SYMPOSIUM: FEATURED ESSAY

A GENERATION LOST: THE REGULATION OF FOLLOW-ON BIOPHARMACEUTICALS IN THE UNITED STATES

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This essay was written for the keynote address delivered at the Elon University Law Review 2024 Symposium, "The Doc is in: Prescribing Treatment for the Health Crises Through the Legal System." It looks back on the generation-long efforts to create a regulatory pathway for the approval of follow-on biopharmaceuticals (a.k.a. biologics) and explains how deficient institutional design has impeded progress towards robust biosimilar markets.

The story begins in the late 1990s when members of Congress and regulators at the Food and Drug Administration (FDA) began discussing the creation of a pathway for the approval of follow-on versions of biologics—the new and often miraculous products of the biotechnology revolution of the 1970s and 1980s. The goal was to create a legislative and regulatory framework that would resemble the highly successful Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), which heralded the age of affordable pharmaceutical drugs. Yet, in the years that followed, these initiatives were met with numerous roadblocks that have resulted in repeated delays and compromises and, ultimately, in the passing of the Biologics Price Competition and Innovation Act of 2010 (BPCIA). Almost fifteen years after the enactment of BPCIA, the Act, with its many structural problems, has shaped the regulation of biologics in the United States and the marketplace for these products. The price of BPCIA's design flaws—in the many billions of

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dollars and inestimable human suffering—is borne, as always, by patients.

This essay tells the story of BPCIA and the regulatory and public health realities with which it has left us. It will explain how BPCIA's flawed design could (still) be corrected by a relatively simple act of Congress, and it will make the (not-so-bold) prediction that the political compromise necessary for amending BPCIA is highly unlikely to occur any time soon. It will also suggest that the generation of failed efforts to instill effective competition into biologics markets and buckling healthcare budgets are the reason for the government's recent pushes toward direct price controls like those incorporated into the Biden Administration's Inflation Reduction Act.

TABLE OF CONTENTS

I. BACKGROUND: THE HATCH-WAXMAN ACT OF 1984

In 1984, Congress came up with an ingenious framework for increasing the availability and affordability of pharmaceuticals.[1] Enacted as the Drug Price Competition and Patent Term Restoration Act, this statute came to be known as the Hatch-Waxman Act after Senator Orrin Hatch and Representative Henry Waxman, who championed it.[2] Now, forty years later, the Hatch-Waxman Act has proved to be a remarkably innovative piece of legislation that revolutionized United States pharmaceutical markets and heralded a new era of pharmaceutical innovation and affordability.[3]

The commercial reality of pharmaceutical markets from the 1960s through the early 1980s was of brand-name companies dominating most drug markets with a single product and a few opportunistic competitors who would occasionally attempt to bite off some market share with their own attempted knockoffs of these products.[4] Regulatory approval of each knockoff product was an uphill battle, the IP landscape dangerous, and market conditions inhospitable to competition.[5] The result was that brand-name pharmaceutical products were subject to minimal competition, alternatives to each product were few, if any, and prices remained high even after the patents covering the brand-name product had expired.[6] The Hatch-Waxman Act sought to change that reality.[7]

The basic idea of the Hatch-Waxman Act was this: In order to make pharmaceutical products cheaper, it is necessary to instill competition into pharmaceutical markets by encouraging third parties to make their own copycat versions of these products.[8] The idea was simple; the devil was, as always, in the details. And details galore there were. The Hatch-

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[1] Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 35 and 42 U.S.C.).

[2] Anna Yeo, *The Little-Known Bill that Made Drugs more Affordable*, STAT (Sept. 10, 2024), https://www.statnews.com/2024/09/10/stat-video-explainer-prescription-prices-patent-law-hatch-waxman-generic-drugs/.

[3] *See, e.g.*, Brookings Institution, *Hatch-Waxman at 40*, YOUTUBE (Sept. 19, 2024), https://www.youtube.com/watch?v=4APisbOErpM.

[4] *See* Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y, L. & ETHICS 293, 297–301 (2015).

[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] *See Hatch-Waxman at 40*, *supra* note 3.

Waxman Act has been widely regarded as a uniquely complex piece of legislation.[9] It creates an elaborate regulatory regime involving multiple government agencies, primarily the FDA and the United States Patent and Trademark Office (USPTO), but also the federal court system, and legions of regulators, patent agents, attorneys, and scientists who drive the process of bringing competing pharmaceutical products to market.

Still, if we are to try to distill the Hatch-Waxman Act to its essential elements, these would be it. First, allow the FDA to approve knockoff—or as we came to call them, "follow-on" or "generic"—products without the need for their developers to go through the same regulatory processes as the original product, thereby saving generic developers huge amounts of resources that would have been necessary otherwise.[10] Second, lower generic developers' patent infringement risks by allowing and even incentivizing them to challenge patents covering brand-name products before they launch their competing products.[11] And, third—and most importantly—have the FDA announce follow-on products that it approves to be chemically and therapeutically equivalent to the products they seek to imitate such that pharmacists would be able to substitute one (cheap) product for the (expensive) other without having to involve the prescribing doctor or to debate the clinical merits of the substitution.[12] In short, the Hatch-Waxman Act lowered entry barriers for would-be competitors in pharmaceutical markets and made their prospects in these markets more lucrative.[13]

The initial success of the Hatch-Waxman Act at encouraging generic entry may not have been a surprise. But, the extent of the Act's success and the fact that it is still considered to be an ongoing success story forty years after its enactment makes it one of the most important statutes ever enacted in the area of food and drug law. To illustrate: In the first year after the Hatch-Waxman Act was enacted, the FDA received hundreds of generic product applications, and in the forty years since then, it has approved many thousands of applications for generic products.[14] The Hatch-Waxman Act is regarded by many as singularly responsible for the creation of a thriving generic pharmaceutical industry and the significant

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[9] *See, e.g.*, CONG. RSCH. SERV., THE HATCH-WAXMAN ACT: A PRIMER 5 (2016), https://crsreports.congress.gov/product/pdf/R/R44643/3.

[10] *Id.* at 5–6.

[11] *Id.* at 6–8.

[12] 21 U.S.C. § 355(j)(2)(A)(ii)–(iv).

[13] *See Hatch-Waxman at 40*, *supra* note 3.

[14] *See* Yaniv Heled, *The Biologics Price Competition and Innovation Act at 10—A Stocktaking*, 7 TEX. A&M U. J. PROP. L. 81, 90 (2021) [hereinafter Heled, *BPCIA at 10*].

decreases in drug prices that came with it—often by as much as 80 to 90 percent.[15] Given this success, it was, therefore, not a surprise that when the time came to create a similar regulatory pathway for the approval of follow-on biologics, the Hatch-Waxman Act served as the starting model for the new framework.[16]

II. WHAT BIOLOGICS ARE AND HOW THEY ARE DIFFERENT FROM SMALL-MOLECULE DRUGS

Before delving deeper into the fine details of biologics regulation, it is necessary to understand what biologics are and how they are different from small-molecule drugs (a.k.a. "drugs," for short) in several ways that pose challenges for creating a regulatory pathway for approval of follow-on biologics. The FDA defines biologics as

> a diverse category of products . . . [of] generally large, complex molecules . . . [that] may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs. There are many types of biological products approved for use in the United States, including therapeutic proteins . . . , monoclonal antibodies . . . , and vaccines.[17]

Additional important classes of biologics that are not expressly mentioned in the FDA definition include viral vectors, such as those used in gene therapies, whole cells and tissues (including blood products), and other products that require involving living cells in the production process rather than chemical fabrication from scratch by human chemists.[18]

As stated in the FDA definition, biologics are typically large and highly complex molecules.[19] Whereas small-molecule drugs weigh about or less than nine hundred daltons (which is the unit used for expressing

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[15] *See infra* note 117.

[16] *See, e.g.*, Access to Life-Saving Medicine Act, H.R. 6257, 109th Cong. (2006) (the first bill, introduced by Rep. Henry Waxman, proposing a pathway for the approval of follow-on versions of biologics).

[17] *Biological Product Definitions*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf (last visited Nov. 4, 2024).

[18] *See What are "Biologics" Questions and Answers*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers (Feb. 6, 2018) [hereinafter *What are "Biologics"*].

[19] *Id.*

molecular mass)[20] and have simple chemical structures, biologics size usually starts in the several thousand daltons and can go upwards of hundreds of thousands of daltons.[21] Their sheer size also means that biologics tend to have highly complex structures that are difficult to fabricate, control, and imitate in a lab setting.[22] For example, the two small molecule drugs, acetaminophen (Tylenol) and ibuprofen (Advil), weigh about 150 and 205 daltons, respectively.[23] In contrast, insulin—one of the smallest and best-characterized biologics—weighs 5808 daltons,[24] and a typical human antibody weighs about 150,000 daltons.[25] And while small molecule drugs have pretty simple structures, biologics tend to have highly complex elaborate three-dimensional structures.[26]

As a result of biologics' size and complexity, their structure is usually very sensitive to changes in their environment.[27] Accordingly, biologics are almost never administered orally and must be given intravenously or in some other way that bypasses the digestive system. Another consequence of the size and complexity of biologics—and a crucial practical difference between them and small-molecule drugs—is that, unlike small-molecule drugs, biologics are also difficult to manufacture, characterize, and imitate with precision.[28] There are several reasons for that.

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[20] *See Regulatory Knowledge Guide for Small Molecules*, NAT'L INSTS. OF HEALTH (Nov. 2023), https://seed.nih.gov/sites/default/files/2024-03/Regulatory-Knowledge-Guide-for-Small-Molecules.pdf.

[21] Favour Danladi Makurvet, *Biologics vs. Small Molecules: Drug Costs and Patient Access*, 9 MED. IN DRUG DISCOVERY, Mar. 2021, at 1–2, http://dx.doi.org/10.1016/j.medidd.2020.100075.

[22] *Id.*; *What are "Biologics"*, *supra* note 18.

[23] *Acetaminophen*, NAT'L INST. OF STANDARDS AND TECH., https://webbook.nist.gov/cgi/cbook.cgi?ID=C103902&Mask=8 (last visited Nov. 5, 2024); *Ibuprofen*, NAT'L INST. OF STANDARDS AND TECH., https://webbook.nist.gov/cgi/cbook.cgi?ID=C15687271&Mask=200 (last visited Nov. 5, 2024).

[24] *Insulin*, *Pub Chem*, NAT'L LIBR. OF MED., https://pubchem.ncbi.nlm.nih.gov/compound/Insulin (last visited Nov. 6, 2024).

[25] *Antibody Structure and Classification*, THERMO FISHER SCI. INC., https://www.thermofisher.com/us/en/home/references/molecular-probes-the-handbook/technical-notes-and-product-highlights/antibody-structure-and-classification.html (last visited Nov. 6, 2024).

[26] *See* Makurvet, *supra* note 21.

[27] *See id.* at 1.

[28] *See* W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1032–37 (2016); Yaniv Heled, *The Case for Disclosure of Biologics Manufacturing Information*, 47 J. L. MED. & ETHICS 54, 56 (2019) [hereinafter Heled, *The Case for Disclosure*].

First, much as we marvel at the state of our biotechnologies, scientists still have not come up with a way to accurately imitate the way that cells create proteins from specific DNA sequences, including giving them the necessary three-dimensional structures and supplementing them with all sorts of additions that are essential for their proper function.[29] As a result, the making of biologics requires using genetically engineered living cells that are part of very elaborate processes with hundreds of steps and variables that must be carefully controlled and monitored.[30] Second, our current technologies for characterizing the final biological product are quite limited in their capabilities.[31] As a result, comparing one biologic to another—even two biologics from the same batch at the same plant—is difficult.[32] Third, biologics—much like many other biological products like beer, bread, wine, and cheese—almost never come out exactly the same. Their final structure and characteristics are heavily dependent on those many hundreds of factors that need to be controlled during their manufacture and have a significant effect on the final product.[33] Call it "pharmacological terroire."

Biologics are often described as miracle drugs since they treat, and sometimes even actually cure, diseases that used to be considered, until relatively recently, either lethal or "for life." Examples include autoimmune conditions like rheumatoid arthritis, Crohn's disease, and psoriasis, all sorts and manners of cancers, genetic diseases like sickle cell anemia, cystic fibrosis, blindness-causing macular degeneration, and more.[34]

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[29] *See* Price & Rai, *supra* note 28, at 1033–36.

[30] *Id.*

[31] *Id.* at 1036–37.

[32] *Id.*

[33] *Id.* at 1033–35.

[34] *See, e.g.*, *Adalimumab*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125057s423lbl.pdf (last visited Nov. 6, 2024) (indicating adalimumab for the treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, plaque psoriasis, and other autoimmune diseases); *Herceptin*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/103792s5354lbl.pdf (last visited Nov. 6, 2024) (indicating trastuzumab for the treatment of metastatic breast cancer and metastatic gastric cancer); *Casgevy*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/174615/download (last visited Nov. 6, 2024) (indicated for the treatment of sickle cell disease); *Trikafta*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212273s004lbl.pdf (last visited Nov. 6, 2024) (indicated for the treatment of cystic fibrosis); *Vabysmo*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761235s005lbl.pdf (last visited Nov. 6, 2024) (indicated for the treatment of macular degeneration).

Biologics are also the most expensive and commercially lucrative class of drugs in the United States and worldwide pharmaceutical markets. For instance, the most expensive pharmaceutical products on the market currently (and ever) are all biologics, with the most expensive being a product by the name of Lenmeldy, a gene therapy product for a type of childhood cancer called metachromatic leukodystrophy (MLD) that comes with a price tag of $4.25 million for a one-time treatment.[35] It is followed by Hemgenix, another gene therapy for treating hemophilia B, which costs $3.5 million, and then several other one-time gene therapies for devastating and mostly lethal childhood conditions such as Duchenne muscular dystrophy, cerebral adrenoleukodystrophy, beta thalassemia, and spinal muscular atrophy, with price tags ranging between $2.1 million and $3.5 million.[36] These are followed by several gene therapies that might require more than one dose and have price tags ranging between $1.1 million and $1.3 million annually.[37]

Looking at the list of top-selling medications for chronic conditions, eight out of the top ten best-selling pharmaceutical products of 2023 (and sixteen out of the top twenty) are biologics.[38] Unlike the gene therapies listed above, which hold the record for most expensive pharmaceutical products, these top-selling biologics "only" cost tens of thousands of dollars per year.[39] Overall, biologics' share of the total expenditure on pharmaceuticals in the United States is currently more than 50% and rising.[40] Yet they only account for a small fraction—3% by some estimates—of the drugs that doctors prescribe.[41]

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[35] Leigh Ann Anderson, *10 of the Most Expensive Drugs in the U.S.*, DRUGS.COM, https://www.drugs.com/article/top-10-most-expensive-drugs.html (Apr. 1, 2024).

[36] *Id.*

[37] *Id.*

[38] Zoey Becker, Angus Liu, Kevin Dunleavy, Fraiser Kansteiner & Eric Sagonowsky, *The Top 20 Drugs by Worldwide Sales in 2023*, FIERCE PHARMA (May 28, 2024, 3:00 AM), https://www.fiercepharma.com/special-reports/top-20-drugs-worldwide-sales-2023; Paul Verdin, *Top Companies and Drugs by Sales in 2023*, 23 NATURE REVS. DRUG DISCOVERY 240, 240 (2024).

[39] *See, e.g.*, Brian K. Chen, Y. Tony Yang & Charles L. Bennett, *Why Biologics and Biosimilars Remain So Expensive: Despite Two Wins for Biosimilars, the Supreme Court's Recent Rulings do not Solve Fundamental Barriers to Competition*, 78 DRUGS 1777, 1777 (2018).

[40] *The Use of Medicines in the U.S. 2024, Usage and Spending Trends and Outlook to 2028*, IQVIA INST. OF HUM. HEALTH, 47 (May 7, 2024), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024 [hereinafter *Use of Medicines in the U.S.*].

[41] Dongzhe Hong et al., *Biosimilar Uptake In The US: Patient And Prescriber Factors*, 43 HEALTH AFFS. 1159, 1159 (Aug. 2024).

Now that we have a little more background about what biologics are, this might sound like just another story about a new biomedical technology: it's terrific, it's expensive, it gets cheaper over time, so more of us, and not just the rich, could enjoy it. The trouble is that this paradigm has not been working quite this way for biologics. Biologics prices tend to remain very high for a very long time after they have entered the market and even long after their patents have expired.[42]

The problem of persistently high pharmaceutical prices might sound familiar. As you recall, this was the same problem that the Hatch-Waxman Act was meant to solve in 1984.[43] Thus, given the public health need, on the one hand, and what appears to be a highly successful ready-made solution in the Hatch-Waxman Act, on the other hand, it would look like the solution is a Hatch-Waxman Act for biologics. The good news is that Congress already passed such an Act in 2010 called the Biologics Price Competition and Innovation Act (BPCIA).[44] The bad news is that it does not work, or—if you prefer to see the glass-half-full—that it does work, but very poorly. Comparing BPCIA to the Hatch-Waxman Act's track record,[45] the conclusion must be that BPCIA has failed to produce the hoped-for effect on competition and pricing in biologics and that we have wasted a lot of time creating it and then waiting for almost fifteen years for it to finally "kick in."

III. THE EARLY DAYS OF THE EFFORTS TO MAKE BIOLOGICS CHEAPER

To understand why BPCIA does not work, we need to go all the way back to the early days of discussions of follow-on biologics. Toward the end of the 1990s, regulators and policymakers were faced with an increasing stream of applications for follow-on versions of biologics approved in the preceding decades.[46] They had to address the question: How should the FDA evaluate and approve follow-on versions of biologics once they came off patent?[47] At first, the thinking was that the FDA ought to use its existing authorities under the Hatch-Waxman Act to approve

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[42] *See* Heled, *BPCIA at 10*, *supra* note 14, at 86.

[43] *See supra* notes 4–7 and accompanying text.

[44] Biologics Price Competition and Innovation Act, Pub. L. No. 111-148, §§ 7001–7003, 124 Stat. 119, 804–21 (2010) [hereinafter BPCIA].

[45] *See* discussion *infra* Parts III–V; *see also* Heled, *BPCIA at 10*, *supra* note 14, at 87–93.

[46] *See* Krista Hessler Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671, 685–88, 697–98 (2010).

[47] *Id.* at 698–99.

generic versions of biologics.[48] The FDA, however, declined to do that for several reasons, some of which were good and some not so good.[49]

The primary reason for the FDA's reluctance to start approving follow-on biological products as generics under the Hatch-Waxman Act was technological.[50] As explained earlier, one of the main pillars of the Hatch-Waxman Act was the FDA's ability to pronounce a follow-on, would-be-generic product as bioequivalent to the original product that it sought to imitate.[51] Doing so required the FDA (and generic applicants) to evaluate the comparability of the two products, which was not very difficult for most small-molecule drug products.[52] However, comparing biologics is not nearly as straightforward, and the FDA felt that it could not do that technologically.[53]

Another, perhaps not-so-good, reason for the FDA's declining to develop a regulatory pathway for the approval of follow-on biologics was its position that it could not do so without explicit Congressional authorization.[54] Apparently, this position was the result of significant pressure on the FDA from members of Congress allied with the pharmaceutical industry and from the pharmaceutical industry itself, who filed numerous citizen petitions and threatened to take the FDA to court if it ever attempted to create such a pathway on its own.[55]

After several years of continuous tug-of-war on the Hill between the proponents and opponents of a regulatory pathway for follow-on biologics—with the FDA stuck in the middle, mostly abstaining from doing anything—something very interesting happened. In 2003, the European Union passed legislation that laid the groundwork for the approval of follow-on biologics and, starting in January 2006, actually approved several follow-on biologics for marketing in Europe.[56] Thereafter, opponents of

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[48] *Id.* at 685–86, 697–98, 700.

[49] *Id.* at 699 n.220 and accompanying text.

[50] *See id.* at 686; *see generally* Janet Woodcock et al., *The FDA's Assessment of Follow-on Protein Products: a Historical Perspective*, 6 NATURE REVS. DRUG DISCOVERY 437, 441–42 (2007) (discussing the technological challenges of the FDA approving biologic follow-ons).

[51] *See supra* note 12 and accompanying text.

[52] *See supra* note 28 and accompanying text.

[53] *See* Carver et al., *supra* note 46, at 686.

[54] *Id.* at 697–701.

[55] *Id.* at 698–702.

[56] Directive 2001/83/EC, of the European Parliament and Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, annex I, pt. II, ¶ 2, 2001 O.J. (L 311) 67, 67 *as amended by* Directive 2003/63/EC, annex I, pt. II, ¶ 4, 2003 O.J. (L 159) 46, 78–79; Emily H. Jung et al., *FDA and EMA Biosimilar Approvals*, 35 J. GEN. INTERNAL MED. 1908, 1908 (2019).

follow-on biologics in the United States could no longer maintain that comparing brand-name biologics to their follow-on versions was technically infeasible.

The FDA, however, continued to insist that it lacked the legislative authority to approve follow-on biologics without explicit authorization.[57] This ongoing insistence ultimately led Representative Henry Waxman (the same one from the Hatch-Waxman Act) to introduce, in September 2006, the first bill that would give the FDA the authority and instruct it to create a regulatory pathway for the approval of follow-on biologics.[58]

The introduction of the Waxman bill was quickly followed by a "counter bill" authored by Congressional allies of the pharmaceutical industry.[59] At least on its face, this "counter bill" also seemed to accept the proposition of a pathway for follow-on biologics. However, it included significant perks for brand-name pharmaceutical companies in the form of a previously unheard-of twelve to fifteen years of market exclusivity.[60] It also proposed a regulatory design that explicitly foreclosed an FDA designation of two biological products as therapeutically equivalent—a hallmark and pillar of the Hatch-Waxman Act—and made it exceedingly difficult for follow-on biologics to obtain FDA approval and compete with original products.[61] The introduction of these bills started a legislative battle that lasted three-and-a-half years.[62] During that time, both sides introduced numerous bills and "counter bills" that represented vastly different visions of what a regulatory pathway for follow-on biologics should look like.[63]

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[57] *See* Carver et al., *supra* note 46, at 698 n. 217 and 699 n.220 and accompanying text.

[58] Access to Life-Saving Medicine Act, H.R. 6257, 109th Cong. (2006) (the First Waxman Bill). An almost identical bill was introduced in the Senate by Senator Charles Schumer. S. 4016, 109th Cong. (2006).

[59] *See* Patient Protection and Innovation Biologic Medicines Act of 2007, H.R. 1956, 110th Cong. (2007).

[60] *Id.*

[61] *Id.*

[62] *See* Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOM. & TECH. L. REV. 419, 436–38 (2012) (discussing the bills); Yaniv Heled, *Follow-On Biologics Are Set Up to Fail*, 2018 U. ILL. L. REV. ONLINE 113, 116–17 (2018) [hereinafter Heled, *Set Up to Fail*].

[63] *See* Heled, *Set Up to Fail*, *supra* note 62, at 116–17.

IV. THE ENACTMENT OF THE BIOLOGICS PRICE COMPETITION AND INNOVATION ACT (BPCIA)

As we know, bitter legislative battles are not unusual, and it was widely anticipated that some mutually agreeable arrangement would eventually emerge—like the one that led to the enactment of the Hatch-Waxman Act.[64] These hopes, however, were dashed by the enactment of BPCIA, which did not reflect such a compromise, in March 2010.[65]

Much about how the sausage is made usually remains hidden from the public eye, so there is very little information about exactly how things turned out the way they did. What appears to have happened is that allies of the pharmaceutical industry from within the Democratic Party, led by Representative Anna Eshoo of California, were able—despite vocal opposition by the White House, the Generic Pharmaceutical Association (GPhA), and other stakeholders—to add the language of BPCIA to the then-pending bill of the Affordable Care Act, a.k.a. Obamacare.[66] They did so at a key point in the legislative efforts to pass the Act, which was the main legislative project of the Obama Administration.[67] Achieving that, the congressional allies of the pharmaceutical industry basically strongarmed the Obama Administration and most members of the Democratic Party in Congress, who otherwise supported the Waxman bills, to enact BPCIA as the price for passing the Affordable Care Act.[68]

The enactment of BPCIA as part of the Affordable Care Act was a big victory for the congressional allies of the pharmaceutical industry. The bill included almost everything the pharmaceutical industry was seeking during the legislative battle that preceded the enactment of BPCIA.

First, BPCIA created an unprecedented market exclusivity period of twelve to twelve-and-a-half years for new biologics.[69] This exclusivity means that the FDA is not allowed to approve any follow-on products to a biologic during that period, regardless of any patents that might cover that product in addition.[70] For comparison, this exclusivity is much longer

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[64] *See* Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 590 (2003) (discussing the Act's dual goals of "making available lower cost generic drugs and preserving incentives to develop new drugs").

[65] *See* BPCIA, *supra* note 44.

[66] *See* Heled, *Set Up to Fail*, *supra* note 62, at 117.

[67] *Id.*

[68] *Id.*

[69] 42 U.S.C. § 262(k)(7)(A), (m)(2)(A).

[70] *Id.*

than the respective four to five-year market exclusivity period afforded to new products under the 1984 Hatch-Waxman Act.[71]

Second, BPCIA created an elaborate system of patent dispute resolution, colloquially known as the "Patent Dance," that would have placed developers of follow-on biologics at a significant legal and commercial disadvantage had the courts not later ruled that participating in it was optional.[72] Again, for comparison, the Hatch-Waxman Act included none of the several disadvantages that the Patent Dance system imposed on developers of follow-on products.

Third, unlike the Hatch-Waxman Act, which created only one pathway for approving follow-on products, BPCIA created two separate pathways for approval of follow-on biologics.[73] One pathway allows for the approval of "biosimilars," which are follow-on products that are deemed to be "similar" to but not fungible with the original biologic that they seek to imitate.[74] The other pathway allows for the approval of "interchangeable biologics," which are clinically alternative versions of the original product.[75] Of these two pathways, only the latter one, for the approval of interchangeable biologics, resembles the arrangement of the Hatch-Waxman Act in that it makes the two products fungible at the pharmacy level.[76] However, BPCIA makes the approval of a follow-on biologic as interchangeable much more onerous than what is required of a "regular" biosimilar and significantly more so than what is required under the Hatch-Waxman Act for holding two products fungible.[77]

Fourth, and no doubt BPCIA's most significant design flaw, is that it endorses the position that regulatory filings submitted to the FDA—including manufacturing information—are proprietary and, therefore,

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[71] 21 U.S.C. § 355(c)(3)(E)(ii).

[72] Sandoz Inc., v. Amgen Inc., 137 S. Ct. 1664, 1674–75 (2017) (holding that participation in the Patent Dance dispute resolution framework of BPCIA was not mandatory and could not be enforced by injunction); *see* Heled, *Set Up to Fail*, *supra* note 62, at 118–19 (discussing the several disadvantages that partaking in the Patent Dance would impose on follow-on biologics developers).

[73] 42 U.S.C. § 262(i)(2), (k)(2)(A), (k)(2)(B), (k)(4).

[74] 42 U.S.C. § 262(i)(2), (k)(2)(A).

[75] 42 U.S.C. § 262(i)(3), (k)(2)(B), (k)(4).

[76] *Id.* § (k)(2)(B).

[77] *Compare* 42 U.S.C. § 262(i)(2), (k)(2)(A), (k)(2)(B), (k)(4) (requiring that the new drug is biosimilar to the reference product, can produce an equal treatment to any patient, and that the two products can be switched during treatment without diminishing safety or efficacy), *with* 21 U.S.C. § 355(j)(2) (requiring that "the active ingredients of the new drug are of the same pharmacological or therapeutic class" as the reference drug and "the new drug can be expected to have the same therapeutic effect as the listed drug when administered").

confidential and cannot be shared with follow-on product developers.[78] Understanding this crucial piece of BPCIA and its profound effects on competition in biologics markets is essential for realizing why BPCIA has been such a failure compared to the Hatch-Waxman Act.

As discussed earlier, the basic idea of increasing competition in pharmaceutical markets that lies at the heart of the Hatch-Waxman Act and that animated the efforts to create a similar pathway for biologics is founded on several pillars.[79] First, authorize the FDA to approve follow-on versions of original pharmaceutical products.[80] Second, approval should be made possible without forcing follow-on product developers to go through the same expensive and burdensome regulatory processes as the original product.[81] Third, lower follow-on product developers' legal risks.[82] Fourth—and most importantly—have the FDA pronounce follow-on products as therapeutically equivalent to the original products so pharmacists are able to substitute them seamlessly.[83] By holding regulatory filings confidential, BPCIA effectively knocks down pillars two and four. When combined with patents and the twelve-year market exclusivity, the prohibition on disclosure of biologics manufacturing information has created a uniquely powerful trifecta of intellectual property protections that make entry barriers to biologics markets extremely high.[84]

Let me explain: Because of biologics' complexity, current scientific methods and tools do not allow for their full and precise characterization.[85] As a result, it is difficult, if not impossible, to establish that two biologics are exactly the same.[86] Instead, the characterization of biologics primarily relies on the characterization and meticulous control of the process by which they are made.[87] Indeed, industry pundits have often held that when it comes to biologics, "the process [of making the product] is the

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[78] *See* Heled, *Set Up to Fail*, *supra* note 62, at 119; Heled, *The Case for Disclosure*, *supra* note 28, at 63 & 75 nn.136–38 and accompanying text.

[79] *See supra* notes 10–12 and accompanying text.

[80] *See supra* note 10 and accompanying text.

[81] *See supra* note 10 and accompanying text.

[82] *See supra* note 11 and accompanying text.

[83] *See supra* note 12 and accompanying text.

[84] *See* Heled, *The Case for Disclosure*, *supra* note 28, at 54.

[85] *See supra* note 28 and accompanying text.

[86] *See supra* note 28 and accompanying text.

[87] *See supra* note 28 and accompanying text.

product."[88] In other words, to guarantee the identity of two biologics, it is necessary to meticulously replicate the process of making the biologic.[89]

The manufacturing information of biologics is an integral part of biologics license applications (BLAs) that original biologics developers submit to the FDA when they apply for marketing approval for their products.[90] If follow-on product developers have no access to the manufacturing information of the product that they seek to imitate, they are forced to re-develop this information by "rediscovering" the process of making the biologic.[91] In other words, follow-on biologics developers are forced to participate in a sort of regulatory "hide-and-seek," in which they try to fashion a follow-on product sufficiently similar to the original product to produce comparable clinical results.[92] And they must do this through reverse-engineering the process of making the original biologic without being able to compare the manufacturing processes.[93]

The need for such reverse engineering in the development of follow-on biologics is the root cause of the failure of BPCIA as a means of lowering biologics prices. This failure is due to the fact that to develop a successful imitation of the original product, follow-on developers have to go through an expensive and time-consuming trial and error process that is aimed at recreating the hundreds of steps and variables involved in making a close enough version of the original biologic—precisely what BPCIA purportedly meant to avoid.[94] If developers of follow-on biologics have to spend huge amounts of money[95] recreating a version of an original biologic, then they later must roll that expenditure onto patients, which

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[88] Donna. M. Gitter, *Innovators and Imitators: An Analysis of Proposed Legislation Implementing an Abbreviated Approval Pathway for Follow-on Biologics in the United States*, 35 FLA. ST. U. L. REV. 555, 561 n.21 (2008) (describing "the maxim that, for biopharmaceuticals, the 'process is the product.'"); *see* Carver et al., *supra* note 46, at 708–09.

[89] *See* Price & Rai, *supra* note 28.

[90] *See* 21 C.F.R. § 601.2(a) (2024).

[91] Heled, *The Case for Disclosure*, *supra* note 28, at 56–57.

[92] *Id.*

[93] *See* W. Nicholson Price II & Arti. K. Rai, *Are Trade Secrets Delaying Biosimilars*, 348 SCIENCE 188, 188 (2015) (describing attempts of follow-on biologics makers to imitate original products as "rang[ing] from merely expensive to nearly impossible and creat[ing] much of the cost barrier for biosimilar entrants").

[94] *See id.*

[95] Developing a follow-on biologic is estimated to cost between $100–250 million and even more for monoclonal antibody products. *See* FED. TRADE COMM'N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION, at iii (2009); Erwin A. Blackstone & Joseph P. Fuhr, *The Economics of Biosimilars*, 6 AM. HEALTH & DRUG BENEFITS 469, 471 (2013).

makes the follow-on product a lot more expensive than it ought to have been.

Also, looking at the need to reverse engineer the original biologic from a public policy perspective leads to the conclusion that it is a very wasteful outcome. Developers of follow-on products must invest considerable resources, which, arguably, would have been better spent on other research and development (R&D) projects, only to try to recreate a product that already exists and is available on the market. In that, BPCIA mandates the expansion of limited societal R&D resources to re-develop information that already exists in files at the FDA but remains artificially and unnecessarily out of reach.

But, the worst outcome of the need to reverse engineer original biologics is that it is unethical. BPCIA instructs the FDA to require follow-on product developers to conduct experiments on human subjects to make sure that their follow-on product is sufficiently effective and has a side-effect profile no worse than the original product's.[96] Moreover, when the follow-on product seeks approval as interchangeable, BPCIA requires it to undergo a "switching study" in order to determine the impact of alternating between the original product and the proposed follow-on product.[97] Let me reiterate this: BPCIA requires the FDA to expose human subjects to the risk of significant harm only to confirm that a follow-on product is not more dangerous or less efficacious than an already-approved product. And the main reason for putting already vulnerable human subjects at such risk is to protect the financial interests of pharmaceutical companies in their submissions to the FDA.

To recap, without access to original biologics manufacturing information, follow-on biologics lack the competitive edge necessary to drive down prices to levels seen in generic drug markets. This lack of access to manufacturing information also wastes limited societal R&D resources and unnecessarily exposes human subjects to a risk of bodily harm.

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[96] *See* 42 U.S.C. § 262(k)(2)(A)(i)(I)(bb)–(cc), (k)(4)(A)(ii).

[97] *See* U.S. FOOD & DRUG ADMIN., CONSIDERATIONS IN DEMONSTRATING INTERCHANGEABILITY WITH A REFERENCE PRODUCT: GUIDANCE FOR INDUSTRY, 7–14 (2019), https://www.fda.gov/media/124907/download.

V. THE AFTERMATH OF BPCIA AND THE PRESENT REALITY OF COMPETITION IN BIOLOGICS

Since the enactment of BPCIA, several other developments have hampered competition in United States biologics markets and kept biologics prices high. Successful lobbying efforts by the pharmaceutical industry at the state level have made the substitution of original biologics with their follow-on versions more difficult and cumbersome than the automatic substitution of small-molecule drugs, making such substitution less likely to occur.[98] FDA delays in implementing BPCIA, especially of a regulatory route for approval of products as interchangeable, have further delayed the entry of competition into biologics markets.[99] In addition, protracted legal battles have accompanied virtually any and every attempt to gain FDA approval for follow-on biological products, even where the market exclusivity in the original biologic has long expired and when the follow-on product has already been in use in other countries.[100] To be sure, filing lawsuits, so long as they are not merely to harass, is legal under BPCIA and not outside the norm in the pharmaceutical industry, where actors treat litigation as part of the cost of doing business. Still, these legal fights represent a high cost for the public, not just because of the direct legal costs, but mostly because every day of delay in the entry of competing products into the market could be worth tens of millions of dollars in savings that do not accrue.[101]

As a result of all of this, the picture of competition in biologics markets is disheartening, even grim, when compared to the results of the Hatch-Waxman Act. During the fourteen-and-a-half years since the enactment of BPCIA in March of 2010 until the time of writing of this essay, the FDA has approved a total of sixty-six follow-on biologics for a total of seventeen original products.[102] Notably, according to the IQVIA Institute, it seems like at least some of these approved biosimilars are not even available on the market and, currently, there are actually biosimilars

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[98] Heled, *Set Up to Fail*, *supra* note 62, at 125–28.

[99] *See* Heled, *BPCIA at 10*, *supra* note 14, at 93–96.

[100] *See* Heled, *Set Up to Fail*, *supra* note 62, at 128–130.

[101] *See* Ana Santos Rutschman, *Regulatory Malfunctions in the Drug Patent Ecosystem*, 70 EMORY L.J. 347, 379–80 (2020); Michael A. Carrier, *The U.S. District Court for the Northern District of Illinois Dismisses Antitrust Case Challenging Patent Thicket (Humira)*, CONCURRENCES, June 8, 2020, at 2–4.

[102] *See Purple Book: Database of Licensed Biological Products*, U.S. FOOD & DRUG ADMIN., https://purplebooksearch.fda.gov/advanced-search (last visited Nov. 7, 2024) [hereinafter *Purple Book Data*].

available only for twelve original biologics out of the more than 300 biologics that were marketed in the United States in 2023.[103] Of these seventeen original biologics that have approved biosimilars, only eight original products have biosimilars approved as interchangeable.[104] That means that out of more than 600 original biologics approved to date by the FDA,[105] only seventeen products have approved follow-on products, and only eight of those could be substituted automatically at the pharmacy level.[106] The prices of these follow-on products were 18–50% lower than those of the original products, and, in total, they account for an average of 23% of the markets in which they compete.[107]

For sixteen out of the seventeen original biologics for which biosimilars have been approved, there have been between one to six approved biosimilars, with the original biologic Humira—the world's best-selling drug for many years—being an outlier with fifteen approved biosimilars.[108] Thus, excluding the Humira biosimilars, there is an average of about 3.19 approved biosimilars for each of these sixteen original products.[109] As these numbers show, almost fifteen years after BPCIA was signed into law, it has resulted in minimal competition in only a handful of product markets and led to relatively small to modest price drops in all of these markets.[110]

Comparing these numbers with the track record of the Hatch-Waxman Act further illustrates and reinforces this conclusion. As I explained elsewhere, a direct comparison of the track records of the Hatch-Waxman Act and BPCIA would not be instructive.[111] Still, it is possible to glean some potentially valuable insight into the comparative performance of these two statutes by comparing the ratios of approved

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[103] *Use of Medicines in the U.S.*, *supra* note 40.

[104] *See Purple Book Data*, *supra* note 102.

[105] This number includes all categories of biologics. If we exclude vaccines, tests, allergens, and antitoxins, the number of products is about 460. *See Use of Medicines in the U.S.*, *supra* note 40.

[106] *See Purple Book Data*, *supra* note 102.

[107] *Biosimilars in the United States 2023-2027, Competition, Savings, and Sustainability*, IQVIA INST. OF HUM. HEALTH, 23 (Jan. 31, 2023), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027; *Use of Medicines in the U.S.*, *supra* note 43, at 42, 58. Biosimilars' market share in specific product markets varies dramatically, between 2 to 82%. *Id.* at 58.

[108] *See Purple Book Data*, *supra* note 102.

[109] *See id.*

[110] *See Use of Medicines in the U.S.*, *supra* note 40.

[111] *See* Heled, *BPCIA at 10*, *supra* note 14, at 88–89.

follow-on products to original products under both regimes.[112] A comparison of these ratios that I conducted a few years ago, at the 10th anniversary of BPCIA, compared the ratio of approved original products and approved follow-on products ten years after each of the two statutes was passed.[113] My findings showed that ten years after the Hatch-Waxman Act was enacted, there were 1.91 approved generic product applications per each original product application.[114] In other words, for every ten original small-molecule drug products approved by the FDA, there were about nineteen approved applications for generic versions of these products.

Turning to BPCIA's track record, by March 23, 2020, a decade after its enactment, the ratio was about 0.1 follow-on biologics per one original product or one follow-on product per ten original products.[115] Comparing the ratios of follow-on to original products under the Hatch-Waxman Act and BPCIA ten years after their respective enactment dates, therefore, shows that BPCIA performed at about 5% of the Hatch-Waxman Act at about the same time after it was enacted. Put differently, at their respective 10th anniversaries, the Hatch-Waxman Act performed twenty times better than BPCIA. This comparison looks even worse for BPCIA if we consider the fact that the follow-on product approvals under the Hatch-Waxman Act are generic products, which are true substitutes for the original products they seek to imitate; in contrast, the follow-on products approved under BPCIA by that point were all non-interchangeable biosimilars that could not be automatically substituted.[116]

Furthermore, research on trends in small-molecule drug prices shows that price drops of above seventy percent typically only occur once four or more competitors have entered the same product market with their competing products.[117] By September 24, 1994, a decade after the enactment of the Hatch-Waxman Act, there were 292 such small-molecule

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[112] *Id.* at 88–91.

[113] *Id.*

[114] *Id.* at 90.

[115] *Id.* at 91.

[116] *See id.* at 92.

[117] *See* Ryan Conrad & Randall Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, U.S. FOOD & DRUG ADMIN. (Dec. 2019), https://www.fda.gov/media/133509/download?attachment [https://perma.cc/RVM9-2375]; *see also Generic Competition and Drug Prices*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices (Oct. 17, 2024) [https://perma.cc/3UZJ-R39Y].

drug products on the market.[118] In comparison, by the time of writing this article, there were only seven original biologics with four or more approved competing biosimilar products and only one of the original products, Humira, had the requisite number of interchangeable competing products.[119]

What all of these numbers show is that almost fifteen years after the enactment of BPCIA and more than a generation since the onset of discussions regarding bringing competition to biologics markets, the levels of competition (and price drops) in biologics markets are nowhere near the levels that we have seen in small-molecule drugs subsequent to the enactment of the Hatch-Waxman Act.

Another thing that these numbers tell us is that entry barriers into biologics markets make it significantly more difficult to compete in these markets than in small-molecule drug markets. When a specific biologic product market is lucrative enough, then determined, sophisticated, and sufficiently well-funded developers may endeavor to make the risky and significant upfront investment necessary to come up with their competing products. However, for those biologics whose market value might not provide a clear path for recouping the hefty initial investment—which appears to be most products[120] —the current BPCIA framework creates little incentive for potential competitors to attempt to enter the market, leaving most biologics product markets with little or no price competition. To put all of this succinctly, BPCIA does not do what it was, at least officially, supposed to do. Despite high expectations for the opening up of biologics markets for competition after BPCIA's enactment,[121] fifteen years later, with very few exceptions, biologic product markets are still highly concentrated, competition is minimal or non-existent, and prices remain high even after exclusivities in the original products have expired.

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[118] *See Drugs@FDA Data Files*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-data-files [https://perma.cc/LC2E-DSFR] (Oct. 22, 2024) (data includes original and supplemental approved applications). The results exclude tentatively approved applications and supplemental applications for which there was an approved original application.

[119] *See Purple Book Data*, *supra* note 102.

[120] *See supra* notes 102–05 and accompanying text.

[121] *See, e.g.*, Noel Courage & Ainslie Parsons, *The Comparability Conundrum: Biosimilars in the United States, Europe and Canada,* 66 FOOD & DRUG L.J. 203 (2011) ("Billions of dollars' worth of biologics are going off patent in the next decade. The end of patent protection on blockbuster biologics opens the door for other companies that would like to get a slice of this lucrative market with their own versions of biologics").

VI. THE FUTURE OF BPCIA

Looking at pharmaceutical markets as a zero-sum game, one might get the wrong impression that the big winners of the current situation are pharma companies—both brand-name and follow-on developers. The supposed reason for that would be that pharma companies reap enormous profits from the increasing market demand for biologics while being able to maintain high prices with minimal price erosion in most biologics markets. But if we look at things from a broader perspective or longer timeframe, I believe a more accurate perspective is that the current situation has only losers.

First and foremost, the biggest losers are patients for whom BPCIA has brought very little change and whose access to life-saving biologics remains limited for most biologics. Then there are payors, for whom BPCIA provides very little salve to an ever-growing expenditure on biologics. However, I would argue that we need to add pharmaceutical companies themselves to the list of losers, at least in the long term. That is because the current trends in biologics prices are untenable and would ultimately inevitably lead to one form or another of government price controls for pharmaceuticals that would undermine pharmaceutical companies' business models.

I believe that we are already seeing the beginning of such movement toward price controls in the mandatory price negotiations framework that was passed as part of the Inflation Reduction Act of 2022[122] and, perhaps even more tellingly, in explicit promises to curb pharmaceutical prices that candidates for office have been making in recent election campaigns.[123] Indeed, in many ways, pharmaceutical companies are fast on their way to becoming victims of their own immense success. But this does not have to be how things shake out.

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[122] Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 11001, 136 Stat. 1818.

[123] *See, e.g.*, Li Zhou, *Kamala Harris's Plan to Reduce Prescription Drug Costs, Explained*, VOX (Jul. 16, 2019, 4:50 PM), https://www.vox.com/2019/7/16/20696192/kamala-harris-plan-prescription-drug-costs; The White House, *Remarks by President Biden and Vice President Harris on the Progress They Are Making to Lower Costs for the American People | Largo, MD* (Aug. 15, 2024), https://www.whitehouse.gov/briefing-room/speeches-remarks/2024/08/15/remarks-by-president-biden-and-vice-president-harris-on-the-progress-they-are-making-to-lower-costs-for-the-american-people-largo-md/; 1600 Daily, The White House's Evening Newsletter, *Congress Didn't Act on Prescription Drug Prices. So President Trump Did* (Jul. 27, 2020), https://trumpwhitehouse.archives.gov/articles/congress-didnt-act-on-prescription-drug-prices-so-president-trump-did/.

As I have argued elsewhere, it is not too late to reshape BPCIA in the image of the Hatch-Waxman Act.[124] Doing so would be quite simple legislatively. All it would require is for Congress to make modest amendments to BPCIA or to narrow Section 331(j) of the Federal Food, Drug, and Cosmetic Act such that the FDA is allowed to share information contained in regulatory filings with developers of follow-on products.[125] And it would not even be the first time Congress has done precisely that when it wanted to open a regulated technology market to competition.[126] Despite vocal protestations and warnings that doing so would constitute a violation of pharmaceutical companies' Fifth Amendment right against government taking, there is actually Supreme Court precedent explicitly holding that Congress may do just that, provided that it gives sufficient advance notice.[127]

However, it is probably unrealistic to expect that Congress would be able to do something like this without the consent, even if implicit, of the pharmaceutical industry itself. Indeed, from a political expediency standpoint, it seems much more likely that members of Congress would support (or at least not openly oppose) legislative measures for directly curbing the price of pharmaceuticals than they would tinker with an obscure statute (that is, BPCIA) that no member of their constituency has probably ever heard about and which might affect something as vague as competition in biologics markets. In short, without the pharmaceutical industry actually wanting to fix BPCIA, it is exceedingly unlikely to happen.

As Yogi Berra said: "It's tough to make predictions, especially about the future."[128] But if I had to risk a prediction here, it would be that BPCIA will remain unchanged for the foreseeable future. Instead, we are likely to see more and more increasingly aggressive proposed legislative measures for curbing pharmaceutical prices at both the federal and state levels.

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[124] *See* Heled, *The Case for Disclosure*, *supra* note 28.

[125] 21 U.S.C. § 331(j); *see* Heled, *The Case for Disclosure*, *supra* note 28, at 62–64 (proposing such amendments as a means for increasing competition in biologics markets).

[126] *See* Heled, *The Case for Disclosure*, *supra* note 28, at 58–59 (discussing the example of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)).

[127] *See id.* at 59–62 (discussing Ruckelshaus v. Monsanto, 467 U.S. 986 (1984)).

[128] Yogi Berra, *Quotable Quote*, GOODREADS, https://www.goodreads.com/quotes/261863-it-s-tough-to-make-predictions-especially-about-the-future (last visited Nov. 7, 2024).