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The Economic Burdens of Life: Trade Secrecy and the Insulin Pricing Crisis in the United States

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Cover Page Footnote

J.D. Candidate, 2021, University of Georgia School of Law. I wish to thank Dean Elizabeth Weeks for her invaluable advice and comments throughout the process. Thank you also to Konstantin Toropin for proofreading, as well as endless support and encouragement.

THE ECONOMIC BURDENS OF LIFE: TRADE SECRECY AND THE INSULIN PRICING CRISIS IN THE UNITED STATES

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[*]J.D. Candidate, 2021, University of Georgia School of Law. I wish to thank Dean Elizabeth Weeks for her invaluable advice and comments throughout the process. Thank you also to Konstantin Toropin for proofreading, as well as endless support and encouragement.

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I. INTRODUCTION

In 1923, the Nobel Prize in Physiology or Medicine was awarded to Frederick Banting and James Macleod "for the discovery of insulin."[1] In his Nobel lecture in 1925, Banting delivered a technical description of the discovery and its applications, concluding with the observation that insulin would not cure diabetes, but would provide diabetics with the ability to cope with "the economic burdens of life."[2] Having sold his patent on the discovery to the University of Toronto for only a dollar in the interest of public health,[3] Banting could not have fathomed how ironic his concluding remark would become.

The economic burdens of life with diabetes have ballooned, with patients in the United States experiencing a 700% increase in the price of insulin in the past two decades.[4] For those who rely on insulin, the individual health consequences of skyrocketing prices can be disastrous. Insufficient insulin can lead to critical health problems, including renal failure, amputation, heart disease, blindness, and even death.[5]

Currently, ninety percent of the world's supply of insulin, and one hundred percent of the U.S.'s supply, come from just three drug manufacturers: Eli Lilly, Novo Nordisk, and Sanofi.[6] Although these manufacturers have attempted to reduce their prices in response to recent public and congressional outrage,[7] more could still be done. Policy changes to the intellectual property protections surrounding biologic drugs would help to ensure continued access to insulin for the millions of Americans who rely on the drug.

The intellectual property protections available to manufacturers of pharmaceuticals in the United States include patent, regulatory exclusivity, and trade

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[1] THE NOBEL PRIZE IN PHYSIOLOGY OR MEDICINE 1923, NOBEL PRIZE https://www.nobelprize.org/prizes/medicine/1923/summary/ (last visited Dec. 31, 2019).

[2] Frederick G. Banting Nobel Lecture, Diabetes and Insulin (Sept. 15, 1925), *in* NOBEL LECTURES, PHYSIOLOGY OR MEDICINE 1922-1941 (Elsevier Publishing Co. 1965), https://www.nobelprize.org/prizes/medicine/1923/banting/lecture/.

[3] Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 NEW ENG. J. MED. 1171, 1171 (2015).

[4] Drew Pendergrass, *How Insulin Became Unaffordable*, HARV. POL. REV. (Jan. 22, 2018), https://harvardpolitics.com/united-states/how-insulin-became-unaffordable/ (noting that price increase accounts for inflation).

[5] *Id.*; Tiffany Stanley, *Life, Death, and Insulin*, WASHINGTON POST (Jan. 7, 2019), https://www.washingtonpost.com/news/magazine/wp/2019/01/07/feature/insulin-is-a-lifesaving-drug-but-it-has-become-intolerably-expensive-and-the-consequences-can-be-tragic/.

[6] JUDITH A. JOHNSON, CONG. RESEARCH SERV., IF11026, INSULIN PRODUCTS AND THE COST OF DIABETES TREATMENT 2 (2018).

[7] Stine Jacobsen, *Novo Nordisk to cut insulin prices in the U.S.*, THOMSON REUTERS (Sept. 6, 2019), https://www.reuters.com/article/us-novo-nordisk-usa/novo-nordisk-to-cut-insulin-prices-in-the-us-idUSKCN1VR1JO.

secrecy.[8] Makers of insulin rely heavily on trade secrecy, a protection that can theoretically last forever, to prevent their manufacturing processes from falling into competitors' hands.[9] The complexity and difficulty of manufacturing insulin and similar drugs[10] means that trade secret protections around manufacturing processes effectively stymie new entrants to the insulin market.[11] The relative lack of competition keeps prices high to the detriment of those who rely on insulin to survive.[12] A reduction in trade secret protections for the processes these three companies use to manufacture insulin would facilitate the entry of new competitors into the insulin market, thus reducing prices.

This Note serves to: (1) provide background on insulin and its uses for treating diabetes; (2) describe the current intellectual property environment around pharmaceuticals; (3) lay foundation for the current regulatory framework governing insulin specifically; (4) describe how the Hatch-Waxman Act of 1984 and the Biosimilars Act of 2010 create the opportunity for less expensive follow-on forms of insulin; and (5) argue that relaxing the trade secret protections around the insulin manufacturing process is likely to be successful in increasing competition and lowering prices in the insulin market.

II. BACKGROUND

The following sections provide background information on insulin and its clinical application for managing diabetes. To facilitate the reader's understanding of the particular policy challenges insulin pricing poses, this section goes into detail about how the prevalence of diabetes raises the level of urgency surrounding this issue. This section also discusses how insulin differs from chemical medications and the problems that arise as a result of the differences between the two.

A. DIABETES

The primary application of commercial insulin is to manage diabetes mellitus, a chronic condition commonly referred to simply as diabetes.[13] Diabetes is caused by the body's inability to properly regulate the level of glucose, a type of

[8] KEVIN J. HICKEY ET AL., CONG. RESEARCH SERV., R45666, DRUG PRICING AND INTELLECTUAL PROPERTY LAW: A LEGAL OVERVIEW FOR THE 116TH CONGRESS 3 (2019); W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Price Competition and Innovation*, 101 IOWA L. REV. 1023, 1046 (2016).

[9] Price & Rai, *supra* note 8, at 1046.

[10] *Id.* at 1048-49.

[11] *Id.*

[12] Greene & Riggs, *supra* note 3, at 1171.

[13] MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444 (last visited Oct. 3, 2019).

sugar, in the blood.[14] Cells throughout the body require glucose for energy, and the pancreas produces insulin to prevent glucose levels from rising too high.[15]

There are two types of diabetes.[16] Though the exact cause is unknown, type one diabetes results when the body's immune system destroys the cells in the pancreas that produce insulin.[17] Type two diabetes, which is far more common in the U.S.,[18] is thought to be influenced by lifestyle factors such as diet and exercise.[19] Cells in the body of a patient with type two diabetes become resistant to insulin such that the body cannot produce enough to regulate blood glucose levels effectively.[20]

Diabetes, particularly type two, is extremely common in the U.S.[21] According to estimates by the Centers for Disease Control and Prevention (CDC), over thirty million Americans, or slightly less than one in every ten, suffer from diabetes.[22] Worse still, the CDC estimates that nearly seven million of those thirty million people have not been formally diagnosed.[23] The issue with diabetes, however, is not just in the number of people affected with the disease. Diabetes also affects some regions and ethnicities more than others. The highest concentrations of people with diabetes are in the southeastern U.S.,[24] and the condition disproportionately affects African-Americans, Hispanic Americans, and Native Americans.[25]

Diabetes takes an enormous toll on public health in the United States, both in terms of loss of life and productivity, and in terms of the financial burden it places on both those with the disease and the healthcare industry more generally.[26] In 2013, the CDC estimates that diabetes caused roughly 75,000 deaths among people aged fifteen and older, and that diabetes-linked conditions such as renal failure and heart disease caused an additional 293,000 deaths in the same

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[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] AMERICAN DIABETES ASSOCIATION, https://www.diabetes.org/diabetes (last visited Oct. 3, 2019).

[19] *Id.*

[20] MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444 (last visited Oct. 3, 2019).

[21] AMERICAN DIABETES ASSOCIATION, https://www.diabetes.org/diabetes (last visited Oct. 3, 2019).

[22] CENTERS FOR DISEASE CONTROL AND PREVENTION: NATIONAL DIABETES STATISTICS REPORT, 2020 (2020), https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.

[23] *Id.*

[24] *Id.* at 5.

[25] *Id.* at 4.

[26] *See generally* CENTERS FOR DISEASE CONTROL AND PREVENTION: DIABETES STATE BURDEN TOOLKIT, https://nccd.cdc.gov/Toolkit/DiabetesBurden (last visited Mar. 2, 2020).

age group.[27] The CDC further estimates that in 2013, diabetes and diabetes-linked conditions cost the United States over $300 billion in healthcare costs.[28]

Without an adequate supply of insulin, a diabetic patient can quickly experience severe medical issues, including renal failure, amputation, heart disease, blindness, and even death.[29] The urgency surrounding the issue of access to insulin reflects the often devastating health effects individuals with diabetes suffer when they do not get the required dose. A Yale Diabetes Center survey conducted in 2017 found that one quarter of respondents reported undercompliance with their prescribed dose of insulin because of the cost.[30] Of those patients reporting cost-related underuse, one third reported that they had not discussed the cost issue with their doctor,[31] which suggests that the problem of underuse of insulin by diabetics is perhaps even worse than we realize. The fundraising website Go Fund Me lists hundreds of fundraisers for individual diabetics in need of help paying for insulin, with fundraising goals ranging from a few hundred dollars to several thousand.[32]

The following section discusses insulin in greater depth and explains how its discovery and evolution over the past century have contributed to the current pricing crisis.

B. INSULIN

1. How Insulin Works in the Body

As mentioned previously, insulin is a hormone that occurs naturally in the body.[33] As such, pharmaceutical insulin is what is known as a biologic drug, or simply a biologic. Biologics are substances derived from a living organism and are distinct from chemical medications that are manufactured purely through chemical synthesis.[34] Biologics have a broad array of clinical applications,

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[27] *Id.* (2013 is the most recent year for which such data are available.)

[28] *Id.*

[29] Stanley, *supra* note 5.

[30] Darby Herkert et al., *Cost-Related Insulin Underuse Among Patients With Diabetes*, 179:1 JAMA INTERNAL MEDICINE 112, 112-13 (2019).

[31] *Id.* at 113.

[32] GO FUND ME, https://www.gofundme.com/mvc.php?route=homepage_norma/search&term=insulin (last visited Nov. 5, 2019). Appeals for help paying for insulin have become so commonplace that Go Fund Me published an article specifically advising individuals of alternative sources of insulin and how best to use Go Fund Me to raise money to pay for it. GO FUND ME: HOW TO GET INSULIN WHEN YOU CAN'T AFFORD IT: 6 IDEAS, https://www.gofundme.com/c/blog/how-to-get-insulin (last visited Jan. 12, 2020).

[33] MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444 (last visited Oct. 3, 2019).

[34] FOOD AND DRUG ADMINISTRATION: CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER), https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers (last visited Jan. 12, 2020).

including treatment of cancer, rheumatoid arthritis, and infertility.[35] Some examples of biologics include vaccines, gene therapy products, and recombinant therapeutic proteins such as insulin.[36] The distinction between biologics and chemical medications is important because there are major differences between these two classes of products in terms of their structure and manufacture and how they fit into the regulatory framework for pharmaceuticals. This regulatory framework will be discussed in detail in later sections.

In general, the molecules of which biologics are comprised are much larger and more complex than the molecules that make up chemical medications.[37] One commentator provides the following example to illustrate the difference between chemical drugs and biologic drugs: "In terms of size and rough complexity, if an aspirin were a bicycle, a small biologic would be a Toyota Prius, and a large biologic would be an F-16 fighter jet."[38] Insulin is a small biologic made up of a chain of fifty-one amino acids, and the specific way in which the amino acid chain folds and twists determines the chemical identity of the substance.[39]

The pancreas, part of the endocrine system in human beings and some other mammals, produces insulin to regulate the level of glucose in the blood.[40] With a few exceptions, insulin must be injected into the layer of fat beneath the skin in order for the body to metabolize it.[41] If swallowed, digestive acids would break the protein in the hormone down so as to render it ineffective for purposes of managing blood glucose.[42]

2. Development of the Manufacturing Process for Pharmaceutical Insulin

Frederick Banting, a physician in Toronto, Canada, discovered insulin in 1921 with the help of graduate student Charles Best.[43] From the beginning, insulin was seen as something of a 'miracle drug,' transforming diabetes from a lethal disease into a manageable chronic condition.[44] Motivated by the public health

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[35] *Id.*

[36] *Id.*

[37] Price & Rai, *supra* note 8, at 1026.

[38] *Id.* (citation omitted).

[39] David M. Dudzinski, *Reflections on Historical, Scientific, and Legal Issues Relevant to Designing Approval Pathways for Generic Versions of Recombinant Protein-Based Therapeutics and Monoclonal Antibodies*, 60 FOOD & DRUG L. J. 143, 188 (2005).

[40] AMERICAN DIABETES ASSOCIATION, https://www.diabetes.org/diabetes/medication-management/insulin-other-injectables/insulin-basics (last visited Oct. 4, 2019).

[41] *Id.*

[42] *Id.*

[43] Greene & Riggs, *supra* note 3, at 1171. The splitting of the 1923 Nobel Prize for the discovery between Banting and James Macleod, the head of the physiology lab at the University of Toronto where Banting and Best made their discovery, rather than between Banting and Best is a fascinating story of academic politics that is beyond the scope of this note. *See generally*, Louis Rosenfeld, *Insulin: Discovery and Controversy*, 48(12) CLINICAL CHEMISTRY 2270 (2002).

[44] Greene & Riggs, *supra* note 3, at 1171.

implications of their discovery rather than the potential for monetizing it, Banting and Best sold the patent for insulin to the University of Toronto for a mere one dollar.[45]

In its nearly 100-year history, pharmaceutical insulin, or commercial insulin as it is sometimes called, has undergone numerous changes.[46] In the early days after the discovery, insulin makers manufactured the substance using extracts from the whole pancreas of a cow or pig.[47] This method posed two serious problems. First, this process made it difficult to manufacture at the scale needed to meet demand.[48] Second, the animal extracts used also caused severe side effects in some patients.[49]

Today, insulin production no longer relies on livestock, but rather on microorganisms.[50] In the early 1980's, insulin makers began using recombinant DNA technology to manipulate the DNA of microbes such as E. coli, essentially reprogramming the microbe at the DNA level.[51] These genetically altered microbes produce insulin that is chemically identical to the insulin the human pancreas produces naturally.[52] Recombinant insulin does not cause the same side effects that animal extract varieties once did.[53] It also achieves a much higher standard of purity and effectiveness,[54] with several different subtypes available depending on the patient's specific needs.[55] The first recombinant human insulin to receive FDA approval was Eli Lilly's Humulin in 1982.[56]

Insulin makers have since made small modifications to recombinant human insulin's molecular structure to create what are known as insulin analogs.[57] There are five different types of insulin analog available today: "long-acting, rapid-acting, intermediate-acting, short-acting (regular insulin), and premixed."[58] These various types allow diabetic patients to control the window of effectiveness of the insulin to counteract the blood glucose spike that occurs during and shortly

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45 *Id.*

46 *Id.* at 1172.

47 *Id.*

48 *Id.*

49 *Id.*

50 *Id.*

51 *Id.*

52 *Id.*

53 *Id.*

54 *Id.*

55 AMERICAN DIABETES ASSOCIATION, https://www.diabetes.org/diabetes (last visited Oct. 3, 2019).

56 *See* Dudzinski, *supra* note 39, at 165.

57 JUDITH A. JOHNSON, CONG. RESEARCH SERV., IF11026, INSULIN PRODUCTS AND THE COST OF DIABETES TREATMENT 1 (2018).

58 *Id.*

after meals.[59] The vast majority of diabetic patients in the U.S. use some form of insulin analog to manage the condition.[60]

In the U.S., the price of insulin rose by 700% over the past twenty years.[61] Price spikes vary depending on the specific type of the drug.[62] For example, between 2001 and 2015, "the price of one type of insulin (insulin lispro) increased 585% (from $35 to $234 per vial)."[63] Depending on the patient's needs, a vial of insulin may last only about two weeks,[64] resulting in an out-of-pocket cost of roughly $500 per month for an uninsured person. In short, diabetes presents a tremendous public health challenge in the U.S. and the lack of affordable insulin seriously exacerbates the issue. A primary contributor to the insulin pricing issue is the intellectual property protections available to manufacturers of pharmaceuticals, which the next section explores in detail.

III. INTELLECTUAL PROPERTY PROTECTION FOR PHARMACEUTICALS

The purpose of intellectual property law is to codify an innovator's property rights in her innovation.[65] Pharmaceutical products and other forms of medical intervention are perhaps one of the best examples of the need to balance the rights of the innovator with the social utility of the innovation.[66] Modern pharmaceutical technology is one example of an ethical quandary that has played out in capitalist societies throughout history: how does a government protect the average, non-wealthy person from being priced out of a product necessary for survival without punishing or unduly disincentivizing the maker of that product?[67]

Some governments respond to this dilemma by recognizing the innovator's property rights in the innovation itself through intellectual property law.[68] In the U.S., pharmaceutical companies benefit from several different types of

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[59] *Id.*

[60] *Id.* ("In 2000, of privately insured adults with type 2 diabetes using insulin, 19% were using analog insulins; by 2010, 96% were using these products.")

[61] Pendergrass, *supra* note 4.

[62] *See* JUDITH A. JOHNSON, CONG. RESEARCH SERV., IF11026, INSULIN PRODUCTS AND THE COST OF DIABETES TREATMENT 1 (2018).

[63] *Id.*

[64] *Id.*

[65] KEVIN J. HICKEY, CONG. RESEARCH SERV., IF10986, INTELLECTUAL PROPERTY LAW: A BRIEF INTRODUCTION 1 (2018).

[66] Alexandra E. Blasi, *An Ethical Dilemma: Patents & Profits v. Access & Affordability*, 33 J. LEGAL MED. 115, 115 (2012).

[67] *Id.*

[68] KEVIN J. HICKEY, CONG. RESEARCH SERV., IF10986, INTELLECTUAL PROPERTY LAW: A BRIEF INTRODUCTION 1 (2018).

protection for intellectual property. The following sections discuss three such protections: (1) patent, (2) regulatory exclusivity, and (3) trade secret.

A. PATENT

Patents provide the innovator with a period of time during which competitors are excluded from manufacturing the product, an arrangement that is essentially a temporary, lawful monopoly.[69] Pharmaceutical innovators may apply for patent protection for the active ingredient in a product, the delivery method, a manufacturing method, a device or other technology needed to administer the drug, or other innovations.[70] The term of patent protection lasts twenty years,[71] and legislation specific to pharmaceuticals provides for up to an additional five years to account for delays in FDA approval.[72]

In exchange for the period of exclusivity, the patent holder must disclose the details of the innovation for use by others in the future.[73] The Patent Act of 1952 requires that the patent holder disclose:

> [A] written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.[74]

Thus, the incentive to innovate is preserved while providing the public an opportunity to benefit later from more competition and lower prices.[75]

The patent system is not without its drawbacks. One issue in the pharmaceutical context is under-disclosure.[76] The benefits of the patent system to society at large rely on full disclosure of the details of the innovation in the patent application so that competitors can replicate the innovation once the patent expires, thereby lowering the price.[77] However, the majority of patents do not describe

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[69] *See* KEVIN J. HICKEY ET AL., CONG. RESEARCH SERV., R45666, DRUG PRICING AND INTELLECTUAL PROPERTY LAW: A LEGAL OVERVIEW FOR THE 116TH CONGRESS 6 (2019).

[70] *Id.* at 13.

[71] *Id.* at 10.

[72] *Id.*

[73] Alan Devlin, *The Misunderstood Function of Disclosure in Patent Law*, 23 HARV. J. L. & TECH. 401, 407 (2010).

[74] 35 U.S.C. § 112(a)(2018).

[75] *See* Devlin, *supra* note 73, at 407.

[76] *Id.* at 411.

[77] *Id.* at 409.

the invention in enough detail for competitors to replicate it once the patent expires.[78]

B. REGULATORY EXCLUSIVITY

Another form of intellectual property protection available to pharmaceutical innovators is regulatory exclusivity, which prevents the FDA from approving a follow-on product for a specified period of time.[79] There are two types of regulatory exclusivity:

> (1) data exclusivity, which precludes applicants from relying on FDA's safety and effectiveness findings for the reference product … to demonstrate the safety and effectiveness of the follow-on product; and (2) marketing exclusivity, which precludes FDA from approving any other application for the same pharmaceutical product and use, regardless of whether the applicant has generated its own safety and effectiveness data.[80]

The Biosimilars Act, discussed in detail in subsequent sections, provides marketing exclusivity for name-brand biologics by barring applications for FDA approval of follow-on products for four years after the name-brand product is licensed.[81] For eight years after that, the FDA will accept applications for approval of follow-on products, but will not approve any of them for licensing.[82] Regulatory exclusivity bears some similarity to patent in that it arises in federal statute and provides a fixed term of protection that must eventually lapse.[83]

C. TRADE SECRET

Trade secrecy protects information that: (1) confers economic benefit upon the holder because (2) it is not generally known and (3) the secrecy of which the holder takes reasonable steps to preserve.[84] As a general matter, an innovator must choose between patent protection and trade secrecy protection.[85] Trade secret is an attractive choice because it covers innovations that are, for whatever

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[78] *Id.* at 411.

[79] KEVIN J. HICKEY ET AL., CONG. RESEARCH SERV., R45666, DRUG PRICING AND INTELLECTUAL PROPERTY LAW: A LEGAL OVERVIEW FOR THE 116TH CONGRESS 23 (2019).

[80] *Id.*

[81] *Id.* at 24-25.

[82] *Id.* at 25.

[83] See *Id.* at 23-24.

[84] Michael Risch, *Why Do We Have Trade Secrets?,* 11 MARQ. INTELL. PROP. L. R. 1, 6-7 (2007).

[85] Price & Rai, *supra* note 8, at 1042.

reason, not eligible for patent, and because it is much cheaper to maintain than patent protection.[86]

Trade secrecy is an outlier in the law of intellectual property in that the approach it takes to the balancing of interests is very different from that of patent. Rather than balancing the interests of the society at large with those of the innovator, trade secrecy has been criticized for most often benefitting the holder of the secret while discouraging competition by hindering the sharing of information.[87] Another criticism is that trade secret provides cover for companies who engage in business practices that put the public at risk.[88]

Furthermore, in contrast to a patent's fixed period of exclusivity, there is no prescribed term of trade secret protection. The holder has a cause of action for misappropriation of the information for as long as the holder benefits economically and takes reasonable steps to preserve the secrecy.[89] Pharmaceutical companies, and makers of biologics in particular, patent the products themselves and rely heavily on trade secrecy to protect their manufacturing processes and techniques.[90]

In the following sections, this Note explores how the intellectual property environment surrounding pharmaceuticals perpetuates the insulin pricing crisis discussed above,[91] and how policymaking could potentially alleviate what has become a serious public health problem in the U.S.

IV. REGULATORY FRAMEWORK FOR INSULIN AND BEYOND

As discussed previously, insulin has been commercially available as a pharmaceutical product for nearly a century.[92] In that time, the pharmaceutical industry has undergone massive growth, becoming one of the largest and most profitable industries in the country.[93] This industry growth, as well as tremendous technological advances in pharmaceuticals and increased focus on public safety, have resulted in a complex statutory framework relevant to all pharmaceuticals, and to insulin specifically. The following sections discuss how, in spite of

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[86] Julie E. Zink, *When Trade Secrecy Goes Too Far: Public Health and Safety Should Trump Corporate Profits*, 20 VAND. J. ENT. & TECH. L. 1135, 1138 (2018).

[87] See Price & Rai, *supra* note 8, at 1044. The tangentially related issue of under-disclosure discussed in Section III(A), *infra*, would seem to leave no viable alternative. However, the more that is known about a product, the easier the disclosure requirement is to enforce. Patent requires disclosure even if it does not always get it in full, whereas the entire purpose of trade secret is to withhold information. See *Id.* at 1044-45.

[88] *See generally*, Zink, *supra* note 86 (identifying examples of chemical companies using trade secret protection to hide the health hazards of their products).

[89] *Id.* at 1138.

[90] *Id.* at 1046.

[91] *Supra* section II.

[92] *Supra* section II(B).

[93] Catherine D. Deangelis, *Big Pharma Profits and the Public Loses*, 94(1) MILBANK QUARTERLY 30, 30 (2016).

legislative efforts to increase competition and lower prices for pharmaceuticals, insulin prices remain burdensome, if not prohibitive, for many patients.

A. BIOLOGICS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (1938) AND THE PUBLIC HEALTH SERVICE ACT (1944)

Insulin and a handful of other biologics occupy a somewhat confusing space in federal law that originates in a century-old bifurcation in the way drugs are regulated in the U.S.[94] This section provides an overview of this history to clarify the current regulatory environment for insulin.

The FDA has authority to review and approve all prescription drugs before they can enter the market.[95] However, this authority arises out of two different pieces of legislation with differing requirements.[96] The first is the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA).[97] The FFDCA defines "drug" in relevant part as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."[98] Pharmaceutical products within the scope of FFDCA include insulin and a small number of other biologics, and all chemical medications.[99]

The second is the Public Health Service Act of 1944 (PHSA).[100] The PHSA is a recodification of the Biologics Act of 1902, "the first enduring scheme of national regulation for any pharmaceutical product."[101] Because the Biologics Act focused mostly on vaccines, its recodification in the PHSA is restricted to biologics,[102] and the pharmaceutical products in scope of the PHSA include the majority of biologic drugs (i.e., all biologics other than the few in scope of the FFDCA).[103] The version of the PHSA in effect today defines "biological product" as:

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94 AGATA DABROWSKA, CONG. RESEARCH SERV., R44620, BIOLOGICS AND BIOSIMILARS: BACKGROUND AND KEY ISSUES 3 (2019).

95 AGATA DABROWSKA, CONG. RESEARCH SERV., IF11075, FDA AND DRUG PRICES: FACILITATING ACCESS TO GENERIC DRUGS 1 (2019).

96 AGATA DABROWSKA, CONG. RESEARCH SERV., R44620, BIOLOGICS AND BIOSIMILARS: BACKGROUND AND KEY ISSUES 5 (2019).

97 21 U.S.C. ch. 9 (2018).

98 21 U.S.C. § 321(g)(1) (2018).

99 AGATA DABROWSKA, CONG. RESEARCH SERV., R44620, BIOLOGICS AND BIOSIMILARS: BACKGROUND AND KEY ISSUES 3-4 (2019).

100 42 U.S.C. ch. 6A (2018).

101 Dudzinski, *supra* note 39, at 147. The Biologics Act was enacted in response to multiple incidents of vaccine contamination that resulted in numerous deaths. The Act only provided for regulation of manufacturing conditions, labeling, and interstate traffic of drugs, and not the safety or efficacy of the products themselves. *Id.* at 148.

102 Dudzinski, *supra* note 39, at 152.

103 *See* AGATA DABROWSKA, CONG. RESEARCH SERV., R44620, BIOLOGICS AND BIOSIMILARS: BACKGROUND AND KEY ISSUES 3-4 (2019).

> a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.[104]

Until 1941, pursuant to its agreement with Banting and Best, the researchers who discovered insulin,[105] the University of Toronto monitored and tested each batch of insulin for quality prior to sending it to market.[106] In 1941, just days before the University's patent on insulin expired, Congress amended the FFDCA to empower the FDA to regulate insulin out of fear that safety standards would decrease once the University lost the right to examine each batch.[107] Insulin and a handful of other small biologics remained within the purview of the FFDCA, even though the vast majority of modern biologics fall within the scope of the PSHA.[108] The next section will focus on legislative efforts to remedy some of these existing problems by creating a "follow-on" pharmaceutical market.

B. CREATION OF THE FOLLOW-ON PHARMACEUTICAL MARKET

Congress' attempt to increase competition in this area while still preserving intellectual property protections, often referred to as the "follow-on" pharmaceutical market, is the next piece of the insulin pricing puzzle. In most instances, the U.S. differs from most other industrialized nations in that it takes a generally free-market approach to prescription drug pricing.[109] This is to say that pharmaceutical companies are free to charge whatever the market will bear for their products, and the government has no power to intervene.[110] This system stands in contrast to those operative in Canada and the European Union, where single-payer healthcare systems give the government more power to keep prices manageable.[111] The U.S. government is not empowered to negotiate prices with

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104 42 U.S.C. § 262(i)(1) (2018).

105 *Supra* section II(B).

106 Dudzinski, *supra* note 39, at 153.

107 *Id.*

108 AGATA DABROWSKA, CONG. RESEARCH SERV., R44620, BIOLOGICS AND BIOSIMILARS: BACKGROUND AND KEY ISSUES 8-9 (2019).

109 Marie Salter, *Reference Pricing: An Effective Model for the U.S. Pharmaceutical Industry?,* 35 NW. J. INT'L L. & BUS. 413, 415 (2015).

110 Hannah Brennan, et. al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 Yale J. L. & Tech. 275, 284 (2016).

111 Jessica R. Underwood, *What the E.U. has that the U.S. Wants: An Analysis of Potential Regulatory Systems for Follow-On Biologics in the United States*, 10 DEPAUL J. HEALTH CARE L. 419, 423 (2007).

pharmaceutical companies, even for those drugs covered under government healthcare programs such as Medicare.[112]

The trade-off inherent in this unusual paradigm is punishingly high costs for prescriptions coupled with an extraordinary degree of pharmaceutical innovation.[113] Two federal statutes, discussed below, the Hatch-Waxman Act (1984) and the Biosimilars Act (2009), attempt to navigate the narrow path between protecting commercial incentives to innovate and expanding American consumers' access to life-saving medical products, with different degrees of success.

Broadly speaking, the process by which prescription drugs arrive on the market in the United States under these two statutes is as follows. First, a drug innovator spends billions of dollars developing and testing a brand new medication.[114] Second, the innovator obtains approval to market the drug from the Food and Drug Administration (FDA)[115] and files a patent application with the Patent and Trademark Office (PTO) in which it must disclose the molecular structure of the substance and how to manufacture it.[116] Third, the innovator enjoys twenty years[117] of protection from competition under the patent and may charge for the product whatever amount the market will bear.[118] Finally, once the patent expires, different drug manufacturers can begin to produce follow-on versions of the drug[119] and obtain abbreviated approval from the FDA for the follow-on product.[120] The follow-on product often enters the market at a price tremendously lower than that of the reference product.[121] The next sections describe the mechanics of the Hatch-Waxman Act and the Biosimilars Act in more detail.

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112 Hannah Brennan et. al., *supra* note 110, at 285-86.

113 *See generally id.* (discussing the case of sofosbuvir, a medication first marketed in 2013 to cure hepatitis C at a staggering cost of $100,000.)

114 Michael Enzo Furrow, *Pharmaceutical Patent Life-Cycle Management After* KSR v. Teleflex, 63 FOOD & DRUG L. J. 275, 283 (2008).

115 FOOD AND DRUG ADMINISTRATION: ABOUT FDA PRODUCT APPROVAL, https://www.fda.gov/news-events/approvals-fda-regulated-products/about-fda-product-approval (last visited Oct. 5, 2019).

116 KEVIN J. HICKEY ET AL., CONG. RESEARCH SERV., R45666, DRUG PRICING AND INTELLECTUAL PROPERTY LAW: A LEGAL OVERVIEW FOR THE 116TH CONGRESS 8-9 (2019).

117 In certain circumstances, the PTO may grant an additional five years of patent protection to account for delays in FDA approval. *Id.* at 10.

118 Hannah Brennan et. al., supra note 110, at 284.

119 The term "follow-on" encompasses both generic products (exact copies of chemical medications, discussed fully in section IV(B)(1), *infra*) and biosimilar products (approximations of biologic medications, discussed fully in section IV(B)(2), *infra*).

120 KEVIN J. HICKEY ET AL., CONG. RESEARCH SERV., R45666, DRUG PRICING AND INTELLECTUAL PROPERTY LAW: A LEGAL OVERVIEW FOR THE 116TH CONGRESS 20 (2019).

121 Price & Rai, *supra* note 8, at 1027.

1. The Hatch-Waxman Act (1984)

The first piece of federal legislation that provided an abbreviated pathway to approval for follow-on drugs was the Drug Price Competition and Patent Term Restoration Act of 1984.[122] The Act is commonly known as the Hatch-Waxman Act in honor of its co-authors, Senator Orrin Hatch (R-UT) and Representative Henry Waxman (D-CA).[123] The Hatch-Waxman Act made a series of amendments to the FFDCA, meaning that its provisions only apply to chemical medications and the handful of biologics, including insulin, that the FFDCA regulates.[124]

The Hatch-Waxman Act created two different abbreviated pathways to FDA approval for follow-on products.[125] The purpose of these two options is to remove costly barriers to FDA approval for new manufacturers of previously approved products, thereby increasing competition and lowering prices.[126] The first option is the Abbreviated New Drug Application (ANDA).[127] In an ANDA, the maker of the generic drug must show proof that the generic is a bioequivalent of (i.e., has a chemical structure identical to) the name-brand drug, or reference product.[128] FDA approval for the reference product required extensive clinical trial data proving the drug's efficacy, safety, and purity.[129] The pathway to FDA approval under an ANDA is abbreviated in that the maker of the generic need not repeat the clinical trials but instead may rely on the data for the reference product because the two substances are chemically identical.[130] This saves the generic drug maker considerable time and money, thus facilitating the greatly reduced price.[131]

The second option is known as the "505(b)(2)" pathway. Section 505(b)(2) of the Act "applies only to those variations from approved drugs that cannot be brought under an ANDA."[132] A 505(b)(2) applicant does not need to show bioequivalence to the reference product, and may rely on clinical trial data produced

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122 Pub. L. No. 98-417, 98 Stat. 1585 (1984); KEVIN J. HICKEY ET AL., CONG. RESEARCH SERV., R45666, DRUG PRICING AND INTELLECTUAL PROPERTY LAW: A LEGAL OVERVIEW FOR THE 116TH CONGRESS 20 (2019).

123 Erik Neumann, *Sen. Orrin Hatch's influence of US healthcare*, ABC NEWS (Jan. 2, 2019) https://abcnews.go.com/Health/sen-orrin-hatchs-influence-us-healthcare/story?id=60120082.

124 Dudzinski, *supra* note 39, at 170.

125 JOHN R. THOMAS, CONG. RESEARCH SERV., R44643, THE HATCH-WAXMAN ACT: A PRIMER 6 (2016).

126 *Id.*

127 *Id.*

128 Pub. L. No. 98-417 (j)(2)(A)(III)(iv).

129 KEVIN J. HICKEY ET AL., CONG. RESEARCH SERV., R45666, DRUG PRICING AND INTELLECTUAL PROPERTY LAW: A LEGAL OVERVIEW FOR THE 116TH CONGRESS 20 (2019).

130 *Id.* at 20-21.

131 JOHN R. THOMAS, CONG. RESEARCH SERV., R44643, THE HATCH-WAXMAN ACT: A PRIMER 6 (2016).

132 Dudzinski, *supra* note 39, at 198.

by a third party (such as the maker of the reference product).[133] What section 505(b)(2) amounts to is an abbreviated approval method for the very small number of biologics that fall within the scope of the FFDCA.[134]

The FDA has approved a handful of follow-on biologic drugs under section 505(b)(2), perhaps the most contentious of which was its approval of a human growth hormone called Omnitrope, which is used primarily for enhancement of fertility in women, in 2006.[135] Sandoz, the manufacturer of Omnitrope, claimed in its application for approval that Omnitrope was "indistinguishable" from the reference product, Genotropin.[136] The FDA, however, initially refused to review Sandoz's application for abbreviated approval for Omnitrope, citing uncertainty as to whether Omnitrope could be shown to be sufficiently similar to Genotropin as required under section 505(b)(2).[137] The U.S. District Court for the District of Columbia held that FDA had a duty to review Sandoz's application for approval within the statutory 180-day period, thereby affirming that biologics could theoretically qualify for approval under section 505(b)(2).[138] The FDA indicated later that the FFDCA did not create an abbreviated pathway for the biologics outside of its scope, and that Congress would need to act in order for one to exist.[139]

The FDA has approved just one follow-on insulin product under Hatch-Waxman.[140] In 2015, Eli Lilly received FDA approval to market Basaglar, a follow-on insulin that references Lantus, a drug manufactured by Sanofi.[141] For reasons that will be discussed in greater detail in section IV(C), *infra*, Basaglar has had very little impact, if any, on pricing in the insulin market.[142]

Hatch-Waxman has been extraordinarily successful in increasing competition in the market for chemical medications and lowering prices while preserving

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[133] *Id.*

[134] *Id.* This interpretation of 505(b)(2)'s grant of authority has not been free of controversy. The FFDCA does not specifically include or exclude biologics in its broad definition of "drug" (*see supra* note 98), but the FDA quickly realized that the differences between chemical medications and biologics created confusion and uncertainty as to what path to approval these follow-on products should take. *Id.* at 196-97.

[135] AGATA DABROWSKA, CONG. RESEARCH SERV., R44620, BIOLOGICS AND BIOSIMILARS: BACKGROUND AND KEY ISSUES 7 (2019).

[136] *Id.*

[137] *Id.*

[138] Sandoz, Inc. v. Leavitt, 427 F. Supp. 2d 29, 38 (2006) (rejecting the FDA's argument that the 180-day period was aspirational rather than mandatory).

[139] Anna Wilde Mathews & Jeanne Whalen, *FDA Clears Copycat Version of Human Growth Hormone*, WALL ST. J. (June 1, 2006), https://www.wsj.com/articles/SB114904669181067236.

[140] JUDITH A. JOHNSON, CONG. RESEARCH SERV., IF11026, INSULIN PRODUCTS AND THE COST OF DIABETES TREATMENT 2 (2018).

[141] *Id.*

[142] *Id.*

incentives for drug companies to innovate new products.[143] That said, most biologics are outside the scope of Hatch-Waxman because they are regulated under the PHSA, rather than the FFDCA.[144] The following section addresses legislation tailored to address this much larger group of products.

2. The Biosimilars Act (2009)

Congress passed the Biologics Price Competition and Innovation Act of 2009,[145] commonly known as the Biosimilars Act, as part of the Patient Protection and Affordable Care Act of 2010 (also known as "The Affordable Care Act," President Obama's signature legislative achievement, addressing a host of issues, including health insurance, health care delivery, and public health in the U.S.).[146] Many parts of the Affordable Care Act, including the Biosimilars Act, are amendments to the PHSA.[147] Thus, the Biosimilars Act applies to the biologics that are within the scope of the PHSA.[148]

The Biosimilars Act mirrors Hatch-Waxman in that it provides an abbreviated pathway to FDA approval (referred to in the statute as "licensing") for post-patent forms of biologics.[149] Because of their much more complex molecular structure, biologic drug makers need not show that their product is a generic, or identical to the reference product on a molecular level.[150] They must only show that their product is either (1) biosimilar to the reference product, or (2) interchangeable with the reference product.[151] These critical terms are defined in the statute, as discussed below.

A product is biosimilar to the reference product if it meets five criteria.[152] First, it must be shown to be sufficiently similar through analytical studies, animal studies, and clinical trials.[153] Second, it must use the same mechanism(s) of action for the condition(s) of use.[154] Third, it must be intended to be prescribed for the

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143 Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L. J. 417, 417-18 (2011).

144 AGATA DABROWSKA, CONG. RESEARCH SERV., R44620, BIOLOGICS AND BIOSIMILARS: BACKGROUND AND KEY ISSUES 8-9 (2019).

145 42 U.S.C. § 262 (2018).

146 Pub. L. No. 111-148, 124 Stat. 119 (2010).

147 AGATA DABROWSKA, CONG. RESEARCH SERV., R44620, BIOLOGICS AND BIOSIMILARS: BACKGROUND AND KEY ISSUES 8 (2019).

148 See *Id.*

149 JOHN R. THOMAS, CONG. RESEARCH SERV., R44643, THE HATCH-WAXMAN ACT: A PRIMER 12 (2016). The Biosimilars Act also "established regulatory exclusivities that are available to brand-name and follow-on firms…[and] stipulate[d] intricate procedures for identifying and resolving patent disputes with respect to follow-on biologics." *Id.*

150 *See* 42 U.S.C. § 262(i)(2)(2018).

151 *Id.*

152 42 U.S.C. § 262(k)(2)(A)(i) (2018).

153 *Id.*

154 *Id.*

same condition(s) as the reference product.[155] Fourth, the method of administration, dosage, and potency must be the same as those of the reference product.[156] Fifth, the manufacturing facility must meet the relevant standards to assure safety, purity, and potency.[157]

A product is interchangeable with a reference product if meets three criteria.[158] First, it must be biosimilar to the reference product.[159] Second, it must produce the same clinical results as the reference product.[160] Third, the risk of alternating between the reference product and the interchangeable product must not place the patient at additional risk.[161]

Because insulin falls within the regulatory scope of the FFDCA, it was never eligible for the abbreviated approval pathway provided for in the Biosimilars Act, which only applies to products regulated under the PHSA.[162] The limited use of the 505(b)(2) option under the Hatch-Waxman Act has been available, but an important provision of the Biosimilars Act only recently made this distinction moot for purposes of expedited FDA approval.[163] The Biosimilars Act, enacted on March 23, 2010, provides that no later than ten years from the date of enactment, all applications for approvals of biologics submitted under Hatch-Waxman will transition into applications for biosimilar licenses under the Biosimilars Act.[164]

What this means for insulin is that any applications for FDA approval of a follow-on product must meet the biosimilarity or interchangeability standards discussed above. FDA guidance on the transition indicates that any name-brand insulins previously approved have transitioned into licenses under the Biosimilars Act[165] and that sponsors of applications for follow-on insulin (and other biologics currently approved under Hatch-Waxman) must resubmit any applications currently pending under Hatch-Waxman.[166] For the purposes of this

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155 *Id.*

156 *Id.*

157 *Id.*

158 42 U.S.C. § 262(k)(4) (2018).

159 *Id.*

160 *Id.*

161 *Id.*

162 JUDITH A. JOHNSON, CONG. RESEARCH SERV., IF11026, INSULIN PRODUCTS AND THE COST OF DIABETES TREATMENT 1-2 (2018).

163 AGATA DABROWSKA, CONG. RESEARCH SERV., R44620, BIOLOGICS AND BIOSIMILARS: BACKGROUND AND KEY ISSUES 8-9 (2019).

164 *Id.*

165 U.S. FOOD & DRUG ADMIN., INTERPRETATION OF THE "DEEMED TO BE A LICENSE" PROVISION OF THE BIOLOGICS PRICE COMPETITION AND INNOVATION ACT OF 2009: GUIDANCE FOR INDUSTRY (2018).

166 Chad A. Landmon & Christopher M. Gallo, Ph.D., *Fixing the Follow-On Insulin Regulatory Approval "Dead Zone,"* BIOSIMILAR DEVELOPMENT (Sept. 2, 2019), https://www.biosimilardevelopment.com/doc/fixing-the-follow-on-insulin-regulatory-approval-dead-zone-0001.

Note, suffice it to say that the bifurcated pathways to approval are joined as of March 23, 2020.

Given the incentives for makers of follow-on products, the obvious question is why, after nearly a century of progress and an extraordinary degree of demand, there is still only one follow-on insulin. To answer this question, the following section explores the shortcomings of the abbreviated approval mechanisms provided for in the Hatch-Waxman and Biosimilars Acts with regard to biologic drugs.

C. THE PROBLEM WITH ABBREVIATED APPROVAL AND TRADE SECRECY

Hatch-Waxman's abbreviated approval pathway mechanism has been highly successful in lowering prices for chemical medications.[167] However, in spite of the fact that insulin has been eligible for abbreviated approval via the 505(b)(2) option since 1984,[168] only one follow-on insulin product, Basaglar, is currently on the market,[169] and insulin prices continue to rise.[170] As of March 23, 2020, the transition to licenses means that insulin will continue to be eligible for abbreviated approval, now under the Biosimilars Act. The Biosimilars Act attempted to recreate the success of Hatch-Waxman and facilitate more competition in the biologics market.[171] However, this goal has not been realized because abbreviated approval mechanisms do not account for the ways in which biologics are different from chemical medications.[172]

As mentioned, biologics are comprised of much larger and more complex molecules than chemical medications.[173] In fact, it is the case that the exact molecular structure of some biologics has never been precisely described because the analytical technology required to do so does not yet exist.[174] This is one of the most salient differences between biologics and chemical medications from a regulatory perspective. Once a generic drug maker knows the molecular structure of a chemical medication, the substance can be reverse-engineered and synthesized in many different ways, all arriving at the same result.[175] This is not the case with biologics. Without specific information about how the reference product was manufactured, it is very difficult to say with certainty how similar the follow-

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167 Kelly, *supra* note 143, at 417-18.

168 *See* Dudzinski, *supra* note 39, at 191.

169 JUDITH A. JOHNSON, CONG. RESEARCH SERV., IF11026, INSULIN PRODUCTS AND THE COST OF DIABETES TREATMENT 2 (2018).

170 Julia Belluz, *The absurdly high cost of insulin, explained*, VOX (May 24, 2019), https://www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive#.

171 Kelly, *supra* note 143, at 417.

172 Ryan Timmis, *The Biologics Price Competition and Innovation Act: Potential Problems in the Biologic-Drug Regulatory Scheme*, 13 NW. J. TECH. & INTELL. PROP. 215, 226 (2015).

173 Price & Rai, *supra* note 8, at 1026.

174 *Id.* at 1036.

175 *Id.* at 1034.

on product is to the reference product.[176] As discussed in section III(C), makers of biologics like insulin often use patents to protect their products and trade secrecy to protect their manufacturing processes. Since trade secret protection can theoretically last forever, the provision of an abbreviated path to approval is of very little use because makers of follow-on products will not be able to demonstrate that their products are biosimilar to the name brand products.

Now that the transition to licensed products under the Biosimilars Act is effective, any follow-on insulins must meet the requirements of biosimilarity or interchangeability as described above.[177] This is a higher standard than what Hatch-Waxman formerly required of follow-on biologics under 505(b)(2), meaning that the barrier to entry for follow-on insulins that could help lower prices just got higher.[178] Given the sluggishness of the follow-on insulin market until now (only one follow-on product for a drug that has been available for decades), [179] the transition seems likely to stall the market even further. The final part of this Note argues that a reduction of trade secret protection for manufacturing processes is needed to address the urgent public health problem that insulin pricing poses.

V. FINDING A SOLUTION TO THE INSULIN PRICING PROBLEM

The discussion above paints a grim picture. The abbreviated pathway to approval provided for under federal law has not achieved its goal of increasing competition and lowering prices in the insulin market. As progress stalls, many people with diabetes continue to struggle to pay for the medication they need as insulin prices continue to rise.

It should be noted that some steps have been taken in 2019 by both corporations and governments to alleviate the insulin pricing crisis. For example, the three major insulin manufacturers, Eli Lilly, Sanofi, and Novo Nordisk, have each announced that they will lower the list prices of their insulin products.[180] Furthermore, pharmacy benefits manager, Express Scripts, announced a price cap of twenty-five dollars per month for its members.[181] Colorado recently passed legislation capping the price of insulin at $100 per month for insured patients.[182]

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176 *Id.*

177 John White & Jennifer Goldman, *Biosimilar and Follow-On Insulin: The Ins, Outs, and Interchangeability*, 35:1 J. PHARMACY TECH. 25, 28 (2019).

178 *Id.*

179 JUDITH A. JOHNSON, CONG. RESEARCH SERV., IF11026, INSULIN PRODUCTS AND THE COST OF DIABETES TREATMENT 2 (2018).

180 Jacobsen, *supra* note 7.

181 Alison Kodjak, *Express Scripts Takes Steps to Cut Insulin's Price to Patients*, NPR NEWS (Apr. 3, 2019) https://www.npr.org/sections/health-shots/2019/04/03/709212404/express-scripts-takes-steps-to-cut-insulins-price-to-patients 1/.

182 Belluz, *supra* note 170.

These efforts have one thing in common: they illustrate the fact that attention is increasingly being directed at this issue. The increase in attention, however, does not mean that the issue is solved. Unfortunately, all of the measures identified above are too limited in scope to serve as a complete solution to the problem. After all, Novo Nordisk or Express Scripts, for example, may decide tomorrow that the price guarantees they make today are no longer economically viable, which will leave diabetic patients in much the same place they are now. Many diabetics with health insurance in Colorado are seemingly out of immediate danger, but Colorado is home to only a very small percentage of all diabetics in the U.S.[183] This is why legislation at the federal level is necessary to correct this issue for good.

As discussed in section III(C) *infra*, trade secret is one of the three forms of intellectual property protection available to pharmaceutical innovators. In order for an innovation to qualify for this protection, it must: (1) confer economic benefit upon the holder, (2) not be generally known, and (3) be the object of reasonable steps by the holder to maintain its secrecy.[184]

Makers of pharmaceutical products, and biologic drugs in particular, avail themselves of trade secret protection quite liberally.[185] Trade secret is particularly attractive for protecting the manufacturing processes for insulin and other biologics, which has a major impact on competition.[186] Biologics like insulin differ considerably from chemical medications in terms of the difficulty of manufacturing them.[187] Small-molecule chemical medications are relatively simple to describe scientifically,[188] and a generic manufacturer can use any of a number of methods to synthesize the compound, all of which produce a result easily proven to be identical to the reference product.[189]

Insulin and other biologics, by contrast, have much more complex chemical structures.[190] Small differences in the method of synthesis can lead to broad variation in the final result.[191] This means that showing biosimilarity is very difficult unless the manufacturer uses the same method that the maker of the reference product used.[192] Furthermore, the precise molecular identity of some biologic drugs is not known because the analytical techniques needed to make that determination do not yet exist.[193]

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183 CENTERS FOR DISEASE CONTROL AND PREVENTION: NATIONAL DIABETES STATISTICS REPORT, *supra* note 22.

184 Risch, *supra* note 84, at 6-7.

185 Price & Rai, *supra* note 8, at 1028.

186 *Id.*

187 Timmis, *supra* note 172 at 226.

188 Price & Rai, *supra* note 8, at 1033-34.

189 *Id.* at 1034.

190 *Id.*

191 *Id.* at 1035.

192 *Id.* at 1036.

193 *Id.* at 1028.

Crucially, to qualify for abbreviated approval under the Biosimilars Act, the maker of the biosimilar must make a product that not only is biosimilar, but can be shown to be biosimilar.[194] Because trade secret protection can theoretically last indefinitely,[195] makers of would-be biosimilar insulins may never have access to manufacturing process information, all but foreclosing the possibility of producing a follow-on insulin that the maker is able to prove is biosimilar to the reference.[196] A claim that X is the same as Y is impossible to prove or disprove when Y's identity is not known.

A scaling back of trade secret protection for pharmaceuticals would ameliorate this problem. The Biosimilars Act does not require the maker of a reference product to disclose manufacturing information to any greater extent than is required under Hatch-Waxman, which means that it is unlikely to be successful in increasing competition in the insulin market now that insulin is within its scope.[197] Insulin will likely continue to be more trouble than it is worth to biosimilar manufacturers.

The Defend Trade Secrets Act of 2016 provides an extremely broad scope of the type of information that may be eligible for trade secret protection:

> [A]ll forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing.[198]

The breadth of the protection available under the DTSA means that makers of follow-on insulins will have an extremely difficult time showing that their products are biosimilar.

Statutorily eliminating biologics manufacturing process information from trade secret eligibility (as an amendment to the Biosimilars Act, for example) would force pharmaceutical companies to choose among three alternatives. They could: (a) include process information in their patent application, (b) apply for separate patent protection for the process and the product, or (c) leave the process information with no protection at all. Acknowledging choice (c) to be in all likelihood the least popular of these, the net effect would be that the process by which biologics like insulin are manufactured would become part of the public

194 42 U.S.C. § 262(k)(2)(A)(i)(2018).

195 *See* 18 U.S.C. § 1839(3)(2018).

196 *See* Price & Rai, *supra* note 8, at 1036.

197 Timmis, *supra* note 172 at 226.

198 18 U.S.C. § 1839(3) (2018).

domain once the patent expires, rather than remaining secret indefinitely as it does today.

This change would naturally have downstream effects, both positive and negative. The first advantage would be that insulin and other biologics would become more attractive to makers of follow-on products. Armed with the knowledge needed to create a biosimilar without going through the costly process of additional research and development, follow-on firms could produce biosimilar insulins more cheaply.

The second advantage would be that the growing fund of public knowledge about insulin and other biologics would facilitate greater innovation in the field over time.[199] By keeping critical information about their discoveries secret, pharmaceutical companies prevent other companies, universities, and private research firms from benefitting from it.[200] Trade secret law is often criticized for its tendency to cause redundancy and duplication of effort,[201] and repetition of clinical trials to prove that a follow-on is biosimilar or interchangeable can cost hundreds of millions of dollars.[202] A free flow of information about process in a field where process has a tremendous influence on the identity and quality of the final product[203] would have substantial value to society.[204]

To that end, the third advantage to reducing trade secret protections would be a rebalancing of the public and private interests at stake in the market for insulin. The free-market approach to drugs and other medical products that operates in the U.S. presumes that the same forces at work in the markets for Coca-Cola and iPhones are at work in similar ways in the markets for insulin and other healthcare products.[205] As discussed previously, the free-market approach has undoubted advantages,[206] but the ethical implications of letting the market decide who can afford insulin and who cannot should not be ignored. A reduction of protection for an already immensely profitable industry[207] would ease the burden on people who rely on insulin for survival.

On the other hand, this approach does have drawbacks. For example, as with any limitation on intellectual property protection, there is the concern that this would decrease incentives to innovate.[208] Insulin makers may decide to slow or halt development of costly new products if they fear that they will not be able to

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199 *See* Zink, *supra* note 86, at 1142.

200 Price & Rai, *supra* note 8, at 1049.

201 *Id.*

202 *Id.*

203 *Id.* at 1033-34.

204 *Id.* at 1048-49.

205 *See* Salter, *supra* note 109, at 432.

206 *Id.* at 433.

207 Deangelis, *supra* note 93, at 30.

208 *See* Kevin J. Hickey, CONG. RESEARCH SERV., IF10986, INTELLECTUAL PROPERTY LAW: A BRIEF INTRODUCTION 1 (2018).

recoup their losses.[209] However, this particular issue seems to be of less concern here than in other situations in which cutting edge biologics are not yet on the market. Insulin's age and long history in the market will likely shield it from this negative effect because several safe and effective varieties already exist. Thus, while reducing trade secret protections for biologics may have the effect of making some drug manufacturers more reluctant to develop entirely new biologic drugs, it will likely have the opposite effect of improving competition for drugs that are already on the market. Furthermore, a compromise might be made to restrict the scaling-back of trade secret protection to insulin alone, rather than to all biologics. Using insulin as a sort of pilot for a broader scheme of reducing trade secret protections in the pharmaceutical industry would provide lawmakers and the public with some context for the effectiveness of such a scheme.

A second potential drawback to this proposal is the possibility of a chilling effect on insulin production in general. Once information about manufacturing insulin enters the public domain, regulatory agencies like FDA will have the ability to set manufacturing standards accordingly.[210] The more that is known about a substance, the easier it is to regulate.[211] An increase in the minimum standard may raise production costs, thus deterring current producers from continuing to make insulin, and discouraging new firms from entering the insulin market in the first place.

Trade secrecy has kept the barriers to entry high for competitors in the insulin market.[212] There is no question that, in general, insulin and other biologics are more difficult and more expensive to produce than chemical medications.[213] Thus, the U.S. is unlikely to see drastic price reductions for these products such as those that resulted from the enactment of Hatch-Waxman.[214] However, the current situation is clearly untenable for patients, and a scaling back of trade secrecy in the insulin market would likely help facilitate price reduction.

VI. CONCLUSION

For the reasons outlined above, a relaxation of trade secret protection for insulin is the intellectual property policy that is most likely to improve the current state of the insulin market from the patient's perspective. With a decrease in trade secret protection, pharmaceutical companies will be forced to patent their manufacturing processes, thus ameliorating the problem of under-disclosure.[215] The patent system's balancing of individual and public interest will lower the barriers

209 See *Id.*

210 *See* Price & Rai*, supra* note 8, at 1039.

211 *Id.*

212 *See generally id.* (explaining how trade secrecy of biologics creates high entry barriers).

213 Timmis, *supra* note 172, at 226.

214 *See id.* at 227 ("[H]igh prices will remain the norm for biologics generally.").

215 *See* Price & Rai*, supra* note 8, at 1042.

to entry for follow-on firms once patents expire,[216] and the expansion of the public fund of knowledge will facilitate further innovation in the future.[217]

[216] *See id.* at 1048-49.

[217] *See* KEVIN J. HICKEY ET AL., CONG. RESEARCH SERV., R45666, DRUG PRICING AND INTELLECTUAL PROPERTY LAW: A LEGAL OVERVIEW FOR THE 116TH CONGRESS 8 (2019).