Our Broken System: Modifying the U.S. Pharmaceutical Regulatory Scheme to Decrease Surging Prescription Drug Prices

INTRODUCTION

The average person will no longer be able to afford his or her medication if the trend of surging prescription drug prices continues. Prices began to spike in 2014, and this trend continues with no signs of stopping.[1] The recent surge is the result of a number of problems. First and foremost, our system encourages expensive patented drugs.[2] Pharmaceutical companies have also begun to focus on strategies that increase generic drug prices, such as growth pharma, which attempts to decrease competition for certain generic drugs.[3] Increased generic prices are a problem because our system balances the high cost of patented drugs with cheap generics.[4] Furthermore, the Food and Drug Administration's (FDA) extremely slow approval process[5] impedes the availability of new generics, which exacerbates the problems caused by growth pharma.[6] As a result, the prices of many generics have increased dramatically: at least 315 generics have doubled in price since 2010, many of which suffer from low competition.[7] The fractured American model of private insurance companies and pharmacy benefit managers interacting with pharmaceutical companies also makes it more difficult for consumers to negotiate for lower prescription drugs prices.[8] All the while, prescription drug prices continue to increase.

Because the problem arises from several sources, several solutions are needed. These include employing bulk-buying power, increasing effective patent terms, implementing reference pricing for drugs on patent, and improving FDA-approval rates for low competition generics. However, if our system of prescription drug delivery does not change, the pharmaceutical industry will fail its customers by putting the medications they need out of reach.

Part I of this Note will delve into the evidence that shows prescription drug prices are rising, the effects of rising prices on consumers, and the reasons behind rising prescription drug prices. Part II of this Note will describe the various regulatory solutions that could be employed to stop surging prescription drug prices. Part III of this Note will conclude that several changes to the U.S. pharmaceutical regulatory scheme are necessary.

PART I

A. Rising Prescription Drug Prices and their Effects on Consumers

Prescription drug prices in the United States have dramatically increased in recent years. From 2007 to 2013, U.S. prescription drug expenditures increased on average about 2.7% a year.[9] In 2014, however, prescription drug prices spiked: U.S. prescription drug expenditures increased by about 12.7%.[10] Prescription drug prices fared no better in 2015. By some estimates, prices increased from 9.8% to 10.4%,[11] and U.S. prescription drug expenditures increased by 14%.[12] In fact, prescription drugs had "the second-highest increase among the 20 largest products and services tracked by the Bureau of Labor Statistics' Producer Price Index" in 2015.[13] Moreover, wholesale-price increases for the top 30 selling prescription drugs from 2010-2014 increased on average by 76% over the five-year stretch, which was "more than eight times general inflation" for the same period of time.[14] Examples include the EpiPen, which has steadily increased in price from $100/pack in 2009 to $608/pack in 2016[15] and Daraprim, which increased in price from $13.50/pill to $750/pill in 2015.[16] Other examples include Tetracycline, an antibiotic, which increased in price from $0.06/250 mg pill in 2013 to $4.60/250 mg pill in 2015,[17] and cancer drugs: "the cost for each additional year lived by a patient [using cancer drugs] has skyrocketed from $54,000 in 1995 to $207,000 in 2013."[18]

It is not at all surprising that increases in prescription drug prices have occurred simultaneously with increases in private health insurance and Medicare expenditures. To save costs, many employer-based plans have increased their deductibles.[19] In fact, employer-based plans now have deductibles that are 50% bigger than they were five years ago,[20] and 80% of employees now pay deductible of at least $1500.[21] Moreover, premiums for employer-based plans have increased by 20% since 2011,[22] and for plans sold on the Affordable Care Act's exchanges, the average premiums will increase by 25% in 2017.[23]

Medicare Part D increased its deductible from $320 in 2015 to $400 in 2017.[24] Premiums have also begun to increase for certain Medicare Part D plans. The average monthly premiums for stand-alone PDP plans increased by 6% in 2016.[25] But, premiums for three of the most popular PDPs increased by at least 20% in 2016.[26] It is also becoming more common for Medicare Part D plans to use coinsurance instead of copayments.[27] The consequence of such a trend could be larger out-of-pocket costs for beneficiaries.[28]

B. The Reasons Behind Surging Prescription Drug Prices

1. The Cost of Patented Drugs

Drugs under patents are significantly more expensive than their generic counterparts.[29] The cost of research and development (R&D) is a major contributor to the difference in price.[30] The R&D process is a long and laborious process, and it has a very low rate of success: "the likelihood that a drug entering clinical testing will eventually be approved is estimated to be less than 12%."[31] The cost of bringing a prescription drug to market, therefore, must include the development costs of all failed drugs.[32] Ultimately, the average total cost to bring one prescription drug to market reaches a baffling $2.6 billion, and the process takes between 10 to 15 years.[33]

To protect this large investment, drug companies file for patent protection concurrently with the research process.[34] Patents offer 20 years of intellectual property protection from the date the inventor and the inventor's assignees file with the United States Patent and Trademark Office (USPTO).[35] Patent protection is incredibly important because, once a drug goes off patent, it can lose up to 80-90% of its value to generic competition.[36] Thus, every year a drug has on patent is incredibly valuable to its developers. However, effective terms for most patents are significantly less than 20 years.[37] In fact, the average effective term for pharmaceutical patents is 11-12 years and can range as lows as 7 years.[38] More importantly, drug patents' effective terms are suffering from a debilitating downward trend; therefore, pharmaceutical companies have less time to recoup costs.[39]

Another issue, for pharmaceutical R&D, is that it has becoming increasingly inefficient in recent years. The cost to develop new drugs, new chemical entities (NCE)[40], and new biological entities (NBE)[41] has steadily increased since the 1970s.[42] In 1979, the cost to develop a NCE or a NBE was $199 million.[43] In 2012, that number had increased to $1.5 billion.[44] Similarly, the price to develop a new drug increased from $179 million in the 1970s, to $2.6 billion in the 2000s and early 2010s.[45] Furthermore, the number of drugs approved per billion dollars of R&D expenditures declines every nine years by 50%.[46]

Patent "evergreening" also keeps the prices of pharmaceuticals high. Evergreening is a strategy where pharmaceutical companies create slightly different variations of older drugs and file for patent protection.[47] Evidence of this phenomenon can be found by comparing the value of pharmaceutical industry patents to those filed by not-for-profit institutions, such as universities.[48] One study found that patents filed by not-for-profit institutions were on average cited more often than pharmaceutical industry patents, which suggests that not-for-profit pharmaceutical patents

are more valuable than pharmaceutical industry patents.[49] The comparatively low value of pharmaceutical industry patents indicates that evergreening is a widespread practice.[50]

2. BigPharma M&A, Inefficient FDA Regulations, and the Rising Costs of Generics

Generic drugs account for 88% of prescriptions filled, but they only constitute 28% of pharmaceutical spending.[51] Since generic drugs are so inexpensive, they have saved Americans over $1.68 trillion over the past decade.[52] Their low cost was the result of a large amount of competition amongst many different generic manufacturers.[53] However, 22% of the top selling generics have increased in price faster than inflation and some have even increased in price by over 5,000%.[54] This is a cause for concern because the dramatic rise in generic prices coincided with the dramatic overall increase in the price of prescription medication since 2014.[55]

The rise in generic drug prices has much to do with a new strategy amongst generic drug companies called "growth pharma." Growth pharma is a strategy that focuses on merging with or acquiring other drugs companies or parts of other drug companies to gain control over a certain generic market.[56] The success of this strategy has increased its popularity: the first half of 2015 saw $221 billion in deals, which is triple the amount of money spent on M&A in the first half of 2014.[57] The most famous example of growth pharma was the Teva-Allergen merger, which was a $40.5 billion deal that created the world's largest generic drug manufacturer.[58] Moreover, growth pharma is in many ways the response to the increasing difficulty pharmaceutical companies face when trying to develop new drugs:

> "[p]harma companies believe acquisitions are the only way to keep their revenues growing as fast as investors expect—and with today's complex breakthrough medicines, it's often cheaper for a company to acquire the next blockbuster drug than to develop it in-house."[59]

The result of growth pharma has been to reduce competition in the generic drug market.[60] For example, a healthy generic market may normally have 4 or 5 different competing drugs; however, after a series of mergers or acquisitions, there may only be 1 or 2 competing drugs.[61]

The FDA further exacerbates the decrease in generic drug competition because there is a massive backlog for FDA approval of generics, which acts like a bottleneck on generic drug competition.[62] The "median time it takes for the FDA to approve a generic is now 47 months or nearly four years despite the addition of about 1,000 new FDA employees and new user fee funds."[63] Moreover, in 2014, the FDA was unable to approve thousands of generic applications from 2013, which did not allow the FDA to review any of the 1,500 applications filed in 2014.[64] Currently, there are 4,036 generic applications that have yet to pass FDA approval.[65]

3. Cost of Marketing and Sales

Drug marketing is an enormous expense. In 2012 alone, the pharmaceutical industry spent $27 billion on drug promotion.[66] The largest portion, $15 billion, is spent on face-to-face sales and promotional activities for doctors and pharmacy directors.[67] However, the fastest growing portion has been direct-to-consumer advertising (DCA).[68] In 1997, the FDA eased restrictions on how pharmaceutical companies advertised to the public.[69] Since 1997, the amount spent on DCA has quadrupled to $3.1 billion.[70] Not only is DCA an added cost, but it also effectively increases the demand for drugs.[71]

Furthermore, pharmaceutical companies often spend more money on marketing and sales than on R&D: in 2013, ten major pharmaceutical companies spent more money on marketing and sales than on R&D.[72] This includes Johnson & Johnson, who spent $17.7 billion on marketing and sales but only $8.2 billion on R&D.[73] Another example is Pfizer, who spent $14.6 billion on marketing and sales while only spending $6.6 billion on R&D.[74]

PART II

Regulatory Solutions to Surging Prescription Drug Prices

1. Bulk-Buying Power

The U.S suffers from a fractured system of buying prescription medications. This system consists of private insurance companies, pharmacy benefit managers (PBM), and pharmaceutical companies.[75] Insurance companies and PBMs negotiate with pharmaceutical companies to set prescription drug prices.[76] After the price is set, PBMs create formularies[77] for the insurance companies;[78] then, insurance companies decide what particular beneficiaries will pay in premiums, copayments, co-insurance, and deductibles.[79] This system, using the power of the free market, is supposed to drive down the price of prescription drugs because of competition between insurance companies, PBMs, and pharmaceutical companies. In reality, Americans pay significantly more than their European counterparts in part because many European systems allow for bulk-buying power.[80]

France, the U.K., and Germany use a public insurance model that covers the vast majority of prescription drug users in their respective countries.[81] For example, Germany's Statutory Health Insurance (SHI) provides 90% of German citizens with health insurance.[82] Comparatively, the largest PBM in 2014, Express Scripts, only had 29% of the U.S. prescription drug market share.[83] Moreover, CVS health and Optum Rx only had 24% and 22% respectively.[84] Because European public health insurance systems cover such a high percentage of prescription drug consumers, they have the ability to use bulk-buying power.[85] Bulk-buying power works by decreasing the number of buyers for prescription drugs.[86] Therefore, pharmaceutical companies become more sensitive to the price their consumers are willing to

pay.[87] In other words, the consumer has significantly more power in France, the U.K., and Germany than in the United States.

It may be very difficult to implement the power of bulk-buying in the United States. To create a system that could use European-style bulk-buying would require the U.S. to switch to a public health system much like many European countries. A more practical solution would be to allow Medicare to negotiate with pharmaceutical companies directly.[88]

2. Longer Patent Terms

The 20 years that American utility patents promise[89] means little when the average effective life for pharmaceutical patents is around 11-12 years[90] — especially because effective terms for pharmaceutical patents are continuing to decrease.[91] However, increasing the amount of time that a drug has on patent may relieve the pressures of short effective terms by allowing pharmaceutical companies, who spend enormous sums on R&D, to spread their R&D costs over more years and consequently decrease their drug prices.[92]

Longer effective terms could also improve innovation because, as effective patent lives increase, so does the amount of time in which profits can be made. A successful drug can make $3 billion a quarter.[93] That means even a month-long extension on a patent could add hundreds of millions or even billions of dollars to your revenue stream.[94] Adding years to patent terms, therefore, can create a powerful incentive to innovate.

Effective patent terms can be increased simply by allowing patent terms to run from FDA approval instead of filing with the USPTO.[95] To alleviate fears of patents lasting for too long, the USPTO could implement a system where they can evaluate the value of each drug to be patented. Drugs that meet the threshold of patentability but are not remarkable enough to gain the maximum level of protection could receive 15 years of protection from FDA approval.[96] The

most valuable and innovative drugs would receive 20 years from FDA approval.[97] This would require the USPTO to make value judgments, which it is already apt to make. The USPTO must resolve whether a new drug is novel and non-obvious, which is essentially a measure of the drug's worth.[98] Simply adding another step, where the USPTO takes the standards it already uses to decide patentability and uses them to decide the patent term, should be an easy decision for the USPTO to make.

3. Using Referencing Pricing and Additional Clinical Benefit to Set Prices for Patented Drugs

The U.S. government should use its considerable negotiating position with pharmaceutical companies in another way: regulating the price of prescription drugs on patent. Many other countries around the world, including France, Germany, and the U.K., regulate the price of prescription drugs directly, which is another reason why their prices are significantly below the prices in the United States.[99] To set the prescription drug prices, these countries use different metrics to decide a prescription drug's value. The two most effective and easily applied methods to the American system are additional clinical benefit and reference pricing.[100]

First, additional clinical benefit should be considered. In Germany, pharmaceutical companies must send data pertaining to new drugs trying to enter the German market to the Federal Joint Committee (FJC).[101] The FJC sets the reimbursement rate of new drugs to the German market by rating the level of "additional clinical benefit" the new drug will provide.[102] For drugs that have a high additional clinical benefit, their reimbursement rate is not subject to reference pricing.[103] However, if the drug has little additional clinical benefit, the reimbursement rate is set by reference pricing.[104] Measuring additional clinical benefit would attack the practice of evergreening patents directly by penalizing incremental patents. Moreover, the PTO is already

in a position to decide additional therapeutic benefit because it must already decide the value of patent by inspecting a proposed patent's novelty and non-obviousness.[105]

Second, a scheme of reference pricing must follow the valuation of additional clinical benefit. Reference pricing involves creating a reference group made up of similar drugs and then comparing the prices of drugs within that group to the new drug.[106] Reference groups are set up by comparing active ingredients, pharmacological class, and therapeutic class.[107] After the reference group is created, a reference price must be set.[108] The reference group looks to prices of similar drugs within the country as well as from different countries.[109] The number of countries used for price comparison can be anywhere from four to more than twenty.[110] Then, reference prices can be set either by "the average of all medicines within a group" or by "the lowest price in [the] group."[111] Averaging would not give the lowest price, but it would negatively affect pharmaceutical innovation the least, which is why it is the better method of price setting.[112]

An interesting feature of the U.K. Pharmaceutical Price Regulation Scheme (PPRS) is that the profit limits they set are flexible.[113] The limit can be increased if new evidence that shows a drug is more valuable than initially thought.[114] The PPRS also reserves the right to decrease the upper limit.[115] This could be applied to reference pricing, either by allowing the price of the drug to increase above the reference price or decrease below the reference price, which would allow flexibility in the system. It could also be a method of removing reference pricing altogether for a drug that has shown extensive additional clinical value.

Another interesting feature of the PPRS is that it does not apply to generic drugs, only brand name drugs.[116] The most effective method to reduce the recent increase in generic prices is to increase competition. Reference prices may interfere with generics and the prices they are set

at.[117] Moreover, setting reference prices for patented drugs is a quid pro quo. The government gives the pharmaceutical company a legal monopoly, but the pharmaceutical company promises to keep the prices of their drugs below a certain level.

4. Improving FDA Efficiency

The FDA's sluggish approval rate for new drugs has exacerbated the prescription drug problem. The approval rate has allowed many generics to become the victims of growth pharma by acting as a bottleneck for generic competition.[118] In response, the FDA will begin meeting on October 21, 2016 to "discuss plans for the second iteration of the *Generic Drug User Fee Act (GDUFA II)* under which the FDA says it will begin offering eight-month and ten-month reviews of abbreviated new drug applications (ANDAs) between 2018 and 2022."[119]

A faster and more efficient approach would be to give shorter review times for possible competitors of generics that suffer from low competition.[120] The FDA is already allowed to "move up in the queue applications for generic drugs that 'could help mitigate or resolve a drug shortage and prevent future shortages."[121] The FDA should equate preventing price hikes caused by monopolistic conditions to its goal of preventing future shortages.[122] If the FDA is not be able to evaluate if a drug is experiencing low competition, then another agency, like Office of the Assistant Secretary for Planning and Evaluation, could aid the FDA in its evaluation.[123] The goal of such a policy should be to approve a number of generics that will compete with generics that have spiked in price because of low competition.[124]

CONCLUSION

The recent increase in prescription drug prices is an incredibly complex issue. The causes of the recent spike are related to increasing R&D costs, decreasing generic competition, decreasing effective patent terms, long FDA approval times, growth pharma, PBMs and private

insurance, as well as many other causes. In short, a single policy, regulation, or law will not be able to unravel our current predicament. A myriad of laws and regulations will be necessary to reduce the current dramatic increases in prescription drug price, including but not limited to: allowing Medicare to negotiate directly, increasing patent terms, using reference pricing for patented drugs, and improving the FDA's approval process for generics. Simply put, our prescription drug development and delivery system needs to change.

The societal purpose of the pharmaceutical industry is to provide life-altering medicines to the general public. However, it is beginning to fail its customers by putting the medications they need out of reach. Our regulatory scheme must now be modified to combat the recent price spikes and incentivize the pharmaceutical industry to spend more money and effort on innovative R&D. If these modifications to the U.S. regulatory scheme occur, the pharmaceutical industry will continue to innovate while also making life-altering medication accessible to the common man.

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example, "[a] biological product is defined under section 351(i) of the [Public Health Service Act] as a 'virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product ... applicable to the prevention, treatment or cure of a disease or condition of human beings.").

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[57] Wieczner, *supra* note 3.

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[63] Brennan, *supra* note 5.

[64] Greene, *supra* note 6.

[65] Sydney Lupkin, *FDA Fees On Industry Haven't Fixed Delays In Generic Drug Approvals*, NPR (Sept. 1 2016) http://www.npr.org/sections/health-shots/2016/09/01/492235796/fda-fees-on-industry-havent-fixed-delays-in-generic-drug-approvals.

[66] *Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients*, THE PEW CHARITABLE TR. (Nov. 11, 2013), http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients.

[67] *Id.*

[68] *Id.*

[69] *Id*.

[70] *Id*.

[71] *Id*. ("[DCA has] encouraged one-third of respondents to speak to their doctors about the promoted drug and one-fifth to request the prescription.[15] In one study, doctors were more likely to prescribe a branded antidepressant when asked for it by name than when patients didn't specify which treatment they wanted.[16]").

[72] Ana Swanson, *Big Pharmaceutical Companies are spending far more on marketing than research*, THE WASH. POST (Feb. 11, 2015),

https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/.

[73] *Id.*

[74] *Id.*

[75] Joanna Shepard, *The Fox Guarding the Henhouse: The Regulation of Pharmacy Benefit Managers by a Market Adversary*, 9 N.W. J. L. & Soc. Pol'y 1, 2 (2013).

[76] *Id*.

[77] *Id*. at 5 ("list of preferred drugs for different medical conditions…for which the [health insurance] plan will provide coverage.")

[78] *Id*.

[79] *See id*.

[80] Kounang, *supra* note 8; Paris, *supra* note 8.

[81] Marie Salter, Comment, *Reference Pricing: An Effective Model for the U.S. Pharmaceutical Industry?*, 35 N.W. J. INT'L L. & BUS. 413**,** 424-426 (2015); Jerry Stanton, Comment, *Lesson*

for the United States from Foreign Price Controls on Pharmaceuticals, 14 CONN. J. INT'L L. 149, 162-163 (2000).

[82] Salter, *supra* note 81, at 424-25.

[83] *Market share of the top 5 pharmacy benefit managers in the U.S. prescription market in 2014*, STATISTA, https://www.statista.com/statistics/239976/us-prescription-market-share-of-top-pharmacy-benefit-managers/ (last visited Nov. 6, 2016).

[84] *Id*.

[85] *See* Kounang, *supra* note 8.

[86] *Id*.

[87] *Id*.

[88] Tami Luhby, *Here's one fix for high drug prices*, CNN (Sept. 28, 2015), http://money.cnn.com/2015/09/28/news/economy/medicare-drug-prices/index.html ("Medicaid and the Veterans Health Administration…can bargain directly. Medicare pays 83% of a brand-name drug's official price, on average….Medicaid pays 48% and the Veteran Health Administration [pays] 46%.").

[89] 35 U.S.C. § 154(a).

[90] Sarayloo, *supra* note 37, at 59.

[91] Bloom, *supra* note 36.

[92] *Id.*

[93] Richard Anderson, *Pharmaceutical industry gets high on fat profits*, BBC (Nov. 6, 2014), http://www.bbc.com/news/business-28212223.

[94] *Id*.

[95] Herper, *supra* note 36.

[96] *See id*.

[97] *See id*.

[98] *See* 35 U.S.C. § 102(a) (2012); *see* 35 U.S.C. § 103 (2012).

[99] Salter, *supra* note 81, at 424-426; *Understanding the 2014 Pharmaceutical Price Regulation Scheme*, ABPI 1, 1 (2014), http://www.abpi.org.uk/our-work/policy-parliamentary/Documents/understanding_pprs2014.pdf [hereinafter PPRS].

[100] Salter, *supra* note 81, at 415; Sebastian Sieler et al., *AMNOG Revisited*, MCKINSEY & COMPANY (May 2015), http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/amnog-revisited.

[101] Salter, *supra* note 81, at 424-426; Sieler, *supra* note 100.

[102] Olga Khazan, *Why Medicine is Cheaper in Germany*, THE ATLANTIC (May 22, 2014), http://www.theatlantic.com/health/archive/2014/05/why-medicine-is-cheaper-in-germany/371418/; Sieler, *supra* note 100.

[103] Salter, *supra* note 81, at 424-426; Sieler, *supra* note 100.

[104] Salter, *supra* note 81, at 424-426; Sieler, *supra* note 100.

[105] *See* 35 U.S.C. § 102(a); *see* 35 U.S.C. § 103.

[106] Salter, *supra* note 81, at 417.

[107] *Id*.

[108] *Id*. at 419-20.

[109] *Id*.

[110] *Pharmaceutical Pricing: The use of external reference pricing*, RAND 1, 28 (2013), file:///Users/dangutt/Downloads/RAND_RR240.pdf.

[111] Salter, *supra* note 81, at 419.

[112] *Id*.

[113] PPRS, *supra* note 99, at 6.

[114] *Id*.

[115] *Id*.

[116] *Id*. at 1.

[117] Salter, *supra* note 81, at 420.

[118] Wieczner, *supra* note 3; *see* McCluskey, *supra* note 3.

[119] Brennan, *supra* note 5.

[120] Greene, *supra* note 6.

[121] *Id*.

[122] *Id*.

[123] *Id*.

[124] *Id*.