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Katherine Macfarlane

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# Camouflaging State Biosimilar Laws as Pro-Patient Legislation

*Katherine Macfarlane*<sup>1,2</sup>

## I. INTRODUCTION

In the late 1990s, a new class of medication became available to patients suffering from chronic, debilitating autoimmune diseases such as rheumatoid

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1. Associate Professor of Law, University of Idaho College of Law, B.A., Northwestern University, J.D., Loyola Law School, Los Angeles. This essay benefited immensely from the comments received at the 2016 Nova Law Review Symposium and the 2016 Loyola University Chicago Beazley Institute for Health Law Symposium, where I exchanged ideas with scholars, providers, pharmacists and patients. I was diagnosed with rheumatoid arthritis (“RA”) at 13 months, and have taken many of the biologics at issue in this essay. I did not speak openly about my struggles with RA or the medications used to treat it until recently, and am grateful to Lene Andersen, Abby Sher, Laura Grey, Carey Tolleson and my workshop classmates for encouraging me to do so. This essay is dedicated to the army of RA warriors fighting for better treatment, affordable medication, and the freedom to lead the life we choose. You can learn more about chronic illness activism via the hashtag #chroniclife.

2. From 2013 to 2015, I volunteered as a patient blogger for the website Creaky Joints, which is affiliated with the non-profit Global Healthy Living Foundation (“GHLF”). In May 2015, I testified as a GHLF patient advocate at the Louisiana Capitol regarding a pending biosimilar bill. In connection with my testimony, I participated in conference calls, conducted legal research regarding the pending bill, drafted my testimony, and gave media and television interviews. I was not compensated or reimbursed for my blogging or my Louisiana testimony and Louisiana media efforts. In July 2015, I was a member of a panel organized by the Congressional Arthritis Caucus, and again represented GHLF as a patient advocate. In preparation for the Caucus, I participated in conference calls, conducted legal research, spent approximately 5 hours preparing my remarks, and gave a press interview. GHLF reimbursed my out-of-pocket expenses, including hotel and air travel, associated with my trip from Los Angeles, CA to Washington, D.C., but I was not compensated for any of my additional work. Sometime in the fall of 2015, I participated in a call with fellow GHLF patient advocates, and described my experience testifying in Louisiana. I was not paid for that call. I also provided recommendations to Dr. Ben Nowell, GHLF’s Director of Patient-Centered research regarding the Creaky Joints data collection project known as Arthritis Power. I was not compensated for consulting with Dr. Nowell. Sometime in fall 2015, I was contacted by the organizers of the February 2016 Biosimilars Market Access Summit. I was asked to participate as a presenter, and I suggested that GHLF’s legislative specialist, Steve Marmaras, also be invited to speak. Steve signed on, and GHLF agreed to reimburse me for travel expenses connected with the summit. Thereafter, I ceased advocacy and blogging for GHLF. In December 2015, I learned that Steve Marmaras had withdrawn from the Biosimilars Market Access Summit. GHLF reimbursed me for the travel expenses I incurred in connection with my trip from Idaho to Virginia for the summit.

arthritis (RA).<sup>3</sup> These wonder drugs, known as biologics, gave patients who failed conventional RA treatments<sup>4</sup> the ability to function in ways never before imagined.<sup>5</sup> For RA patients, “the availability of new biologic treatments . . . transformed management of [their] disease . . .”<sup>6</sup> Biologics, the most effective RA medication for purposes of reducing joint damage, even help patients increase their workforce presence by reducing the number of days they must miss from work due to their disease.<sup>7</sup>

Biologics are made “by extracting cellular proteins from animals.”<sup>8</sup> They are “complex, protein-based drugs,” that include medications such as insulin, Enbrel, and other “monoclonal antibodies,” which treat RA and similar autoimmune diseases, as well as drugs that treat cancer and multiple sclerosis.<sup>9</sup> The biologics used to treat RA “work by blocking the activity of a key chemical or cell involved in inflammation that gives rise to joint swelling

3. Carol M. Ostrom, *What's Behind the Whopping Price Tags on the Newest Generation of Drugs*, SEATTLE TIMES (Aug. 17, 2008, 11:36 PM), <http://www.seattletimes.com/seattle-news/health/whats-behind-the-whopping-price-tags-on-the-newest-generation-of-drugs/> (“Rheumatoid arthritis is a nasty disease. Unchecked, the inflammation, destructive changes to joints and dissolution of bone it causes — along with the pain — can lead to disability, lost work time and the need for orthopedic interventions.”).

4. Jeffrey R. Curtis & Jasvinder A. Singh, *The Use of Biologics in Rheumatoid Arthritis: Current and Emerging Paradigms of Care*, 33 CLINICAL THERAPEUTICS 679, 680–81 (2011) (explaining that before the advent of biologics, conventional RA treatments included combinations of non-steroidal anti-inflammatory drugs (e.g., aspirin, ibuprofen), analgesics, glucocorticoids (e.g., prednisone, methylprednisolone), and disease-modifying anti-rheumatic drugs.); *Using Biologic Drugs to Treat Rheumatoid Arthritis*, CONSUMER REP. (Mar. 2013), <http://www.consumerreports.org/cro/2013/03/using-biologic-drugs-to-treat-rheumatoid-arthritis/index.htm#> [hereinafter CONSUMER REPORTS] (“Between 30 to 70 percent of people who have not benefitted from other rheumatoid arthritis medications experience some measure of relief from biologics.”).

5. Curtis & Singh, *supra* note 4, at 679, 682, 684 (explaining that in contrast to prior methods of treatment, “biologics are highly effective in reducing RA symptoms, slowing disease progression, and improving indices of physical function and quality of life. Clinical responses are often rapid [as] most patients experience improvements within a few weeks of starting treatment” or even “a few days after the first dose.”); Lene Andersen, *A Beginner's Guide to RA: Biologics*, HEALTHCENTRAL (Dec. 3, 2014), <http://www.healthcentral.com/rheumatoid-arthritis/c/80106/173224/guide-biologics/> (“Biologics were a revolution in RA treatment . . . [causing] a seachange, not only in the rates of control of RA, but also in how it is treated. Biologic medications are very effective in treating RA, leading to a significant amount of people with RA achieving remission or low disease activity.”).

6. Curtis & Singh, *supra* note 4, at 679–80.

7. Paresh Chaudhari, *The Impact of Rheumatoid Arthritis and Biologics on Employers and Payers*, 5 BIOTECHNOLOGY HEALTHCARE 37, 40 (2008).

8. Brian R. Bouggy, *Follow-On Biologics Legislation: Striking a Balance Between Innovation and Affordability*, 7 IND. HEALTH L. REV. 367, 368 (2010).

9. ANDREW W. MULCAHY ET AL., THE COST SAVINGS POTENTIAL OF BIOSIMILAR DRUGS IN THE UNITED STATES I (2014), [https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND\\_PE127.pdf](https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf).

and other symptoms.”<sup>10</sup>

Biologics have molecular structures “usually 100 to 1,000 times” larger than drugs like aspirin, known as “small molecule drugs.”<sup>11</sup> Small molecule drugs are made up of “relatively simple chemical compounds” that can be easily replicated.<sup>12</sup> Because biologics are structurally complex, “it is more difficult to determine whether one biological drug is actually identical to another.”<sup>13</sup> Thus, there is no such thing as a “generic” biologic.<sup>14</sup> Rather, biologic copies are known as biosimilars<sup>15</sup> and replicate biologics with “highly similar, but slightly variant, living organisms or processes . . . .”<sup>16</sup>

Biologics are not only the most effective kind of medication for certain autoimmune diseases, but also the most expensive<sup>17</sup> and financially burdensome, even for the privately insured.<sup>18</sup> A small molecule drug costs approximately \$2 a day, whereas “[i]n 2013, the average daily cost in the United States of a biologic drug was \$45 . . . .”<sup>19</sup> If the Affordable Care Act’s pre-existing condition protection is eventually repealed, many patients treated with biologics may lose their health insurance and be forced to purchase biologics out-of-pocket (or not at all).<sup>20</sup>

10. Peter C. Taylor, *Biologic Therapies for RA*, in BIOLOGICS . . . THE STORY SO FAR: A PATIENT GUIDE TO BIOLOGIC THERAPIES IN THE TREATMENT OF RHEUMATOID ARTHRITIS 8 (2013), <http://www.nras.org.uk/data/files/Publications/Biologics.pdf>.

11. Stacey L. Worthy & John F. Kozak, *Follow-On Biologics: Protecting Consumers Through State Pharmacy Law in Light of FDA Actions*, 17 QUINNIPIAC HEALTH L.J. 207, 220 (2014).

12. *Id.* at 217.

13. Jason Kanter & Robin Feldman, *Understanding and Incentivizing Biosimilars*, 64 HASTINGS L.J. 57, 59 (2012) (explaining that biologics’ complexity increases their cost); *What Are “Biologics” Questions and Answers*, U.S. Food & Drug Admin., <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm> (last updated Aug. 5, 2015) (stating that “most biologics are complex mixtures that are not easily identified or characterized”).

14. Kanter & Feldman, *supra* note 13, at 59.

15. *Id.*

16. Joanna M. Shepherd, *Biologic Drugs, Biosimilars, and Barriers to Entry*, 25 HEALTH MATRIX 139, 143 (2015).

17. *Rheumatoid Arthritis Treatment Costs*, Rheumatoid Arthritis, <https://www.rheumatoidarthritis.org/treatment/costs/> (last updated Aug. 3, 2016) (describing biologics as “the most expensive forms of medications available to patients” being treated for RA and “[a]dding to the expense is the fact that biologics are usually administered by a healthcare professional through an IV or by injection” which “alone creates additional health care costs.”); *see also* Curtis & Singh, *supra* note 4, at 697 (“The treatment of RA places a substantial financial burden on healthcare systems and individual patients. Indeed, a major problem associated with the use of biologics is cost . . . . Estimates show that the introduction of biologics has increased, 3-fold, the total annual direct cost of treating RA patients.”).

18. Curtis & Singh, *supra* note 4, at 697.

19. Jon Tanaka, “*Shall*” We Dance? Interpreting the BPCIA’s Patent Provisions, 31 BERKELEY TECH. L.J. 659, 661 (2016).

20. Emily C. Wilson, *Stop Re-Victimizing the Victims: A Call for Stronger State Laws*

Enbrel, a biologic marketed by Amgen, is the most prescribed medication for RA.<sup>21</sup> In 2014 alone, Amgen's Enbrel sales totaled \$4.4 billion.<sup>22</sup> Patients who take Enbrel will not be surprised by the large sums the drug brings in for its manufacturer; after all, an Enbrel prescription could "cost over \$1,000 under a high-deductible plan."<sup>23</sup> Moreover, Enbrel's discount card is not available for anyone on Medicare or Medicaid.<sup>24</sup> This is particularly difficult for RA patients, as "[a] substantial number of rheumatoid arthritis patients are Medicare enrollees, and many struggle to afford any type of self-injectable biologic because of the significant copays . . . ."<sup>25</sup>

Biosimilars are poised to shake up the American pharmaceutical market: they are generally cheaper than biologics and are anticipated to lower costs,

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*Prohibiting Insurance Discrimination Against Victims of Domestic Violence*, 23 AM. U. J. GENDER, SOC. POL'Y & L. 413, 423 (2015) (commenting that the Affordable Care Act ("ACA") requires that insurance companies cover patients who have preexisting conditions; before the ACA, a preexisting conditions could preclude someone from insurance coverage); Nadja Popovich et al., *Here's How 'Obamacare' Covered Americans with Pre-Existing Conditions. What Happens Next?*, GUARDIAN (Jan. 26, 2017), <https://www.theguardian.com/us-news/ng-interactive/2017/jan/26/obamacare-what-next-healthcare-preexisting-conditions> (listing RA and Lupus as preexisting conditions likely to result in coverage denial before the ACA).

21. *What Results Could I Expect with ENBREL?*, AMGEN, <https://www.enbrel.com/rheumatoid-arthritis/ra-enbrel-treatment-results/> (last visited Apr. 9, 2017).

22. Carly Helfand, *Big Question for Pfizer: Will Enbrel's EU Biosim Bring on the Pain?*, FIERCEPHARMA (Jan. 19, 2016, 11:34 AM), <http://www.fiercepharma.com/sales-and-marketing/big-question-for-pfizer-will-enbrel-s-eu-biosim-bring-on-pain>.

23. CONSUMER REPORTS, *supra* note 4 (noting that some biologics cost more than \$5,000 per week); Jack Hoadley et al., *It Pays to Shop: Variation in Out-of-Pocket Costs for Medicare Part D Enrollees in 2016*, HENRY J. KAISER FAM. FOUND. (Dec. 2, 2015), <http://kff.org/report-section/it-pays-to-shop-variation-in-out-of-pocket-costs-for-medicare-part-d-enrollees-in-2016-findings/> (noting that Medicare Part D enrollees pay approximately \$4,872 per year out of pocket for Enbrel); Alison Kodjak, *Specialty Drugs Can Prove Expensive Even with Medicare Coverage*, NAT'L PUB. RADIO (Dec. 3, 2015, 10:20 AM), <http://www.npr.org/sections/health-shots/2015/12/03/458216778/specialty-drugs-can-prove-expensive-even-with-medicare-coverage> ("The out-of-pocket cost for Enbrel, a rheumatoid arthritis medicine, for example, could reach almost \$50,000 a year, if it's not covered."); Adam Rubenfire, *Rheumatoid Arthritis Drug Prices on the Rise*, MODERN HEALTHCARE (Apr. 1, 2016), <http://www.modernhealthcare.com/article/20160401/NEWS/160409993> (explaining that RA drugs are often placed on a specialty tier, "which increases the patient's cost-sharing responsibilities." "The wholesale cost of Enbrel . . . has increased 80.3% since 2013, and now exceeds \$4,000 for a 30-day supply . . ."); PEW CHARITABLE TRUSTS, SPECIALTY DRUGS AND HEALTH CARE COSTS (2015), [http://www.pewtrusts.org/~media/assets/2015/11/specialty-drugs-and-health-care-costs\\_artfinal.pdf](http://www.pewtrusts.org/~media/assets/2015/11/specialty-drugs-and-health-care-costs_artfinal.pdf) ("[P]atients who need specialty drugs face higher out-of-pocket (OOP) costs, because health plans often require a co-insurance payment, which is a set percentage of a drug's price. Some plans charge a co-insurance as high as 33 percent.").

24. *Co-Pay, Cost, and Coverage: See How We Can Help*, AMGEN, <https://www.enbrel.com/support/financial-assistance/> (last visited Apr. 9, 2017) (indicating people with commercial or private insurance may be eligible for the ENBREL Support Co-Pay Card; people with Medicare or Medicaid may qualify for a low-income subsidy).

25. Rubenfire, *supra* note 23.

but to what extent remains to be seen.<sup>26</sup> As a result, biosimilars make biologic manufacturers nervous about the effect biosimilars may have on their market share.<sup>27</sup> After Pfizer announced that it would begin to offer a Remicade<sup>28</sup> biosimilar “at a 15 percent discount to [Johnson & Johnson’s] current wholesale prices,” Johnson & Johnson, which manufactures Remicade, saw its “shares [fall] more than 2 percent.”<sup>29</sup>

I am also nervous about the effect biosimilars will have, but what I feel is nervous excitement. I was diagnosed with RA in 1981 at 13 months old. Although there are more treatments available for RA patients now than there were in 1981,<sup>30</sup> my disease’s progression has outpaced scientific innovation. In 2002, I began taking Remicade after less potent RA drugs, including Celebrex and Methotrexate, failed to control my intense flares. I struggled to walk and stand, and I was only 22 years old. I took Remicade for about six

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26. Lindsay Kelly, *Biologics in the Practice of Law*, 39 HARV. J.L. & PUB. POL’Y 21, 31 (2016) (explaining that although prices are unlikely to fall “steeply,” a biosimilar launched in September 2015 was offered at a fifteen percent discount from the biologic price; the RAND corporation also projects a thirty-five percent price decrease between 2014 and 2024 as biosimilars are introduced); *Guidance for Industry on Biosimilars: Q & As Regarding the Implementation of the BPCI Act of 2009: Background*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm259806.htm> (last updated Feb. 19, 2016) (describing the requirements for a biosimilar application which needs “information demonstrating that the biological product is biosimilar to a reference product” through various studies and that biologics have exclusivity over biosimilars for 12 years).

27. See, e.g., Tracy Staton, *Aiming to Shield \$14B in Sales, AbbVie Smacks Amgen with a Patent Suit over Humira Biosim*, FIERCEPHARMA (Aug. 8, 2016, 9:58 AM), <http://www.fiercepharma.com/pharma/aiming-to-shield-14b-sales-abbvie-smacks-amgen-a-patent-suit-over-humira-biosim> (describing the patent infringement dispute between AbbVie and Amgen regarding Amgen’s new Humira biosimilar, and that some companies, like Amgen, market and profit from both biologics and biosimilars).

28. Christian Nordqvist, *Remicade (Infliximab): Uses and Cautions*, MED. NEWS TODAY, <http://www.medicalnewstoday.com/articles/248273.php> (last updated Mar. 7, 2017) (explaining that Remicade is a biologic that “reduces inflammation and pain for patients with autoimmune diseases.” It works by suppressing patients’ immune systems, which can make patients who take it more susceptible to infection. Also, it must be administered intravenously, in either a clinic or hospital). Based on my personal experience with Remicade, “infusions,” the shorthand phrase for each Remicade treatment, take approximately three hours to complete. Understaffed infusion centers or delays in retrieving the medication from storage facilities can add up to two hours to the treatment time.

29. Ransdell Pierson, *J&J Shares Lose Ground on Fears of Pfizer’s Answer to Remicade*, REUTERS (Oct. 18, 2016, 1:36 PM), <http://www.reuters.com/article/us-johnson-johnson-results-idUSKCN12I15K>; see Zachary Brenman, *Genentech Files Complaint over Amgen’s Development of Avastin Biosimilar*, REG. AFF. PROFS. SOC’Y (Feb. 20, 2017), <http://www.raps.org/Regulatory-Focus/News/2017/02/20/26890/Genentech-Files-ll> (describing a biosimilar dispute with Avastin).

30. Katherine S. Upchurch & Jonathan Kay, *Evolution of Treatment for Rheumatoid Arthritis*, 51 RHEUMATOLOGY vi28, vi28–vi30 (2012) (describing the history of RA treatments, current treatments of RA, and future therapies for RA).

months, but found it difficult to manage its immunosuppressant side effects — I had a constant cold. When I asked my physician how to avoid getting sick, he recommended that I avoid crowds. This was not an option, and I searched for a new form of treatment.

Since 2002, I have tried and failed the biologics Xeljanz, Humira, Kineret, and Enbrel. My insurance refused to cover a prescription for the biologic Cimzia. In July 2016, I restarted Humira, a medication I first took in 2006. I hoped that it would work more effectively on my thirty-six-year-old body than it did for me at twenty-six. Right away, I knew that Humira was not working. However, my physician insisted on keeping me on Humira for six months to see if it might eventually work. During those six months, my knees were permanently swollen, and I used a cane to help with even the shortest walks. My left elbow was swollen and limited in its range of motion, affecting my ability to shower and get dressed. To combat the pain and swelling, I was placed on twenty milligrams of prednisone, which caused insomnia and weight gain. In December 2015, my physician finally concluded that Humira was not working and agreed to let me try Remicade again. The doctor's nurse stated that unless I qualified for a prescription assistance plan, I would be responsible for twenty percent of Remicade's \$8,700 per infusion cost.<sup>31</sup> My first two infusions would be scheduled two weeks apart, and then I would receive the medication monthly. As a result, I faced approximately \$23,000 in unexpected yearly out-of-pocket medical costs. However, with access to a Remicade biosimilar, I can benefit from Remicade, yet pay a fraction of the biologic's current cost. Biosimilars often sound like the financial miracle I have been waiting for.

In 2013, I began to chronicle my experiences as an RA patient in a blog I wrote for the online patient community Creaky Joints, a website managed by the Global Healthy Living Foundation (GHLF).<sup>32</sup> Through GHLF, I became involved in lobbying efforts surrounding biosimilar legislation. In 2015, I testified in support of legislation ultimately passed in Louisiana, which

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31. Jeffrey R. Curtis et al., *Cost and Effectiveness of Biologics for Rheumatoid Arthritis in a Commercially Insured Population*, 21 J. MANAGED CARE & SPECIALTY PHARMACY 318, 326 (2015) (noting the average administration cost of Remicade (Infliximab) was \$1,888 for commercially insured individual). In the author's experience, a Remicade infusion involves the following costs: price of the biologic itself; pre-infusion steroid and pain relief medication; and costs associated with an out-patient surgical procedure, including IV insertion and monitoring of patient vitals. I have been informed by the hospital that administers my Remicade that the cost of the medication is around \$8,700, exclusive of the additional costs related to infusing the drug. There are, of course, other costs—the lost wages caused by a three-hour infusion and its side effects, as well as the physical pain caused by insertion of a large needle that remains in a patient's vein for around three hours.

32. Kat Macfarlane: *Articles*, GLOBAL HEALTHY LIVING FOUND.: CREAKY JOINTS, <https://creakyjoints.org/author/katmacfarlane/> (last visited Apr. 9, 2017) (collection of eighteen essays written for CREAKY JOINTS).

required physician notification within five days after a biosimilar was exchanged for a biologic.<sup>33</sup> Since then, my perspective on laws like the one passed in Louisiana changed. I no longer think that notification is necessary. In fact, I am concerned that notification provisions only impede patients' access to biosimilars. Biologics are often shipped to patients by specialty pharmacies. There is some delay between the time a medication is prescribed and when it is received—shipping from a special pharmacy requires the pharmacy to verify when the patient can receive the medication, as it often needs to be refrigerated upon arrival. Until that information is received, the medication will not ship. Once it ships, unless a patient pays for express delivery, the medication arrives within several days of mailing. A patient may receive notification of an exchange before she receives the medication itself. This abnormal procedure may discourage the patient from taking a required dose on time, and may delay or halt future use of the biosimilar. The notification provision communicates to the patient that something is amiss, and may dissuade the patient from accessing an equally effective and potentially cheaper form of treatment.

This article is inspired by my experience as a patient and advocate. It identifies the stakeholders who have shaped state biosimilar legislation and argues that not all stakeholders are represented.

Following this introduction, Part II compares federal biosimilar regulation with state biosimilar regulation. Part III describes the flaws of state biosimilar regulation. The essay concludes with a recommendation that state legislative hearings and access to state legislators considering sponsorship of biosimilar legislation be driven by patient voices and patient demands.

## II. BIOSIMILAR REGULATION

Biosimilars are regulated through both federal and state legislation.<sup>34</sup> Federal legislation established an abbreviated market license pathway for biosimilars and set guidelines for the circumstances in which a pharmacist may exchange a biologic for a biosimilar.<sup>35</sup> At the state level, legislation

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33. LA. STAT. ANN. § 37:1164(16), (58); 1226.1 (2015); Katherine Macfarlane, Patient Advocate, Glob. Health Living Found., Testimony at House of Representatives Health and Welfare Committee Consideration of HB 319 (May. 6, 2015), <https://www.50statenetwork.org/wp-content/uploads/2015/05/GHLF-LA-Kat-HB-319-Testimony-5-6-15-FINAL8.pdf>.

34. Jesse C. Vivian, *Legal Aspects of Biosimilars*, 41 U.S. PHARMACIST 16, 17 (2016).

35. *Information on Biosimilars*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/> (last updated May 10, 2016) (noting the Public Health Service Act was amended “to create an abbreviated licensure pathway for biological products” that are biosimilar or interchangeable “with an FDA-licensed biological product”).



targets the kind of notice that must be provided to doctors and/or patients when substitution occurs, adding an additional step to the relatively straightforward substitution procedure envisioned at the federal level.<sup>36</sup> Both federal and state biosimilar regulations have been the subject of intense debate. Generally, biologic manufacturers prefer regulation that differentiates their products from biosimilars.<sup>37</sup> They argue that safety requires specific naming, labeling, and notification rules.<sup>38</sup> Luckily, the FDA issued draft guidance regarding naming and labeling conventions.<sup>39</sup> Nevertheless, biosimilar manufacturers, by contrast, prefer laws that do not hinder their products' market access, either through cumbersome naming and labeling requirements or by way of notification provisions that may raise red flags with patients and providers about their products' safety.<sup>40</sup> A description of these debates and the difference between federal and state legislation follows.

#### A. Federal Regulation

With the Biologics Price Competition and Innovation Act of 2009 (BPCIA),<sup>41</sup> Congress created an abbreviated pathway for biosimilar manufacturers to obtain a license to commercially market biosimilars.<sup>42</sup> Whereas a biologic license application requires clinical data demonstrating that the biologic is efficacious and safe, a biosimilar license application need only show that its product is biosimilar to or interchangeable with a biologic that has already received a license.<sup>43</sup> A biosimilar applicant may rely on

36. *Information on Biosimilars*, *supra* note 35; Jordan Paradise, *The Legal and Regulatory Status of Biosimilars: How Product Naming and State Substitution Laws May Impact the United States Healthcare System*, 41 AM. J.L. & MED. 49, 69, 75 (2015) ("Many laws also require patient notification or consent to the substitution . . .").

37. Paradise, *supra* note 36, at 72 (stating that large biotech and pharmaceutical companies support "unique names for biosimilars," indicating a preference for differentiation between biologics and biosimilars).

38. *Id.*

39. U.S. FOOD & DRUG ADMIN., LABELING FOR BIOSIMILAR PRODUCTS: GUIDANCE FOR INDUSTRY (2016) [hereinafter LABELING FOR BIOSIMILARS].

40. *Id.* at 72–73.

41. 42 U.S.C.A. § 262 (West 2015); Jenny M. Alsup, *You Can Dance if You Want To? Initial Interpretations of the BPCIA's Patent Dance with Sandoz and Amgen*, 8 HASTINGS SCI. & TECH. L.J. 137, 140 (2016) (explaining that the BPCIA, in addition to creating a biosimilar "statutory pathway," also "lays out a scheme for litigation of related patent issues").

42. *Amgen*, 794 F.3d at 1351. Sandoz filed a petition for a writ of certiorari, and Amgen cross-petitioned. Certiorari was granted on January 13, 2017. The Supreme Court will be tasked with resolving issues regarding when biosimilar manufacturers must give biologic manufacturers notice of their intent to market a biosimilar under the BPCIA. *See Sandoz Inc. v. Amgen Inc.*, SCOTUSBLOG, <http://www.scotusblog.com/case-files/cases/sandoz-inc-v-amgen-inc/> (last visited Apr. 9, 2017) (listing the issues, proceedings, and orders of the case).

43. *Amgen*, 794 F.3d at 1351.

“publicly-available information regarding the [FDA]’s previous determination that the reference product is safe, pure, and potent.”<sup>44</sup> Despite the abbreviated biosimilar license pathway, biologic manufacturers still receive “twelve years of regulatory exclusivity,” a time in which a product that is biosimilar to the biologic cannot enter the market.<sup>45</sup> A biosimilar cannot even submit a license for four years after a biologic’s license is approved.<sup>46</sup>

Through the BPCIA’s pathway, an approved biosimilar license applicant’s drug may be found to be either biosimilar or interchangeable.<sup>47</sup> If biosimilar, the drug “is highly similar, but not identical to, the innovator drug”; if interchangeable, “the drug is therapeutically interchangeable with the innovator and does not adversely affect safety or efficacy.”<sup>48</sup> When a healthcare provider prescribes a biologic, a pharmacist cannot substitute it for a drug that is only biosimilar to the biologic.<sup>49</sup> A pharmacist may exchange a biologic for a biosimilar if the biosimilar is interchangeable.<sup>50</sup>

The FDA issued draft guidance regarding biosimilar products’ naming and labeling<sup>51</sup> and will finalize this guidance by May 31, 2019.<sup>52</sup> In August 2015, the FDA proposed that biosimilars and biologics “have non-proprietary names”, “a 4-letter suffix . . . composed of four lowercase letters, and not carry any meaning.”<sup>53</sup> On June 1, 2016, the FDA published additional naming guidance that asked biosimilar license applicants to submit up to 10 potential

44. *Id.* (quoting 42 U.S.C. § 262(k)(2)–(5)).

45. Kelly, *supra* note 26, at 24; See 42 U.S.C. § 262(k)(7)(A). Exclusivity provisions are intended to shield “pioneering manufacturers” from competition from competitors who rely on their research and data but do not share in the original manufacturers’ costs. Gregory Dolin, *Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials*, 98 IOWA L. REV. 1399, 1450 (2013).

46. Kelly, *supra* note 26, at 25; 42 U.S.C. § 262(k)(7)(B).

47. Daniel Kadin, *Taking Biosimilars to the Next Level: Why Federalizing the Substitution of Biosimilars Promotes Innovation, Competition, and Patient Safety*, 45 SW. L. REV. 405, 408 (2015).

48. *Id.*

49. *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, U.S. Food & Drug Admin., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm> (last visited Apr. 9, 2017).

50. Kadin, *supra* note 47, at 419.

51. *US FDA Proposals for Naming of Biologicals and Labelling of Biosimilars*, 5 GENERICS & BIOSIMILARS INITIATIVE J. 140, 140 (2016).

52. *Survey: Doctors Want FDA to Reverse Course on Biosimilar Naming*, INSIDE HEALTH POL’Y (Nov. 17, 2016), <https://insidehealthpolicy.com/daily-news/survey-doctors-want-fda-to-reverse-course-biosimilar-naming>.

53. *FDA Issues Draft Guidance on Naming Biologicals*, GENERICS & BIOSIMILARS INITIATIVE (Apr. 9, 2015), <http://www.gabionline.net/Guidelines/FDA-issues-draft-guidance-on-naming-biologicals>.

suffixes to be used in a product's nonproprietary name.<sup>54</sup> Within weeks, the FDA withdrew its June 1, 2016, draft guidance, explaining that its publication was an administrative error.<sup>55</sup> In January 2017, the FDA issued yet another naming guidance, reiterating that "biological products [such as biosimilars should] bear a nonproprietary name that includes an FDA-designated suffix" so that "the nonproprietary name designated for each originator biological product, related biological product, and biosimilar product will be a proper name that is a combination of the core name and a distinguishing suffix that is devoid of meaning and composed of four lowercase letters."<sup>56</sup>

In March 2016, the FDA issued draft guidance regarding the labeling of biosimilar products.<sup>57</sup> It recommended that "applicants incorporate relevant data and information from the reference product labeling, with appropriate product-specific modifications."<sup>58</sup> Whether data is relevant "will depend on whether the applicant is seeking approval for all conditions of use (e.g., indication(s), dosing regimen(s)) or fewer than all conditions of use of the reference product for the biosimilar product."<sup>59</sup>

The response to the FDA's draft guidance has been controversial.<sup>60</sup> With respect to naming, "[b]iosimilar makers have argued that distinct names will impede the adoption of biosimilars."<sup>61</sup> Labeling practices are also hotly contested.<sup>62</sup> Despite the debates over FDA guidance, the BPCIA's purpose is clear: it was intended to encourage scientific innovation and to give patients access to more affordable therapies.<sup>63</sup>

54. Zachary Brennan, *FDA Calls on Companies to Select 10 Suffixes for Biosimilar, Biologic Names*, REG. AFF. PROF. SOC'Y (June 1, 2016), <http://www.raps.org/Regulatory-Focus/News/2016/06/01/25038/FDA-Calls-on-Companies-to-Select-10-Suffixes-for-Biosimilar-Biologic-Names-by-Preference/>.

55. Zachary Brennan, *FDA Withdraws Document Calling on Biosimilar Developers to Submit 10 Random Suffixes*, REG. AFF. PROF. SOC'Y (June 21, 2016), <http://www.raps.org/Regulatory-Focus/News/2016/06/21/25173/FDA-Withdraws-Draft-Document-Calling-on-Biosimilar-Developers-to-Submit-10-Random-Suffixes/>.

56. U.S. FOOD & DRUG ADMIN, NONPROPRIETARY NAMING OF BIOLOGICAL PRODUCTS: GUIDANCE FOR INDUSTRY 1 (2017), <http://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf>.

57. See LABELING FOR BIOSIMILARS, *supra* note 39, at 1.

58. *Id.* at 3.

59. *Id.* at 5.

60. See generally Elizabeth Callahan & Irena Royzman, *FDA's Proposal for Naming Biosimilars Pleases Some, Disappoints Others*, JD SUPRA (Sept. 16, 2015), <http://www.jdsupra.com/legalnews/fda-s-proposal-for-naming-biosimilars-39306/> (providing arguments for and against the FDA's proposal for naming biosimilars).

61. *Id.*

62. See Vishal Gupta & Richard Praseuth, *Controversy and Guidance for Biosimilar Labeling*, 35 BIOTECHNOLOGY L. REP. 137, 137 (2016) (stating that there is controversy over labeling of biosimilars).

63. Brian F. McMahon, *The Biologics Price Competition and Innovation Act of 2009: Legislative Imprudence, Patent Devaluation, and the False Start of a Multi-Billion Dollar*

As of December 2016, four products have been granted a biosimilars license: Amjevita, Erelzi, Zarxio, and Inflectra.<sup>64</sup> These products are biosimilar to, respectively, Humira, Enbrel, Neupogen, and Remicade.<sup>65</sup> To date, no biologics have been deemed interchangeable.<sup>66</sup>

### B. State Regulation

States have considered biosimilar naming and whether to impose “patient consent, recordkeeping, and physician notification requirements.”<sup>67</sup> State legislation regarding biosimilars has certain common features.<sup>68</sup> First, state laws permitting substitution of a biosimilar require that the FDA has deemed the biosimilar interchangeable, a step the FDA has yet to take.<sup>69</sup> Second, state laws often give the prescriber the ability to prevent substitution.<sup>70</sup> Third, state laws generally require some form of provider notification if substitution occurs.<sup>71</sup> At least twelve states require patient notification.<sup>72</sup> Fourth, state laws mandate that pharmacists keep additional records regarding biosimilar

*Industry*, 100 KY. L.J. 635, 685 (2012); JOHN GLADSTONE MILLS III ET AL., PATENT LAW BASICS § 12:20 (Rev. ed. 2016); Brian F. King, *Emerging Market for Biosimilars: State Legislation Should Reconcile Biosimilar Substitution Laws with Existing Laws on Generic Substitution*, 18 DEPAUL J. HEALTH CARE L. 31, 36 (2016).

64. CTR. FOR DRUG EVALUATION & RES., LIST OF LICENSED BIOLOGICAL PRODUCTS WITH (1) REFERENCE PRODUCT EXCLUSIVITY AND (2) BIOSIMILARITY OR INTERCHANGEABILITY EVALUATIONS TO DATE 1–2 (2016), <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM439049.pdf>.

65. *Id.* (showing that the proper name for the biosimilar is the same as the biologic, just with the 4-letter suffix); Zachary Brennan, *FDA Approves Third Biosimilar in US, First for Amgen's Blockbuster Enbrel*, REG. AFF. PROF. SOC'Y (Aug. 30, 2016), <http://www.raps.org/Regulatory-Focus/News/2016/08/30/25739/FDA-Approves-Third-Biosimilar-in-US-First-for-Amgens-Blockbuster-Enbrel/> (describing approval of Erelzi and Zarxio); *FDA Approves Amjevita, a Biosimilar to Humira*, U.S. FOOD & DRUG ADMIN. (Sept. 23, 2016), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm522243.htm> (describing Amjevita approval); Sy Mukherjee, *Why These Copycat Drugs Aren't Slashing Best-Sellers' Prices*, FORTUNE (Oct. 18, 2016), <http://fortune.com/2016/10/18/pfizer-johnson-johnson-remicade-biosimilar/> (describing limited savings offered by Remicade biosimilar Inflectra).

66. *FDA Finally Addresses Interchangeable Biosimilars*, LAW360 (Feb. 28, 2017), <https://www.law360.com/articles/891538/fda-finally-addresses-interchangeable-biosimilars>.

67. Shepherd, *supra* note 16, at 152.

68. Richard Cauchi, *State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars*, NAT'L CONF. OF ST. LEGISLATURES. (Nov. 15, 2016), <http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx>.

69. *Id.*

70. *Id.*

71. *Id.*

72. *Id.*

substitution.<sup>73</sup> Fifth, some states provide immunity to pharmacists who comply with state law in making a substitution.<sup>74</sup> Sixth, some laws ask a pharmacist to compare the cost or price of a biologic versus the interchangeable biosimilar, and in five states, substitution is only permitted if it would result in a prescription for a lower-cost medication.<sup>75</sup>

Indiana's recent biosimilar legislation exemplifies typical state legislation.<sup>76</sup> It allows a pharmacist to exchange a biologic for a biosimilar only if:

- (1) the FDA has deemed the biosimilar to be interchangeable; (2) the prescriber includes a 'may substitute' instruction in the prescription; (3) the pharmacist informs the customer of the substitution; (4) the pharmacist notifies the prescriber within five days of substitution; (5) a record is kept of the substitution for at least five years.<sup>77</sup>

State legislation creates controversy when it regulates "physician notification, patient consent, documentation, and record retention."<sup>78</sup> As of March 2017, 27 states and Puerto Rico passed some form of biosimilar substitution law governing how a prescription for a biologic might be exchanged for an interchangeable biosimilar.<sup>79</sup>

### III. SELLING LEGISLATION AS "PATIENT-FRIENDLY"

Proponents of state biosimilar legislation have justified it as protecting "patient safety . . . the physician-patient relationship" and "transparency and communication between patients and their treatment care teams."<sup>80</sup> Though proponents of state biosimilar legislation have embraced the patient-friendly label, these proponents represent interests that are not necessarily patient-friendly.<sup>81</sup> A closer look at the entities and individuals supporting state biosimilar legislation suggests that the laws may not always be designed with patients in mind.<sup>82</sup>

73. *Id.*

74. *Id.*

75. *Id.*

76. Kadin, *supra* note 47, at 420 (stating that Indiana legislation should be a model for biosimilar legislation).

77. *Id.*

78. King, *supra* note 63, at 39.

79. Cauchi, *supra* note 68.

80. Leigh Purvis, *A Sense of Déjà Vu: The Debate Surrounding State Biosimilar Substitution Laws*, INSIGHT ON THE ISSUES, Sept. 2014, at 2, [http://www.aarp.org/content/dam/aarp/research/public\\_policy\\_institute/health/2014/the-debate-surrounding-state-biosimilar-substitution-laws-AARP-ppi-health.pdf](http://www.aarp.org/content/dam/aarp/research/public_policy_institute/health/2014/the-debate-surrounding-state-biosimilar-substitution-laws-AARP-ppi-health.pdf).

81. *Id.*

82. *Id.*

Three categories of stakeholders typically support state biosimilar legislation: biologic manufacturers, patient advocacy groups, and physicians who treat patients with diseases that biologics treat.<sup>83</sup> Biologic drug companies have an interest in protecting their market share and preventing biosimilars from competing with their own products.<sup>84</sup> Patient advocacy groups that support restrictive biosimilar legislation have been criticized as holding views “often closely aligned with those of the drug industry.”<sup>85</sup> Physicians generally support state laws on biosimilars.<sup>86</sup> However well intentioned, physicians with patients on biologics may not necessarily speak for their patients or have interests that align with their patients’ concerns.

Louisiana’s biosimilar legislation<sup>87</sup> provides an illustrative example of the way biosimilar legislation proponents may not always be patient-friendly. In 2015, Representative Scott Simon, Chairman of the Health and Welfare Committee, introduced House Bill 319 (HB 319) during the Louisiana legislature’s regular session.<sup>88</sup> The bill sought to amend certain laws “relative to interchangeable biological products; to provide for definitions; to provide for licensure penalties; to require certain information to be sent to a prescriber; and to provide for related matters.”<sup>89</sup> HB 319 was supported by the Coalition of State Rheumatology Organizations,<sup>90</sup> the Louisiana Oncology Society,<sup>91</sup> and GHLF, which “represents more than 80,000 chronically ill patients.”<sup>92</sup> LouisianaBio, the Louisiana chapter of the Biotechnology Industry Organization, an international trade organization representing biotech companies and involved in passing numerous state biosimilar bills, wrote a letter to the editor of *The Advocate*, a Baton Rouge newspaper, supporting HB 319.<sup>93</sup> The bill’s supporters echoed a consistent

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83. Jeff Evans, *State Laws, Regulatory Concerns Complicate Biosimilars Landscape*, RHEUMATOLOGY NEWS (Nov. 23, 2015), <http://www.mdedge.com/rheumatologynews/article/104643/rheumatoid-arthritis/state-laws-regulatory-concerns-complicate>.

84. Purvis, *supra* note 80, at 1–2.

85. *Id.*

86. Evans, *supra* note 83.

87. Interchangeable Biological Products Act, H.B. No. 319, 41st Reg. Sess. 391 (La. 2015).

88. *Id.*

89. *Id.*

90. Press Release, Coal. of State Rheumatology Orgs., Biosimilars Legislation Enacted in Louisiana (July 6, 2015), <http://csro.info/app/document/8431393>.

91. *Support Louisiana HB 319 Legislation*, LA. ONCOLOGY SOC’Y, <https://www.laoncologysociety.org/support-louisiana-hb-319-legislation/> (last visited Apr. 9, 2017).

92. Letter from Seth Ginsberg, President, Glob. Health Living Found., to Louisiana House of Representatives (May 19, 2015), <https://www.50statenetwork.org/wp-l>

93. Rhonda Melancon, *Letter: In Support of Alternative Drug Treatments*, ADVOCATE

theme: without the new legislation, patients' safety would be at risk.

I testified in support of HB 319 on behalf of GHLF during a Health and Welfare Committee hearing, as did a physician. In addition to my testimony, I gave a radio and television interview in support of the proposed bill.

As far as I am aware, only one organization opposed the Louisiana bill. The Academy of Managed Care Pharmacy contended that it "would place unnecessary restrictions on the substitution of biosimilars determined to be interchangeable with reference biologic products by the [FDA]."<sup>94</sup> For instance, Louisiana Pharmacy Practice Act's definition of "biologic product" references the BPCIA's definition, but makes no distinction between biosimilar and interchangeable products, a key distinction under the BPCIA.<sup>95</sup> As explained above, a pharmacist cannot substitute a biologic for a drug that is only biosimilar to the biologic, but may exchange a biologic for a biosimilar if the biosimilar is interchangeable.

Moreover, pursuant to the Louisiana Pharmacy Practice Act, if a pharmacist substitutes a biosimilar deemed interchangeable by the FDA, the pharmacist must "[n]o later than five business days following the dispensing of a biological product . . . communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer."<sup>96</sup> Ultimately, Representative Simon's bill was signed into law on July 1, 2015.<sup>97</sup>

After my experience in Louisiana, I was tapped by GHLF to participate in the Congressional Arthritis Caucus' July 13, 2015, Biosimilar Briefing. I was joined by two rheumatologists, one representing the Arthritis Foundation and the other representing the Coalition of State Rheumatology Organizations, as well as representatives from Amgen and Sandoz. During pre-briefing organizational calls, I gleaned that GHLF's interests aligned with those of Amgen and the rheumatologists. I asked whether state biosimilar laws might be preempted by federal law and was asked to refrain from raising the issue at the Biosimilar Briefing.

At the time, Amgen and Sandoz were engaged in litigation over a Sandoz biosimilar that would compete with an Amgen biologic.<sup>98</sup> During my panel

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(May 7, 2015, 3:15 PM), [http://www.theadvocate.com/baton\\_rouge/opinion/letters/article\\_cc6ddcbe-5180-57c8-8f31-144b385c799d.html](http://www.theadvocate.com/baton_rouge/opinion/letters/article_cc6ddcbe-5180-57c8-8f31-144b385c799d.html).

94. Letter from Edith A. Rosato, Chief Exec. Officer, Acad. of Managed Care Pharmacy, to Governor Bobby Jindal, State of La. (June 17, 2015), [http://amcp.org/uploadedFiles/Production\\_Menu/Policy\\_Issues\\_and\\_Advocacy/Letters,\\_Statements\\_and\\_Analysis\\_-\\_docs/2015/gov\\_veto\\_req\\_hb319\\_biosimilars.pdf](http://amcp.org/uploadedFiles/Production_Menu/Policy_Issues_and_Advocacy/Letters,_Statements_and_Analysis_-_docs/2015/gov_veto_req_hb319_biosimilars.pdf).

95. LA. STAT. ANN. § 37:1164(4) (2016).

96. LA. STAT. ANN. § 37:1226.1(A).

97. Press Release, Coal. of State Rheumatology Orgs., *supra* note 90.

98. See John T. Aquino, *Court Ends Amgen's 'Pointless' Biosimilar Suit Against Sandoz*, BLOOMBERG BNA (July 26, 2016), <https://www.bna.com/court-ends-amgens-n73014445282/>

presentation, I emphasized the need to inform patients and providers alike of medication substitution even after a biosimilar is deemed interchangeable to a biologic.<sup>99</sup> Amgen and the physicians echoed my concerns. Sandoz's representative took a more skeptical approach to biosimilar restrictions.

A closer examination of the stakeholders who advocate for state biosimilar legislation on the grounds that it is patient-friendly is needed. Invocation of patient safety concerns may be nothing more than a rhetorically effective way to advance laws that may not actually help or protect patients.

#### A. *Biologic Companies*

Biologic manufacturers have been vocal supporters of state biosimilar legislation.<sup>100</sup> Critics argue that the Biotechnology Industry Organization (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 products."<sup>101</sup> This is true even though there are currently no FDA-approved interchangeable biosimilars.

BIO lobbies on behalf of over 1,100 biotechnologies around the world.<sup>102</sup> BIO's lobbying efforts helped pass the first state-level biosimilar legislation in Virginia.<sup>103</sup> Pharmacists opposed the law, arguing that it created "too much red tape for substitution, thereby threatening the impact of biosimilars within the state."<sup>104</sup> In California, the entities lobbying for the bill's passage included AbbVie, Amgen, BIO, Genentech, and PhRMA.<sup>105</sup> Relying on their "political power and insider influence," companies like Amgen seek to reduce competition and protect its market share.<sup>106</sup>

With respect to biosimilars, biologic manufacturers have an easily discernible goal: stop the introduction of products that would threaten their market share.<sup>107</sup> Labeling laws that might limit patient access as "patient-

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(explaining the procedural history of Amgen's litigation over Sandoz's biosimilar).

99. In 2015, I ended my relationship with GHLF. *See supra* note 2.

100. PUBLIC CITIZEN, COMPETITION INHIBITORS: HOW BIOLOGICS MAKERS ARE LEVERAGING POLITICAL POWER TO MAINTAIN MONOPOLIES AND KEEP PRICES SKY-HIGH 24 (2014), <http://www.citizen.org/documents/report-biologics-industry-leverages-political-power-to-maintain-monopolies-and-inflate-prices.pdf>.

101. *Id.*

102. Kate Traynor, *Virginia Passes Nation's First Biosimilar Substitution Law*, AM. SOC'Y HEALTH SYS. PHARMACISTS (May 15, 2013), <http://www.ashp.org/menu/News/PharmacyNews/NewsArticle.aspx?id=3892>.

103. *Id.*

104. *Virginia Bill First to Allow Biosimilar Substitution*, PHARMACY TIMES (Apr. 18, 2013), <http://www.pharmacytimes.com/publications/issue/2013/april2013/virginia-bill-first-to-allow-biosimilar-substitution>.

105. PUBLIC CITIZEN, *supra* note 100, at 26–27.

106. *Id.* at 27.

107. *See* John Alan Little, Jr., *Taking from Trailblazers: Learning from Those Who Have*



friendly” obscures the laws’ real purpose and may garner patient support under false pretenses. However, if patients need biosimilars, stakeholders who stymie the introduction of biosimilars have interests that are not aligned with patients’ interests. As a result, when biologic manufacturers or its lobbyists support laws regarding its market competitors, any claims that the laws are patient-friendly should be closely scrutinized.

### B. Patient Advocacy Groups

One advocacy group, GHLF, has greatly impacted state biosimilar legislation. GHLF has lobbied in support of state biosimilar legislation in Missouri, Oregon, Illinois, Texas, Louisiana, North Carolina, Washington, Colorado, and Utah.<sup>108</sup> It wrote Ohio legislators to urge passage of state biosimilar legislation with patient notification provisions.<sup>109</sup> It also wrote similar letters to state legislators in Montana, Hawaii, Kentucky, Connecticut, Idaho, Oregon, and Missouri.<sup>110</sup> It opposed legislation in Michigan that did not include notification provisions.<sup>111</sup> GHLF’s President, Seth Ginsburg, argued that an insurer should not be able to switch patients from a biologic to a biosimilar.<sup>112</sup>

GHLF receives support for its community and advocacy efforts from pharmaceutical companies AbbVie, AMGEN, AstraZeneca, Bristol-Myers Squibb, Endo, Genentech, Horizon Pharma, Janssen, Lilly, Pfizer, and

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*Gone Before When Approving Biosimilars*, 44 GA. L. REV. 1097, 1103 (2010) (At the time the BPCIA was passed, biologic manufacturers feared that an abbreviated biosimilar pathway would allow biosimilars to rely on biologic manufacturers’ intellectual property to lower biosimilar production costs; “the entry of biosimilars into the market might make it impossible to recoup [biologic manufacturers’] investment in research and development.”; Eric Sagonowsky, *With Billions at Stake, Will Biosims Finally Make a Mark in the U.S. in 2017?*, FIERCEPHARMA (Dec. 22, 2016, 8:05 AM), <http://www.fiercepharma.com/pharma/billions-at-stake-a-range-biosim-battles>.

108. *Victories*, 50-ST. NETWORK, <https://www.50statenetwork.org/victories/> (last visited Apr. 9, 2017).

109. Letter from Seth Ginsburg, President, Glob. Health Living Found., to Anne Gonzalez & Stephen A. Huffman, Chair & Vice-Chair, Health & Aging Comm. (Apr. 19, 2016), [https://www.50statenetwork.org/wp-content/uploads/2016/04/GHLF-OH-HB-505-Comment-Letter\\_Support-4-19-16-locked.pdf](https://www.50statenetwork.org/wp-content/uploads/2016/04/GHLF-OH-HB-505-Comment-Letter_Support-4-19-16-locked.pdf).

110. *Letters and Testimony*, 50-ST. NETWORK, <https://www.50statenetwork.org/letters-and-testimony/> (last visited Apr. 9, 2017).

111. Rachelle Crow-Hercher, Patient Advocate, Glob. Health Living Found., Testimony at Senate Health Policy Committee Consideration of HB-4812 (Feb. 16, 2016), <https://www.50statenetwork.org/wp-content/uploads/2016/02/GHLF-MI-Rachelle-HB4812-Testimony-2-13-16.pdf>.

112. Andrew Pollack, *Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions*, N.Y. TIMES (July 15, 2016), <https://www.nytimes.com/2016/07/16/business/makers-of-humira-and-enbrel-using-new-drug-patents-to-delay-generic-versions.html>.

Takeda Pharmaceuticals.<sup>113</sup> The biologic Enbrel is an Amgen product, as is Neupogen.<sup>114</sup> AbbVie makes Humira,<sup>115</sup> and Janssen makes Remicade.<sup>116</sup> Each of these biologics is facing market competition from a biosimilar. In addition, GHLF receives support from BIO, the international trade association that has aggressively lobbied on behalf of its pharmaceutical company members for state biosimilar legislation.<sup>117</sup> To the extent that GHLF's lobbying efforts are aligned with those of its corporate sponsors, it too may be taking advantage of the "patient-friendly" label to advance legislation that is friendly to biologic manufacturers, but not necessarily friendly to patients.

### C. Physicians

Laws like those passed in Indiana and Louisiana do not necessarily help patients.<sup>118</sup> If state laws make it harder to substitute interchangeable biosimilars, there will be fewer substitutions, potentially forcing a patient to stick with a more expensive biologic even if a safe and less expensive biosimilar is available.<sup>119</sup> If laws require doctors to consent to substitution, this requirement "may increase undue patient anxiety towards biosimilars (and generics) and deter their use."<sup>120</sup> If the FDA has determined that a biosimilar is clinically indistinguishable from a biologic, why would doctors support legislation that makes it more difficult for patients to obtain a biosimilar?

Like pharmaceutical companies, doctors have good reason to stand behind legislation that is labeled patient-friendly. In supporting such laws, the physicians themselves give the appearance of supporting their patients' interests and supporting such laws is good PR.

However, physicians may not be aware of their patients' interests. For example, patients, but not physicians, will feel the economic consequences of taking a more expensive biologic. A physician suffers no economic loss if his or her patient must incur astronomical expenses related to medication.<sup>121</sup>

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113. *Our Partners*, CREAKY JOINTS, <https://creakyjoints.org/about-us/our-partners/> (last visited Apr. 9, 2017).

114. *Products*, AMGEN, <http://wwwext.amgen.com/products/> (last visited Apr. 9, 2017).

115. *Products*, ABBVIE, <https://www.abbvie.com/our-science/products.html> (last visited Apr. 9, 2017).

116. *Products*, JANSSEN, <http://www.janssen.com/products> (last updated Apr. 3, 2017).

117. *Id.*

118. Kadin, *supra* note 47, at 420 (referencing Indiana law); H.B. No. 319, 41st Reg. Sess. 391 (La. 2015), (referencing Louisiana law).

119. Kadin, *supra* note 47, at 421.

120. *Id.* at 425.

121. Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 861, 867 (2016) (explaining that

In fact, because physicians often delegate medication authorization paperwork to their nurses and other members of their office staff, they may never learn what a biologic costs or how much a biosimilar can save their patients.<sup>122</sup> Physicians may be too far removed from understanding the stakes at issue in biosimilar legislation, rendering their testimony and support a poor proxy for the patient voice.

#### IV. CONCLUSION

This essay challenges the assumption that state biosimilar legislation advances patient interests by protecting patients' safety. Despite federal law providing that a biologic prescribed by a physician may be substituted for an interchangeable biosimilar without any additional communication or action, numerous state laws have added communication requirements that make the biologic to biosimilar exchange more difficult.<sup>123</sup> Skeptical physicians and patients may hesitate to accept a biosimilar in exchange for a biologic. As a result, patients may have restricted access to less expensive forms of effective medication.

Testimony on bills affecting biosimilars should exclude, or at least deprioritize, testimony from companies with an economic stake in a biosimilar bill's passage. Patients should be heard from first and patient testimonials should outnumber industry testimonials. Doctors who wish to support biosimilar legislation could be asked to show that their patients support the doctors' legislative stance and that his or her patients will benefit with respect to treatment options and cost if the legislation passes. The assumption that doctors speak effectively for their patients must be challenged.

Finally, though pharmacy organizations have opposed state legislation, in general, and notification requirements, in particular, they have done so for reasons unrelated to patient safety. Rather, the notification requirements have been characterized as overly burdensome.<sup>124</sup>

State biosimilar legislation opponents need better advocates. If patient advocacy groups' interests align with biological manufacturers who have a financial interest in making it more difficult for biosimilars to enter a market, then they cannot speak for patients who have different interests. What is

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"physicians write prescriptions, pharmacists sell medications, and patients or their insurers pay for them." Physicians often do not know the cost of the drugs they prescribe and are unlikely to discuss the cost of the drug with the patient.).

122. The last time I discussed changing biologics with my rheumatologist, we settled on Remicade. He never mentioned its cost, nor did he ask whether I had private insurance. He never mentioned whether he was open to prescribing the Remicade biosimilar, which, by then, was available in the U.S. *See also Id.* at 861.

123. Cauchi, *supra* note 68.

124. *Virginia Bill First to Allow Biosimilar Substitution*, *supra* note 104.

needed is an army of informed patient advocates, armed with data about the economic benefits of biosimilars and their scientifically-proven safety. Those voices are missing.

I regret my decision to testify in support of Louisiana's biosimilar legislation. I was lured by the siren song of patient safety concerns. I was uninformed about what interchangeability meant for purposes of my own medication. I now see what legislators saw: a sympathetic and articulate law professor who suffered from a devastating disease and took the very medication the biosimilar state laws implicated. I was a good choice for purposes of lobbying in favor of notification requirements.

I hope that others read this article, state lawmakers and patients alike, and look more closely at the laws that are being sold as friendly to patients like myself. The decision to support state biosimilar legislation must rest on much more than a patient-friendly label and marketing campaign.