I. INTRODUCTION

The United States and the United Kingdom differ greatly in the amount of government control involved in pharmaceutical pricing. Historically, the U.S. has favored a system where pharmaceutical prices are largely unregulated. This has caused the U.S. to be the world’s primary profit center for new medical innovations. Conversely, the U.K. has employed a system where drug prices have been set by government agencies to decrease the price of drugs in order for the National Health Service plan to support the greatest number of patients. As a result, there is a gap between new medical innovations being offered and what the government system will reimburse, leaving U.K. residents without the latest medical technology.

Prior to the passage of the Patient Protection and Affordable Care Act (PPACA), there was concern that healthcare reform would have a negative effect on medical innovation in the U.S. as the threat of price controls similar to those of the U.K. loomed. This
article will address how government cost controls impact pharmaceutical innovation, and how cost controls affect patient access to new medicines. First, this article will outline the current market-driven system in the U.S. Secondly, it will describe the government-run pricing system in the U.K. Finally, this article will analyze whether the recent reforms in health care will have a negative affect on pharmaceutical innovation.

II. U.S. PHARMACEUTICAL INNOVATION

To begin, the U.S. has historically maintained a relatively free market system in the pharmaceutical industry. However, regulations to ensure safety and effectiveness exist. Beginning in 1962, pharmaceutical manufacturers have been required to obtain regulatory approval by the Food and Drug Administration (FDA) before beginning clinical testing. Clinical testing usually continues through three successive phases. The cost of getting a drug through this regulatory process is enormous. A study by Joseph DiMasi, an economist at the Tufts Center for the Study of Drug Development, found that the total research and development cost per new drug is $802 million in year 2000 valuation. Moreover, it can take around twelve years for a company to obtain market approval on a new drug. Typical patent protection for a pharmaceutical drug is twenty years, with ten to fifteen of those years committed to the testing and approval process. The high cost of research and development, coupled with the length of time for FDA approval, leaves limited time for patent protection at the time of marketing. Several provisions have been employed by the FDA to extend the time during which companies can market their drugs free of generic competition, which will allow pharmaceutical companies to recoup their investment in drug research.

Such a provision was formed in 1984 through the Drug Competition and Patent Term...
Restoration Act, otherwise known as the Hatch-Waxman Act. This Act provides up to five years market exclusivity to companies introducing a new chemical entity to the market and up to three years market exclusivity for conducting clinical trials to support changes to products already on the market. These exclusivity provisions allow the innovating companies to generate profits on their drugs before generic competitors can undercut their prices.

The huge investment of time and money required to develop a drug and obtain approval by the FDA raised concerns that pharmaceutical companies would forego developing drugs to treat rare or unusual conditions because they would not see a return on their investment due to a limited market. In response, Congress passed the Orphan Drug Act in 1983. This Act provides manufacturers with seven years of market exclusivity after the FDA’s approval of the drug, as well as grants and tax credits for each new orphan drug developed. This provides an incentive for pharmaceutical companies to research and develop innovative and effective drugs for the orphan drug market.

Next, after a drug is approved, it enters the market to be sold. The U.S. healthcare system consists of both private and public payers that utilize various reimbursement policies. In contrast with many other countries, the U.S. does not utilize a form of drug price regulation to control spending due to concern that regulatory controls drive down profits and discourage flow of capital to support the development of new drugs. The U.S. is regarded as the global leader of pharmaceutical innovation, and government officials have stated that the U.S. is covering most of the global cost for developing new drugs.

The lack of price regulation in the U.S. has been criticized for causing excessively

---

14. Id. at 35.
15. Id.
16. Id. at 37.
18. Id. Orphan drugs are defined as those intended to treat diseases and conditions that affect 200,000 or fewer Americans, or for which the sales in the United States are not reasonably expected to cover the drug manufacturer’s cost of research and development for the drug.
high prices for medicines compared to other countries. Researcher have repeatedly found that people in the U.S. pay more for pharmaceuticals than people in Western European countries. One study compared the average prices of the thirty drugs with the greatest total U.S. spending in 2003 to the prices of the same drugs in the U.K. and France. The authors concluded that the U.S. paid more for these drugs than the U.K., and the U.K. paid more than France. Manufacturer sales prices for most new drugs in countries within the Organization for Economic Co-operation and Development (OECD) have sales prices for most new drugs that are forty to fifty percent below U.S. prices. Patient advocates and researchers have expressed concern that this cost burden has been increasing costs of health care, thereby reducing access to medications for uninsured populations, and threatening general public health.

Proponents of the relatively free-market system in the U.S. emphasize the advantages of using the latest and most innovative medical solutions. One study found that the availability of new drugs was responsible for forty percent of the increase in life expectancy over a fourteen year time period from 1986-2000. Another study from Columbia University and the National Bureau of Economic Research found that life expectancy increased in states where access to newer drugs in Medicare and Medicaid programs were highest in demand.

A study by the Pardee RAND Graduate School examined the effects that new drugs have on the medical system. There are two main effects: the substituting effect and the access effect. The substituting effect is when treated patients might switch from an old

---

22. Id.
23. See Vernon, supra note 1, at 22.
25. Id.
26. Id.
32. Id. at 5.
drugs to the new one and benefit from advantages in the clinical effects of the new drug.33 The access effect is when untreated patients might derive treatment from the new drug due to its possibly fewer side effects, better safety portfolios, more patient subgroups, more competition to give a greater number of patients access to treatments, or more advertising efforts from pharmaceutical companies.34 This study found statistically significant access effects of new drugs, in terms of increasing the number of drugs prescribed.35 In particular, the study found that more creative drugs (i.e., new chemical entities) tend to have larger, more significant access effects, whereas less creative drugs (i.e., generic drugs) contribute smaller or even negative access effects.36 For example, when a new chemical entity was introduced to a drug class, “prescriptions in [that] drug class increased an average of 7% in the first three months, 18.3% . . . by months four to six, and 24.5% by months seven to twelve.”37 The findings of this study confirmed the hypothesis that new drugs can impact population health by changing the clinical effectiveness on existing treatments and changing the quantity of prescriptions written and/or people treated.38

Having access to innovative drugs also has economic benefits. To illustrate, economic studies have shown that newer, more expensive drugs are worth their price.39 One study demonstrated that for each dollar spent on newer drugs, $6.17 was saved.40 Another study estimated that a ten percent reduction in mortality due to heart disease could yield a present value of as much as $5.5 trillion to current and future generations.41

Additionally, it has been argued that to get innovative medications first and rock bottom prices later, pharmaceutical companies must participate in a delicate “choreography” of patent-protected monopoly and aggressive competition.42 Drug companies introduce most new drugs in the U.S. first, and affluent Americans pay high

33. Id.
34. Id.
35. Id. at 20.
36. Id.
37. Cong., supra note 31, at 73.
38. Id. at 20.
39. Hooper, supra note 11.
40. Id.
41. Brouwers, supra note 27, at 37. “A similar reduction in mortality due to cancer is estimated to have a present value of $4.4 trillion.”
42. Huber, supra note 4.
prices while the patents last.  

Subsequently, less affluent Americans, along with public and private insurers in the U.S., U.K., Canada, and the rest of the developed world, get a drastically discounted ride on their economic coattails.  

Stated simply, three-dollar drugs in New York in 1996 are purchased in London for thirty-cents and then are offered for three-cents ten years later in Kuala Lumpur.  

Unless pharmaceutical innovations are sold to the wealthy first, they will never become inexpensive.  

Price-depressing strategies makes the pursuit of new drugs unprofitable and lowers the incentive for continued research and development.  

A decline in innovation could compromise long-term global health.

III. BRITISH PHARMACEUTICAL REGULATION

The British government has a vastly different view than the U.S. about controlling costs for pharmaceuticals. The one area where the two countries are similar is in the testing and approval process. Drug approval in the U.K. is nearly identical to that of the U.S. system under the FDA, where there is a three-phase clinical trial regimen.  

After a product makes it through the approval process, the National Institute for Health and Clinical Experience (NICE) determines the cost-effectiveness of the new drug and provides guidance on treatments for patients using the National Health Service (NHS), without giving any deference to drug manufacturers.  

Essentially, a new drug does not just have to be effective to be approved by NICE for use in the U.K., it must also offer value for the money.  

Even if a new drug is innovative and life saving, it will not be approved by NICE if it does not offer a certain level of economic value.

The evaluation system that NICE uses is called the “quality-adjusted life year” (QALY), which determines whether the increment in the cost of that treatment is worth

43. Id.
44. Id.
45. Id.
46. Id.
47. Id.
48. Huber, supra note 4.
52. Id.
the increment in the health gain.53 A QALY scores a person’s health on a scale from zero to one: zero if you are dead and one if you are in perfect health.54 Using the zero-to-one increments and average life spans after a given treatment, NICE determines a person’s quality-adjusted life years.55 Then, the cost of a treatment or procedure is divided by the quality-adjusted life year to arrive at the cost per QALY, which is the ceiling on how much will be spent for that person.56 NICE cannot refuse treatments to patients who need them, and an expensive drug may still receive a positive NICE rating if it provides enough benefit to produce a favorable ratio.57

Currently, NICE is on the verge of losing some of its power to reject new drugs for inclusion on the NHS plan.58 It was announced in November, 2010, that NICE will continue to give advice about which drugs are deemed effective, but will no longer decide whether patients should be given treatments that doctors recommend, as those decisions are being made only by doctors now.59 The decision-making by doctors will be made under a value-based system, where local doctor groups will decide which drugs to purchase for patients.60 Pharmaceutical companies such as Eli Lilly & Co. have warned that using a value-based pricing system may lead to delays in products entering the market.61 The ultimate goal of this new system seeks to improve access to drugs, but some within the industry fear that introducing a new pricing system will actually cause delays in access to new drugs.62

The British government has established itself as a monopsony purchaser of drugs, thus enabling a variety of profit controls on the pharmaceutical industry organized through the Pharmaceutical Price Regulation Scheme (PPRS).63 The PPRS has drawn criticism in the

53. Id.
54. Id.
55. Id.
56. Id. For example, if a person receives a hip replacement, the patient might start at .5 and go up to .7, improving by .2. Patients live for an average of fifteen years following hip replacements, and .2 multiplied by fifteen equals three quality-adjusted life years. The hip replacement costs $15,000, so it’s 15,000 divided by three to arrive at a $5,000 cost per QALY.
58. Silverman, supra note 3.
59. Id.
61. Id.
62. Id.
63. “Monopsony” is defined as monopoly power on the buyer’s side. See Ceccoli, supra note 6, at 160.
U.K. On the patient level, it has been argued that when prices are out of line with value, the NHS is not making the best use of available resources to improve patient health.\textsuperscript{64} Patients feel this through reduced access to drugs.\textsuperscript{65} For example, if too much money is spent on an existing drug, doctors may have to balance their budgets by restricting access to new, innovative drugs.\textsuperscript{66} In the case of Herceptin and Gleevec, two breakthrough first-in-class drugs to treat cancer, OECD countries experienced launch delays of twenty-three months and six months, respectively, compared to the U.S.\textsuperscript{67} Furthermore, the weighted average age of diabetes drugs in the U.S. is five years, while it is seven to eight years in the U.K.\textsuperscript{68}

Another criticism of the PPRS is that it is driving down international funding for pharmaceutical research and development.\textsuperscript{69} Many countries control pharmaceutical profits through international reference pricing, where countries link the pricing of their pharmaceutical products to the pricing of another country.\textsuperscript{70} The U.K. acts as a reference pricing country to other countries such as France, Italy, Canada, Belgium, Switzerland, Poland, Netherlands, Finland, Hungary, Norway, Ireland, and Japan.\textsuperscript{71} Together, these markets account for about twenty-five percent of world pharmaceutical sales.\textsuperscript{72} Thus, the profit control and pricing in the U.K. is not only reducing resources for research and development in its own country, but also for every country that uses its pricing as a reference point. Without OECD cost controls, estimates suggest that revenues for innovative drugs would increase by thirty-five to forty-five percent.\textsuperscript{73} Moreover, if the OECD controls had been absent in the past, the incentives for research and development investment would have led to as many as a hundred and ten to one hundred and forty more innovative drugs available in the U.S. today.\textsuperscript{74}

Today, the U.S. accounts for half of pharmaceutical research and development achievements.
spending, while Europe accounts for only a third.75 “U.S. prescription drug costs grew at an annual rate of ten percent between 1992 and 2001... driven mainly by higher volumes and shifting the mix toward newer, more innovative medicines.”76 The U.K. saw slower growth around four to five percent.77 Since the pharmaceutical industry has maintained a close correlation between its research and development investment and its free cash flow, patients in OECD countries typically gain access to innovative medicines, if at all, only after a substantial delay and at a level of availability well below that offered to U.S. patients.78 Therefore, while drug costs are lower in the U.K., patients pay the cost of not having access to innovative medicines.

IV. U.S. HEALTHCARE REFORM

Prior to the signing into law of the PPACA, there was much debate about how healthcare reform would impact pharmaceutical innovation and access to newer drugs.79 Some experts believed that price controls were imminent, and feared that the short-term benefit to consumers of reducing costs would lead to a long-term negative impact on social welfare by reducing the number of new drugs being brought to the market.80

Concerns about whether healthcare reform would weaken the pharmaceutical industry were warranted based on lessons from recent history. The Clinton Administration’s Health Security Act (HSA) of 1993 had a negative impact on the industry, despite never being passed by Congress.81 While this legislation was being drafted, stories about the high probability of price controls were leaked, causing anxiety for pharmaceutical companies.82 The industry believed that the HSA would be so damaging that twenty-one large companies guaranteed to keep their prices below consumer inflation starting in

75. See id. at 22-23.
76. Id. at 10-11.
77. Id. at 10.
78. Id. at 12, 33.
82. Id. at 10. The first event causing anxiety was the appointment of Hillary Clinton to lead the group writing the HSA, and she was known to favor price controls. The second event was a speech by President Clinton that stated that pharmaceutical prices were too high. Id. at 11.
1993, in order to convince Congress that legislation was not necessary.83

The HSA was ultimately defeated in Congress and the industry experienced a rally for a few months afterwards, but evidence “show[s] that pharmaceutical company stocks sustained significant price declines [from then] until late 1993.”84 Furthermore, research and development concentrated companies experienced much greater losses on average.85 The negative effects of the HSA on the industry are indicative of the fact that threats of price regulation will reduce research and development assets and spending.86

Unlike the HSA in the 1990s, the PPACA of 2010 will actually benefit the U.S. pharmaceutical industry.87 The industry was able to thwart price controls and tighter federal regulations, but also ensure that millions of uninsured Americans receive coverage.88 The industry as a whole agreed to contribute eighty-five billion dollars over the next decade in the form of industry surcharges and lower prices they will receive from government programs.89 Moreover, a new influx of covered Americans will now have access to prescription drug coverage, thereby increasing the number of customers for pharmaceutical companies.90

In addition to the eighty-five billion dollar contribution by the industry, the PPACA imposes an annual fee on any “covered entity engaged in the business of manufacturing or importing branded prescription drugs” beginning in 2011.91 In determining the annual fee, government programs such as Medicare will provide a yearly report to the Department of Treasury, disclosing the prior year’s sales for each branded drug for all manufacturers covered by the program.92 Then, “the Secretary of Treasury will calculate the annual fee for each pharmaceutical manufacturer or importer based on reports from other specified federal government agencies based on a ratio of its branded drug sales to

83. Id. at 12.
84. Id. at 32.
85. Id.
86. GOLEC ET AL., supra note 81, at 31.
88. Id.
89. Id.
90. Id.
92. “Covered entity” includes “any manufacturer or importer with gross receipts from branded prescription drug sales.”
the branded drug sales of all covered entities for the prior year (i.e., market share).” 93 The annual fee will increase to a maximum of $4.1 billion in 2018, and then decrease to $2.8 billion in 2019 and subsequent years.94

Furthermore, the PPACA includes several important provisions to continue encouraging pharmaceutical companies to invest in research and development. First, Section 9023 provides a tax credit to small companies of 250 employees or fewer to encourage new therapies.95 These credits will assist in “qualified investments,” which include projects to conduct preclinical or clinical research to support marketing approval for a new drug; projects that develop molecular diagnostics; and the development of drug-delivery technologies.96

Second, Section 10409 of the PPACA establishes the Cures Acceleration Network (CAN), which is administered by the National Institutes of Health (NIH).97 CAN will reward grants and contracts for “revolutionary advances in basic research” and “the development of high need cures, including through the development of medical products and behavioral therapies.”98 CAN will also support private, institutional, and governmental agencies in development efforts, and with facilitating the review of “high need cures” by the FDA.99

Additionally, Section 2709 of the PPACA prohibits health plans from denying coverage of certain routine patient costs associated with participation in “approved clinical trials.”100 This provision will likely encourage participation in clinical research, as medical costs for doing so will not fall directly on the researcher or participant.101

Another advantage for the pharmaceutical industry in the PPACA involves greater patent protection for some products.102 A provision exists that grants manufacturers

92. Id. at 1-2.
93. Id.
94. Id.
95. Patient Protection and Affordable Care Act (PPACA), 42 U.S.C.A § 9023 (2010).
96. Id.
97. 42 U.S.C.A § 10409.
98. Id. NIH will deem a product to provide a “high need cure” if it “is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition,” and if it is a product “for which the incentives of the commercial market are unlikely to result in its adequate or timely development.”
99. Id.
100. 42 U.S.C.A § 2709. “Approved clinical trials” are clinical trials for the prevention, detection, or treatment of cancer or other life-threatening disease or condition.
101. See id.
102. THE HENRY J. KAISER FAMILY FOUNDATION, SUMMARY OF NEW HEALTH REFORM LAW 9, June 18,
twelve years to sell biologics—expensive new therapies made of human proteins and cells—before generics can be developed.\textsuperscript{103} This provision will help incentivize manufacturers to continue researching and developing expensive new therapies, because the PPACA has retained the ability to recoup the investment dollars spent on such innovations.

As demonstrated above, the PPACA contains several beneficial provisions that, along with a lack of profit control, will continue to incentivize pharmaceutical companies to research and develop new medical innovations. One similarity between the U.K. regulatory system and the PPACA is the annual fee imposed on pharmaceutical manufacturers, where the amount owed to the government is based on each manufacturer’s respective market share.\textsuperscript{104} This is marginally similar to the U.K. profit repayment system, where manufacturers are required to repay profits that exceed the target forecast for that year.\textsuperscript{105} Both systems are centered on the philosophy that companies that strive to innovate and continue to grow will be expected to pay higher fees for such successes. However, the PPACA limits the amount it forces companies to pay, while the U.K. system has no limit on how much they require companies to repay.\textsuperscript{106} This is a key difference that will be crucial to maintaining competition and innovation amongst U.S. pharmaceutical manufacturers.

Another similarity between the PPACA and the U.K. system involves a newly created agency in the U.S., the Independent Payment Advisory Board.\textsuperscript{107} This entity will have substantial authority to force changes in policies under Medicare, Medicaid, and the Children’s Health Insurance Program to meet mandated cost reduction targets.\textsuperscript{108} For example, changes in Medicare Part D could be included, which would significantly decrease the prices for drugs.\textsuperscript{109} This advisory board is similar to the PPRS in the U.K., which administers the profit control policies to ensure that the British government is

\textsuperscript{103}. Id.
\textsuperscript{104}. Sanzo, supra note 91, at 2.
\textsuperscript{106}. See Sanzo, supra note 91; PPRS, supra note 105.
\textsuperscript{107}. Ian D. Spatz, Health Reform Accelerates Changes in the Pharmaceutical Industry, 29:7 Health Affairs 1331, 1334 (2010).
\textsuperscript{108}. Id.
\textsuperscript{109}. Id.
receiving value for what they spend on pharmaceutical products.110

It is difficult to assess the impact that the PPACA will directly have on pharmaceutical research and development.111 Brand-name companies use revenue to pay for research and development, so any provision that reduces revenue or profits will impact innovation.112 The abovementioned provisions that bear similarities to the U.K. regulatory system are two such provisions that could negatively impact the revenue of companies, leading to reductions in research and development.113 Yet, most of the impact that the PPACA will have on research and development comes from the increased Medicaid rebates and the net cost of providing discounts in the Medicare drug coverage gap.114 The number of newly covered patients resulting from the PPACA may counteract those discounts, but it is still an issue that pharmaceutical manufacturers must take into account when determining research and development budgets.115

In the foreseeable future, the PPACA will likely have little impact on U.S. pharmaceutical innovation. The relatively free-market of the U.S. is not compromised by the legislation, despite new challenges in handling greater government regulation. Pharmaceutical companies in the U.S. succeeded in staving off price and profit controls, which have negatively affected drug innovation in the U.K. For the time being, the U.S. will remain the epicenter of research and development for pharmaceutical manufacturers around the world, and patients here will continue to enjoy having first access to the latest medicines.

V. CONCLUSION

The U.S. pharmaceutical industry has historically been characterized as the market-driven pharmaceutical system of the world. Despite government regulations in the quality of products, manufacturers have long avoided price and profit controls by the federal government, leaving the door open for enormous profits to be invested in research and development. On the other hand, companies in the U.K. have endured profit controls and determinations about the value of their products from the British government. These

111. Spatz, supra note 107, at 1334.
112. Id.
113. Id.
114. Id.
115. Id. at 1334-35.
differing cost control policies has led to vast differences in the advancement of pharmaceutical innovation and to significant disparities in patient access to medicines.

The PPACA does not impose price or profit controls on pharmaceutical companies in the U.S., and contains several provisions to promote research and development. Companies will likely see a decrease in drug prices due to Medicare and Medicaid rebates, but the PPACA will be providing drug coverage to millions of new Americans, who were previously unable to afford prescriptions. Thus, there appears to be a positive outlook for the U.S. to remain the world’s leader in pharmaceutical innovation. As scientists are on the verge of major medical advances, policymakers must maintain incentives to fund such breakthroughs in order to keep innovative medicines in the hands of U.S. patients.