owned by Roche; and the business model of most small biotechnology companies involve gaining funding from, licensing to, or being acquired by a giant pharmaceutical maker.



Source: Saurabh Aggarwal, "What's Fueling the Biotech Engine—2012 to 2013," 32 Nature Biotech 32, p. 33, 2014.

It is the case that there is a separate trade association for biotechnology companies, BIO, and it does represent many smaller biotech companies, but its largest members are the

same as those of PhRMA. Pfizer, Merck and Johnson & Johnson serve on the organization's executive committee.¹⁰⁷ Meanwhile, PhRMA, seeking to associate with the image of the new biotech companies, defines itself as representing "the country's leading biopharmaceutical researchers and biotechnology companies." In other words, the rivalry between the two trade associations notwithstanding, they both represent the interests of the brand-name biologics industry.

Individually, together, and as an aggregate of the political investments of the member companies, BIO and PhRMA have enormous political power and influence. As an industry and through its trade association, Big Pharma's political reach is legendary. For many years, the industry leaned heavily Republican. In the 2002 midterms, the industry spent extraordinarily heavily on Republican candidates and took and earned very significant credit for keeping the House of Representatives in Republican hands.¹⁰⁸ When the Medicare Part D benefit was created during the Bush II administration, the enacting legislation was heavily criticized as a giveaway to Big Pharma; and even during the roll call vote, it appeared there weren't sufficient Republican votes to pass the bill in the House. Yet in what became the longest roll call vote in the history of the House, Billy Tauzin, the lead champion of the bill and chair of the House Commerce Committee, twisted enough arms to win passage.¹⁰⁹ Remarkably, Tauzin, who had had a cancerous tumor removed and treated with the biologic Avastin, would leave the House even before his term expired, to become the CEO of PhRMA.¹¹⁰

Tauzin, however, would engineer a political repositioning of Pharma, moving it to become far more bipartisan in its support and political strategy, beginning immediately after the 2006 wave election that turned both the House of Representatives and Senate from Republican to Democratic control.¹¹¹ From this new, bipartisan stance, Tauzin and PhRMA were able to cut a deal with the Obama administration to avoid any meaningful

¹⁰⁷ Executive Committee, Biotechnology Industry Organization, available at: <https://www.bio.org/node/3848>.

¹⁰⁸ Adam Nagourney, "The 2002 Elections: The Overview," The New York Times, November 6, 2002, available at: <http://www.nytimes.com/2002/11/06/us/2002-elections-overview-gop-retakes-control-senate-show-presidential-influence.html>.

¹⁰⁹ Michelle Singer, "Under the Influence," CBS News, July 23, 2007, available at: <http://www.cbsnews.com/news/under-the-influence>.

¹¹⁰ Robert Pear, "House's Author of Drug Benefit Joins Lobbyists," The New York Times, December 16, 2004, available at: <http://www.nytimes.com/2004/12/16/politics/16drug.html?fta=y&r=0>.

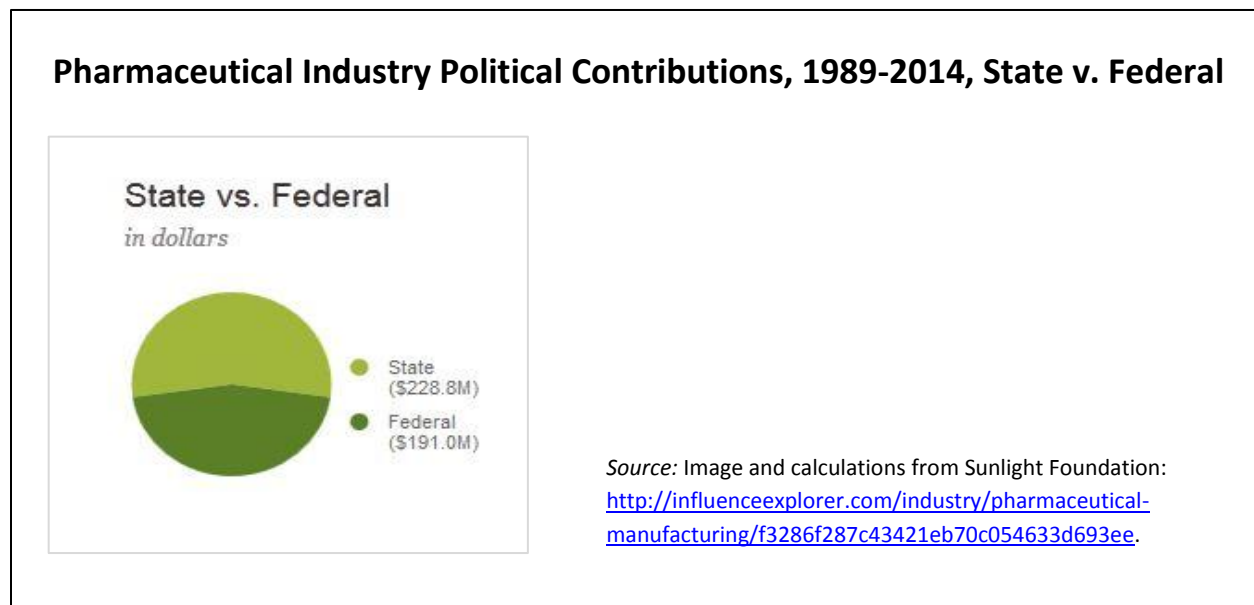
¹¹¹ Center for Responsive Politics, "Pharmaceuticals/Health Products," available at: <http://www.opensecrets.org/industries/indus.php?ind=H04>.

pharmaceutical price controls in the Affordable Care Act (although, ironically, some in the industry apparently thought he cut too soft a deal).¹¹²

If anything, Pharma's political strength increased under Tauzin. And, the industry's overall political influence was enhanced still further by the rising importance of biologics in the pharmaceutical industry product mix, with biotechnology and PhRMA's rival, BIO, giving the industry the sheen of sleekness, scrappiness and innovativeness. "Innovation" has always been the industry's calling card — with research and development expenses the central justification for government-granted monopolies, high prices and no price controls — and the de facto merging of the biotech industry into the pharmaceutical industry has enhanced both sides' political influence.

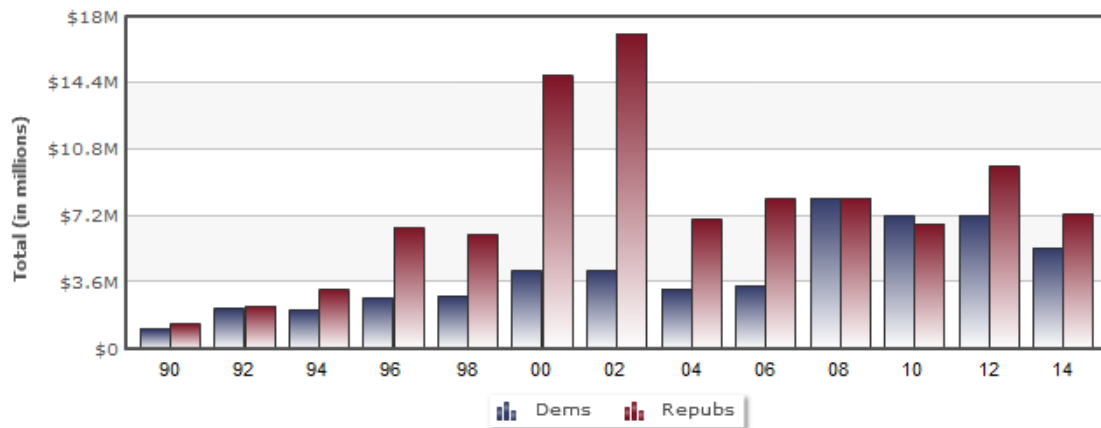
The pharmaceutical industry is a major contributor to elections, providing more than \$400 million in reported contributions over the last quarter century, according to a data analysis from the Sunlight Foundation, split roughly evenly between state and federal elections. One pure biotech company, Amgen, has forced its way into the top 10 list of biggest pharmaceutical industry campaign spenders.

The following graphics produced by the Sunlight Foundation and the Center for Responsive Politics detail the industry's political spending.



¹¹² David D. Kirkpatrick and Duff Wilson, "One Grand Deal Too Many Costs Lobbyist His Job," The New York Times, February 12, 2010, available at: <http://www.nytimes.com/2010/02/13/health/policy/13pharm.html>.

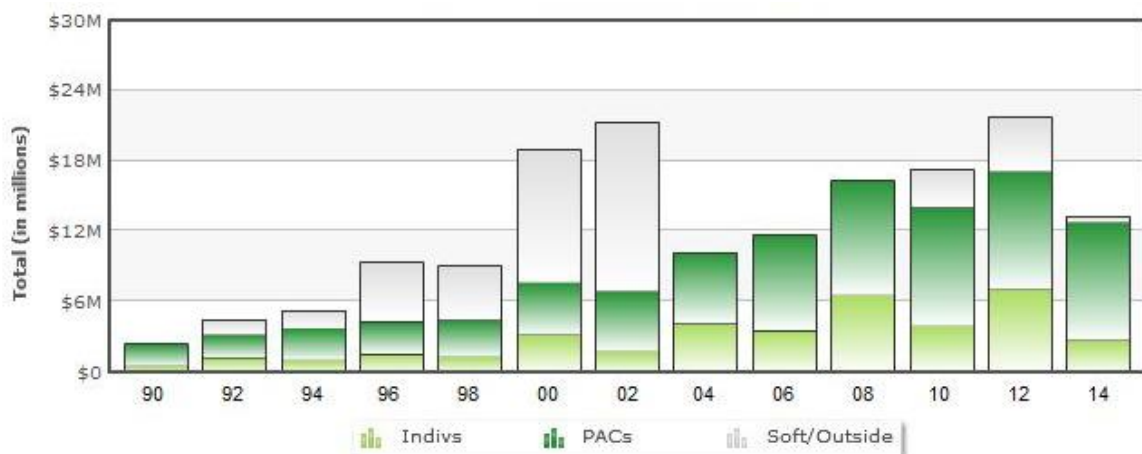
Pharmaceutical Industry Political Contributions by Party, 1990-2014



Source: Image and calculations from Center for Responsive Politics:

<http://www.opensecrets.org/industries/indus.php?ind=H4300>.

Pharmaceutical Industry Contribution Trends, 1990-2014



Source: Image and calculations from Center for Responsive Politics:

<http://www.opensecrets.org/industries/indus.php?ind=H4300>.

Top Pharmaceutical Company Political Spenders, 1989-2014



Source: Image and calculations from Sunlight Foundation:

<http://influenceexplorer.com/industry/pharmaceutical-manufacturing/f3286f287c43421eb70c054633d693ee>.

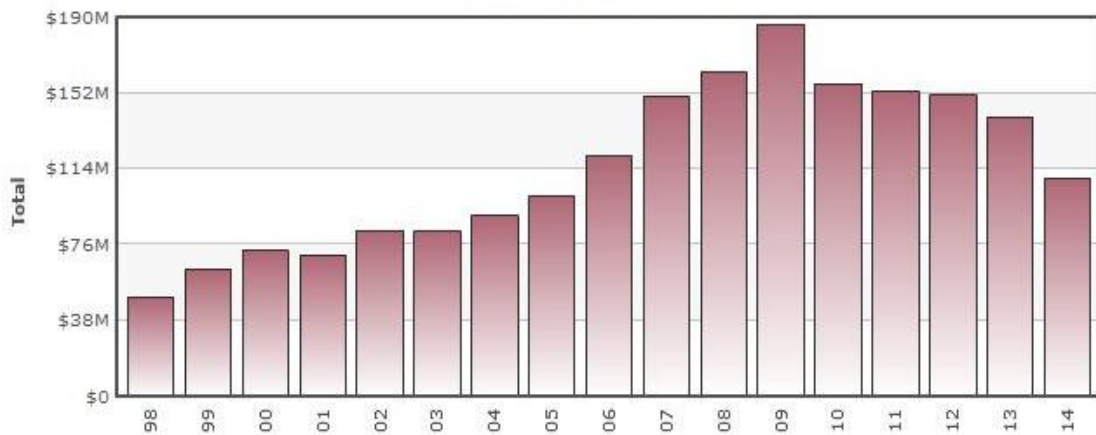
Top Pharmaceutical Company Political Spenders, 2014

Rank	Organization	Amount	 Dems	 Repubs
1	Pfizer Inc	\$1,447,490	42.1%	57.9%
2	Amgen Inc	\$1,311,914	46.2%	53.8%
3	Merck & Co	\$962,695	50.6%	49.4%
4	McKesson Corp	\$936,850	40.6%	59.2%
5	Abbott Laboratories	\$786,345	36.2%	63.7%
6	DE Shaw Research	\$764,797	15.0%	0.0%
7	AstraZeneca PLC	\$744,583	46.8%	53.2%
8	Sanofi	\$730,705	34.7%	61.8%
9	AmerisourceBergen Corp	\$717,021	42.7%	57.3%
10	Eli Lilly & Co	\$677,050	38.2%	56.2%
11	AbbVie Pharmaceuticals	\$628,250	45.9%	54.1%
12	Johnson & Johnson	\$610,513	45.4%	54.0%
13	GlaxoSmithKline	\$580,004	40.6%	59.3%
14	United Therapeutics	\$496,550	14.1%	0.3%
15	Novartis AG	\$488,640	52.0%	47.8%
16	Ischemix	\$449,600	56.2%	0.0%
17	Genentech Inc	\$441,085	58.9%	40.9%
18	Cardinal Health	\$372,690	34.3%	65.7%
19	Exoxemis Inc	\$352,600	0.0%	0.7%
20	Allergan Inc	\$352,200	25.3%	74.7%

Source: Image and calculations: <http://www.opensecrets.org/industries/contrib.php?cycle=2014&ind=H04>.

As much it has spent on campaign contributions, the industry's stock in trade has long been its enormous lobbying expenditures, totaling \$1.8 billion since 1998, according to the Sunlight Foundation.¹¹³

Pharmaceutical Industry Lobbying Totals, 1998-2014



Source: Image and calculations from Center for Responsive Politics,
<http://www.opensecrets.org/industries/indus.php?ind=H4300>.

Even more than its enormous expenditures on lobbying, what has set the industry apart has been its reliance on the revolving door — relying on former government officials to do its lobbying. Tauzin, of course, represents one of the all-time greatest revolving door abuses, particularly since he took a job running the pharmaceutical industry trade association just months after shepherding through the Congress a benefit worth hundreds of billions of dollars to that very industry. But revolving door is the norm for the industry.

The Center for Responsive Politics reports that PhRMA employs more people who have gone through the revolving door than any other organization or business except the U.S. Chamber of Commerce (and excepting lobby firms). The Center reports 52 current or former employees of PhRMA who have spun through the revolving door. BIO, which is headed by former Representative James Greenwood, has followed PhRMA's example. It

¹¹³ Sunlight Foundation, Influence Explorer, available at:
<http://influenceexplorer.com/industry/pharmaceutical-manufacturing/f3286f287c43421eb70c054633d693ee>.

ranks twelfth on the Center for Responsive Politics revolving door list with 33 current or former revolving door employees.¹¹⁴

VI. The Alliance for Safe Biologic Medicines

One advocacy vehicle for the brand-name biologics industry in its policy fights over biosimilar naming and substitution is the Alliance for Safe Biologic Medicines, a joint industry-patient group organization advocating for industry-favored positions. The organization describes itself as “composed of diverse healthcare groups and individuals — from patients to physicians, biotechnology companies that develop innovative and biosimilar medicines and others who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion.”¹¹⁵

Industry members in the Alliance include Amgen, Genentech and BIO. The Alliance maintains a steering committee of patient and health groups.

Not noted in the presentation of these patient groups is that every single one — with the potential exception of two that appear not to disclose funders — are funded by industry. These include:

- Alliance for Patient Access¹¹⁶
- American Academy of Dermatology¹¹⁷
- American Autoimmune Related Diseases Association (AARDA)¹¹⁸
- Colon Cancer Alliance¹¹⁹
- Global Colon Cancer Association¹²⁰
- Global Healthy Living Foundation¹²¹
- Health HIV¹²²

¹¹⁴ Center for Responsive Politics, “Revolving Door: Top Organizations,” available at: <http://www.opensecrets.org/revolving/top.php?display=D>.

¹¹⁵ Alliance for Safe Biologics, “Who We Are,” available at: <http://safebiologics.org/who-we-are.php>.

¹¹⁶ Alliance for Patient Access, “Associate Members,” available at: <http://1yh21u3cjptv3xjderldco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/01/AssociateMembersListJuly2014.pdf>.

¹¹⁷ American Academy of Dermatology, “Current Corporate Partners,” available at: <https://www.aad.org/support-aad/corporate-partners/current-corporate-partners>.

¹¹⁸ American Autoimmune Related Diseases Association, “Annual Report 2013,” available at: <http://www.aarda.org/wp-content/uploads/2014/07/Annual-Report-FY2013-web.pdf>

¹¹⁹ Colon Cancer Alliance, “Sponsors,” available at: <http://www.ccalliance.org/about/sponsors.html>.

¹²⁰ Global Colon Cancer Association, “Sponsors,” available at: <http://www.globalcca.org/Sponsors.html>.

¹²¹ Corporate funding approximating roughly half of revenues, or potentially virtually all funding, disclosed in Global Healthy Living Foundation, IRS Form 990, available at: http://990s.foundationcenter.org/990_pdf_archive/204/204039120/204039120_201212_990.pdf.

¹²² Health HIV, “Fundors and Supporters,” available at: www.healthhiv.org/modules/info/healthhiv_supporters.html.

- Kidney Cancer Association¹²³
- National Psoriasis Foundation¹²⁴
- ZeroCancer¹²⁵

Notably, in their policy interventions, these organizations typically emphasize their patient representation and health concerns, but do not disclose their corporate funding. This is the case, for example, in the organizational-customized, standard-form letters submitted to the FDA on the issue of biosimilar naming by the Alliance for Patient Access,¹²⁶ the Colon Cancer Alliance,¹²⁷ and Health HIV.¹²⁸

Conclusion

The biotech sector has emerged as the cutting edge of the broader pharmaceutical industry. Many of these medicines have extraordinary pricetags, however, venturing into the six figures per year, per patient.

In the best-case scenario, these sky-high prices will mean a huge drain on consumer pocketbooks and the public treasury. In the worst-case — and most likely — scenario, it will mean both a huge drain on consumers and taxpayers, but also that many people who would otherwise obtain needed biologic medicines will not.

If the high prices of biologics were due to some external, objective cost, then this all would be unfortunate, but unavoidable.

But the high prices are not due to objective costs. They are due entirely to government-granted monopolies, which give biologics makers the ability to charge whatever they believe the market will bear.

As this report has endeavored to show, those monopolies in turn are not due to strong policy considerations, but the political influence of BIO and Big Pharma.

¹²³ [Kidney Cancer Association](http://www.kidneycancer.org/about-us/website-sponsors), “Website Sponsors,” available at: <http://www.kidneycancer.org/about-us/website-sponsors>.

¹²⁴ [National Psoriasis Foundation](https://www.psoriasis.org/giving/ways-to-give/corporate-members), “2014 Corporate Members,” available at: <https://www.psoriasis.org/giving/ways-to-give/corporate-members>.

¹²⁵ [ZeroCancer](http://zerocancer.org/about/partners), “Corporate Sponsors and Partners,” available at: <http://zerocancer.org/about/partners>

¹²⁶ Letter from Brian Kennedy, Alliance for Patient Access to Margaret Hamburg, FDA, October 22, 2012, available at: <http://safebiologics.org/pdf/afpa-naming-letter.pdf>.

¹²⁷ Letter from Andrew Spiegel, Colon Cancer Alliance to Margaret Hamburg, FDA, August 29, 2012, available at: <http://safebiologics.org/pdf/CCA.pdf>.

¹²⁸ Letter from James Sykes, Health HIV to Margaret Hamburg, FDA, October 24, 2012, available at: <http://safebiologics.org/pdf/health-hiv-letter-on-naming.pdf>.

Pro-consumer policy choices remain available, and can save consumers and taxpayers many tens of billions of dollars:

- Pursuant to its charge under the Biologic Price Competition and Innovation Act, the Food and Drug Administration should speed its establishment of a pathway for approval of biosimilars and interchangeables.
- For products determined to be interchangeable, the FDA should authorize the interchangeable biosimilar to use the same nonproprietary name as the reference product.
- States should not adopt rules restricting pharmacist substitution of interchangeable biologics, in the absence of a finding that the FDA has failed to establish an appropriate standard of interchangeability.
- The United States should cease efforts to include pro-monopoly data and marketing exclusivity terms in international trade agreements.
- Patient groups, academics and others receiving financial support from biologic and pharmaceutical companies should disclose that industry funding in public statements and submissions on matters of direct interest to their industry backers; federal and state legislatures and regulatory agencies should insist on such disclosures in testimony, documents and other materials provided to them.

Biosimilars offer the prospect of bringing price-lowering competition to the biologics market, but the United States is not on track to benefit from that competition, or at least not at scale. Whether that changes depends entirely on whether elected officials and high government appointees decide to stop listening to the siren call of BIO and Big Pharma, and start serving the interests of the public.