

12-1-2016

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Nicole C. Perez, *International Reciprocity: If a Drug Is Good Enough for Great Britain, It Should Be Good Enough for the United States*, 25 U. Miami Bus. L. Rev. 169 (2016)

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International Reciprocity: If a Drug Is Good Enough for Great Britain, It Should Be Good Enough for the United States

Nicole C. Perez*

The pharmaceutical industry is one of the largest, and most lucrative, industries in the world, worth about one trillion U.S. dollars. Specifically, the United States accounts for more than one-third of the global pharmaceutical market with about 340 million dollars in sales. Not only is the pharmaceutical industry one of the biggest industries profit-wise, but it is also an industry that affects almost every single person in the world. In a nation where healthcare issues are always on the rise, ensuring that American citizens benefit from pharmacology is essential to improving the nation's healthcare system. The Food and Drug Administration (FDA) is responsible for protecting the public's health by assuring its consumers that the pharmaceutical drugs approved in the United States are both safe and effective. However, with great responsibility, great problems are sure to follow.

The FDA's approval process for pharmaceutical drugs is highly stringent, costly, and lengthy. While it makes sense to have a stringent approval process for pharmaceutical drugs, the cost and duration of the process outweigh the benefits that the FDA is trying to achieve. The FDA's stringent approval process refuses to allow U.S. consumers access to potentially life-saving medicines that have already been approved in other countries,

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such as Great Britain, whose pharmaceutical regulatory system is most similar to that of the United States than any other country. By enacting an international reciprocity agreement that allows the U.S. to automatically approve drugs that have been approved in similar countries, the cost and duration of the FDA's drug approval process would substantially decrease, which could potentially save millions of lives.

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I. INTRODUCTION

The big, bad, pharmaceutical industry: one of the largest, and most lucrative, industries in the world. With a net worth of about one trillion U.S. dollars, the global pharmaceutical industry is responsible for the development, production, and marketing of medications around the world.¹ Specifically, the United States is responsible for the largest portion of the global market, generating more than forty percent of the global revenue.² However, despite generating the largest pharmaceutical market in the world,³ the pharmaceutical industry in the United States is certainly not free of criticism.

The Food and Drug Administration (FDA) is responsible for protecting the public's health by assuring the safety and efficacy of pharmaceutical drugs in the United States.⁴ However, the process through which the FDA regulates such drugs is highly stringent, costly, and lengthy.⁵ The FDA justifies its lengthy and expensive process by exercising a "better safe than sorry" attitude. However, critics attack the FDA's over-cautious approval process because it refuses to allow access to potentially life-saving medicines that have already been approved in other countries, such as Great Britain.⁶ The regulatory system of Great

¹ *Statistics and Facts About the Pharmaceutical Industry Worldwide*, STATISTA, <http://www.statista.com/topics/1764/global-pharmaceutical-industry/> (last visited Jan. 16, 2016).

² *Id.*

³ *Id.*

⁴ *About FDA: What We Do*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last updated Dec. 7, 2015).

⁵ Julie C. Relihan, Note, *Expediting FDA Approval of AIDS Drugs: An International Approach*, 13 B.U. INT'L L.J. 229, 230 (1995).

⁶ *Id.* at 231.

Britain is most similar to that of the United States than any other country.⁷ Therefore, choosing to automatically approve drugs in the United States that have already been approved in Great Britain seems like a no-brainer. Nevertheless, the United States has yet to approve such a system.

Although there is no international agreement in place, there have been efforts to harmonize with other countries in the past. In 1991, the United States President's Council of Competitiveness (President's Council) proposed a series of procedures and reform measures intended to accelerate the FDA approval of new drugs.⁸ The President's Council proposed that the FDA give automatic approval to drugs that have already been approved by foreign countries that have a reciprocity agreement with the United States.⁹ The proposal emphasized that only those countries that have very similar standards to the FDA would be accepted and negotiated on a country-by-country basis.¹⁰ However, this agreement has, of course, not yet happened.

Due to the stringent standards of the FDA, it is difficult for the United States to enter into any sort of reciprocity agreement. Thus, this comment will address why a reciprocity agreement allowing the automatic approval in the United States of drugs already approved in Great Britain would be beneficial. Furthermore, this comment will also address how adopting some aspects of Great Britain's drug regulation process would minimize many of the FDA's harshest criticisms. Part II of this comment will address the history of the FDA and its current drug approval process, as well as common criticisms of the FDA approval process. Part III of this comment will address the drug regulation and approval process in Great Britain. Part IV of this comment will compare the regulations and approval process between the United States and Great Britain. Finally, part V of this comment will address the benefits of automatically approving drugs from Great Britain in the United States.

⁷ Rosemary P. Wall, *International Trends in New Drug Approval Regulation: The Impact On Pharmaceutical Innovation*, 10 RUTGERS COMPUTER & TECH. L.J. 317, 324 (1984).

⁸ Relihan, *supra* note 5, at 256.

⁹ Amelia A. Esber, Note, *Curing the Drug Lag: A Proposal for International Harmonization of Pharmaceutical Approval*, 31 ARIZ. J. INT'L & COMP. L. 125, 147 (2014).

¹⁰ *Id.*

II. THE REGULATION AND APPROVAL PROCESS OF THE FDA

A. History

1. The Pure Food and Drugs Act of 1906

Prior to 1906, there was an influx of counterfeit and contaminated drug materials entering the United States from overseas.¹¹ It was not until after the Civil War, when interstate commerce began expanding significantly, that the United States realized it needed to create a federal rule regulating the pharmaceuticals entering the country.¹² Subsequently, Congress passed the Pure Food and Drugs Act of 1906.¹³ The purpose of the 1906 Act was to protect consumers by prohibiting the adulteration and misbranding of pharmaceuticals by their manufacturers.¹⁴ However, the 1906 Act suffered a setback when the Supreme Court of the United States held that “the law did not prohibit false health claims, only false statements about the identity or ingredients of drugs.”¹⁵ Therefore, in essence, a manufacturer could lie about the therapeutic claims of a drug without any repercussions. As a result, Congress amended the 1906 Act to include the prohibition of false and fraudulent label claims of therapeutic effectiveness.¹⁶ Although this was a genuine attempt to cure the loophole of the 1906 Act, the language of the Amendment required that the promoter of the pharmaceutical had “deliberately lied to defraud the public,” which was almost impossible to prove.¹⁷ Therefore, although the Pure Food and Drugs Act of 1906 was a noble start to regulating pharmaceuticals in the United States, it was clear that more aggressive reform efforts were needed in order to protect consumers.

¹¹ Wallace F. Janssen, *Outline of the History of U.S. Drug Regulation and Labeling*, 36 FOOD DRUG COSM. L.J. 420, 423 (1981).

¹² *Id.* at 425.

¹³ Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, §§ 1-13, 34 Stat. 768, (1906), *repealed by* Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1040, 1059 (codified as amended at 21 U.S.C. §§ 301-99f (2012)).

¹⁴ Janssen, *supra* note 11, at 427.

¹⁵ *Id.*

¹⁶ *Id.* at 428. In 1912, Congress passed the Sherley Amendment, which prohibited the fraudulent claims of therapeutic effectiveness of pharmaceuticals.

¹⁷ *Id.*

2. The Food, Drug and Cosmetic Act of 1938

In 1937, tragedy struck when the drug “Elixir Sulfanilamide” was responsible for the deaths of more than 100 people in 15 different states.¹⁸ Sulfanilamide was a drug used to treat streptococcal infections, and it was proven to safely and effectively cure the infections in both tablet, and powder, form.¹⁹ However, the problems with the drug arose when a Tennessee Pharmaceutical company reported a demand for the drug in liquid form.²⁰ As a result, the pharmaceutical company’s chief chemist and pharmacist created the liquid form of the drug by mixing different chemicals, and distributed it all over the country.²¹ The problem, however, was that the drug was not tested for toxicity because at that time, there was no food or drug law that required safety studies be done on new drugs.²²

Following the tragic deaths of innocent consumers, Congress enacted The Food, Drug and Cosmetic Act of 1938. The 1938 Act responded to the Elixir tragedy by requiring that a pharmaceutical company seeking to market its drug to the public must first file an application for approval of the new drug.²³ Once the FDA received the new drug application, it had the option of testing the safety of the drug on human subjects.²⁴ If the FDA did not approve, reject, or request additional data from the pharmaceutical company within sixty days, then such failure to respond would lead to automatic approval of the drug.²⁵ By requiring this extra step in the application process, the FDA’s main concern was preventing another Elixir tragedy by ensuring that new pharmaceuticals were safe to pass on to consumers.

3. The Drug Amendments of 1962

In the 1960s, another pharmaceutical tragedy occurred, but this time it was in Europe. The tragedy struck when the drug “thalidomide” was found to cause birth defects in babies born by mothers who had taken the experimental drug, as a part of a clinical trial, during their pregnancies.²⁶ As a result, Congress passed the 1962 Amendments, which required that a

¹⁸ Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA CONSUMER MAG., June 1981, at 1.

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 355 (2012).

²⁴ *Id.*

²⁵ *Summary of NDA Approvals & Receipts, 1938 to the Present*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/aboutfda/whatwedo/history/productregulation/summaryofndaapprovalsreceipts1938tothepresent/default.htm>, (last updated Jan. 18, 2013).

²⁶ Esber, *supra* note 9, at 128.

new drug undergo a series of clinical tests to not only prove the safety of the drug, but also to verify the effectiveness of the drug.²⁷ During clinical testing, the FDA has the right to stop any testing, or order changes to the testing, if the drug is deemed unsafe or ineffective.²⁸ The major change created by the 1962 Amendments is the requirement of proof of efficacy, in addition to the proof of safety requirement.

B. New Drug Application: The Approval Process of the FDA

The Food, Drug and Cosmetic Act of 1938 provided for two different routes of approval for drug marketing in the United States. The first route is that the drug must be one that is exempted from the 1938 Act by the 1962 Amendments.²⁹ The second route of approval, which is the route that this comment will be focusing on, is that the FDA must approve the drug under the New Drug Application (NDA) procedures.³⁰ Under the NDA approval process, there are four stages that must be accomplished before a decision can be rendered on whether or not to approve the drug. The four stages of the NDA approval process are the following: (1) pre-clinical testing; (2) investigational new drug stage; (3) NDA stage; and (4) post-marketing surveillance.

1. First Stage: Pre-Clinical Testing

The first step of the NDA approval process is pre-clinical testing, which lasts about eighteen months.³¹ During this stage, the drug sponsor must conduct clinical investigations to show that the drug is reasonably safe by performing the drug testing and analysis on animals.³² The main purpose of these pre-clinical tests is to ensure that the drug is reasonably safe for human beings before commencing the human preliminary clinical investigations.³³

2. Second Stage: Investigational New Drug Application

After the pre-clinical testing, if the drug sponsor concludes that the drug is shown to be both safe and effective for humans, then the sponsor must file an Investigational New Drug (IND) Application.³⁴ In the IND

²⁷ 21 U.S.C. § 355(d).

²⁸ Esber, *supra* note 9, at 129.

²⁹ David W. Jordan, Note, *International Regulatory Harmonization: A New Era in Prescription Drug Approval*, 25 VAND. J. TRANSNAT'L L. 471, 478 (1993).

³⁰ *Id.*

³¹ *Id.* at 479.

³² 21 C.F.R. § 312.23(a)(8) (2016).

³³ Jordan, *supra* note 29, at 479.

³⁴ Esber, *supra* note 9, at 130.

application, the drug sponsor must include the results of the pre-clinical testing, including both the animal toxicology, and the human testing studies conducted.³⁵ After submitting the IND to the FDA, the drug sponsor must wait thirty days while the FDA reviews the IND.³⁶ If the FDA responds favorably within thirty days, or does not respond at all, then the drug sponsor is permitted to begin clinical testing.³⁷ However, the FDA has the option to place the IND on “clinical hold” within the thirty days, which would prevent further commencement of that specific IND due to possible concerns regarding the drug.³⁸

In addition, there are three phases of clinical investigations that are conducted during the IND stage. Phase I begins with initial introduction testing of the new drug on about twenty to eighty human subjects, whom consist of both patients and volunteers.³⁹ The studies conducted during this phase are designed to determine “the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.”⁴⁰

Phase II begins to specify the broad testing from Phase I. The studies in Phase II are conducted to “evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition,” and to “determine the common short-term side effects and risks associated with the drug.”⁴¹ Here, the primary consideration is the *effectiveness* of the drug on human subjects, whom have the specific disease that the drug intends to treat.⁴² Phase II involves well controlled, and closely monitored studies, on no more than several hundred human subjects within an average of about eighteen months.⁴³

Finally, Phase III is the longest and most extensive phase of clinical testing, lasting about three years on average.⁴⁴ The trials in Phase III are conducted only after preliminary evidence from both Phases I and II show that the drug has been *effective*.⁴⁵ The studies conducted in Phase III are “intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.”⁴⁶ Phase III

³⁵ 21 C.F.R. § 312.22 (c).

³⁶ *Id.* § 312.40(b)(1).

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.* § 312.21(a)(1).

⁴⁰ *Id.* § 312.21(b).

⁴¹ *Id.*

⁴² *Id.* (emphasis added).

⁴³ *Id.*; see also Jordan, *supra* note 29, at 480.

⁴⁴ Jordan, *supra* note 29, at 480.

⁴⁵ 21 C.F.R. § 312.21(c) (emphasis added).

⁴⁶ *Id.*

studies have the most subjects of the three phases, ranging from about several hundred to several thousand subjects.⁴⁷

It is important to note that, during the IND stage, the FDA may terminate clinical testing at any phase of the IND stage if it is found that there are deficiencies in the IND, or in the actual conduct of an investigation under an IND.⁴⁸ Furthermore, the drug sponsor itself may be required to terminate the investigation if any substantial doubt arises as to the safety and efficacy of the drug.⁴⁹

3. Third Stage: New Drug Application

If the three phases of the IND stage are successfully completed, the drug sponsor must then file a New Drug Application (NDA) with the FDA.⁵⁰ The NDA “has become the principal regulatory device for the control of drugs in the United States.”⁵¹ The goals of the NDA are to provide enough information to permit the FDA to find whether the drug is safe and effective in its proposed uses, whether the benefits of the drug outweighs the risks, whether the drug’s proposed labeling is appropriate in its information, and whether the methods used in manufacturing and controlling the drug maintain the drug’s quality adequately in order to preserve the drug’s identity, strength, quality, and purity.⁵² The NDA is basically a compilation of all the information from the IND phase, and in essence, tells the drug’s “whole story.”⁵³

After an NDA has been filed, the FDA has six months to approve or reject the NDA.⁵⁴ If the FDA approves the NDA, the drug sponsor must then maintain records of data relating to clinical experience and other data or information received or obtained with respect to the drug.⁵⁵

4. Fourth Stage: Post-Market Surveillance

Finally, the fourth and final stage of the approval process is post-marketing surveillance. Although the Food, Drug and Cosmetic Act of 1938 does not specifically require drug sponsors to conduct post-

⁴⁷ *Id.*

⁴⁸ *Id.* § 312.44(a); *see also id.* § 312.44(b) (listing specific grounds for termination of the IND).

⁴⁹ 21 C.F.R. § 312.44(b)(vii).

⁵⁰ 21 U.S.C. § 355(a)-(b).

⁵¹ Jordan, *supra* note 29, at 481.

⁵² *New Drug Application (NDA)*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/> (last updated Feb. 3, 2015).

⁵³ *Id.*

⁵⁴ 21 U.S.C. § 355(c).

⁵⁵ *Id.* § 355(k).

marketing surveillance, it has become routine through agency practice.⁵⁶ The goal of post-marketing surveillance is find out more information about a drug's safety and efficacy by monitoring instances of adverse or uncommon reactions to the drug.⁵⁷ The post-marketing surveillance stage is extremely important because it detects any unknown side effects caused by the drug that are not detected in the previous stages.⁵⁸ A major issue concerning post-marketing surveillance is that the FDA may lack the money and/or staff necessary in order to provide efficient and effective surveillance of new drugs.⁵⁹ As a result, the FDA made it "mandatory"⁶⁰ for drug companies to report when drugs show adverse effects, however, such reporting is often too late, or never occurs at all.⁶¹

C. Generic Drug Approval Process

When a drug has successfully completed the NDA approval process, it is approved and marketed as a "brand name" drug. A brand name drug is "the first to contain a particular active ingredient or ingredients to receive FDA approval for a specified use."⁶² In order to protect a drug company's exclusivity of its newly approved drug, the company develops the drug under a patent, which allows the company the sole right to sell the drug while the patent is in effect.⁶³ However, once the patent expires, generic drug companies can compete with the brand name drug by entering their generic version of the drug into the market.⁶⁴

1. What is a Generic Drug?

A generic drug is a copy of a brand name drug, which can enter the market once the brand name drug's patent, or period of exclusivity, has expired.⁶⁵ Generic drugs play a large role in competing with brand name drugs because generic drugs are often priced much lower than brand name drugs, which is mainly due to lower development costs.⁶⁶ Due to their

⁵⁶ Jordan, *supra* note 29, at 483.

⁵⁷ Esber, *supra* note 9, at 131.

⁵⁸ *Id.* at 131-32; see also Richard Deyo, *Gaps, Tensions, and Conflicts in the FDA Approval Process: Implications for Clinical Practice*, 17 J. AM. BD. FAM. MED. 142, 142-49 (2004): Some experts claim that approximately half of all new drugs have unknown side effects that are not discovered until the post-marketing surveillance stage.

⁵⁹ Deyo, *supra* note 58, at 142-49.

⁶⁰ The author of this Note added quotations for emphasis.

⁶¹ Deyo, *supra* note 59, at 142-49.

⁶² Justina A. Molzon, *The Generic Drug Approval Process*, 5 J. PHARMACY & L. 275, 275 (1996).

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

lower prices, many believe that generic drugs are inferior to brand name drugs, and are therefore not as effective.⁶⁷ This belief, however, is unfounded given that generic drugs contain the exact same active ingredients as the brand name drug, and they must have the same safety and efficacy standards as the brand name drug as well.⁶⁸ Although generic drugs may differ in inactive ingredients, such as capsules versus tablets, they are still equally comparable in regard to dosage form, strength, route of administration, quality, performance, and intended use.⁶⁹

2. History of Generic Drug Regulation

In 1984, Congress passed the Waxman-Hatch Act, which is largely responsible for the increase of generic drugs available on the market today.⁷⁰ The Act was passed in order to “achieve objectives related to competitive and commercial forces in the regulated drug industry.”⁷¹ The Act represented an effort to create a balance between the competing forces in the pharmaceutical industry: generic drugs and brand name drugs.⁷² The Act also extended the abbreviated new drug application (ANDA) process, which allowed for generic versions of brand name drugs to enter the market when the brand name patent or period of exclusivity expired.⁷³ The Act simplified the ANDA approval process by “eliminating the need for sponsors to repeat duplicative, unnecessary, expensive and ethically questionable clinical and animal research to demonstrate the safety and efficacy of the drug product.”⁷⁴ The reasoning behind this change was that it was recognized that the safety and efficacy of the drug had been adequately and sufficiently demonstrated by the studies conducted by the brand name drug manufacturer.⁷⁵ Furthermore, the fact that the brand name drug had already been accepted by the medical community and had already been in widespread use, showed that the drug was acceptable, and there was no need to conduct double testing on the same product.⁷⁶

3. The ANDA Approval Process

The application for generic drugs is called an “abbreviated new drug application” because the approval process does not need to duplicate the

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.* at 276.

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.*

safety and efficacy trials that were previously conducted for the brand name drug; hence the term “abbreviated.”⁷⁷ An ANDA is submitted to propose a generic drug that is already the “same” as a previously FDA approved drug.⁷⁸ The generic drug manufacturer must submit enough information to show that the generic drug described in the ANDA is the same as the previously approved brand name drug in regards to its active ingredient, dosage form, strength, and route of administration.⁷⁹ Furthermore, the generic manufacturer must also comply with the same FDA requirements that were imposed on the brand name product.⁸⁰ Therefore, the generic manufacturer must meet the same standards for manufacturing practices, identity, strength, quality, and purity.⁸¹

The only difference permitted between a generic drug and a brand name drug is the contents of the label of the generic drug.⁸² The labeling submitted by the generic drug must contain the same information as the brand name drug, except for the modifications of the generic drug due to the brand name drug’s patent of exclusivity.⁸³ The generic drug’s labeling can also differ in regards to tablet shape, color, capsule, etc.⁸⁴

4. Bioequivalence: How Alike Are They?

In addition to all the gathered information regarding the chemistry, manufacturing, control, and labeling of the generic drug, the generic manufacturer must also include information about the drug’s bioequivalence on the ANDA.⁸⁵ The bioequivalence of the drug is demonstrated by showing that the generic drug delivers the same amount of active ingredient, at the same rate and extent, as the brand name drug.⁸⁶ In order to reach such a conclusion, the generic manufacturer must conduct a bioequivalence study.⁸⁷

Bioequivalence studies are conducted at a fraction of the cost of a brand name clinical study, and usually involve about eighteen to twenty-four human volunteers.⁸⁸ Typically, in bioequivalence studies, each volunteer receives both the brand name drug, and the test drug, because

⁷⁷ *Id.* at 277.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

blood levels of the drug, even from the same product, will vary in different people.⁸⁹ For a generic product to be found bioequivalent to the brand name drug, the generic product's absorption to the blood can only differ from the brand name's absorption by less than ten percent.⁹⁰ Therefore, due to the various regulations and strict FDA requirements, there is no reason to believe that a generic drug is less effective than a brand name drug.

D. Major Criticisms of the FDA Approval Process in the United States

1. The Drug Lag

The most common criticism of the FDA's pharmaceutical approval process is the drug lag. Since the passage of the 1962 Amendments to the Food, Drug and Cosmetic Act of 1938, the time required to gain approval for new drugs has risen substantially.⁹¹ Before the 1962 Amendments, it took about three to four years for an NDA to become approved, and enter the market.⁹² Today, it takes about eleven to fourteen years for a new drug to enter the marketplace after approval, which is more than triple the amount of time of approval before the enactment of 1962 Amendments.⁹³ Many critics agree that the 1962 Amendments have largely contributed to the drug lag because the Amendments added the stringent efficacy requirement to the already strict safety requirement of the FDA.⁹⁴

Arguably the biggest problem that has arisen as a result of the drug lag is the increase in deaths of Americans who are waiting on potentially life-saving drugs to be accepted by the United States. The bacterial meningitis outbreak, which occurred at Princeton University in 2013, is a prime example. Bacterial meningitis is a deadly bacteria, which causes swelling of the membranes covering the brain and spinal cord.⁹⁵ Once infected, those whom are lucky enough to survive are often left with permanent disabilities such as paralysis and mental disabilities.⁹⁶ In March 2013,

⁸⁹ *Id.* at 278.

⁹⁰ *Id.* at 279.

⁹¹ Jordan, *supra* note 29, at 484.

⁹² *Id.*

⁹³ The Independent Institute, *The Drug Development and Approval Process*, FDAREVIEW.ORG, http://www.fdareview.org/approval_process.shtml, (last visited Jan. 9, 2016).

⁹⁴ Esber, *supra* note 9, at 126.

⁹⁵ Alex Tabarrok, *The FDA and International Reciprocity*, MARGINAL REVOLUTION (Nov. 19, 2013), <http://marginalrevolution.com/marginalrevolution/2013/11/the-fda-and-international-reciprocity.html>.

⁹⁶ *Id.*

seven cases of bacterial meningitis were diagnosed at Princeton University. There is no approved vaccine in the United States for this disease; however, Europe, Australia, and Canada all have an approved vaccine known as Bexsero.⁹⁷ As a result, The Centers for Disease Control and Prevention (CDC) were able to lobby the FDA into allowing “special and unusual permission” to import Bexsero to the United States, but only for this specific instance.⁹⁸ Princeton was then able to administer the vaccine to any student who wanted it.⁹⁹

The point of grave concern in this situation is that the bacterial meningitis vaccine, Bexsero, is in clinical trials in the United States, but the FDA has slowed the testing and approval process of the vaccine.¹⁰⁰ Even more concerning is the fact that the FDA clinical testing of Bexsero, thus far, has in fact confirmed that “the vaccine will help protect against the exact strain of bacteria that is causing the outbreak.”¹⁰¹ It has been proven that the clinical trial length of new drugs is the main reason as to why it takes so long for new drugs to be approved.¹⁰² This can be attributed to a number of factors, including increased regulatory requirements, the need for more study subjects, an increase in difficulty of recruiting subjects, and the nature of the disease being investigated.¹⁰³ However, if the FDA had expedited this clinical testing process, knowing that the vaccine protects against bacterial meningitis, some of the cases at Princeton could have potentially been prevented. Furthermore, regardless of the Princeton outbreak, bacterial meningitis kills approximately five hundred people a year in the United States alone.¹⁰⁴ Such a statistic alone should encourage the FDA to expedite the approval of a potentially life-saving vaccine.

⁹⁷ Henry I. Miller, *Meningitis Outbreaks Call For FDA Leadership; Don't Hold Your Breath*, FORBES.COM (Dec. 16, 2013), <http://www.forbes.com/sites/henrymiller/2013/12/16/meningitis-outbreaks-call-for-fda-leadership-dont-hold-your-breath/#5d30a868684c29c686f1684c>.

⁹⁸ Tabarrok, *supra* note 95.

⁹⁹ *Id.*

¹⁰⁰ Miller, *supra* note 97.

¹⁰¹ K. Lloyd Billingsley, *FDA Meningitis Vaccine Delay Killing Americans: Column*, USATODAY.COM, (Mar. 3, 2014), <http://www.usatoday.com/story/opinion/2014/03/03/fda-meningitis-vaccine-delay-princeton-ucsb-column/5992077/>.

¹⁰² Michael Dickson, *The Cost of New Drug Discovery and Development*, DISCOVERY MED. (June 20, 2009), <http://www.discoverymedicine.com/Michael-Dickson/2009/06/20/the-cost-of-new-drug-discovery-and-development/>.

¹⁰³ *Id.*

¹⁰⁴ Tabarrok, *supra* note 94.

2. Political Power of the FDA

Like any other business relationship, conflicts often arise between the FDA and pharmaceutical companies. However, critics of the FDA argue that pharmaceutical companies are hesitant to challenge decisions by the FDA in a legal environment based on the fear that the FDA will retaliate in the future.¹⁰⁵ Critics further argue that the FDA delays its consideration of a pharmaceutical company's new drug if any controversy arises between the two during the approval process.¹⁰⁶ Therefore, critics contend that if the FDA evaluated new drugs solely on their scientific and therapeutic merits, then the drug approval process would be much quicker.¹⁰⁷

In essence, critics could argue that the FDA is basically a monopoly, being the sole approver of pharmaceuticals in the United States. Studies show that regulatory agencies, such as the FDA, structure their employees to perform their tasks cautiously, usually with excessive caution,¹⁰⁸ in order to prevent any backlash for approving a drug that may turn out to be harmful. Consequently, FDA employees have a "natural bias" to withhold new and potentially useful drugs from the market.¹⁰⁹ However, critics argue that preventing effective new drugs from the public, especially from those whom have no other means of treatment, is just as harmful as letting potentially harmful drugs slip through the cracks.¹¹⁰ Therefore, critics believe that the FDA must restructure the mindset of their employees to allow a more efficient drug review process.¹¹¹

3. Heavy Costs Associated with Drug Approval

Similar to the drug lag, the efficacy requirement of the 1962 Amendments to the Food, Drug and Cosmetic Act of 1938 increased the testing requirements for new drug approval.¹¹² As a result, the costs associated with drug approval increased in order to meet the new efficacy requirement.¹¹³ In 2014, it cost an estimated 2.4 billion dollars to develop a new drug.¹¹⁴ Due to the astronomical costs of approving new drugs in

¹⁰⁵ Esber, *supra* note 9, at 134.

¹⁰⁶ Jordan, *supra* note 29, at 486.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* at 487.

¹⁰⁹ *Id.*

¹¹⁰ *Id.* at 488.

¹¹¹ *Id.*

¹¹² Esber, *supra* note 9, at 133.

¹¹³ *Id.*

¹¹⁴ The Apothecary, *Crisis in Pharma: It Costs \$2.6 Billion to Develop a New Medicine; 2.5 Times More Than in 2003*, FORBES.COM, (Nov. 26, 2014), <http://www.forbes.com/>

the United States, evidence has shown that many “orphan drugs,”¹¹⁵ which are potentially useful drugs, were not being introduced in the United States because the high costs of FDA approval would exceed any potential sales revenue of the drug.¹¹⁶ Furthermore, as a result of the lack of useful drugs, due to the high costs of FDA approval, many Americans sought treatment overseas, or resorted to using black-market drugs from unapproved suppliers who were selling the unapproved drugs.¹¹⁷

Although ANDA’s have much lower development costs compared to NDA’s due to its abbreviated application, an ANDA cannot exist without an already approved NDA.¹¹⁸ Therefore, if researchers continue to steer away from bringing new, helpful drugs into the United States as a result of the high development costs, then the United States will be absent of both the useful drugs, and its cheaper generic counterpart.

III. THE DRUG REGULATION AND APPROVAL PROCESS IN GREAT BRITAIN

A. History

As a result of the previously discussed thalidomide disaster in Great Britain,¹¹⁹ the Committee on Safety of Drugs was created in 1963.¹²⁰ This committee later became the Committee on Safety of Medicines (CSM) under the regulation of the Medicines Act of 1968.¹²¹ The Medicines Act provides the legal framework for the control of medicines in the United Kingdom, and requires that pharmaceuticals be licensed before being allowed in the open market.¹²² Then, the Medicines Control Agency was created in 1989, and merged with the Medical Devices Agency in 2003 to become the Medicines and Healthcare Products Regulatory Agency

sites/theapothecary/2014/11/26/crisis-in-pharma-rd-it-costs-2-6-billion-to-develop-a-new-medicine-2-5-times-more-than-in-2003/#57db4732164138f510cb1641.

¹¹⁵ “Orphan drugs” are potentially useful drugs that were not being brought for approval into the U.S. market because the costs of FDA approval of these drugs would exceed their potential sales revenue. See Dale H. Gieringer, *The Safety and Efficacy of New Drug Approval*, 5 CATO J. 177, 179 (1986).

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ Molzon, *supra* note 62, at 275.

¹¹⁹ As previously discussed on page 5 of this note.

¹²⁰ *Medicines & Medical Devices Regulation: What You Need to Know*, MHRA.GOV.UK, 3, <http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con2031677.pdf>, (last updated Apr. 2008) [hereinafter *Medicines & Medical Devices Regulation*].

¹²¹ *Id.*

¹²² *Id.*

(MHRA).¹²³ The criteria on which the MHRA bases its evaluations consist of safety, quality, and efficacy.¹²⁴ The Commission on Human Medicines (CHM), formerly the CSM, provides expert advice to the MHRA in the review of all drugs.¹²⁵ In addition, the MHRA works closely with the European regulator, the European Medicines Agency (EMA), whose legislation supersedes the MHRA.¹²⁶

B. The Drug Approval Process of the MHRA

Before any medicine can be introduced into the market, a license referred to as a “marketing authorization” must be issued by the MHRA.¹²⁷ In order to receive this authorization, pharmaceutical companies and researchers must apply to the MHRA for permission to test their drugs through clinical trials.¹²⁸ In order to obtain permission to begin a clinical trial, the pharmaceutical company must show that it has satisfied the strict safety criteria of the MHRA.¹²⁹ Once the clinical trials are completed, the test results establishing how well the medicine works, any side effects, details of what the medicine contains, how the medicine works in the body, and who it is meant to treat, are sent the MHRA for assessment.¹³⁰ The assessment team of the MHRA is composed of experts from different relevant specialties, whom have undergone additional training in medicine assessment specifically.¹³¹ The duration of the MHRA assessment process depends on the type of medicine, the quality of the initial information of the medicine supplied by the manufacturer, how much further detail is required, and how soon any uncertainties can be resolved.¹³² During its assessment, the MHRA must comply with “strict timeframes and performance targets” for the licensing of medicines.¹³³ The pharmaceutical company must be able to show the MHRA that the manufacture, distribution, and supply of the medicine meet the required safety and quality standards of the MHRA.¹³⁴ Once the MHRA is satisfied that the

¹²³ *Id.*

¹²⁴ *How We Regulate Medicines*, THE MEDS. & HEALTHCARE PRODS. REGULATORY AGENCY (NATIONAL ARCHIVES), <http://webarchive.nationalarchives.gov.uk/20101111071140/mhra.gov.uk/howweregulate/medicines/index.htm>, (last modified July 14, 2010).

¹²⁵ *Id.*

¹²⁶ Esber, *supra* note 9, at 136.

¹²⁷ *Medicines & Medical Devices Regulation*, *supra* note 119, at 5.

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.* at 6.

medicine is both safe and effective, it grants the pharmaceutical company the marketing authorization for the medicine.¹³⁵

1. Post-Market Surveillance

In Great Britain, manufacturers are required by law to report to the MHRA any important defects that are discovered in their drugs after they have been on the market.¹³⁶ When a medicine is suspected or discovered to be faulty, the MHRA immediately works with the manufacturers on “the most appropriate and timely action to take,” which may mean completely recalling the medicine from the market.¹³⁷ If an issue arises with a medication, but a total recall is unnecessary, the MHRA then issues warnings about defective medicines, problems with the medicine, and any side effects discovered from the medicine.¹³⁸ These warnings are sent out to healthcare professionals and organizations, and are also publicized widely both in print and online, including the MHRA website.¹³⁹ The MHRA prioritizes responding to any possible concerns of new drugs, so the MHRA holds the power to prosecute manufacturers for not reporting any such concerns.¹⁴⁰

In addition, patients are also permitted, but not required, to report any concerns with medicines they are taking through what is known as the Yellow Card Scheme.¹⁴¹ The Yellow Card Scheme allows patients to report side effects directly, either online or by phone, without having to rely on a healthcare professional to do so.¹⁴² The Yellow Card Scheme is a highly useful tool because the reports go straight to the pharmaceutical companies, which allow the companies to make a change in their product and be aware of any concerns.¹⁴³

Although there have naturally been instances where the MHRA has approved drugs that were too dangerous or ineffective to stay on the market, the MHRA enforces its immediate withdrawal procedures as soon as any serious concern is reported.¹⁴⁴

¹³⁵ *Id.*

¹³⁶ *Id.* at 13.

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 12.

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ *See e.g., id.* at 14.

IV. AN INTERNATIONAL COMPARISON: THE FDA v. THE MHRA

The drug regulation system in Great Britain is substantially comparable to the regulation system in the United States.¹⁴⁵ Specifically, the regulation in Great Britain is actually more similar to that of the United States than any other nation.¹⁴⁶ Nevertheless, the two systems differ in certain areas, such as the focus of pre- and post-market surveillance, the safety and efficacy requirement, and the politics of the regulatory agencies.¹⁴⁷

A. Pre-Market v. Post-Market Surveillance

In Great Britain, the MHRA focuses more on the post-market surveillance stage, whereas the FDA in the United States focuses more on the pre-market evaluation process.¹⁴⁸ The MHRA approval process generally requires much less time than that of the FDA because the MHRA primarily monitors the safety and efficacy of the drug *after* the drug has obtained approval.¹⁴⁹ The FDA, on the other hand, generally requires more time during the approval process because it determines the safety and efficacy of a drug before the approval is granted.¹⁵⁰ As a result, drugs are approved an average of two years sooner in Great Britain than in the United States.¹⁵¹ The FDA attempts to discover any adverse side effects, safety issues, and efficacy issues of a drug during its lengthy and costly clinical trial stage.¹⁵² However, it has been noted that the MHRA's approach of focusing more on the post-market stage more accurately reflects scientific reality: "[W]hile short-term, pre-market tests are well designed to reveal frequent side effects, only long-term experience in a large, widely varied population is likely to yield rare and perhaps more serious reactions, as well as genetic and other long term toxic responses to a drug."¹⁵³

Furthermore, the MHRA requires mandatory reporting of adverse drug reactions, as well as other studies or new information, regarding the newly approved drug.¹⁵⁴ The FDA, on the other hand, lacks the legal

¹⁴⁵ Esber, *supra* note 9, at 137.

¹⁴⁶ Wall, *supra* note 7, at 324.

¹⁴⁷ Esber, *supra* note 9, at 137-38.

¹⁴⁸ Relihan, *supra* note 5, at 246.

¹⁴⁹ *Id.* (emphasis added).

¹⁵⁰ *Id.*

¹⁵¹ Wall, *supra* note 7, at 325.

¹⁵² Relihan, *supra* note 5, at 246.

¹⁵³ Wall, *supra* note 7, at 325.

¹⁵⁴ *Id.*

authority to enforce manufacturers to report such instances.¹⁵⁵ In the United States, the decision of the manufacturer to report an incident regarding a drug is completely subjective, and the FDA can only *recommend* a manufacturer to submit information concerning the new drug.¹⁵⁶ In addition, when an instance of non-reporting by a manufacturer does occur, the FDA rarely seeks assistance from the Department of Justice to take legal action against the manufacturer.¹⁵⁷ In Great Britain, however, the MHRA has the direct legal authority to prosecute manufacturers for failing to report any adverse instances relating to a drug already out in the market.¹⁵⁸

B. Safety and Efficacy Requirements

Another major difference between the regulatory system in Great Britain and the regulatory system in the United States is the emphasis on the safety and efficacy requirements.¹⁵⁹ In the United States, the FDA is responsible for determining that both the safety and efficacy requirements have been met for a new drug.¹⁶⁰ In Great Britain, however, the MHRA is only primarily concerned with the safety requirement.¹⁶¹ The responsibility of determining the therapeutic efficacy of the drug lies in the hands of a separate medical advisory committee.¹⁶² As a result, patients in Great Britain are able to obtain access to new drugs that have not been authorized for human use, as long as a physician prescribes the drug for therapeutic purposes.¹⁶³ The MHRA's focus on safety, rather than efficacy, allows new drugs to enter the market quicker because it does not require the extensive studies of determining the drug's efficacy.¹⁶⁴ Therefore, the system in Great Britain is less expensive, and less time consuming, than the approval system in the United States.¹⁶⁵

C. Politics

One final distinction between the regulatory system of the United States and the regulatory system of Great Britain is the weight of politics within the agencies. As previously discussed, the MHRA and FDA differ

¹⁵⁵ Relihan, *supra* note 5, at 135.

¹⁵⁶ *Id.* (emphasis added).

¹⁵⁷ *Id.*

¹⁵⁸ *Medicines & Medical Devices Regulation*, *supra* note 119, at 13.

¹⁵⁹ Wall, *supra* note 7, at 326.

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ Esber, *supra* note 9, at 138.

¹⁶⁴ Relihan, *supra* note 5, at 248.

¹⁶⁵ *Id.*

in their responsibilities in regards to the safety and efficacy of drugs.¹⁶⁶ The MHRA, by using a separate advisory committee to determine the efficacy of a drug, isolates approval decisions from political, private, and commercial influences.¹⁶⁷ The FDA, on the other hand, is responsible for determining all the requirements of a new drug, without the input or assistance of any outside committee.¹⁶⁸ By using separate medical advisory committees to make such decisions, a manufacturer in Great Britain can feel confident that “the submission of additional, persuasive scientific data will result in an objective, expeditious, and positive evaluation.”¹⁶⁹ The FDA, however, being the sole authority for drug approval, is subject to undue influence by political pressures, which interfere with the fair, scientific evaluation of a new drug.¹⁷⁰ Therefore, the approval process in Great Britain “may justifiably be viewed as scientific, rather than political, because it leaves scientific evaluation of new drug uses to the scientists as opposed to vesting this authority in bureaucrats far less suited to the task.”¹⁷¹

V. ADOPTING ASPECTS OF REGULATION FROM GREAT BRITAIN: A RATIONAL SOLUTION

A. Adopting Facets of Great Britain’s Drug Regulation Process

1. Emphasis on Post-Market Surveillance

One of the major critiques of the current drug approval process of the FDA is the length and cost associated with the process. By focusing primarily on the pre-market surveillance stage, the FDA spends more time and money trying to determine the safety and efficacy of a drug before it enters the market.¹⁷² Instead, the FDA should follow the MHRA and focus primarily on the post-market surveillance stage, rather than the pre-market stage. By doing so, the FDA would eliminate the lengthy and costly clinical trial stage, and the post-market surveillance would depict a more accurate reality of any adverse side effects resulting from the drug.

Furthermore, the MHRA requires mandatory reporting of drug reactions, as well as other studies or new information regarding the newly

¹⁶⁶ *Id.*

¹⁶⁷ Esber, *supra* note 9, at 138.

¹⁶⁸ Wall, *supra* note 7, at 326.

¹⁶⁹ *Id.* at 324.

¹⁷⁰ *Id.*

¹⁷¹ *Id.* at 326.

¹⁷² Relihan, *supra* note 5, at 246.

approved drug.¹⁷³ The FDA should adopt this regulation because as of now, the FDA has no authority to require any drug manufacturer to report any side effects. If the FDA enforced such reporting, it would save time and money by no longer being the only authority surveying any side effects. In addition, the FDA should adopt the policy of the MHRA that allows patients themselves to report any adverse side effects of drugs.¹⁷⁴ By opening up a resource that would allow patients to directly report any side effects, the FDA would get a first-hand look at how patients are reacting, and what side effects are issues are arising. This would also save time by eliminating the need for the patient to wait for their doctor to report the side effect, with the possibility of the doctor forgetting to report, or just simply deciding not to. In addition, allowing patients to report side effects on their own would make them feel more connected to the system, and allow them to have more confidence in the medicines they are taking. Therefore, it seems logical for the FDA to consider adopting these aspects of the MHRA in regards to post-market surveillance.

2. Emphasis on Safety Rather Than Efficacy

Another reason the FDA drug approval process is so lengthy and costly is the requirement of meeting both the safety and efficacy standard of a new drug.¹⁷⁵ The MHRA, however, focuses primarily on the safety of a drug.¹⁷⁶ By focusing primarily on the safety requirement, the MHRA is able to get drugs out on the market quicker, which saves money and lives. For example, patients are able to use a drug that may not be authorized for human use yet, as long as a physician prescribed the drug for therapeutic purposes.¹⁷⁷ By doing so, patients are able to use potentially live saving drugs, regardless of their efficacy for their specific disease, as long as it is therapeutically effective. The FDA should adopt this process because it would speed up the current drug approval lag, and it would allow patients in the United States to obtain quicker access to drugs that may be beneficial on a therapeutic level. Therefore, by focusing primarily on safety rather than efficacy, the FDA would be able to speed up its lengthy approval process, and save money and lives in the meantime.

3. Eliminate Risk of Political Influence

In any governmental agency, political influences can largely impact any decisions or regulations. The MHRA, however, seeks to resolve that

¹⁷³ Wall, *supra* note 7, at 325.

¹⁷⁴ *Medicines & Medical Devices Regulation*, *supra* note 117, at 12.

¹⁷⁵ Wall, *supra* note 7, at 326.

¹⁷⁶ *Id.*

¹⁷⁷ Esber, *supra* note 9, at 138.

issue by using independent medical advisory committees in determining the efficacy of new drugs during the approval process.¹⁷⁸ By doing so, the MHRA is able to focus solely on the scientific analysis of new drugs, rather than make decisions based on political bias. The FDA should work towards adopting this policy in order to minimize the large criticism it faces regarding political influences. Critics assert that the FDA, being the sole authority for drug approval, is easily subject outside political pressures, which may interfere with the fair, scientific evaluation of a new drug.¹⁷⁹ Therefore, in order to make sure that the best and most effective drugs are entered into the market, the FDA should enlist in independent medical advisory committees in order to ensure that consumers in the United States are receiving the best medical care, based purely on a scientific analysis.

B. Automatically Adopting Drugs Already Approved in Great Britain

1. Minimize the Drug Lag

The drug lag associated with the approval process of the FDA can be greatly improved by adopting drugs that are already approved by the MHRA. The drug lag in the United States is concerning because the slower that drugs are approved, the slower they are available to consumers who would greatly benefit from them. The FDA and the MHRA both have a primary requirement of safety in regards to new drugs, so the FDA need not worry about automatically approving drugs that were inherently unsafe. By approving drugs in the United States that have already been approved in Great Britain, the FDA will prosper because it will be able to use that time, which would have otherwise been used for evaluating that same drug, and invest that time into another drug that has not been approved elsewhere. Therefore, the FDA would relieve itself of doing double the work, and would be able to move on to evaluating other drugs quicker.

Furthermore, allowing automatic approval of drugs in Great Britain would prevent another disaster from occurring, like that of the meningitis outbreak in 2013, where the vaccine was approved in Great Britain, but not yet in the United States due to delayed clinical trials.¹⁸⁰ If such a system of automatic approval was in force during the outbreak, it could have prevented the lives lost as a result of the delay in the approval of the vaccine. The clinical trial stage of new drugs is the lengthiest stage in the

¹⁷⁸ *Id.*

¹⁷⁹ Wall, *supra* note 7, at 324.

¹⁸⁰ Miller, *supra* note 95.

approval process, which attributes mostly to the drug lag.¹⁸¹ Therefore, if the FDA can eliminate this lengthy process for drugs that have already been approved in Great Britain, the drug lag would decrease significantly, and many lives would be saved.

In addition, minimizing the drug lag would consequently decrease the costs associated with drug approval in the United States significantly. By adopting approved drugs from Great Britain in the United States, both the FDA and drug manufacturers would save millions of dollars in research and manpower. Instead of spending money conducting clinical trials on a drug that is already widely used in Great Britain, drug manufacturers can use that money towards researching new drugs that are not yet available anywhere else.

2. Eliminate Political Influences

By automatically adopting drugs that have already been approved in Great Britain, the United States can prevent the FDA from being influenced by outside political pressures or biases in the approval process. Unlike the FDA, the drugs that are approved in Great Britain go through a medical advisory committee, independent of the MHRA, to prevent any political influence.¹⁸² A main concern of the FDA in the United States is that there may be political bias as to whether or not a drug should be approved.¹⁸³ If the United States agreed to adopt already approved drugs in Great Britain, however, then the FDA would not be the sole authority as to whether or not a drug is approved. This would allow the drug manufacturers to feel more comfortable when presenting their new drug to the FDA because if the FDA showed any bias, the drug manufacturer could leave to Great Britain, therefore taking business away from the FDA. As a result, having another agency that introduces new drugs into the United States can intimidate the FDA into making sure that a fair, unbiased, and purely scientific analysis is conducted on any new drugs.

In addition, approving drugs in the United States that are already approved in Great Britain would also prevent drug manufacturers from increasing their prices. By adopting drugs already approved in Great Britain, drug manufacturers would be unable to jack up their prices because they would not be the only providers of that drug. As a result, the consumers would not be forced in to overpaying for a drug, just because there is only one manufacturer of that drug in the United States. Therefore, automatic approval would prevent drug manufacturers from benefitting off of their monopolization of their drug.

¹⁸¹ Dickson, *supra* note 100.

¹⁸² Esber, *supra* note 9, at 138.

¹⁸³ *Id.* at 134.

3. FDA's Safety Concerns Are Minimal

The FDA asserts that it keeps up its stringent approval process in order to ensure that the drugs entering the market are both safe and effective. However, the approval process in Great Britain has almost the same requirements as the FDA, with additional safety provisions. Both the FDA and the MHRA focus on the safety and efficacy of new drugs, although the MHRA focuses primarily on the safety requirement. The safety and efficacy of new drugs is the most important factor throughout the approval process, so the fact that both agencies rely on those requirements is what matters the most. It has already been shown that the regulatory system of Great Britain is most similar to that of the United States than any other country. Therefore, there should be little apprehension in choosing to automatically approve drugs in the United States that have already been approved in Great Britain.

Furthermore, implementing international reciprocity for pharmaceuticals can arguably be synonymous to the generic drug approval process here in the United States. By using the approval process used for ANDAs, the FDA can treat drugs that have been approved in other countries as generic drugs, which would bypass the whole new drug analysis. As a result, the drug lag for that specific drug would be reduced significantly, and the costs for approving the new drug would also be substantially lower. This way, the FDA is ensured that the drug is safe and effective for its consumers, and it also bypasses the time and money it takes to approve a brand new drug. As a result, the FDA will still feel like an authoritative figure by having the drug undergo their own FDA process, while ultimately benefitting the consumers and the people who need these drugs in order to survive. Understandably, it can be intimidating for the FDA to automatically approve drugs from foreign nations, therefore simply analyzing the new drugs under the ANDA system can make everyone happy.

VI. CONCLUSION

While it is true that no regulatory system or agency can be truly perfect, there are certainly things that can be done in order to make improvements. The FDA struggles to maintain a proficient approval process for new drugs in the United States. By automatically approving drugs that have already been approved in Great Britain, the United States can minimize some of the criticisms of the FDA, and have the opportunity to save money, time, and most importantly, lives.