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# Who Can Afford It?: The Patient Protection and Affordable Care Act's Failure to Regulate Excessive Cost-Sharing of Prescription Biologic Drugs

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# WHO CAN AFFORD IT?: THE PATIENT PROTECTION AND AFFORDABLE CARE ACT'S FAILURE TO REGULATE EXCESSIVE COST- SHARING OF PRESCRIPTION BIOLOGIC DRUGS

MICHAEL CALLAM\*

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## I. INTRODUCTION

Fifty-year-old Michael Taffe, a former elite-level gymnast and vice president of a software company, received a phone call that drastically changed his life.<sup>1</sup> He was told he had rheumatoid arthritis, lupus, and diabetes.<sup>2</sup> In the following twelve years, Michael was diagnosed with shingles, gout, Sjögren's syndrome,<sup>3</sup> and an episodic tremor which caused his left hand to spontaneously jump.<sup>4</sup> Additionally, for the past nine and a half years, he has experienced a loud noise in his ears that started one morning and has yet to stop.<sup>5</sup> Unable to continue working at a high-level management position, Michael now works at a golf course where he is better able to focus on his health.<sup>6</sup> Each day, Michael takes numerous prescription biologic drugs.<sup>7</sup> Despite having insurance, he has already spent \$12,000 this year out of his 401K savings account to pay drug costs not covered by his plan.<sup>8</sup>

In a similar story, Jamie Love's wife was diagnosed with cancer and needed a life-saving biologic medication that costs \$100,000 per year.<sup>9</sup> Ironically, Jaime is the director of Knowledge Ecology International, a non-profit organization which works toward improving individuals' access to necessary medications.<sup>10</sup> Jaime's wife is not eligible for Medicare for two more years and is currently covered by his expensive private insurance policy which costs them more than \$2,000 per month.<sup>11</sup> Love is eligible to switch to Medicare, but cannot because it would leave his wife

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<sup>1</sup> John Manuel Andriote, *Breaking the Cycle of Prescription Drug Costs*, ATLANTIC Oct. 9, 2012, <http://www.theatlantic.com/health/archive/2012/10/breaking-the-cycle-of-prescription-drug-costs/263370/>.

<sup>2</sup> *Id.*

<sup>3</sup> Sjögren's syndrome is a chronic autoimmune disease in which a person's white blood cells attack their moisture-producing glands. *About Sjögren's Syndrome*, SJÖGREN'S SYNDROME FOUND., <http://www.sjogrens.org> (last visited Oct. 10, 2012).

<sup>4</sup> Andriote, *supra* note 1.

<sup>5</sup> Andriote, *supra* note 1.

<sup>6</sup> Andriote, *supra* note 1.

<sup>7</sup> Michael takes

Neurontin and Celebrex for pain; Aleve and Advil; aspirin a couple times a day; Irbesartan, Metopropol, Moexipril, Nifedipine, and Triamterene-HCTZ for blood pressure; Glipizide for diabetes; Vitamin D; Folic acid to help with hair falling out; Evoxac (Cevimeline) for the Sjögren's syndrome. There's Methotrexate (which was developed as one of the oldest cancer drugs and which makes him sick) and the 'rescue' drug Lovacin to treat the sickness. Once a month there is the three- to four-hour-long infusion of the biologic drug Remicade.

Andriote, *supra* note 1.

<sup>8</sup> Andriote, *supra* note 1.

<sup>9</sup> Andriote, *supra* note 1.

<sup>10</sup> Andriote, *supra* note 1.

<sup>11</sup> Andriote, *supra* note 1.

uninsured.<sup>12</sup> Until the provisions of the Patient Protection and Affordable Care Act (PPACA)<sup>13</sup> that ban insurers from denying coverage to persons on the basis of their preexisting conditions become effective in 2014, the best hope of keeping his wife alive is for Love to continue making the unaffordable co-payments (co-pays)<sup>14</sup> on his insurance policy.<sup>15</sup>

Similarly, Marie D'Orsaneo lives with rheumatoid arthritis. When her condition worsened, she was prescribed Rituxan, an expensive injectable biologic drug for which prior authorization from her employer was required.<sup>16</sup> While waiting a month for approval, Maria's health deteriorated so rapidly she could not continue her job as a physician's assistant and needed relatives to move into her home to help her perform daily functions.<sup>17</sup> Maria is struggling to afford her prescription of Rituxan that costs approximately \$7,000 per month.<sup>18</sup>

The Taffe, Love, and D'Orsaneo stories demonstrate an emergent problem within modern medicine: insurers are legally permitted to utilize unaffordable cost-sharing requirements, exposing policy holders to financial risk if diagnosed with a chronic disease that requires a biologic drug<sup>19</sup> prescription.<sup>20</sup> Excessive cost-sharing requirements, specifically excessive co-pays or coinsurance,<sup>21</sup> defeat the basic purpose of health insurance of transferring risk from the insured to the insurer.<sup>22</sup>

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<sup>12</sup> Andriote, *supra* note 1.

<sup>13</sup> Patient Prot. & Affordable Care Act, Pub. L. No. 111–48, 124 Stat. 119 (2010).

<sup>14</sup> Co-payment or co-pay is defined as “a fixed amount . . . you pay for a covered health care service, usually when you get the service. The amount can vary by the type of covered health care service.” *Glossary*, HEALTHCARE.GOV, <http://www.healthcare.gov/glossary/c/copayment.html> (last visited Oct. 10, 2012).

<sup>15</sup> *Id.*

<sup>16</sup> Kathleen Kingsbury, *If You Can't Pay: How to Get Insurance to Cover Specialty Drugs*, NBC NEWS (Jan. 18, 2013, 12:54 PM), [http://vitals.nbcnews.com/\\_news/2013/01/18/16586697-if-you-cant-pay-how-to-get-insurance-to-cover-specialty-drugs](http://vitals.nbcnews.com/_news/2013/01/18/16586697-if-you-cant-pay-how-to-get-insurance-to-cover-specialty-drugs).

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> Also known as “specialty drugs” and “biologics.”

<sup>20</sup> Cost-sharing requirements are defined as “the share of costs covered by your insurance that you pay out of your own pocket. This term generally includes deductibles, coinsurance, and copayments, or similar charges, but it doesn't include premiums, balance billing amounts for non-network providers, or the cost of non-covered services.” *Glossary*, HEALTHCARE.GOV, [www.healthcare.gov/glossary/a/actuarial.html](http://www.healthcare.gov/glossary/a/actuarial.html) (last visited Oct. 20, 2012).

<sup>21</sup> Coinsurance is defined as “your share of the costs of a covered health care service, calculated as a percent . . . of the allowed amount for the service.” *Glossary*, HEALTHCARE.GOV, <https://www.healthcare.gov/glossary/co-insurance/> (last visited Nov. 24, 2013).

<sup>22</sup> BLACK'S LAW DICTIONARY 1205 (9th ed. 2009) (insurance is defined as a contract by which one party, the *insurer*, undertakes to indemnify another party, the *insured*, against risk of loss, damage, or liability arising from the occurrence of some specified contingency, and usually to defend the insured or to pay for a defense regardless of whether the insured is ultimately found liable).

Biologic drugs treat serious, complex, and chronic conditions such as cancer and rheumatoid arthritis.<sup>23</sup> It is expected by 2016 that seven of the top ten prescription drugs will be biologic drugs.<sup>24</sup> For employer-provided insurance, biologic drugs make up about seventeen percent of employers' total drug costs, though only about one percent of the workforce consumes them.<sup>25</sup> The average annual price of a biologic drug is \$24,000 and costs are expected to grow by forty percent by 2017.<sup>26</sup>

On March 23, 2010, President Barack Obama signed the PPACA into law.<sup>27</sup> The PPACA includes provisions that create a statutory pathway for litigation of patent issues related to "biosimilar"<sup>28</sup> biological products, also known as follow-on biologics.<sup>29</sup> Utilization of biologic drugs is increasing and is establishing itself as an essential component in modern medicine.<sup>30</sup> Although the statutory pathway of the PPACA is intended to expedite the process of introducing more affordable biosimilar products to the prescription drug market, the potential savings to patients are minimal and the PPACA neglects a serious problem within the current insurance market structure.<sup>31</sup>

This Note will discuss how the PPACA's abbreviated approval pathway for biological products creates an expedited procedure to bring less expensive biologic drugs to the market, but ultimately fails to make those biologic drugs affordable because of its lack of provisions limiting insurers' use of excessive cost-sharing requirements. Part II provides an overview of prescription drugs, compares biologics with traditional prescription drugs, and provides a brief legislative history of prescription drug laws. Part III analyzes the impact of the abbreviated approval pathway on biologic drugs' costs to prescribed patients. It also examines the

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<sup>23</sup> PHARMACY BENEFIT MANAGEMENT INSTITUTE, 2012 SPECIALTY DRUG MANAGEMENT REPORT (2012), available at [http://www.specialtydrugbenefitreport.com/images/stories/PBMI\\_2012\\_SDBR.pdf](http://www.specialtydrugbenefitreport.com/images/stories/PBMI_2012_SDBR.pdf).

<sup>24</sup> *How to Get Your Health Plan to Cover Specialty Drugs*, CNBC NEWS, <http://www.cnbc.com/id/100392819> (last visited Jan. 19, 2013, 4:02 PM). The Independent Specialty Pharmacy Coalition reports that approximately 57 million Americans rely on specialty drugs. *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> Patient Prot. & Affordable Care Act, Pub. L. No. 111-48, 124 Stat. 119 (2010).

<sup>28</sup> Biosimilar is defined as a biologic drug shown to be highly similar to a reference product based on data derived from analytical, animal, and clinical studies. Minor differences are allowed in clinically inactive components as long as no clinically meaningful differences exist between the proposed biosimilar and the reference product with regard to safety, purity, and potency. Requirements to meet the 'no clinically meaningful differences' standard have not been defined in the law and, depending on the FDA's implementation of the biosimilar approval pathway, may be variable among products based on the known safety and efficacy profile of the reference products. Andrew D. Zelenetz et al., *NCCN Biosimilars White Paper: Regulatory, Scientific, and Patient Safety Perspectives*, 9 J. NAT'L COMPREHENSIVE CANCER NETWORK, S3-S4 (Supp. 4 2011).

<sup>29</sup> *Id.* at S21 n.26.

<sup>30</sup> *Id.* at S5.

<sup>31</sup> *See* Patient Prot. & Affordable Care Act, Pub. L. No. 111-48, 124 Stat. 119 (2010).

PPACA's effects on biologics inclusion into health insurance plans. This Note will demonstrate how the PPACA continues to keep prescription biologic drugs unaffordable for insured patients by permitting private insurers to continue to include excessive cost-sharing requirements in insurance plans. Finally, Part IV proposes a recommendation by which the PPACA would be amended to include a modified version of current proposed legislation. To fully address the problem, Congress must formulate and enact legislation that properly protects patients from excessive out-of-pocket costs, while balancing the insurance companies' interests to remain competitive and profitable.

## II. OVERVIEW OF PRESCRIPTION DRUGS

When developing a statutory standard for prescription biologic drugs on a national scale it is essential to have a sound understanding of the evolution of prescription drug legislation. This section explains the differences between biologic drugs and traditional small-molecule drugs. This section then provides an overview of how prescription drugs are a vital component of modern medicine and describes the primary federal regulations created to protect patients. Lastly, this section discusses provisions of the PPACA that attempt to mimic the success of previous legislation by inducing generic biologic drug entry.

### A. *Biologic Drugs v. Traditional Small-Molecule Drugs*

Most traditional prescription drugs are made up of simple molecules mixed together.<sup>32</sup> For this reason, generic versions of small-molecule drugs can be manufactured to be atomically identical to their reference drug.<sup>33</sup> As a result, the manufacturing, marketing, and use in clinical practice of generic small-molecule drugs is relatively easy compared to biologic drugs.<sup>34</sup>

In contrast, a biologic drug is “[a] substance that is made from a living organism or its products and is used in the prevention, diagnosis, or treatment of cancer and other diseases.”<sup>35</sup> Biologics are currently prescribed to treat many conditions

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<sup>32</sup> Bryan A. Liang, *Regulating Follow-on Biologics*, 44 HARV. J. ON LEGIS. 363, 367 (2007) [hereinafter *Regulating Follow-on Biologics*]; see also *Small and Large Molecules: Drugs on a Chemical and Biological Basis*, BAYER HEALTH CARE, <http://www.bayerpharma.com/en/research-and-development/technologies/small-and-large-molecules/index.php> (last visited October 20, 2012) [hereinafter BAYER] (“Classic drug development works with small, chemically manufactured active-substance molecules. One example is acetylsalicylic acid (ASA), aspirin's active ingredient with a molecular weight of about 180 g/mol or 180 Da. These small molecules can be processed into easily ingestible tablets or capsules. If the tablet dissolves in the gastrointestinal tract, the dissolved active substance is absorbed into the bloodstream via the intestinal wall. From there, the small molecules can reach almost any desired destination in the body because of their tiny size. Their small structure and chemical composition often also helps them to easily penetrate cell membranes.”).

<sup>33</sup> Zelenetz, *supra* note 28, at S2; see also AMGEN, BIOLOGICS AND BIOSIMILARS 11, 42 (2011), available at [http://www.amgen.com/pdfs/misc/An\\_Introduction\\_on\\_Biologics\\_and\\_Biosimilars.pdf](http://www.amgen.com/pdfs/misc/An_Introduction_on_Biologics_and_Biosimilars.pdf) [hereinafter AMGEN] (Reference drug is defined as “the innovator product that the biosimilar product is intended to copy.”).

<sup>34</sup> AMGEN, *supra* note 33, at 11.

<sup>35</sup> *Biological Drug Definition*, NAT'L CANCER INST. DICTIONARY OF CANCER TERMS, <http://www.cancer.gov/dictionary?cdrid=426407> (last visited Jan. 2, 2014); see also Su-Ying Liang, et al., *Medicare Formulary Coverage for Top-Selling Biologics*, 27 NATURE

including immune system disorders, cancers, blood conditions, and neurological disorders.<sup>36</sup> Biologics and biosimilars require a considerably more complex manufacturing process.<sup>37</sup> The process includes proteins synthesized from living organisms that must be kept in life-sustaining protected environments.<sup>38</sup> First, the organisms endure protein engineering to gear protein molecules to a specific task.<sup>39</sup> The systematic exchange of amino acids results in the biologic candidate functioning even better than the natural variant.<sup>40</sup> Approximately 80,000 different variants of a protein can be optimized through the use of fully automated, robot-based, high-throughput screening and the use of special testing systems.<sup>41</sup> Consequently, “biologics . . . will inherently exhibit some physiochemical differences in addition to the varying production processes that will also modify the products . . . and therefore biosimilars can be close or ‘similar’ to the innovator products but will not be identical.”<sup>42</sup> The science, regulatory processes, and pharmacovigilance<sup>43</sup> mechanisms for these complex biological products are still in an expensive research and development period.<sup>44</sup>

Biologics and traditional small-molecule drugs have similar development times, but relatively high manufacturing costs and other factors result in biologics being significantly more expensive.<sup>45</sup> The high cost of constructing a biologic drug manufacturing facility and the relatively low production yield of biologic drugs contribute to the high cost of the drugs. In addition, it seems as though a substantial portion of manufacturing costs is attributable to biologic manufacturers’ average net profit of thirty-two percent.<sup>46</sup>

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BIOTECHNOLOGY 1082–84 (2009), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2845541/>.

<sup>36</sup> AMGEN, *supra* note 33, at 8; BAYER, *supra* note 32 (“Biologics bind to specific cell receptors that are associated with the disease process. Monoclonal antibodies are specialized in recognizing a very specific structure on the cell surface. Used in cancer therapy, they bind selectively – for example to the receptors of cancer cells, making it possible to mark and fight specific abnormal cells. Healthy cells are usually not attacked in this process, so that biologics often cause fewer side effects than classic chemotherapy.”).

<sup>37</sup> *Regulating Follow-on Biologics*, *supra* note 32, at 367.

<sup>38</sup> *Regulating Follow-on Biologics*, *supra* note 32, at 367.

<sup>39</sup> BAYER, *supra* note 32.

<sup>40</sup> BAYER, *supra* note 32.

<sup>41</sup> BAYER, *supra* note 32.

<sup>42</sup> Zelenetz, *supra* note 28, at S2.

<sup>43</sup> Pharmacovigilance is defined as procedures that monitor the safety of medicines to detect, assess, understand, and prevent adverse effects or any other safety-related issue. AMGEN, *supra* note 33, at 42.

<sup>44</sup> AMGEN, *supra* note 33, at 21–23.

<sup>45</sup> Kate S. Gaudry, *Exclusivity Strategies and Opportunities in View of the Biologics Price Competition and Innovation Act*, 66 FOOD & DRUG L. J. 587, 587–88 (2011).

<sup>46</sup> *Id.* at 588.

Biologics can be twenty times more expensive per patient than traditional small-molecule pharmaceuticals.<sup>47</sup> For example, the annual price of Herceptin, a biologic that is designed to fight against breast cancer, can exceed \$40,000.<sup>48</sup> A one-year supply of Rebif, a biologic drug commonly used to treat multiple sclerosis, can cost more than \$30,000.<sup>49</sup> The yearly price of Xeljanz, an oral biologic used to treat rheumatoid arthritis, is approximately \$25,000.<sup>50</sup> Most patients require recurrent and large doses because of chronic illnesses, compounding costs and leaving patients in a defenseless position.<sup>51</sup>

### B. Prescription Drugs in Modern Medicine

Since pharmaceuticals are an indispensable division of the modern health care system,<sup>52</sup> it is not surprising that pharmaceutical companies report the largest profit margin of any industry worldwide.<sup>53</sup> Pharmaceutical innovation has allowed a level of alleviation of human sickness and suffering inconceivable a century ago.<sup>54</sup> Prescription drugs help prevent cancer recurrence and can treat and reduce the risk of heart disease, resulting in a forty percent increase in life expectancy.<sup>55</sup>

Alexander Flemings' accidental discovery of penicillin led to the "therapeutic revolution" of the 1940s.<sup>56</sup> World War II accelerated commercial production of penicillin, saving thousands of soldiers' lives.<sup>57</sup> Recently, prescription drugs have reduced the number of deaths in the United States from HIV/AIDS, helped prevent

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<sup>47</sup> Parker Tresemer, *Interests in the Balance FDA Regulations Under the Biologics Price Competition and Innovation Act*, 16 UCLA J.L. & TECH. 15 (2012).

<sup>48</sup> Jon Entine, *FDA Balances Costs, Patient Safety in the Biologics and Personalized Medicine Revolution*, FORBES, July 23, 2012, <http://www.forbes.com/sites/jonentine/2012/07/23/fda-balances-costs-patient-safety-in-the-biologics-and-personalized-medicine-revolution-will-it-get-it-right-or-damage-the-miracle-industry/>.

<sup>49</sup> Gaudry, *supra* note 45, at 587.

<sup>50</sup> Matthew Herper, *Xeljanz, A Cheaper-but-Expensive \$25,000-a-Year Pfizer Pill for Rheumatoid Arthritis, Gets FDA Green Light*, FORBES, Nov. 6, 2012, <http://www.forbes.com/sites/matthewherper/2012/11/06/xeljanz-a-25000-pfizer-arthritis-pill-gets-fda-green-light/>.

<sup>51</sup> See Gaudry, *supra* note 45, at 588.

<sup>52</sup> Paula Tironi, *Pharmaceutical Pricing: A Review of Proposals to Improve Access and Affordability of Prescription Drugs*, 19 ANNALS HEALTH L. 311, 314–15 (2010).

<sup>53</sup> Luke W. Cleland, *Modern Bootlegging and the Prohibition on Fair Prices: Last Call for The "Repeal" of Pharmaceutical Price Gouging*, 15 ALB. L.J. SCI. & TECH. 183, 184 (2004); see also ELIZABETH SIEGEL WATKINS, *MEDICATING MODERN AMERICAN: PRESCRIPTION DRUGS IN HISTORY I* (2007) ("With American paying more than \$200 billion in 2005 for prescription pills, the pharmaceutical business is the most profitable in the nation.").

<sup>54</sup> Tironi, *supra* note 52, at 315.

<sup>55</sup> Tironi, *supra* note 52, at 315.

<sup>56</sup> WATKINS, *supra* note 53, at 2.

<sup>57</sup> WATKINS, *supra* note 53, at 2.



cancer recurrence, and reduced the risk of heart disease.<sup>58</sup> Americans consume more prescription drugs than citizens of any other nation.<sup>59</sup>

Patients' access to prescription medication depends on a number of factors.<sup>60</sup> First, patients must have access to a provider with the capability of determining the appropriateness of a drug and the ability to write a prescription.<sup>61</sup> Second, patients must have means to finance the prescription either through self-financing or health insurance.<sup>62</sup> Lastly, access requires the ability to obtain the prescription either through a retail pharmacy or from a mail-order pharmacy.<sup>63</sup>

In the past, holding insurance provided sufficient protection against the high costs of prescription drugs, but this is not the case in modern medicine.<sup>64</sup> Insurers are permitted to discriminate against some patients based on risk classification.<sup>65</sup> In the context of insurance, discrimination does not automatically mean it is wrong, unjustifiable, or illegal.<sup>66</sup> Risk classification is a necessary evil to avoid adverse selection in the insurance market.<sup>67</sup> Insurers define adverse selection as "the process by which [the insured] utilize private knowledge of their own riskiness when deciding to buy or forgo insurance."<sup>68</sup> Whether the problem of adverse selection has been exaggerated by insurers for financial gain has been highly debated.<sup>69</sup>

Traditionally, physicians determined what prescriptions a patient would take without any input from the patient.<sup>70</sup> During the mid 1990s, the physician-patient

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<sup>58</sup> Tironi, *supra* note 52, at 315.

<sup>59</sup> WATKINS, *supra* note 53, at 4; *see also* NAT'L CENTER FOR HEALTH STATISTICS, U.S. DEP'T OF HEALTH AND HUMAN SERVS., HEALTH, UNITED STATES, 2012: WITH SPECIAL FEATURE ON EMERGENCY CARE 282–83 (2013), *available at* <http://www.cdc.gov/nchs/data/hus/hus12.pdf#091> (reporting that from 2007 to 2010 48.5% of persons used at least one prescription drug within one month, 21.7% of persons used three or more prescription drugs within one month, and 10.6% of persons used five or more prescription drugs within one month).

<sup>60</sup> Tironi, *supra* note 52, at 316.

<sup>61</sup> Tironi, *supra* note 52, at 316.

<sup>62</sup> Tironi, *supra* note 52, at 316 (Insurance includes paying any premium, deductible, coinsurance, or co-pay.).

<sup>63</sup> Tironi, *supra* note 52, at 316.

<sup>64</sup> Tironi, *supra* note 52, at 316.

<sup>65</sup> Joseph J. Hylak-Reinholtz & Jay R. Naftzger, *Is It Time to Shed a "Tier" for Four-Tier Prescription Drug Formularies? Specialty Drug Tiers May Violate HIPAA's Anti-Discrimination*, 32 N. ILL. U. L. REV. 33, 45 (2011). Risk classification occurs everyday in the insurance world; for example, insurers charge smokers higher premiums than non-smokers. *Id.*

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> Peter Siegelman, *Adverse Selection in Insurance Markets: An Exaggerated Threat*, 113 YALE L.J. 1223, 1223 (2004).

<sup>69</sup> *Id.* at 1274. Neither economic theory nor empirical evidence can demonstrate that adverse selection is the critical problem that many courts and scholars claim. *Id.*

<sup>70</sup> Hylak-Reinholtz & Naftzger, *supra* note 65, at 40.

relationship drastically changed regarding the choice of prescription medicine.<sup>71</sup> Access to information and extensive marketing by drug manufacturers provided patients the knowledge to demand brand-name pharmaceuticals.<sup>72</sup>

In response to patients demanding more expensive brand-name prescription drugs, health insurance providers created new insurance models utilizing co-pays.<sup>73</sup> Co-pays provided the dual benefit of offsetting some costs of more expensive brand-name drugs and encouraging patients to seek generic versions.<sup>74</sup> Eventually, formularies started to separate prescription drugs into different tiers.<sup>75</sup> Formularies share the same purpose as co-pays of encouraging patients to seek less expensive medications on different tiers.<sup>76</sup>

The affordability of prescription medications is a serious problem even for insurance holders.<sup>77</sup> In 2007, private health insurance covered approximately 202 million Americans.<sup>78</sup> Although it is most common for Americans to obtain insurance through their employer, the number covered by employer-sponsored insurance is decreasing.<sup>79</sup> In 2005, less than fifty percent of employer-sponsored insurance holders participated in prescription drug coverage and only approximately sixty-four percent had access to outpatient prescription drug coverage.<sup>80</sup>

In response to rising prescription drug costs, private health insurers employ numerous techniques to control out-patient prescription drugs costs including increasing enrollee cost-sharing amounts and using formularies to exclude certain drugs from coverage.<sup>81</sup> Additionally, health insurers apply quantity-dispensing limits, require prior authorization, and use step therapy (starting with the most cost-effective drug and progressing to more costly therapy only if necessary).<sup>82</sup> The

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<sup>71</sup> Hylak-Reinholtz & Naftzger, *supra* note 65, at 40.

<sup>72</sup> Hylak-Reinholtz & Naftzger, *supra* note 65, at 40.

<sup>73</sup> Hylak-Reinholtz & Naftzger, *supra* note 65, at 41.

<sup>74</sup> Hylak-Reinholtz & Naftzger, *supra* note 65, at 41.

<sup>75</sup> Hylak-Reinholtz & Naftzger, *supra* note 65, at 41. The most common structure became a three-tier structure. Hylak-Reinholtz & Naftzger, *supra* note 65, at 41. Most three-tier formularies follow similar pricing: Tier 1 includes only generic drugs and has the lowest co-pay, Tier 2 includes preferred brand-name drugs without generic substitutes and has higher co-pays, and Tier 3 includes non-preferred brand-name drugs and has the highest co-pay. Hylak-Reinholtz & Naftzger, *supra* note 65, at 41.

<sup>76</sup> Hylak-Reinholtz & Naftzger, *supra* note 65, at 41.

<sup>77</sup> Tironi, *supra* note 52, at 316.

<sup>78</sup> Tironi, *supra* note 52, at 328.

<sup>79</sup> Tironi, *supra* note 52, at 328.

<sup>80</sup> Tironi, *supra* note 52, at 328-29.

<sup>81</sup> JANET LUNDY, KAISER FAM. FOUND., PRESCRIPTION DRUG TRENDS 1, 6 (2010), available at <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/3057-08.pdf>.

<sup>82</sup> *Id.* In 2009, 78% of workers with employer-sponsored coverage were in plans with multiple tiers of cost sharing for prescription drugs, almost three times the rate in 2000 (27%). *Id.* Worker copayments have steadily increased from 2000 to 2009 in all categories of prescription drugs: 25% for generic drugs, 80% for preferred drugs, 59% for non-preferred drugs, and 49% for specialty-tier drugs. *Id.*

newest cost-sharing technique employed by insurers is to limit patients to a thirty-day supply to prove it is effective before continuing use.<sup>83</sup>

Another growing trend is for prescription benefit designs to include a “specialty-tier”<sup>84</sup> or “fourth-tier” for extremely expensive specialty drugs, where co-pays are replaced with coinsurance.<sup>85</sup> Medicare drug plans started using specialty-tier formularies (eighty-six percent of plans had specialty tiers in 2008) and the private insurance market followed the trend.<sup>86</sup> In 2004, only four percent of employer-sponsored plans offered a plan with four or more tiers.<sup>87</sup> In 2009, this number jumped to ten percent and only a year later, in 2010, thirteen percent of employer-sponsored plans included a specialty-tier prescription drug formulary.<sup>88</sup> Specialty-tier prescription drugs utilize coinsurance, which is typically a payment by the patient of twenty to thirty-three percent of the drug's cost.<sup>89</sup>

This expensive coinsurance payment is unaffordable for most Americans as the monthly cost of biologic drugs can be in the tens of thousands of dollars.<sup>90</sup> Some states recognize this problem and pass legislation prohibiting the use of specialty tiers.<sup>91</sup> While other states including Maryland, California, Delaware, and Vermont are considering legislation on specialty tiers.<sup>92</sup> Nevertheless, the small percentage of states that have passed this legislation only address one technique utilized by private insurers and do not provide patients adequate protection from other cost-sharing techniques.

### C. Legislative History of Prescription Drugs

Federal legislation is the driving force of prescription generic drug entry into the pharmaceutical market. This section discusses the creation of federal legislation leading up to the PPACA and the creation of an abbreviated statutory pathway for biologic drugs.

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<sup>83</sup> CNBC NEWS, *supra* note 24.

<sup>84</sup> It is widely debated whether “specialty-tiers” are necessary to keep costs down or are the product of poor social policy. Hylak-Reinholtz & Naftzger, *supra* note 65, at 43.

<sup>85</sup> Henry Grabowski et al, *Implementation of the Biosimilar Pathway: Economic and Policy Issues*, 41 SETON HALL L. REV. 511, 529 (2011); *see also* Liang, *supra* note 35, at 1083 (stating the most common cost-sharing technique for biologic drugs is coinsurance which places the patient at a higher risk of financial burden than co-pays).

<sup>86</sup> Tironi, *supra* note 52, at 329.

<sup>87</sup> Hylak-Reinholtz & Naftzger, *supra* note 65, at 43.

<sup>88</sup> Hylak-Reinholtz & Naftzger, *supra* note 65, at 44.

<sup>89</sup> Hylak-Reinholtz & Naftzger, *supra* note 65, at 44.

<sup>90</sup> Hylak-Reinholtz & Naftzger, *supra* note 65, at 44.

<sup>91</sup> *Position Statement - Excessive Cost-Sharing (Specialty Tiers) for High-Cost Medications Represent a Barrier to Patient*, ARTHRITIS FOUND. (Nov. 2011), <http://www.arthritis.org/position-statement-excessive-cost-sharing.php>. In 2010, New York passed legislation banning insurers using specialty tiers and other states including Maryland, California, Delaware, and Vermont have had bills presented on specialty tiers banning. *Id.*

<sup>92</sup> *Id.*

### 1. Prior to the Patient Protection and Affordable Care Act

Regulation of biological products began in the early 1900s when Congress passed the Biologics Control Act of 1902, also known as the Virus-Toxin Law.<sup>93</sup> The Virus-Toxin Law gave the Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) authority to regulate production of vaccines and antitoxins.<sup>94</sup> Non-biological drugs were not federally regulated at this time.<sup>95</sup> In 1906 the Federal Food and Drug Act was passed, outlawing adulterated and misbranded foods and drugs, but made no reference to biologic products.<sup>96</sup>

In 1938, pre-market federal regulation of traditional small-molecule drugs began with the Federal Food, Drug, and Cosmetic Act (FD&C Act).<sup>97</sup> The FD&C Act incorporated provisions of the Virus-Toxin Law to regulate biologic drugs.<sup>98</sup> Between 1938 and 1962, the Food and Drug Administration (FDA) recognized some traditional small-molecule branded drugs as generally safe "old drugs" and allowed generic versions to proceed directly to marketing without having a generic drug manufacturer complete a new drug application (NDA)<sup>99</sup> for the drugs.<sup>100</sup> Key

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<sup>93</sup> Biologics Control Act of 1902, Pub. L. No. 57-244, 32 Stat. 728 (1902).

Vaccines had been around since the late 1700s, and various other biological products, including viruses, therapeutic serums, toxins, and anti-toxins, were available. Most of these products were manufactured using methods that would seem crude today and that created a danger of contamination . . . Following incidents where these two biologics were contaminated with tetanus and resulted in the death of children, Congress passed the Biologics Act of 1902.

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, 682 (2010).

<sup>94</sup> *100 Years of Biologics Regulation*, U.S. FOOD & DRUG ADMIN. (Apr. 9, 2009), <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/100YearsofBiologicsRegulation/ucm070022.htm> ("The first regulations under this Act became effective on August 21, 1903, and mandated that producers of vaccines be licensed annually for the manufacture and sale of vaccines, serum, and antitoxins. Manufacturing facilities also were required to undergo inspections, and licenses could be revoked or suspended when necessary. Production was to be supervised by a qualified scientist. All product labels were required to include the product name, expiration date, and address and license number of the manufacturer. These new controls marked the beginning of a basic change in America's federal public health policy and a steadfast commitment to the protection of public health.").

<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

<sup>97</sup> Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD DRUG L.J. 417, 419 (2011).

<sup>98</sup> *100 Years of Biologics Regulation*, *supra* note 94.

<sup>99</sup> New Drug Application is defined as "the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S." *New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN. (Feb. 21, 2013), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/>.

<sup>100</sup> *Id.*

changes continued from the 1960s through the early 1980s.<sup>101</sup> After the 1962 amendments, the FDA required the submission of safety data in a NDA for virtually all new drugs, including generics, prior to those drugs entering the pharmaceutical market.<sup>102</sup> The FD&C Act authorized the FDA to prevent the marketing of a new drug if the applicant drug manufacturer could not demonstrate the drug's safety.<sup>103</sup> But, the drug manufacturer could market the new drug if the FDA did not reject the NDA within sixty days.<sup>104</sup>

As prescription drug costs became a problem, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) to incentivize generic drug manufacturers to enter the market.<sup>105</sup> Under the Hatch-Waxman Act, the FDA must list the official and proprietary name of each drug approved by the FDA for sale.<sup>106</sup> A brand name drug manufacturer identifies, by patent number and expiration date, any associated patents or methods of using the drug.<sup>107</sup> Drug names and a list of associated patents are published in the Approved Drug Products with Therapeutic Equivalence Evaluations document, commonly referred to as the "Orange Book."<sup>108</sup>

The Hatch-Waxman Act allows generic drug manufacturers to file an abbreviated new drug application (ANDA), bypassing expensive testing and relying on safety and effectiveness clinical-trial data in the Orange Book.<sup>109</sup> However, the application must include data that the generic drug contains the same active ingredient of a drug that been previously FDA-approved, as listed in the Orange Book, and that the proposed generic product is "bioequivalent"<sup>110</sup> to the branded drug.<sup>111</sup> Additionally, generic drug manufacturers are required to file one of four possible certifications for each Orange Book patent listing covering the listed drug: "(I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be

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<sup>101</sup> Carver, *supra* note 93, at 672.

<sup>102</sup> Carver, *supra* note 93, at 672.

<sup>103</sup> Kelly, *supra* note 97, at 419.

<sup>104</sup> Kelly, *supra* note 97, at 419–20.

<sup>105</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

<sup>106</sup> D. Christopher Ohly & Sailesh K. Patel, *The Hatch-Waxman Act: Prescriptions for Innovative and Inexpensive Medicines*, 19 U. BALT. INTELL. PROP. L.J. 107, 115 (2011).

<sup>107</sup> *Id.* at 115–16.

<sup>108</sup> Gaudry, *supra* note 45, at 588.

<sup>109</sup> Ohly & Patel, *supra* note 106, at 116.

<sup>110</sup> Bioequivalent is defined as "the relationship between two preparations of the same drug in the same dosage form that have a similar bioavailability." *Bioequivalence Definition*, FREE DICTIONARY, <http://medical-dictionary.thefreedictionary.com/bioequivalence> (last visited Oct. 13, 2013).

<sup>111</sup> Gaudry, *supra* note 45, at 588.

infringed by the manufacture, use, or sale of the” new drug for which the application is submitted.<sup>112</sup>

The last certification, commonly known as Paragraph IV certification, creates controversy in the pharmaceutical industry.<sup>113</sup> Paragraph IV certifications differ in that generic drug manufacturers attempt market entry prior to the branded drug’s patent expiration, compared to the other certifications which claim there are no existing patent rights that would prevent market entry.<sup>114</sup> Paragraph IV certifications require notification to the patent holder and a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.<sup>115</sup> The patent holder has forty-five days to file a patent infringement claim against the generic drug applicant.<sup>116</sup> This automatically triggers a thirty-month stay preventing FDA approval of the ANDA from the date notice was received.<sup>117</sup> The thirty-month stay may end early upon the patent expiring or a final resolution of the patent litigation.<sup>118</sup>

An important provision in the Hatch-Waxman Act provides if the “first applicant”<sup>119</sup> generic drug manufacturer prevails in a Paragraph IV challenge to a patent, that manufacturer is rewarded with 180 days of marketing exclusivity.<sup>120</sup> During the 180 days of market exclusivity, FDA final ANDA approval to any other generic pharmaceutical manufacturer is suspended.<sup>121</sup> This 180 day marketing exclusivity period is an incentive in the Hatch-Waxman Act that only permits the branded patent holder and the successful ANDA first applicant to manufacture and sell the listed drug.<sup>122</sup>

Biologics were excluded from using the abbreviated approval process under the Hatch-Waxman Act.<sup>123</sup> The rationale was that the process of creating a biologic involved the utilization of biological material, making it difficult to effectively copy and detect differences with the reference drug.<sup>124</sup> Even minor structural deviation

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<sup>112</sup> Ohly & Patel, *supra* note 106, at 116.

<sup>113</sup> Ohly & Patel, *supra* note 106, at 116.

<sup>114</sup> Ohly & Patel, *supra* note 106, at 116.

<sup>115</sup> Ohly & Patel, *supra* note 106, at 116.

<sup>116</sup> Ohly & Patel, *supra* note 106, at 116–17.

<sup>117</sup> Kelly, *supra* note 97, at 424.

<sup>118</sup> Kelly, *supra* note 97, at 424.

<sup>119</sup> “First Applicant” is defined as “an applicant that, on the first day on which a substantially complete application containing a [Paragraph IV] certification . . . is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a [Paragraph IV] certification . . . for the drug.” 21 U.S.C.A. § 355(j)(5)(B)(iv)(II) (bb) (West 2010).

<sup>120</sup> Ohly & Patel, *supra* note 106, at 117.

<sup>121</sup> Ohly & Patel, *supra* note 106, at 117.

<sup>122</sup> Ohly & Patel, *supra* note 106, at 117.

<sup>123</sup> Gaudry, *supra* note 45, at 588.

<sup>124</sup> Gaudry, *supra* note 45, at 588.

may affect a product's effectiveness and safety.<sup>125</sup> These minor structural deviations create a considerable risk of adverse side effects including the immune system attacking the biological agent.<sup>126</sup>

## 2. The Patient Protection and Affordable Care Act

The objective of the PPACA is to “ensure that all Americans have access to quality, affordable health care and will create the transformation within the health care system necessary to contain costs.”<sup>127</sup> As the number of Americans without health insurance continues to rise and premiums become unaffordable, the PPACA aims to reduce rising health care costs by mandating the purchase of insurance to certain uninsured Americans.<sup>128</sup> Congress found medical expenses were a significant factor in sixty-two percent of all personal bankruptcies in the United States.<sup>129</sup>

The PPACA now requires insurers to accept every person or employer who applies for coverage.<sup>130</sup> State operated health benefit exchanges make health insurance available at competitive prices at one central location for potential consumers.<sup>131</sup> Medicaid coverage eligibility expands to additional persons.<sup>132</sup> Insurance companies are prohibited from denying coverage to applicants with pre-existing medical conditions;<sup>133</sup> insurers have a requirement to use a community rating to prevent charging an increased premium to individuals with pre-existing illnesses.<sup>134</sup> Insurers are prohibited from limiting the amount of coverage available and banned from cancelling coverage when the insured individual gets sick.<sup>135</sup>

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<sup>125</sup> Gaudry, *supra* note 45, at 589.

<sup>126</sup> Gaudry, *supra* note 45, at 589.

<sup>127</sup> *The Patient Protection and Affordable Care Act Detailed Summary*, DEMOCRATIC POL’Y & COMM. CTR., <http://www.dpc.senate.gov/healthreformbill/healthbill04.pdf> (last visited Oct. 2, 2012).

<sup>128</sup> Arthur Nussbaum, *Can Congress Make You Buy Health Insurance? The Affordable Care Act, National Health Care Reform, and the Constitutionality of the Individual Mandate*, 50 DUQ. L. REV. 411, 413–14 (2012) (“The linchpin of the Act (and the core of the controversy) is the individual mandate. ACA section 1501(b) requires that all applicable individuals and their dependents maintain minimum essential coverage starting in 2014. Those who fail to obtain the minimum coverage must include a ‘shared responsibility’ payment along with their annual federal income tax return. The shared responsibility payment is a fixed dollar amount penalty, and for individuals who cannot afford the coverage, the amount is reduced based on household income. That payment is specifically labeled as a penalty under the statute and not a tax.”).

<sup>129</sup> *Id.* at 412–13.

<sup>130</sup> *Id.* at 413.

<sup>131</sup> *Id.*

<sup>132</sup> *Id.* Individuals at or below 133% of the poverty level are eligible for Medicaid. *Id.*

<sup>133</sup> *Id.*

<sup>134</sup> *Id.*

<sup>135</sup> *Id.* at 413–14.

In addition, the PPACA includes provisions provided in a part of the law known as the Biologics Price Competition and Innovation Act (BPCIA),<sup>136</sup> to create an abbreviated licensure pathway for biosimilars that are demonstrated “interchangeable”<sup>137</sup> with an FDA-licensed biological product.<sup>138</sup> This legislation generally mimics the goals of the Hatch-Waxman Act, which established an abbreviated pathway for the approval of generic drug products under the FD&C Act.<sup>139</sup>

Not surprisingly, BPCIA requires biosimilar applicants to meet relatively rigorous requirements due to complexity of biosimilars.<sup>140</sup> Applicants are required to submit analytical, animal, and clinical studies, and must submit evidence to show the biosimilar has the same mechanism or mechanisms to that of the reference drug.<sup>141</sup> Additionally, the biosimilar manufacturer must establish the conditions of use of the biosimilar are the same as the reference drug including the same dosage, administration, and strength.<sup>142</sup> Applicants are restricted to the use of one previously approved reference product per biosimilar application.<sup>143</sup> Finally, consent to an inspection of the biosimilar manufacturing must be obtained.<sup>144</sup>

BPCIA takes into consideration many areas that Hatch-Waxman did not address because of the complex nature of biologics.<sup>145</sup> Biosimilars do not have to be chemically identical to its referenced product, but must be “interchangeable.”<sup>146</sup>

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<sup>136</sup> See Patient Prot. & Affordable Care Act, Pub. L. No. 111–48, 124 Stat. 119 (2010).

<sup>137</sup> Interchangeability is defined as

[O]ne of the criteria that those who pay for health care, like insurers and government programs, use when they determine whether a similar medicine can be provided instead of the one prescribed for a patient by his or her doctor. In the chemical drug context, this is somewhat straightforward since, unlike biologics, copies of chemical drugs, called generic drugs, can be made. The molecule of the active ingredient in the generic drug must be the same as the brand drug it copied. If the molecule of the active ingredient is identical – as well as dosage form, administration route and strength – and the absorption in the body is similar enough to the original drug, then the FDA may determine the products are interchangeable, as is the case for most generic drugs.

AMGEN, *supra* note 33, at 14.

<sup>138</sup> Gaudry, *supra* note 45, at 589.

<sup>139</sup> Zelenetz, *supra* note 28, at S5; see also Federal Food, Drug, & Cosmetic Act Pub. L. No. 75-717, § 501, 52 Stat. 1040, 1052-53 (1938).

<sup>140</sup> 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, 562 (2011).

<sup>141</sup> *Id.*

<sup>142</sup> *Id.*

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*

<sup>145</sup> See Grabowski et al., *supra* note 85, at 512.

<sup>146</sup> See Grabowski et al., *supra* note 85, at 513.



Section 7002(a)(4) of the PPACA states the safety standard for determining if a biological product is interchangeable:

Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—(A) the biological product— (i) is biosimilar to the reference product; and (ii) can be expected to produce the same clinical result as the reference product in any given patient; and (B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.<sup>147</sup>

The FDA provides traditional brand name drug manufacturers five years of Orange Book data exclusivity after approval.<sup>148</sup> In contrast, BPCIA provides brand name biologic drug manufacturers twelve years of data exclusivity from biosimilars.<sup>149</sup> Similar to the incentive of a 180-day market exclusivity period in the Hatch-Waxman Act, a one-year market exclusivity period, which excludes others attempting to be interchangeable to a reference product, is awarded to the first biosimilar shown to be interchangeable.<sup>150</sup> However, this does not keep other biosimilars off the market, but only applies to other interchangeable biosimilars.<sup>151</sup>

### III. THE PPACA'S BIOLOGIC DRUG PROVISIONS

This section identifies the factors that prevent biosimilars from enjoying the same success of cost saving for patients compared to traditional generic drugs. It is important to remember the inherent differences between traditional drugs and biologic drugs. Also, this section discusses how the statutory construction of the

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<sup>147</sup> See Patient Prot. & Affordable Care Act, Pub. L. No. 111–48, 124 Stat. 119 (2010).

<sup>148</sup> Addison, *supra* note 140, at 557–58 (noting that “[i]n Europe, this ‘data exclusivity’ period is six or ten years, depending on the country”).

<sup>149</sup> Addison, *supra* note 140, at 558 (stating it is unclear whether the twelve years of exclusivity means data exclusivity or marketing, but presently the FDA seems to imply Markey exclusivity).

<sup>150</sup> Addison, *supra* note 140, at 558 (showing the market exclusivity period may extend to eighteen months if a final court decision or a dismissal with or without prejudice on all patents in suit in an action instituted by the patent holder. The market exclusivity period may extend up to forty-two months after approval of the first interchangeable biosimilar biological product if the applicant that submitted the application if the patent holder of the reference drug and such litigation is still ongoing within such forty-two month period or eighteen months after approval of the first interchangeable biosimilar biological product if the applicant has not been sued); see Patient Prot. and Affordable Care Act, Pub. L. No. 111–48, § 7002(a)(6), 124 Stat. 119 (2010).

<sup>151</sup> Tom Gillespie III et al., *Alternative Routes to Market for Follow-on Biologics*, STERN KESSLER GOLDSTEIN FOX (June 8, 2011), <http://www.skf.com/media/pnc/6/media.1376.pdf>.

PPACA's provisions regarding biologic drugs will permit private insurers to continue utilizing excessive cost-sharing techniques.

A. *Biosimilars are Not a Cost-Effective Solution*

The PPACA, Title VII, *Improving Access to Innovative Medical Therapies, Subtitle A Biologics Price Competition and Innovation*, outlines the approval pathway for biosimilars.<sup>152</sup> Though the legislation mimics the Hatch-Waxman Act, biosimilar and brand name biologics will not compete on the same level as generic small-molecule prescriptions drugs.<sup>153</sup>

1. Factors that Hinder Competition of Biosimilars

Numerous factors hinder competition of biosimilars compared to generic small-molecule drugs.<sup>154</sup> Entrants to the biosimilar market face significant financial hurdles, including substantially higher development and manufacturing costs relative to small-molecule drug manufacturing and costly FDA mandatory clinical testing for some biosimilars.<sup>155</sup> In addition, many biosimilars will not automatically substitute brand name biologics, delaying the rate at which biosimilars acquire market share.<sup>156</sup> This will require biosimilar manufacturers to be more aggressive in marketing and brand development.<sup>157</sup>

Biosimilar manufacturers must take into account that the price differential between a biosimilar and the reference product at market entry and over the ensuing years may not be significant.<sup>158</sup> For example, prior to the PPACA advertisement

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<sup>152</sup> See Patient Prot. & Affordable Care Act, Pub. L. No. 111-48, § 7002, 124 Stat. 119 (2010).

<sup>153</sup> *Under The Microscope: Impact of Abbreviated Approval Pathway for Follow-on Biologics*, ICEMILLER LLP (Sept. 8, 2011), [http://www.icemiller.com/publication\\_detail/id/1732/index.aspx](http://www.icemiller.com/publication_detail/id/1732/index.aspx); see Patient Prot. & Affordable Care Act, Pub. L. No. 111-48, § 7002, 124 Stat. 119 (2010); see also Gaudry, *supra* note 45, at 589 (“Since enactment of the Hatch-Waxman Act . . . the prices of generic drugs are approximately 60% or less that of brand-name drugs. In total, it has been estimated that a generic-drug market offers a savings of \$8 billion to \$10 billion in a single year.”); see also Tresemer, *supra* note 47, at 7 (“Ultimately, the Hatch-Waxman Act addressed the inherent tension between promoting drug discovery and innovation through patent protection and a need to increase market entry of lower-cost generic pharmaceuticals. Between its enactment in 1984 and mid-2007, use of generic pharmaceuticals increased from 19% of all prescriptions to 67%. This marked increase in generic pharmaceuticals established the Hatch-Waxman Act as a highly successful tool for providing cost savings to consumers while continuing to encourage pharmaceutical innovation.”).

<sup>154</sup> Tresemer, *supra* note 47, at 10.

<sup>155</sup> Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 H. MANAGE DECIS. ECON., 469, 469-79 (2007) (noting besides substantial overhead costs, the process for a single, successful product development takes between ten and fifteen years and costs on average \$1.2 billion); Gaudry, *supra* note 45, at 588.

<sup>156</sup> Tresemer *supra* note 47, at 9.

<sup>157</sup> Tresemer *supra* note 47, at 7.

<sup>158</sup> Frank Kopenski Jr., *Understanding Biosimilars and Projecting the Cost Savings to Employers*, MILLIMAN CLIENT REPORT (Dec. 2011),

spending for prescription drugs was 1.5 times greater in 2009 at \$10.9 billion compared to \$6.6 billion in 1999.<sup>159</sup> Additionally, safety and efficacy concerns of biosimilars may lead physicians to be reluctant to substitute a biosimilar for a brand name biologic.<sup>160</sup>

The extent to which patients accept the physician-recommended biosimilars may hinder cost-savings.<sup>161</sup> The future trends in specialty and biosimilar drug utilization and the percentage of new patients using biologics for the first time to treat existing or newly diagnosed healthcare conditions are other factors to be considered.<sup>162</sup> In a Milliman client report, one of the world's largest providers of actuarial and related products and services, demand of biosimilars is more inelastic compared to traditional small-molecule drugs.<sup>163</sup> In that report, a fifty-dollar co-pay differential did not change the utilization of biosimilars to reflect greater demand for less expensive biosimilars.<sup>164</sup>

## 2. Minimal Savings to Patients

The Congressional Budget Office (CBO) estimates that from 2010 to 2019 the abbreviated biosimilar pathway will reduce federal budget deficits by seven billion dollars.<sup>165</sup> From 2009 to 2018, biologic drug spending will be reduced by an estimated twenty-five billion dollars, accounting for roughly 0.5% of national spending on prescription drugs.<sup>166</sup> This translates into projected discounts of biosimilars of only ten to thirty percent of the brand name biologic's price.<sup>167</sup> Furthermore, projections also find brand name biologics will likely retain seventy to ninety percent of their market share after biosimilar entry.<sup>168</sup> The overall savings for biosimilars over brand name biologics will be small and will not become prevalent until 2016, which cannot be classified as "affordable" health care for patients treating a disease with a biologic drug.<sup>169</sup>

Milliman reports projections based on empirical data will lead to minimal savings.<sup>170</sup> Milliman presents a best-case scenario and a more realistic scenario for projected savings of biosimilars:

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<http://publications.milliman.com/publications/health-published/pdfs/understanding-biosimilars.pdf>.

<sup>159</sup> LUNDY, *supra* note 81, at 4.

<sup>160</sup> LUNDY, *supra* note 81, at 4.

<sup>161</sup> Kopenski, *supra* note 158, at 10.

<sup>162</sup> Kopenski, *supra* note 158, at 10.

<sup>163</sup> Kopenski, *supra* note 158, at 19.

<sup>164</sup> Kopenski, *supra* note 158, at 19.

<sup>165</sup> See Grabowski et al., *supra* note 85, at 544.

<sup>166</sup> See Grabowski et al., *supra* note 85, at 545.

<sup>167</sup> See Grabowski et al., *supra* note 85, at 545; see also Kopenski, *supra* note 158, at 13.

<sup>168</sup> Kopenski, *supra* note 158 at 7.

<sup>169</sup> Kopenski, *supra* note 158, at 20.

<sup>170</sup> Kopenski, *supra* note 158, at 6.

If a biosimilar was introduced for every chronic healthcare condition immediately and all patients used a biosimilar product that was thirty percent cheaper, the total covered healthcare costs would decrease by one percent in 2011. A more realistic savings would be lower than one percent, especially if we consider 2011 to be year one and the fact that the average employer does not contribute one hundred percent to the cost of member healthcare coverage. Thus, some of the savings would be reflected in the employee share of the employer healthcare premium.<sup>171</sup>

The report assumes biosimilars will be thirty percent cheaper than brand-name biologics.<sup>172</sup> Although this is the highest projection in relation to the CBO's projected savings, it translates into a less than one percent decrease in total healthcare costs.<sup>173</sup> If it comes to fruition that thirty percent is an over-projection, total healthcare costs savings will be negligible.<sup>174</sup>

#### B. PPACA's Negative Affect on Prescription Biologic Drug Coverage

Sections 1302 and 3307 of the PPACA negatively impact prescription biologic drug coverage because of their vague statutory requirements.<sup>175</sup> In particular, omitting the mandatory inclusion of biologic drugs into the essential health benefits and the metal tiers of coverage design invites insurers to continue keeping patients, like members the Taffe, Love, and D'Orsaneo families, unprotected.

##### 1. Metal Tiers of Coverage & Essential Health Benefits

The PPACA, section 1302(d) Levels Of Coverage, outlines how health insurers must offer plans within health insurance exchanges that meet distinct levels of coverage titled "metal tiers": bronze, silver, gold and platinum.<sup>176</sup> The metal tiers coverage are based on the percentage of full actuarial value<sup>177</sup> of benefits the plan is designed to provide, and are as follows: platinum ninety percent, gold eighty percent, silver seventy percent, and bronze sixty percent.<sup>178</sup> Plans with lower actuarial values

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<sup>171</sup> Kopenski, *supra* note 158, at 16.

<sup>172</sup> Kopenski, *supra* note 158, at 17.

<sup>173</sup> Kopenski, *supra* note 158, at 17.

<sup>174</sup> Kopenski, *supra* note 158, at 17.

<sup>175</sup> Patient Prot. & Affordable Care Act, Pub. L. No. 111-48, §§ 1302, 3307, 124 Stat. 119 (2010).

<sup>176</sup> *See id.* § 1302(d).

<sup>177</sup> *Glossary*, HEALTHCARE.GOV, [www.healthcare.gov/glossary/a/actuarial.html](http://www.healthcare.gov/glossary/a/actuarial.html) (last visited Oct. 20, 2012) (Actuarial value is defined as "the percentage of total average costs for covered benefits that a plan will cover. For example, if a plan has an actuarial value of 70%, on average, you would be responsible for 30% of the costs of all covered benefits. However, you could be responsible for a higher or lower percentage of the total costs of covered services for the year, depending on your actual health care needs and the terms of your insurance policy.").

<sup>178</sup> LARRY LEVITT & GARY CLAXTON, KAISER FAM. FOUND., WHAT THE ACTUARIAL VALUES IN THE AFFORDABLE CARE ACT MEAN 1, 2 n.1 (2011), available at <http://www.kff.org/healthreform/upload/8177.pdf> ("The ACA permits insurers to sell a lower actuarial value Catastrophic Plan in the non-group market to individuals who: (1) are under the age of 30; or

will have a lower premium, since the patient will have higher cost-sharing.<sup>179</sup> The percentages stated are general guidelines, and the percentage actually paid will depend on health care services used and the details of the cost-sharing within the plan.<sup>180</sup>

The PPACA also establishes “Essential Health Benefits” (EHB)<sup>181</sup> which are defined as minimum requirements for the services covered by exchange-sold policies.<sup>182</sup> Although the Secretary of the Department of Health and Human Services (HHS) is required to set EHB based on the “typical” employer plan, “typical” plans are not defined within the PPACA.<sup>183</sup> Section 1302(b)(1) of the PPACA does specify that EHB shall include the category of prescription drugs, but it does not specify what biologic drugs will be incorporated within the category.<sup>184</sup> Experts believe that some biologics will be included in EHB, but limited options are expected.<sup>185</sup>

Section 1302(c) of the PPACA places annual limitations on cost-sharing for patients:

(A) 2014.—The cost-sharing incurred under a health plan with respect to self-only coverage or coverage other than self-only coverage for a plan year beginning in 2014 shall not exceed the dollar amounts in effect under section 223(c)(2)(A)(ii) of the Internal Revenue Code of 1986 for self-only and family coverage, respectively, for taxable years beginning in 2014.

(B) 2015 AND LATER.—In the case of any plan year beginning in a calendar year after 2014, the limitation under this paragraph shall— (i) in the case of self-only coverage, be equal to the dollar amount under subparagraph (A) for self only coverage for plan years beginning in 2014, increased by an amount equal to the product of that amount and the premium adjustment percentage under paragraph (4) for the calendar year; and (ii) in the case of other coverage, twice the amount in effect under

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(2) would otherwise be exempt from the requirement under the ACA to have coverage because available coverage is unaffordable or enrollment in available coverage would be a hardship.”).

<sup>179</sup> *Id.* at 2

<sup>180</sup> *Id.*

<sup>181</sup> Patient Prot. & Affordable Care Act, Pub. L. No. 111–48, § 1302(b)(1), 124 Stat. 119 (2010) (noting the ACA permits insurers to sell a lower actuarial value Catastrophic Plan in the non-group market to individuals who: (1) are under the age of 30; or (2) would otherwise be exempt from the requirement under the ACA to have coverage because available coverage is unaffordable or enrollment in available coverage would be a hardship).

<sup>182</sup> Bruce Pyenson & Charles Scammell, “*Essential Health Benefits*” – *What Is Typical?*, MILLIMAN CLIENT REPORT (May 2011), <http://publications.milliman.com/publications/health-published/pdfs/essential-health-benefits.pdf>.

<sup>183</sup> *Id.*

<sup>184</sup> *Id.* at 8.

<sup>185</sup> Michael D. Dalzell, *How Will Biologics Fit into Healthcare Reform?*, 8 BIOTECHNICAL HEALTHCARE 6, 10 (2011), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278131/>.

clause (i). If the amount of any increase under clause (i) is not a multiple of \$50, such increase shall be rounded to the next lowest multiple of \$50.<sup>186</sup>

The PPACA also provides that the cost-sharing annual limitation “does not include premiums, balance billing amounts for non-network providers, or spending for non-covered services.”<sup>187</sup> This means insurers may construct insurance plans that do not cover most biologic drugs because any cost after the annual cost-sharing limitation is incurred by the insurer.<sup>188</sup> It is economically efficient for insurers to omit biologic drug coverage and leave patients exposed to the risk of paying for these drugs.<sup>189</sup>

## 2. Statutory Construction Invites Exclusion or Limitation

Virtually all employees (ninety-nine percent) with healthcare coverage have a prescription drug benefit, which almost always covers both brand-name and generic drugs.<sup>190</sup> Insurers most commonly use a three-tiered approach to prescription drug pricing, but there is an increasing trend for insurers to move to a four-tiered approach that includes a tier for high-priced or specialty drugs.<sup>191</sup> Specialty drug tiers, which may be brand name or generic, usually include biologic drugs.<sup>192</sup> Because biologics require special handling and are significantly more expensive to manufacture they are subject to different benefit coverage criteria and utilization management.<sup>193</sup> The Kaiser Family Foundation reports that in 2009, “over three-quarters (seventy-eight percent) of workers with prescription drug coverage in plans with four tiers of drug coverage.”<sup>194</sup> EHB are expected to use the same broad definitions typical in the industry, and will continue to allow flexibility utilizing formularies and other common drug cost management tools, most commonly increased co-pays or coinsurance.<sup>195</sup>

Biologics not being included in the definition of EHB will lead managed care organizations and government programs to balance the cost of the biologic with the efficacy of the treatment.<sup>196</sup> It will be hard to justify a biologic that costs \$80,000 to fight cancer and such treatments will have a much harder time finding inclusion in a

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<sup>186</sup> Patient Prot. & Affordable Care Act, Pub. L. No. 111–48, § 1302(c), 124 Stat. 119 (2010).

<sup>187</sup> *Id.*

<sup>188</sup> *Id.*

<sup>189</sup> *Id.*

<sup>190</sup> Pyenson & Scammel, *supra* note 182, at 3.

<sup>191</sup> John Carroll, *When New Drugs Are Costly, How High to Raise Copays?*, MANAGED CARE (June 2006), <http://www.managedcaremag.com/archives/0606/0606.tiers.html>.

<sup>192</sup> Pyenson & Scammel, *supra* note 182, at 8.

<sup>193</sup> Pyenson & Scammel, *supra* note 182, at 8.

<sup>194</sup> ARTHRITIS FOUND., *supra* note 91.

<sup>195</sup> Pyenson & Scammel, *supra* note 182, at 8.

<sup>196</sup> Dalzell, *supra* note 185, at 7.

plan.<sup>197</sup> Section 3307 of the PPACA requires insurers offering a prescription drug plan to include all covered Medicare part D drugs in the categories and classes identified by the Secretary of HHS as categories and classes of drugs determined to be of clinical concern.<sup>198</sup> Section 3307 does not establish criteria to determine drugs of clinical concern; instead, the statute permits the Secretary to establish her own criteria.<sup>199</sup>

On December 16, 2011, the HHS issued a bulletin outlining proposed policies of rulemaking regarding essential health benefits.<sup>200</sup> The bulletin took into account comments from the general public, as well as input from the Department of Labor, the Institute of Medicine, and research conducted by HHS.<sup>201</sup> HHS Secretary, Kathleen Sebelius, has promised the public and many groups—including oncologists, manufacturers, and patient advocacy organizations that are affected by what EHB are consisted of—that they will be heard before HHS issues a proposed rule.<sup>202</sup> However, the Secretary has unlimited discretion and may establish exceptions that permit insurers to exclude prescription drugs from its formulary, a specific covered part D drug, or to otherwise limit access to such a drug.<sup>203</sup>

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<sup>197</sup> Dalzell, *supra* note 185, at 7.

<sup>198</sup> Patient Prot. & Affordable Care Act, Pub. L. No. 111–48, § 3307 (a)(i)(I), 124 Stat. 119 (2010). Section 3307 improves formulary requirements for prescription drug plans and MA-PD plans with respect to certain categories or classes of drugs. *Id.*

<sup>199</sup> *See id.* at § 3307 (a)(ii)(II).

<sup>200</sup> *Essential Health Benefits Bulletin*, CTR. FOR CONSUMER INFO. & INS. OVERSIGHT (Dec. 16, 2011), [http://www.cms.gov/CCIIO/Resources/Files/Downloads/essential\\_health\\_benefits\\_bulletin.pdf](http://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf) (“To meet the EHB coverage standard, HHS intends to require that a health plan offer benefits that are ‘substantially equal’ to the benchmark plan selected by the state and modified as necessary to reflect the 10 coverage categories. Health plans also would have flexibility to adjust benefits, including both the specific services covered and any quantitative limits, provided they continue to offer coverage for all 10 statutory EHB categories and the coverage has the same value. Permitting flexibility will provide greater choice to consumers, promoting plan innovation through coverage and design options, while ensuring that plans providing EHBs offer a certain level of benefits.”).

<sup>201</sup> *Id.* at 1–3.

<sup>202</sup> Dalzell, *supra* note 185, at 7; *Essential Health Benefits: Balancing Coverage and Cost*, INST. MED. NAT’L ACADS. (Oct. 6, 2011), <http://www.iom.edu/~media/Files/Report%20Files/2011/Essential-Health-Benefits-Balancing-Coverage-and-Cost/essentialhealthbenefitsreport-brief4.pdf> (“In both defining and updating the EHB package, the methods used by HHS should be highly visible and allow for current and future enrollees to help define priorities for coverage. As envisioned by the committee, the public deliberation process would enable individuals—working in small group meetings around the country—to participate in a prioritization process, where different elements of coverage—specific services, types of cost-sharing, degree of provider choice, approval requirements, etc.—are discussed and debated. Learning from these groups will help HHS understand potential enrollees’ priorities when tradeoffs are necessary.”).

<sup>203</sup> *See*, Patient Prot. & Affordable Care Act, Pub. L. No. 111–48, § 3307 (a)(i)(II), 124 Stat. 119 (2010).

On November 20, 2012, the Secretary released a proposed rule<sup>204</sup> that clarifies what will be included in the EHB.<sup>205</sup> Pursuant to the proposed rule, health insurance plans will be required to cover “at least the greater of: (i) one drug in every United States Pharmacopeia (USP)<sup>206</sup> category and class; or (ii) the same number of prescription drugs in each category and class as the EHB-benchmark plan.”<sup>207</sup>

HHS’ proposed rule of EHB includes responses to comments from the public and different organizations.<sup>208</sup> A response to a comment regarding prescription drug coverage stated:

*Comment:* Commenters also recommended specific uses of the data we proposed to collect, for example that consumers and states have access to the data. Several commenters urged HHS to use the data for specific purposes, such as to ensure that certain services are covered, that plans are not discriminatory, that prescription drug coverage is comparable to a typical employer plan and that benefit limits do not reduce actuarial value (AV).

*Response:* We note that the purpose of the data collection in this final rule is to collect benefit and coverage information from potential benchmark plans. Accordingly, we addressed comments on potential uses of the data collected to the extent that they are related to the development of benchmark plans.<sup>209</sup>

In accordance with the comment, the EHB Proposed Rule is ambiguous on its face. Specifically, how the requirement to cover “at least the greater of” two options

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<sup>204</sup> Recognition of Entities for the Accreditation of Qualified Health Plans, 77 Fed. Reg. 42658 (July 20, 2012) (to be codified at 45 C.F.R. pt. 156).

<sup>205</sup> *Essential Health Benefits Proposed Rule: Additional Detail with Few Surprises*, MCDERMOTT, WILL & EMORY (Nov. 30, 2012), [http://www.mwe.com/files/uploads/documents/pubs/essential\\_health\\_benefits\\_proposed\\_rule\\_additional\\_detail\\_with\\_few\\_surprises.pdf](http://www.mwe.com/files/uploads/documents/pubs/essential_health_benefits_proposed_rule_additional_detail_with_few_surprises.pdf).

<sup>206</sup> Medicare Prescription Drug, Improvement & Modernization Act of 2003, Pub. L. No. 108-173, § 1860, 117 Stat. 2066 (2003). In December 2003, the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) was signed into law. The United States Pharmacopeial Convention (USP) is named in Section 1860D–4(b) (3) (C) (ii) of the Act, which states

MODEL GUIDELINES—The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered Part D drugs and the additions of new covered Part D drugs.

*Medical Model Guidelines*, U.S. PHARMACOPEIAL CONVENTION, <http://www.usp.org/usp-healthcare-professionals/medicare-model-guidelines> (last updated Sept. 30, 2013).

<sup>207</sup> *Essential Health Benefits Proposed Rule*, *supra* note 205, at 3.

<sup>208</sup> *Essential Health Benefits Proposed Rule*, *supra* note 205, at 1.

<sup>209</sup> Recognition of Entities for the Accreditation of Qualified Health Plans, 77 Fed. Reg. 42658 (July 20, 2012) (to be codified at 45 C.F.R. pt. 156).



will be implemented is unclear.<sup>210</sup> HHS released commentary to clarify the interpretation: “where the benchmark plan does not include coverage in a USP category and class, pursuant to proposed section 156.120, one drug would have to be offered in that USP category and class.”<sup>211</sup> This means that the two options are not to be treated in isolation, but plans must include at least one drug in every USP category and class, even if it already has the same number of prescription drugs in each category and class as the EHB-benchmark plan.<sup>212</sup>

Consistent with the EHB bulletin, health insurance providers are permitted to substitute benefits that are “actuarially equivalent” to the benefits being replaced.<sup>213</sup> Substitution requires insurance providers to “submit an actuarial certification that any substituted benefit(s) are actuarially equivalent to the benefit(s) in the EHB-benchmark plan.”<sup>214</sup> However, prescription drug benefits are subject to special requirements.<sup>215</sup>

Section 1302(d)(3) of the PPACA empowers the Secretary of HHS to establish a reasonable “*de minimis*” variation in the actuarial values (AV).<sup>216</sup> AV is “a measure of the percentage of expected health care costs a health plan will cover and can be considered a general summary measure of health plan generosity.”<sup>217</sup> AV calculation computes the ratio of the total expected payments by the plan for EHB, computed in accordance with the plan’s cost-sharing rules, for a standard population, over the total costs for EHB the standard population is expected to incur.<sup>218</sup> AV calculators are expected to create plan designs, but include a range of variation to be allowed, at a given metal level, to balance the insurance provider’s ability to create competitive and simple plan designs.<sup>219</sup> HHS intends to propose a *de minimis* variation of +/- two percentage points in AV.<sup>220</sup> The reasonable variation is intended to strike “the

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<sup>210</sup> *Essential Health Benefits Proposed Rule*, *supra* note 205, at 3.

<sup>211</sup> *Essential Health Benefits Proposed Rule*, *supra* note 205, at 3. The benchmark plan is based on the approach established in the Children’s Health Insurance Program (CHIP). *Essential Health Benefits Bulletin*, *supra* note 200, at 10.

<sup>212</sup> *Essential Health Benefits Proposed Rule*, *supra* note 205, at 3.

<sup>213</sup> *Essential Health Benefits Proposed Rule*, *supra* note 205, at 3.

<sup>214</sup> *Essential Health Benefits Proposed Rule*, *supra* note 205, at 3. “Actuarial equivalence for purposes of this benefit substitution policy will be determined based on the value of the service without regard to cost-sharing. States will retain the discretion to adopt a stricter standard for benefit substitution or prohibit substitution entirely.” *Health Care Reform: Small Group Plans-Essential Health Benefits (EHB)*, GATEWAY FINANCIAL (Feb. 2013), <http://www.gatewayfinancial.biz/sites/all/files/gatewayfin/attachments/Compliance%20-%20Health%20Care%20Reform%20-%20Essential%20Health%20Benefits%2001-22-13.pdf>.

<sup>215</sup> *Essential Health Benefits Proposed Rule*, *supra* note 205, at 3.

<sup>216</sup> *Actuarial Value and Cost-Sharing Reductions Bulletin*, CTR FOR MEDICARE & MEDICAID SERVICES (Dec. 16, 2011), <http://www.cms.gov/CCIIO/Resources/Files/Downloads/Av-csr-bulletin.pdf>.

<sup>217</sup> *Id.* at 1–2.

<sup>218</sup> *Id.* at 2.

<sup>219</sup> *Id.* at 8.

right balance between ensuring comparability of plans within each metal level and allowing plans the flexibility to use convenient cost-sharing metrics.”<sup>221</sup>

States have the option to choose an EHB benchmark plan based on criteria set by HHS.<sup>222</sup> The options include choosing “from the three largest small group health insurance products, the three largest state employee health plan options, the three largest federal employee health plan options, or the largest commercial HMO plan sold in the state.”<sup>223</sup> The deadline for a state to select a benchmark plan was December 26, 2012, and after this date a plan will be selected by default.<sup>224</sup>

The PPACA mandates that states are liable for costs when state law requires insurance plans to cover services beyond those defined in the EHB rule.<sup>225</sup> However, that provision does not affect the years 2014 and 2015, and those additional state law benefits will be considered essential health benefits for those years.<sup>226</sup>

This option results in a low standard, and the complexity of benefit design will decrease in relation.<sup>227</sup> With such low standards, biologic drug coverage can be expected to decrease as well.<sup>228</sup> Although, the Proposed Rule uses the Guidelines of

<sup>220</sup> *Id.* at 8; *Essential Health Benefits Standards: Ensuring Quality, Affordable Coverage*, CENTER FOR MEDICARE AND MEDICAID SERVICES, <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/ehb-2-20-2013.html> (last visited Oct. 13, 2013) (“To streamline and standardize the calculation of AV for health insurance issuers, HHS is providing a publicly available AV calculator, which issuers would use to determine health plan AVs based on a national, standard population, as required by law. Under the proposed rule, beginning in 2015, HHS will accept state-specific data sets for the standard population if states choose to submit alternate data for the calculator. The proposed rule includes standards and considerations for plans with benefit designs that the AV calculator cannot easily accommodate. Consumer-driven health plans, such as high-deductible health plans and health savings accounts, are compatible with the AV calculator.”).

<sup>221</sup> *Actuarial Value and Cost-Sharing Reductions Bulletin*, *supra* note 216, at 8.

<sup>222</sup> *Essential Health Benefits: What Have States Decided for Their Benchmark?*, KAISER FAM. FOUND. (Dec. 7, 2012), <http://kff.org/health-reform/fact-sheet/quick-take-essential-health-benefits-what-have-states-decided-for-their-benchmark/>.

<sup>223</sup> *Id.*

<sup>224</sup> *Id.* (“The EHB benchmark defines only what benefits must be covered, not what the cost-sharing levels will be. Carriers will develop the cost-sharing features for the products they offer based on the actuarial values for the different metal level plans (bronze, silver, gold, and platinum) spelled out in the ACA.”).

<sup>225</sup> *Id.* (“Twenty-six states plus the District of Columbia recommended an EHB plan or concluded the default plan is acceptable. So far, twenty states and the District of Columbia have selected a small group plan as the state’s EHB benchmark. Three states, Utah, Arizona, and Maryland, chose a state employee health plan as the benchmark. North Dakota, Connecticut, Michigan, and Vermont opted to make their state’s largest commercial HMO plan the EHB benchmark. Nebraska’s Governor submitted an EHB recommendation for a state-defined benefit plan; however, the plan was ultimately not approved by HHS.”).

<sup>226</sup> *Id.*

<sup>227</sup> Bill McGivney, *Essential Health Benefits: Cancer Drugs/Biologics Not “Protected”*, THE OBR BLOG (Dec. 14, 2012, 2:47 PM), <http://www.obroncology.com/blog/2012/12/essential-health-benefits-cancer-drugsbiologics-not-%E2%80%9Cprotected%E2%80%9D/>.

<sup>228</sup> *Id.* (“It is noteworthy that in 2012, the FDA has approved over a dozen new drugs and biologics as cancer therapeutics.”).

the USP as an organizational tool to help plans determine classes and categories of drugs that must be considered, updating these guidelines is not expected to occur for more than two years.<sup>229</sup>

Unexpectedly, “Protected Classes” based on the Medicare Part D Drug Benefit, which were included in the EHB bulletin were omitted in the rule.<sup>230</sup> This is crucial because this results in less protection for prescription biologic drugs listed in the Medicare Part D Benefit.<sup>231</sup> HHS addressed this concern with one sentence on the last page of the EHB bulletin: “we do not intend to adopt the protected class of drug policy in Part D.”<sup>232</sup> The bottom line is that the newly proposed rule further limits the access to and availability of prescription biologic drugs desperately needed by countless patients treating life-threatening illnesses.<sup>233</sup>

### 3. Excessive Cost-Sharing Continuing into the PPACA Era

The PPACA does not include sufficient regulations to avert trends towards increased co-pays, coinsurance, and specialty tiers.<sup>234</sup> Although the PPACA prohibits lifetime and annual dollar caps on insurance benefits, including caps for prescription drugs, it only applies to prescription drugs included in the EHB.<sup>235</sup>

The top-selling biologic drugs of 2006 were covered by most Medicare prescription drug plans, but were subject to prior authorization and placed in a tier with the highest patient cost-sharing.<sup>236</sup> For example, out-of-pocket costs exceeded \$4,000 annually in all cost-sharing schemes under Medicare Part D for patients treating rheumatoid arthritis.<sup>237</sup> On other prescription biologics, at preferred pharmacies with a co-pay, out-of-pocket costs to patients were found to be up to sixty dollars for a thirty-day supply.<sup>238</sup> Many patients take multiple medications to treat one or multiple medical problems.<sup>239</sup> Coinsurance, commonly at a rate of twenty-five percent, was found to be the most common cost-sharing method.<sup>240</sup> Furthermore, patient cost-sharing and utilization management requirements increased from 2006 to 2009.<sup>241</sup>

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<sup>229</sup> *Id.*

<sup>230</sup> *Id.*

<sup>231</sup> *Id.*

<sup>232</sup> *Id.*

<sup>233</sup> *Id.*

<sup>234</sup> ARTHRITIS FOUND., *supra* note 91.

<sup>235</sup> Pyenson & Scammell, *supra* note 182, at 8.

<sup>236</sup> Liang, *supra* note 35, at 1082; Except for diabetes drugs and trastuzumab, a cancer drug. Liang, *supra* note 35, at 1082.

<sup>237</sup> ARTHRITIS FOUND., *supra* note 91.

<sup>238</sup> ARTHRITIS FOUND., *supra* note 91; *see also* Carroll, *supra* note 191 (noting that copayments for biologics are designed to be significantly higher, often running \$100 or more).

<sup>239</sup> ARTHRITIS FOUND., *supra* note 91.

<sup>240</sup> ARTHRITIS FOUND., *supra* note 91.

<sup>241</sup> *See* Liang, *supra* note 35, at 1083.

Current trends in biologic drug coverage suggest insurance plans in the PPACA era will place greater access restrictions on biologics.<sup>242</sup> In anticipation of the PPACA provisions becoming applicable, payers and employers reduced access and increased patients' costs.<sup>243</sup> According to the Zitter Group, a leading business intelligence firm working with life science companies and managed care organizations on product access and reimbursement, seventy-four percent of payers and employers believe healthcare reform will have a significant impact on their costs.<sup>244</sup> This led to "thirty-five percent of payers increasing deductibles, out-of-pocket maximums, and nonfinancial access restrictions on biologics in 2011, and thirty-five percent of employers saying they would do it again in 2012."<sup>245</sup>

Buy-up options will likely be available for biologics excluded from the essential benefits package, for an additional cost.<sup>246</sup> Buy-up options could be too expensive for many people, restricting access to costlier and needed benefits.<sup>247</sup> Individuals entering the health market with low incomes, poor health literacy, or who are at greater risk for chronic, disabling, or life-threatening diseases could particularly be affected.<sup>248</sup>

According to market analysts, if the copayment is greater than twenty-five dollars per drug patients begin to look for different options.<sup>249</sup> Shifting costs may reduce access to patients, but may also reduce premiums enough to support the inclusion of wider biologic coverage within EHB.<sup>250</sup> Again, the inclusion of biologic drugs within insurance plans depends on how the government designs EHB and if there are any gaps in coverage where the patient is required to cover the costs.<sup>251</sup> These experts are using Medicare as a blueprint to speculate on what biologics will be excluded from EHB.<sup>252</sup> Other experts strongly believe HHS will design plans where biologic benefits are carved out of EHB.<sup>253</sup>

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<sup>242</sup> See generally Dalzell, *supra* note 185, at 7.

<sup>243</sup> Dalzell, *supra* note 185, at 7–8.

<sup>244</sup> Dalzell, *supra* note 185, at 7.

<sup>245</sup> Dalzell, *supra* note 185, at 7.

<sup>246</sup> Dalzell, *supra* note 185, at 7.

<sup>247</sup> Dalzell, *supra* note 185, at 7.

<sup>248</sup> Dalzell, *supra* note 185, at 7.

<sup>249</sup> Carroll, *supra* note 191.

<sup>250</sup> Dalzell, *supra* note 185, at 8.

<sup>251</sup> Dalzell, *supra* note 185, at 7–8.

<sup>252</sup> Dalzell, *supra* note 185, at 8. "I keep going back to Medicare, because I think that's our blueprint. As the rules come out, I think we'll see some very interesting things: 'These are the drugs we will not cover. These are the benefit designs that payers have to adhere to.' We don't know what HHS will do until those rules are released, but it's a fair assumption to say, 'Yes, that's probably what they will do.'" Dalzell, *supra* note 185, at 8.

<sup>253</sup> Dalzell, *supra* note 185, at 8.

## IV. PATIENTS NEED PROTECTION

A. *Proposed Recommendation*

Patients need prescription biologic drug cost-sharing protection because the costs of prescription biologics are unaffordable for a vast amount of insured patients.<sup>254</sup> Without this protection, the PPACA cannot fully provide access to quality, affordable health care to all Americans.<sup>255</sup> The PPACA did not address high-cost biologics, leaving insurers to lead the way in forming social policy.<sup>256</sup> Based on the analysis above, amendments to the PPACA are necessary to properly protect patients.

## 1. Modify and Enact the Patients' Access to Treatments Act of 2012

On March 19, 2012, United States Representative David McKinley introduced a bill, the Patients' Access to Treatments Act of 2012 (PATA), to Congress addressing the problem of insurers charging excessive co-pays, coinsurance, or other cost-sharing requirements applicable to prescription drugs in a specialty drug tiers.<sup>257</sup> Representative McKinley sums up the problem in a letter addressed to his colleagues in which he describes how patients with chronic, disabling, and life threatening conditions can find some relief in biological medicines, but certain insurance practices are preventing access to these treatments.<sup>258</sup> He writes, "PATA would end the practice of discrimination between medications with a fixed co-pay and so-called 'specialty drugs' by requiring commercial health insurers to impose the same co-payment obligations for specialty drugs as they do for Tier III medication."<sup>259</sup>

Section 2719B, subsection (a), of PATA places limits on cost-sharing:

Requirement - A group health plan, or a health insurance issuer offering group or individual health insurance, that provides coverage for prescription drugs and uses a formulary or other tiered cost-sharing structure shall not impose co-payment, coinsurance, or other cost-sharing requirements applicable to prescription drugs in a specialty drug tier that exceed the dollar amount (or its equivalent) of co-payment, coinsurance, or other cost-sharing requirements applicable to prescription drugs in a

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<sup>254</sup> See Gaudry, *supra* note 45, at 587; see also *Regulating Follow-on Biologics*, *supra* note 32, at 363–64.

<sup>255</sup> See ARTHRITIS FOUND., *supra* note 91.

<sup>256</sup> James C. Robinson, *Insurers' Strategies for Managing the Use and Cost of Biopharmaceuticals*, 25 HEALTH AFFAIRS 1205, 1206 (2006), available at <http://content.healthaffairs.org/content/25/5/1205.full.pdf>.

<sup>257</sup> Patients' Access to Treatments Act of 2012, H.R. 4209, 112th Cong. (2012).

<sup>258</sup> Letter from David McKinley, Become an Original Sponsor of the Patient Access to Critical Treatment Act Letter (2012), available at [http://www.simpletasks.org/takeaction/PATA\\_Dear\\_Colleague.pdf#toolbar=](http://www.simpletasks.org/takeaction/PATA_Dear_Colleague.pdf#toolbar=).

<sup>259</sup> *Id.*

non-preferred brand drug tier (or prescription drugs in a brand drug tier if there is no non-preferred brand drug tier).<sup>260</sup>

This bill does not solve the problem of excessive cost-sharing requirements because it does not take into account that insurers and the Secretary of HHS hold the power to devise which drugs are included, or more importantly, *excluded* in formularies subsequent to the enactment of PPACA.<sup>261</sup> Enacting the bill as it stands will result in insurance companies redesigning plans that exclude biologic drugs outright. To resolve the problem of formularies created with the intent of excluding biologics, an additional provision to the already stated requirement of PATA is needed. It calls for an insertion of the provision stating, “EHB will include all biologics currently under Medicare part D without exception and include any biologic drug costing equal to or less than the highest costing biologic drug covered under Medicare part D.”

This amendment will alleviate delegating the balance of access and affordability and prevent the continued practice of “off-label and ineffective use, erosion of insurance coverage, and punitive consumer cost-sharing.”<sup>262</sup> It will solve the issue of excessive cost-sharing requirements, and insurers can spread the excess cost throughout all policies.<sup>263</sup> Numerous other countries already delegate this responsibility to governmental entities, which establish a formulary, regulate prices,

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<sup>260</sup> Patients’ Access to Treatments Act of 2012, H.R. 4209, 112th Cong. (2012). The legislation includes a special rule, subsection (b): “if a formulary used by a group health plan or a health insurance issuer offering group or individual health insurance contains more than one non-preferred brand drug tier, then the requirements of subsection (a) shall be applied with respect to the non-preferred brand drug tier for which beneficiary cost-sharing is lowest.” *Id.*

<sup>261</sup> *FAQs About the Formulary*, PRIORITY HEALTH, <https://www.priorityhealth.com/member/pharmacy/using-the-drug-list/faqs#3> (last modified Oct. 12, 2011); *see also* Patient Prot. & Affordable Care Act, Pub. L. No. 111-148, § 3307 (a)(i)(II), 124 Stat. 119, 934 (2010).

<sup>262</sup> Robinson, *supra* note 256, at 1216. Without amending the PPACA,

scenario would be based on increased sophistication on the part of both insurers and biotechnology manufacturers. The effectiveness of insurers’ strategies could grow over time as insurers invest in pharmaceutical expertise, improve coding and information systems, rationalize distribution channels, and migrate to less inflationary physician payment methods. The biopharmaceutical industry could respond by developing products supported by studies of comparative efficacy and cost-effectiveness and by marketing those products only through specialists with the relevant expertise and appropriate incentives.

Robinson, *supra* note 256, at 1216. However, this is an optimistic view that has no definite timeline, and there are too many patients in need of access now. Robinson, *supra* note 256, at 1216.

<sup>263</sup> Robinson, *supra* note 256, at 1216. The author does recognize more research is necessary due to the complexity and difficulty of balancing cost and coverage within insurance plans. Robinson, *supra* note 256, at 1216.

and control cost-sharing of patients.<sup>264</sup> The United States should adopt this proven policy to protect patients.<sup>265</sup>

#### IV. CONCLUSION

Even though insurers must find a balance of providing services with associated costs, the current statutory scheme continues to subject patients in need of life-saving prescription biologics to an ineffective and unaffordable insurance system.<sup>266</sup> The situations of the Taffe, Love, and D'Orsaneo families are prime examples of the growing problem and dangers of permitting excessive cost-sharing requirements applicable to prescription biologics.<sup>267</sup> Though cost-sharing requirements are permitted in the insurance market,<sup>268</sup> allowing insurers to continue the use of excessive cost-sharing requirements is deadly to patients' health and finances.<sup>269</sup>

Since the early twentieth century Congress has regulated the prescription drug industry.<sup>270</sup> Throughout American history new legislation has been created in response to emergent problems.<sup>271</sup> Although the PPACA does address the problem of unaffordable biologic drugs, it attempts to fix the problem in an inefficient and ineffective manner. The PPACA attempts to change our current health care system without changing the manner in which insurers design plans. Insurance providers, both for-profit and non-profit, cannot operate at a loss, but the harm caused by excessive cost-sharing techniques outweighs any inconvenience insurers suffer from implementing a new strategy.

While the underlying purposes of BPCIA provisions of the PPACA parallel those from the Hatch-Waxman Act, the differences between biologics and traditional small-molecule drugs minimize the potential impact of patient savings.<sup>272</sup> There are numerous factors that hinder the performance of biosimilars compared to traditional generic drugs,<sup>273</sup> most notably the steep manufacturing costs, lack of automatic market substitution to reference drugs, and increased safety and efficacy concerns.<sup>274</sup> The result is minimal savings and lower access for patients created from the new

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<sup>264</sup> Robinson, *supra* note 256, at 1216.

<sup>265</sup> Robinson, *supra* note 256, at 1216.

<sup>266</sup> ARTHRITIS FOUND., *supra* note 91.

<sup>267</sup> See Andriote, *supra* note 1; see also CNBC NEWS, *supra* note 24.

<sup>268</sup> The author realizes that cost-sharing requirements are necessary in our current insurance model, but opposes excessive cost-sharing requirements aimed at a particular group of patients. Blue Shield of California, which spends roughly \$200 million annually on specialty drugs is planning to work with market exchanges to develop more affordable plans. See CNBC NEWS, *supra* note 24.

<sup>269</sup> See Andriote, *supra* note 1.

<sup>270</sup> See *100 Years of Biologics Regulation*, *supra* note 94.

<sup>271</sup> See *100 Years of Biologics Regulation*, *supra* note 94.

<sup>272</sup> Gaudry, *supra* note 45, at 629.

<sup>273</sup> Tresemer, *supra* note 47, at 8–9.

<sup>274</sup> Tresemer, *supra* note 47, at 8–10; Kopenski, *supra* note 158, at 3; see also Lundy, *supra* note 81, at 4.

PPACA statutory pathway for biosimilars.<sup>275</sup> From the analysis above, the statutory construction of the PPACA, including the omission of excessive cost-sharing regulations and the ambiguous HHS EHB proposed rule, purports to the continued furtherance of these harmful practices.

Congress should develop a statutory scheme that prohibits insurers utilizing the harmful practice of incorporating unreasonable cost-sharing requirements into insurance policies.<sup>276</sup> Specifically, Congress should amend the PPACA, by modifying and enacting PATA, a bill governing excessive cost-sharing requirements for specialty drugs, specifically biologics. By incorporating this new language into the PPACA, Congress would keep the statutory scheme consistent and appropriately protect patients in need of prescription biologics. In doing so, Congress will further the exact reason for enacting the PPACA—providing quality and affordable care for all Americans.<sup>277</sup>

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<sup>275</sup> Grabowski et al., *supra* note 85, at 544; *see also* LUNDY, *supra* note 81, at 3–4 (discussing the numerous economic and policy considerations related to the development of biologic medications).

<sup>276</sup> NBC News provides tips for individuals to gain access to biologic medications including contacting the drug manufacturer directly, attempting to charm your doctor's office administrator to receive quicker authorization, working with your doctor to document your health industry, asking your employer for help, appealing plan decisions, and always pay attention to deadlines. Kingsbury, *supra* note 16.

<sup>277</sup> *See generally* *The Patient Protection and Affordable Care Act Detailed Summary*, *supra* note 127.