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**The Biologics Act: Hopes for Access to Generic Biologics  
May Instead Be a Catalyst for New Innovation**

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**I. INTRODUCTION**

Recent advances in life sciences and biotechnology offer enormous potential for improving health. Biotechnology has led to major breakthroughs and produced new biologically derived treatments for many types of cancer, cardiovascular disorders, diabetes, and other debilitating or life-threatening diseases.<sup>1</sup> These treatments, referred to as “biologics,” are drugs that are created using biotechnological processes derived from living organisms and will continue to revolutionize the pharmaceutical industry.<sup>2</sup> Biologics include medicines like the breast cancer drug Herceptin and the arthritis drug Humira, as well as vaccines such as those that prevent HPV and cervical cancer.<sup>3</sup>

However, the potential for biologics is curbed by their prohibitive costs.<sup>4</sup> Because biologics are significantly larger and more complex molecules than small-molecule pharmaceuticals, they are much more costly to develop.<sup>5</sup> Patients and healthcare payers and providers pick up this cost – and it is a considerable cost. For example, the cost for

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1. Matthew J. Seamon, *Antitrust and the Biopharmaceutical industry: Lessons from the Hatch-Waxman and an Early Evaluation of the Biologics Price Competition and Innovation Act of 2009*, 34 NOVA L. REV. 629, 631 (2010).

2. U.S. Food and Drug Administration - Center for Biologics Evaluation and Research, *What are “Biologics” Questions and Answers*, <http://www.fda.gov/AboutFDA/CentersOffices/CBER/ucm133077.htm> (last visited March. 29, 2011); Alfred B. Engelberg et al., *Balancing Innovation, Access, and Profits – Market Exclusivity for Biologics*, 361 NEW ENG. J. MED. 1917, 1917 (Nov. 12, 2009).

3. Anthony D. So & Samuel L. Katz, Op-Ed., *Biologics Boondoggle*, N.Y. TIMES, Mar. 8, 2010, at A0.

4. Engelberg et al., *supra* note 2, at 1917.

5. U.S. Food and Drug Administration, *supra* note 2.

an average biologic is more than 20 times that of a small-molecule drug.<sup>6</sup> Many biologics cost thousands of dollars for a course of treatment that can last months or years – costs that are far in excess of those for small-molecule pharmaceuticals.<sup>7</sup> These costs average between \$10,000 to \$20,000 or more per patient, per year.<sup>8</sup> Still, biologics are gaining ground in the pharmaceutical market. In 2008, biologics accounted for about thirty percent of sales of pharmaceutical products and are expected to account for fifty percent of all pharmaceutical sales by 2014.<sup>9</sup>

As biologics continue to grow, lower-cost alternatives to biologic therapies are necessary. After more than a decade of debate and mounting demand for lower-cost “generic” versions of biotechnology products, Congress passed the Biologics Price Competition and Innovation Act (Biologics Act).<sup>10</sup> The Biologics Act is included as Title VII of the Patient Protection and Affordable Care Act.<sup>11</sup> The Biologics Act creates a streamlined FDA approval pathway for generic versions of already-marketed biologic drug products. The purpose of the Biologics Act is to encourage innovation while making generic biologic drugs (biosimilars) accessible and less cost-prohibitive to the public. While the Biologics Act’s impact on innovation and access remains to be seen, it may nonetheless encourage innovation of new biologics. These innovative biologics may not be the intended outcome of the Act, which are more competition in the form of introduction of generic biologics. Instead, it will encourage investment and development of new innovative drugs.

## II. BACKGROUND

### a. *Biologics*

Biologics “represent the cutting-edge of biomedical research.”<sup>12</sup> Biologics are markedly different from small-molecule pharmaceuticals in various ways. While small-

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6. Ian Evans, *Follow-on Biologics: A New Play for Big Pharma*, 83 YALE J. BIOL. & MED. 97 (2010).

7. Jeremiah J. Kelly & Michael David, *No Longer “If,” But “When”: The Coming Abbreviated Approval Pathway for Follow-on Biologics*, 64 Food Drug L.J. 115, 115 (2009). Throughout this article, the term “small-molecule pharmaceutical” is used to represent the class of chemically, as opposed to biologically, synthesized pharmaceutical products.

8. *Id.*

9. So & Katz, *supra* note 3.

10. Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119 (2010).

11. *Id.*

12. U.S. Food and Drug Administration, *supra* note 2.

molecule pharmaceuticals are composed of chemicals, biologics are composed of sugars, proteins, nucleic acids or complex combinations of these substances.<sup>13</sup> Biologics are created using biotechnological processes that stimulate biological molecules, often in living entities such as cells and tissues, as opposed to small-molecule drugs that are synthesized with chemicals.<sup>14</sup> Most biologics are complex mixtures that are not easily identified or characterized. The process of manufacture for biologics differs extensively from small-molecule compounds.<sup>15</sup> Synthesis of biologics requires living organisms such as bacteria or cell culture and requires hundreds of isolation and purification steps.<sup>16</sup>

Due to the complexity of biologics, an exact copy of a biologic is impossible, since changes to the compound itself occur during the manufacturing process.<sup>17</sup> Thus, generic biologics are not identical to the innovator drug, in contrast with small-molecule generic drugs, which must be chemically identical to the innovator drug. Instead, generic biologics are often called “follow-on biologics” or “biosimilars.”<sup>18</sup> This name underscores the fact that follow-on biologics are similar, but not identical to the innovator, biological product.

#### *b. Generics*

Generic pharmaceuticals are a cheaper alternative for consumers. Similarly, generic biologics have been proposed as a possible solution for the continuing skyrocketing pharmaceutical costs. U.S. confidence in and acceptance of this idea is the basis for the fact that approval of generic drugs has been allowed for over twenty-five years. The Hatch-Waxman Act of 1984<sup>19</sup> aimed to strike a balance between incentives for drug innovation and the need for lower drug prices through increased competition.<sup>20</sup> The Hatch-Waxman Act created a growth in the generic industry as a response to the increased demand for lower-cost pharmaceuticals.<sup>21</sup> Generic alternatives facilitated by

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13. *Id.*; A. Taylor Corbitt, *The Pharmaceutical Frontier: Extending Generic Possibilities to Biologic Therapies in the Biologics Price Competition And Innovation Act Of 2007*, 18 DEPAUL J. ART TECH. & INTELL. PROP. L. 365, 376-7 (2008).

14. *Id.*

15. Corbitt, *supra* note 13, at 377.

16. *Id.*

17. *Id.* at 378.

18. Corbitt, *supra* note 13, at 367.

19. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 15 U.S.C. §§ 68b-68c, 70b (2006)).

20. Corbitt, *supra* note 13, at 371.

21. *Id.* at 366.

the Hatch-Waxman Act saved consumers billions of dollars in retail pharmacies alone on prescription drugs by purchasing generic drugs instead of brand name drugs.<sup>22</sup> As a compromise to competing interests from brand name drug manufacturers, new generic pharmaceutical companies and the need for public access to affordable medication, the Hatch-Waxman Act specifically authorizes “Abbreviated New Drug Applications” (ANDAs).<sup>23</sup> ANDAs allow a manufacturer that produces “a generic version of a patented drug to bypass the FDA’s requirement of proving that the drug is safe and effective,” so long as the formula is identical to the brand-name drug.<sup>24</sup>

Similar to ANDAs, an abbreviated pathway for the approval of biosimilars exists in the Biologics Act and is expected to reduce drug costs.<sup>25</sup> The Congressional Budget Office (CBO) estimates that the federal government could save \$5.9 billion over ten years by establishing an abbreviated pathway for the FDA approval of biosimilars, not counting the savings to private purchasers.<sup>26</sup> Additionally, it is estimated that an abbreviated pathway will reduce total expenditures on biologics in the U.S. by about \$25 billion over the same period.<sup>27</sup>

### III. IMPACT OF THE BIOLOGICS ACT

Similar to the Hatch-Waxman act, the Biologics Act provides an expedited FDA approval procedure and is intended to promote the development of lower-cost alternatives to biologics.<sup>28</sup> The Hatch-Waxman Act facilitated the introduction of generics and has succeeded in creating access to significantly lower cost generic drugs for the consumer.<sup>29</sup> Similarly, the Biologics Act attempts to encourage the introduction of biosimilars by

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22. CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY ix (1998), available at <http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf> (in one year alone (1994), consumers of generic drugs saved between \$8 billion and \$10 billion in retail pharmacies alone on prescriptions drugs by purchasing generic drugs instead of brand name drugs).

23. Corbitt, *supra* note 13, at 372.

24. *Id.*

25. CONG. BUDGET OFFICE, COST ESTIMATE, S. 1695, BIOLOGICS PRICE COMPETITION AND INNOVATION ACT OF 2007 1 (2008), available at <http://www.cbo.gov/ftpdocs/94xx/doc9496/s1695.pdf>. The Biologics Act is substantially identical to the S.1695 Biologics Price Competition and Innovation Act of 2007, a biosimilars bill introduced in the 110<sup>th</sup> Congress. See Biologics Price Competition and Innovation Act of 2007, S. 1695, 110<sup>th</sup> Cong. (2007).

26. CONG. BUDGET OFFICE, *supra* note 25, at 1.

27. *Id.*

28. Corbitt, *supra* note 13, at 366.

29. *Id.* at 371.

providing innovator biologics manufacturers with market exclusivity.<sup>30</sup>

The real impact of the Biologics Act on the development of biologics and biosimilars is still uncertain. One possible outcome is the development of more biosimilars, which the Act intended to spur. The Biologics Act will serve its intended purpose and encourage a new market of biosimilars, akin to the Hatch-Waxman Act. Incentivizing the development of biosimilars by creating an abbreviated approval pathway for biosimilars will allow for the development of more biologics in the form of biosimilars. The development of more biosimilars in the market will likely create discounted costs for biologics. As a result, there will be savings in both the private and public expenditures of drugs.<sup>31</sup> In other words, both commercial and government payers will save money by reducing their spending on specialty drugs.

Furthermore, more biosimilars will continue to increase because investment and production of biosimilars is attractive for pharmaceutical companies.<sup>32</sup> Biosimilars still have the potential of bringing in a large profit for pharmaceutical companies, despite the drop in price due to the generic classification.<sup>33</sup> Additionally, because they are just copies of pioneer drugs, the development of biosimilars poses a lower risk than developing an innovator biologic.<sup>34</sup>

Another possible outcome of the Biologics Act could actually be slowing the development of biosimilars and biologics. The Biologics Act incorporates some high hurdles that biosimilars must overcome in order to obtain FDA approval.<sup>35</sup> Because of the high costs and high standards for generic biologics, manufacturers may be slower to develop biosimilars compared to generic small-molecule drugs.<sup>36</sup>

Biologics have also not been subject to generic competition because they are more complex than chemical drugs, making it much more difficult, and expensive, to prove

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30. Joanna T. Brougher, *The Biosimilars Act: Promoting or Discouraging the Development of Generic Biologics?*

A tug-of-war between generic and innovator biologics seems to be where drug developers are headed, 22 BIOTECHNOLOGY & HEALTHCARE, Winter 2010, at 22, available at [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3008392/pdf/bth07\\_4\\_p022.pdf](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3008392/pdf/bth07_4_p022.pdf). See 42 U.S.C. § 262(k)(7).

31. CONG. BUDGET OFFICE, *supra* note 25, at 1.

32. Heidi Ledford, 'Biosimilar' Drugs Poised to Penetrate Market, 468 NATURE 18, 19 (2010), available at <http://www.nature.com/news/2010/101103/full/468018a.html>

33. *Id.*

34. *Id.*

35. Brougher, *supra* note 30, at 22.

36. Steven A. Nash & Rebecca Workman, A New Pathway for Follow-On Biologics, 20 FED. CIR. B.J. 193, 198 (2010).

that a copy is identical to the original drug.<sup>37</sup> Additionally, the production process of biologics made from living organisms is riskier than that of chemical-based drugs and presents safety concerns.<sup>38</sup> Some argue that the Act may hinder innovation of biologics altogether.<sup>39</sup>

Yet another possible outcome is that the Biologics Act may encourage research and development of innovator biologics instead of biosimilars. Since replicating an innovator biologic may be too costly and may take a long period of time to enter the market, a biologic manufacturer may instead develop its own innovative biologic. By potentially discouraging generic competition, the Biologics Act may encourage the development of new biologic products. Rather than assuming costs of replicating biologics already in the market, manufacturers may be more willing to develop new products that target different diseases, resulting in more treatment options.

The Biologics Act provides innovator biologics manufacturers with market exclusivity and delays market entry for manufacturers of generic biologics.<sup>40</sup> Innovators have a lot to gain from developing new biologics. For example, innovator biologics manufacturers are ‘rewarded’ for their research and development with a twelve-year FDA exclusivity period.<sup>41</sup> This exclusivity period is much longer than the exclusivity period allowed by the Hatch-Waxman Act, which allows five years of market exclusivity.<sup>42</sup> The exclusivity period will certainly enhance investment incentives and innovation.<sup>43</sup> The twelve-year data exclusivity period for new biologics is an appropriate approach to balance innovation and lower costs of biosimilars.<sup>44</sup>

Even if the innovator biologic is not granted patent protection, the Act provides a separate way to obtain market exclusivity for twelve years.<sup>45</sup> Considering the long wait period required to obtain a patent and the uncertainty of the patent protection, the

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37. Cobbitt, *supra* note 13, at 378.

38. John Alan Little, Jr., *10<sup>th</sup> Annual Legal Ethics and Professionalism Symposium: Drawing the Ethical Line: Controversial Cases, Zealous Advocacy, and the Public Good*, 44 GA. L. REV. 1097, 1102 (2010).

39. See Melissa Levin, *Follow-On Biologics: Is The Incentive For Development Still Present?* 20 ANN. HEALTH LAW ADVANCE DIRECTIVE 49 (2010).

40. Nash & Workman, *supra* note 36, at 196-97.

41. Katherine N. Addison, *The Impact of the Biosimilars Provision of the Health Care Reform Bill on Innovation Investments*, 10 J. MARSHALL REV. INTELL. PROP. L. 553, 565 (2011).

42. Brougher, *supra* note 30, at 23.

43. Addison, *supra* note 41.

44. Henry Grabowski et al., *Data Exclusivity for Biologics*, 10 NATURE REV. DRUG DISCOVERY 15, 16 (2011).

guaranteed exclusivity period provides an incentive to research and development, since investors will be sure that the costs of development will be recovered due to the FDA approval of the biologic and its resulting exclusivity period.<sup>45</sup>

Thus, the FDA exclusivity period granted by the Biologics Act offers a major opportunity to develop more biologics. The exclusivity period favors innovation rather than copying pioneer drugs to create biosimilars. The opportunities and economic value for innovative biologic manufactures may incentivize the development of innovator biologics, rather than biosimilars as was intended in the Biologics Act.

#### IV. CONCLUSION

The Biologics Act's impact on innovation and access to biosimilars remains to be seen, and much debate about its potential impact continues. While the purpose of the Act to encourage generic competition is yet to be determined, the Act may in fact serve as a catalyst for innovation of new biologics. The costs of biologics may not be reduced as soon as expected, but the promise of new biologics therapies that target a variety of diseases will at least provide the availability of more life-saving treatments.

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45. *Id.*

46. Addison, *supra* note 41.