NOTES

A TOUGH PILL TO SWALLOW: AN EXAMINATION OF WHY FDA REGULATIONS SHOULD RELAX AND LET TORT LAW CURE LIABILITY

TODD P. KENDRICK*

* Todd P. Kendrick is a third-year law student at Elon University School of Law, expecting to graduate in May 2017. He earned his Bachelor of Arts from Virginia Tech. He would like to thank his parents, Karen and Bob, for their tireless love and support. He would also like to thank Dean Enrique Armijo for his guidance, mentorship, and support, as well as Professor Mike Rich for his intellectual stimulation and curiosity on the topic, which provided a more well-rounded piece. This note is in dedication to Professor Rich's legacy and commitment to his learning and professional advancement.

"Laughter, it's said, is the best medicine."[1] But it is not the patient doing the laughing. Instead the pharmaceutical companies have a hold of the patients' wallets and laugh all the way to the bank.[2] The cost of pharmaceutical drugs is astronomical, with many companies posting record-level profits.[3] "We're starting to see the term 'financial toxicity' being used in the literature. Individual patients are going into bankruptcy trying to deal with these prices."[4] However, this hostility towards high costs is misplaced as the pharmaceutical companies are not the root cause of these excessive costs. Each pharmaceutical company is bound to the strict, heavy-handed guidelines established through the Food and Drug Administration ("FDA").[5] While pharmacological drugs vary in their purpose, the cost of one drug regimen, such as cancer drugs, can be as much as $100,000 per year.[6]

The Food and Drug Administration sets these guidelines as a means of determining exactly what requirements must be met in order for a pharmaceutical company to release their newly invented drug for public distribution.[7] These regulations have been set as a guideline where the:

> FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice (CGMP) regulations. The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have.[8]

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[1] Hara Estroff Marano, *Laughter: The Best Medicine*, PSYCHOL. TODAY (Apr. 5, 2009), https://www.psychologytoday.com/articles/200504/laughter-the-best-medicine.

[2] Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC NEWS (Nov. 6, 2014), http://www.bbc.com/news/business-28212223.

[3] Lesley Stahl, *The Cost of Cancer Drugs*, CBS NEWS (June 21, 2015), http://www.cbsnews.com/news/cost-of-cancer-drugs-60-minutes-lesley-stahl-health-care/.

[4] *Id.*

[5] *See Development and Approval Process (Drugs)*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ (last updated Jan. 29, 2016); *Drug Applications and Current Good Manufacturing Practice (CGMP) Regulations*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm 090016.htm (last updated Dec. 17, 2014).

[6] Stahl, *supra* note 3.

[7] *See Development and Approval Process (Drugs)*, *supra* note 5.

[8] *Drug Applications and Current Good Manufacturing Practice (CGMP) Regulations*, *supra* note 5 (describing the intent behind the CGMP).

The requirement of CGMPs is the FDA's way to ensure that each and every pharmaceutical company uniformly, and cohesively, abides by the understanding of the minimum necessities for drug invention, manufacturing, and eventual distribution.[9] These requirements, however, are a contributing factor to the excessive costs related to an individual's purchase of the distributed drugs.

THE FOOD AND DRUG ADMINISTRATION: A HISTORICAL OVERVIEW

Founded, and signed into law, by President Theodore Roosevelt in June 1906, the beginnings of the FDA were established to protect the people.[10] President Roosevelt's main focus was the protection of the people of the United States; this is what he used as he sought to bring this law to life.[11] "The law sought to protect the consumer from being deceived or harmed, mainly by following a favorite assumption that the average man was prudent enough to plot his own course and would avoid risks if labeling made him aware of them."[12] This protection was of the utmost importance to President Roosevelt based upon a history of death and further illness concerning people suffering from unknown, or masked, side-effects of vaccines or cures that were intended to alleviate or heal them of their ailments.[13]

President Roosevelt's push for the passing of these protections was also furthered, and pushed to its breaking point, by the concepts and notions derived from Upton Sinclair's influential novel, "The Jungle."[14] Upton Sinclair's book vilified the meat-packing industry and the sanitation of food to be consumed, illustrating to readers and the people why regulations were necessary for the safety and inspection of meat.[15]

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[9] *Id.*

[10] James Harvey Young, *The Long Struggle for the Law*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/History/CentennialofFDA/TheLongStruggleforthe Law/ (last updated May 19, 2009).

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *Id. See generally* UPTON SINCLAIR, THE JUNGLE (1906) (describing the conditions of meat of meat packing industries in industrialized cities in the United States).

[15] *See* SINCLAIR, *supra* note 14 (describing the conditions of meat packing industries in industrialized cities in the United States).

Between the popular literature and the political push by a popular president, passage of federal regulation seemed like a no-brainer.[16]

Getting its basis from the 1906 Pure Food and Drugs Act,[17] the FDA is a government agency, a component of the Department of Health and Human Services, whose intended purpose is to ensure uniformity in the protection of public health "assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation."[18] President Roosevelt appointed Dr. Harvey Washington Wiley as the first commissioner of the FDA.[19] Dr. Wiley was a leading member of the Bureau of Chemistry, who, along with President Roosevelt sought to ensure the safety of the general public.[20] Today, the FDA is also responsible for the task of delivering and advancing public health by streamlining "innovations that make medicines more effective, safer, and more affordable . . . ."[21] When the FDA follows this directive, their regulatory scheme creates a system, which creates excessively high costs for the individual consumer that are not as affordable as the FDA intended.

While the FDA did not have much strength over pharmaceutical innovation, it did place a regulation upon the labeling of distributable drugs and the clinical trials processes as a whole.[22] This Act laid out the understanding that product labeling was a key interest in the safety of the people because it:

> [P]rohibited "false and misleading" statements on product labels. In the case of drugs, the law listed eleven so-called "dangerous ingredients" including opium (and its derivatives) and alcohol which, if they were present in the

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[16] *See generally What We Do*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/ (last updated Dec. 7, 2015); Louisa Schmidt, Federal Food and Drug Legislation: 1906-1938 (June 1946) (unpublished M.A. thesis, Loyola Univ.) (on file with the Loyola eCommons, Loyola University Chicago) (describing the history and influence behind the passage of the federal regulation).

[17] Act of June 30, 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906) (codified as amended at 21 U.S.C. §§ 1–2 (2012)).

[18] *What We Do*, supra note 16.

[19] *See id.*

[20] *Harvey W. Wiley*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/aboutfda/whatwedo/history/centennialoffda/harveyw.wiley/default.htm (last updated July 28, 2016).

[21] *What We Do*, supra note 16.

[22] Susan White Junod, *FDA and Clinical Drug Trials: A Short History*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm304485.htm (last updated Apr. 11, 2016).

> product, had to be listed on the drug label. This listing requirement alone inspired many manufacturers to abandon use of many dangerous ingredients following passage of the 1906 Act.[23]

This interest in the protection of the people, regarding the labeling of products, began to set the tone for FDA regulations surrounding clinical trials.[24] Although "dangerous ingredients" used in drugs had to be disclosed on the label,[25] the Supreme Court found in *United States v. Johnson*,[26] the newly-formed FDA did not have regulatory powers over therapeutic falsities, only false and misleading statements to the identity and ingredients of the drug.[27] Therapeutic falsities speak more to the effect of the drug and how the drug interacts with the illness and the symptoms. For example, a therapeutic falsity is that marijuana cures cancer; marijuana alleviates some of the pain but does nothing for the actual disease.[28] This lack of regulatory influence, the FDA being denied regulatory powers over advertisements of the ingredients versus effect of drugs, was the first known chink in the armor of the infantile FDA.[29]

The Court in *Johnson* found that a label stating "Dr. Johnson's Cure for Cancer," was not within the meaning of the Act because it claimed to be effective in the curing of cancer.[30] The Court held "we are of opinion that the phrase is aimed not at all possible false statements, but only at such as determine the identity of the article, possible including its strength, quality, and purity, dealt within . . . ."[31] This interpretation, that the FDA did not have regulatory influence over falsified therapeutic claims, was detrimental to the strength the FDA hoped to exercise against pharmaceuticals and clinical trials.[32] However, in dissent, Justice Hughes proffered the notion that permitting false

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[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] 221 U.S. 488 (1911).

[27] *Id.* at 497–98.

[28] Franjo Grotenhermen & Kirsten Müller-Vahl, *The Therapeutic Potential of Cannabis and Cannabinoids*, DEUTSCHES ÄRZTEBLATT INT'L (Jul. 23, 2012), http://www.medicinalgenomics.com/wp-content/uploads/2011/12/therapeutic_potential.pdf.

[29] *See* Junod, *supra* note 22.

[30] *Johnson*, 221 U.S. at 497.

[31] *Id.*

[32] Junod, *supra* note 22.

claims of therapeutic relief was unjust.[33] Justice Hughes focused on the labeling of the drug in question as it moved through interstate commerce.[34] He believed the FDA had the authority to regulate and control the labeling of drugs due to the "curative properties of articles purveyed as medicinal preparations are matters of opinion, and the contrariety of views among medical practitioners, and the conflict between the schools of medicine."[35] Justice Hughes furthered this idea with, "allowing the broadest range to the conflict of medical views . . . are downright falsehoods . . . . This field I believe this statute covers."[36]

Congress promptly took note of this issue and enacted the Sherley Amendment to the Pure Food and Drugs Act.[37] This amendment was a compromise amongst politicians and the medical field, and the statute simply prohibited false therapeutic claims that were "intended to defraud" the consumer.[38] An example of the exercise of this newly amended protection was displayed by the FDA's attempt to seize a product known as Banbar, which was derived from horsetail weed.[39] Banbar was advertised as a cure against Diabetes, which was taken orally, as opposed to insulin injections.[40] Patients chose to use Banbar instead of their insulin injections, against doctors' orders, and offered hundreds of testimonial letters in defense supporting its effectiveness—even though the claim of being a cure was false.[41] Banbar won the dispute, which FDA Chief Walter Campbell vehemently disagreed with and advocated for change.[42] Campbell relayed his displeasure to Congress as they were deliberating a replacement to the 1906 law and stated, "what we are seeking to do here is put the courts on notice . . . that it is the purpose of Congress to have consideration given therapeutic claims."[43]

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[33] *See Johnson*, 221 U.S. at 499 (Hughes, J., dissenting).

[34] *See id.* at 499–505.

[35] *Id.* at 504.

[36] *Id.*

[37] Junod, *supra* note 22.

[38] *Id.*

[39] John P. Swann, *Sure Cure: Public Policy on Drug Efficacy Before 1962*, *in* THE INSIDE STORY OF MEDICINES: A SYMPOSIUM 232 (Gregory J. Higby & Elaine C. Stroud, 1997).

[40] *Id.*

[41] *Id.*

[42] *Id.*

[43] *Id.*

Another falsified therapeutic claim that Congress sought to dispel was from 1937.[44] In this dispute, a drug company developed sulfanilamide, dubbed the first "wonder drug," which was intended to fight streptococcal infections (i.e. strep throat).[45] This drug was released without having been tested on animals or humans prior to its distribution.[46] The drug contained diethylene glycol—a poison similar to anti-freeze—that caused the FDA to send all officers into the field to corral and recover any available bottles and remove the product from public consumption.[47] The FDA was galvanized to act against this product due to its misbranding that it was an "elixir," which implied alcohol content, although none was present.[48] Simply, instead of alcohol, the drug contained a poison. The FDA had to eradicate the drug because the company misled the public by advertising the drug as a cure, with the use of alcohol as the ingredient, instead of poison as the main ingredient.

Congressional concerns with the dangers that pharmaceutical companies proffered under the 1906 Act were addressed and answered with the passing of the Food, Drug, and Cosmetics Act of 1938.[49] This Act required pharmaceutical companies to deliver their safety research and data to the FDA for approval prior to advertising and marketing their innovations.[50] This addition to the new law was added without much discussion and was simply inserted into the text of the statute to be applied against the pharmaceutical companies.[51] This was one of the first times Congress, and the FDA, exercised a heightened level of authority over the pharmaceutical industry.[52]

Safety was a major concern during the passage of this new Act.[53] However, particular methods of testing were not established.[54] Instead, the Act mandated that any and all drugs developed and manufactured were supported with "adequate tests by all methods reasonably

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[44] Junod, *supra* note 22.
[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] *Id.*
[49] 21 U.S.C. § 301 (2012).
[50] Junod, *supra* note 22.
[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *Id.*

applicable to show whether or not the drug is safe."[55] "Reasonable" methods to show the safety of a drug could vary amongst the developing company, but the FDA took the authority to determine what, in their eyes, was sufficiently reasonable.[56] Although there was a level of protection for the people, there was not yet the developed "approval" stamp that exists today.[57] Instead, there was the presumptive belief that if a new drug made its way into marketing and advertising, the FDA had tacitly "approved" the drug.[58] The Act, however, did require the company developing a new drug to disclose every component that was used in its manufacture.[59] Pharmaceutical companies developing a new drug had to disclose this information, and then over the course of sixty days if there was no regulatory response by the FDA it became assumed that they could go ahead and manufacture the drug.[60]

Studies of the newly innovated drug did not require animal testing prior to human trials, but animal autopsies and information from individual companies were only prepared subject to request by the FDA in order for the FDA to ensure the safety of the drug in its review.[61] The minor imposition of animal testing as a precursor to human trials was not something that was detrimental to the pharmaceutical companies' outlook, however, as its effectiveness began to be seen, mandated trials on various animals slowly became more and more prevalent.[62] Topical drugs (placed on the skin) were directed to be tested on pigs, while respiratory drugs were tested on dogs—animal functions that most closely resembled humans.[63]

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[55] *Id.*; 21 U.S.C. § 301 (2012, Supp. 2013, & Supp. 2014).

[56] Junod, *supra* note 22.

[57] *Id.*

[58] PRINCIPLES OF PHARMACOLOGY: BASIC CONCEPTS & CLINICAL APPLICATIONS 1643–44 (Paul L. Munson et al. eds., rev. reprt. 1996).

[59] *Id.*

[60] Junod, *supra* note 22.

[61] *See, e.g.*, Suzanne Junod & Lara Marks, *Women's Trials: The Approval of the First Oral Contraceptive Pill in the United States and Great Britain*, 57 J. HIST. OF MED. & ALLIED SCI. 117, 125 (2002).

[62] *See*, *e.g.*, Junod, *supra* note 22.

[63] *See* Artur Summerfield et al., *The Immunology of the Porcine Skin and Its Value as a Model for Human Skin*, 66 MOLECULAR IMMUNOLOGY 14 (2015) (reviewing the immune cells in the pig skin and proposing a classification corresponding to human skin); *Kingfisher Biotech Circular Subject: Canine as an Animal Model*, KINGFISHER BIOTECH, http://www.kingfisherbiotech.com/newsletter/Canine_Animal_Model_Newsletter.pdf (last visited Feb. 7, 2017).

The FDA did not require animal testing or such strict standardized regulation for drug development at the outset of the 1938 Act.[64] However, their influence began to reach a breaking point. The FDA quickly realized that these levels of testing mirrored human elements and possible side-effects, because the FDA was increasingly cognizant of the side effects.[65] This breaking point was met with an exercise of FDA authority with an article published in the Journal of the American Medical Association ("JAMA") in 1944 that articulated the necessity of standardized testing and proper methods of clinical trials and data analysis.[66]

Congress took this into consideration, and yet again, amended the Food, Drugs, and Cosmetics Act in 1962.[67] This enhanced the recognition of protecting the people from unwanted effects of drugs being marketed and distributed.[68] The new amendment to the Act altered the definition of "new drug" to one that is a "drug not generally recognized among experts as effective as well as safe for its intended use."[69] The amendment allowed the FDA to directly refuse approval of a new drug application ("NDA") and not permit its market, or withdraw its market, if it is found that the intended purpose or effect is lacking.[70]

In 1973 the Court decided *Weinberger v. Hynson, Wescott and Dunning, Inc.*[71] This case was brought by a pharmaceutical company that had drugs already in market, but the FDA stripped and withdrew the drugs due to the newly established amendments.[72] Here, the respondents argued that their preexisting drugs were exempt from this new statutory construction and that they were covered by the blanket protections of the NDA.[73] The Court determined that the new amendment gave authority of the FDA to conduct their review of preexisting drugs and withdraw

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[64] Junod, *supra* note 22.

[65] *See* Walton Van Winkle, Robert P. Herwick, Herbert O. Calvery & Austin Smith, *Laboratory and Clinical Appraisal of New Drugs*, 126 J. AM. MED. ASS'N 958, 959 (1944).

[66] *See id.*

[67] 21 U.S.C. § 321 (2012, Supp. 2013 & Supp. 2014).

[68] Junod, *supra* note 22.

[69] § 321(p)(1).

[70] § 355(d).

[71] 412 U.S. 609 (1973).

[72] *See generally id.*

[73] *Id.* at 632.

them from market should there be "substantial evidence" that the intended effect is lacking.[74] Justice Douglas, writing for the Court stated:

> It is clear to us that FDA has power to determine whether particular drugs require an approved NDA in order to be sold to the public. FDA is indeed the administrative agency selected by Congress to administer the Act, and it cannot administer the Act intelligently and rationally unless it has authority to determine what drugs are 'new drugs' under § 201 (p) and whether they are exempt from the efficacy requirements of the 1962 amendments.[75]

Research began to change as these new impositions upon the pharmaceutical companies took hold, providing strong evidentiary support for their new drug's effectiveness took hold.[76] The institution of the double-blinded study as a means to eliminate physician bias helped alleviate FDA concerns over fabricated documentation as a means to push a drug through.[77] In essence, the double-blinded study made sure that the patient did not know what dosage, if any, of a drug they were taking, while also ensuring the physician was not aware of the same fact.[78] Eliminating any potential bias was tantamount to an "approval." "Randomized double blind placebo control (RDBPC) studies are considered the 'gold standard' of epidemiologic studies."[79] This concept slowly began to infiltrate as a necessary study required by the FDA.

Post World War II studies in Britain, testing the validity of Streptomycin as a cure for Tuberculosis, conducted by Sir Austin Bradford Hill, established the general concept of the randomized double-blinded study.[80] Hill's rationale for a random study was derived from physician bias and the need to deter such action in order to find the best available treatment.[81] He strived to enact a method that would "ensure the avoidance of bias in the selection of subjects for treatment but also to provide an optimal estimate of the likelihood that the differences

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[74] *Id*. at 631–33.

[75] *Id*. at 624.

[76] Shobha Misra, *Randomized Double Blind Placebo Control Studies, the "Gold Standard" in Intervention Based Studies*, 33 INDIAN J. SEXUALLY TRANSMITTED DISEASES & AIDS 131, 131 (2012).

[77] *Id.*

[78] *Id.*

[79] *Id.*

[80] Junod, *supra* note 22.

[81] Richard Doll, *Sir Austin Bradford Hill and the Progress of Medical Science*, 305 BMJ 1521, 1524 (1992).

observed between the treatment groups could have arisen by chance if the treatments were in reality equally effective or ineffective."[82]

The FDA took note of the methods used by Hill and began to implement his idea in American pharmacological studies.[83] The extensive research requirements became a financial swoon for the industry and, in 1953, the National Institutes of Health (NIH) opened its Clinical Center in Bethesda, Maryland.[84] Research spending increased dramatically over a short period of time, which the FDA has used as a basis for their requirements.[85] In 1950 funding for medical research was $161 million dollars, but by 1968 that number had grown to $2.5 billion dollars.[86]

Taking note, and advantage, of the extraordinary increase in funding, pharmaceutical companies began to conduct much more thorough research, which increased the length of time it took for a drug to reach the market.[87] The increase in funding led Senator Estes Kefauver to call for hearings regarding the nature of such studies.[88] After evidence was obtained illustrating the high cost and extravagant profits for private companies, Senator Kefauver targeted his questions during hearings on the product and profitability of the pharmaceutical industry.[89] Further governmental inquiries were made when the pharmaceutical industry tried to defend itself against the stricter research guidelines and clinical trial requirements.[90] Dr. Louis Lasagna commented on these concerns by the industry and challenged their notions.[91] Dr. Lasagna was "shock[ed] that experimental drugs are subject to no FDA regulation of any sort before patients receive them" and that it is "reprehensible for man to be the first experimental animal

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[82] *Id.*

[83] Junod, *supra* note 22.

[84] *See List of NIH Institutes, Centers, and Offices*, NAT'L INST. HEALTH, https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices (last updated May 11, 2016).

[85] *See generally* William J. Curran, *Government Regulation of the Use of Human Subjects in Medical Research: The Approach of Two Federal Agencies*, 98 DAEDALUS 542 (1969) (discussing the financial growth of spending within the medical field).

[86] *See generally id*. at 542.

[87] *See generally id*. at 554.

[88] *Id.* at 549.

[89] Junod, *supra* note 22.

[90] *Id.*

[91] *Id.*

on which toxicity tests are done, simply because . . . [it] saves time and money."[92]

The 1962 amendments offered a more stringent level of control for the FDA in the regulation and introduction of new drug innovations into the market.[93] These changes were an expression of the FDA's confidence in their growing authority to control the pharmaceutical industry—even more than they displayed under the 1938 amendments.[94] The newly amended regulations prohibited testing a drug on humans unless a preclinical study could foresee that the drug could be given to people safely.[95] The delay of getting into human trials furthered the expenses required of the pharmaceutical company.[96] Using these amendments, the FDA unveiled a new procedure that the pharmaceutical industry was supposed to follow.[97] Investigational new drug (IND) applications were created and administered, which required a pharmaceutical company to submit a "[n]otice of claimed investigational exemption for a new drug."[98] An approved IND allows for the advancement of drug trials for drugs in development.[99] However, the denial of an IND can impose numerous setbacks, both financially and research oriented.[100] After an approved IND, the pharmaceutical company may then take that information and insert it into the NDA forms.[101] These regulations led the FDA to a clearer definition of "phase" process regulations.[102]

Congress added to FDA authority by removing the sixty day approval window found in the 1938 Act.[103] In place of the approval

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[92] *Id.*

[93] *See id.*

[94] *See id.*

[95] *See id.*

[96] *See id.*

[97] *See generally id.*

[98] Investigational Drugs; Procedure Regarding Biological Products, 28 Fed. Reg. 5048 (May 20, 1963).

[99] Junod, *supra* note 22.

[100] *The Price of Failure: A Startling New Cost Estimate for New Medicines is Met with Scepticism*, THE ECONOMIST (Nov. 27, 2014), http://www.economist.com/news/business/21635005-startling-new-cost-estimate-new-medicines-met-scepticism-price-failure.

[101] 21 U.S.C. § 355(d) (2012).

[102] *See* Investigational Drugs; Procedure Regarding Biological Products, 28 Fed. Reg. at 179.

[103] *See* § 321.

window, Congress instituted a requirement of articulable positive effects along with a detailed approval by the FDA in order for a drug to go to market.[104] The FDA was also granted the authority to set standards for each and every stage of drug testing.[105] Additionally, the FDA was now permitted to require market withdrawal and the establishment of "Good Manufacturing Practices (GMPs')" to oversee drug manufacturing.[106]

Over the years since the 1962 amendments were applied, the FDA has slowly been increasing their authority over the processes a pharmaceutical company must overcome in order to submit their innovation to the public for purchase, use, and distribution.[107] Rigorous testing is required just to move from one phase to the next.[108]

The FDA's authority to withdraw drugs from the market was challenged in *CIBA Corp. v. Weinberger*.[109] In this case, the petitioners argued that the FDA overstepped its bounds by pulling their drug because of a lack of substantial evidence to the efficacy of the drug.[110] The Court held the FDA acted within its scope and stated the FDA has "jurisdiction in an administrative proceeding to determine whether a drug product is a 'new drug' . . . . A decision that FDA lacks authority to determine in its own proceedings . . . would seriously impair FDA's ability to discharge the responsibilities placed on it by Congress."[111]

The FDA gained another vote of confidence adding to its authority with *Riegel v. Medtronic, Inc.*[112] Here, Justice Scalia reaffirmed the FDA's authority to establish itself as federal regulator and that any state law tort liability claims were preempted.[113] Justice Scalia reasoned that "the solicitude for those injured in FDA-approved devices . . . was overcome in Congress's estimation by solicitude for those who

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[104] *Id.*

[105] *Id.*

[106] *See*, *e.g.*, § 351 (discussing GMPs being implemented for the manufacture and control of ingredients used for adulterated drugs/devices).

[107] *See Phases of Clinical Trials*, CANCER.NET, http://www.cancer.net/navigating-cancer-care/how-cancer-treated/clinical-trials/phases-clinical-trials (last updated Dec. 2015); *see also Overview of Clinical Trials*, CENTERWATCH, http://www.centerwatch.com/clinical-trials /overview.aspx (last visited May 11, 2016).

[108] *Overview of Clinical Trials*, *supra* note 107.

[109] 412 U.S. 640 (1973).

[110] *See id.*

[111] *Id.* at 643.

[112] 552 U.S. 312 (2008).

[113] *Id.* at 330.

would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovation."[114]

"PHARMACEUTICAL GREED" AND THE HIGH PRICED COST OF DRUGS

"Pharmaceutical greed" is a concept many people are aware of and believe it to be true.[115] The idea that a company would jack up their prices for an extra buck is prevalent throughout the media and society alike.[116] The high costs of drugs weigh heavily on those who need them for their potentially life-saving purposes.[117] However, this "greed" cannot simply be placed onto the entire pharmaceutical industry, just as it cannot be placed solely upon the individual companies. While the effects of high costs are felt by the people, these costs are being essentially forced upon the company trying to market their product.[118] These "costs" are based off of the expenses incurred to just simply send a drug to market—not even ensured to recoup those expenses.[119]

The FDA plays a significant role in this matter.[120] The extensive research and development the FDA requires each company to undertake, just simply to gain approval for *testing* of a drug comes with its burdens.[121] This notion was the crux of the defense pharmaceutical companies employed during the Kefauver hearings in the 1960s.[122] Years after those hearings, FDA Chief Counsel William Goodrich noted, but decried, the pleas of the pharmaceutical industry regarding the astronomical costs of research and development for newly discovered drug formulations.[123]

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[114] *Id.* at 326.

[115] *See*, *e.g.*, Martin L. Hirsch, *Side Effects of Corporate Greed: Pharmaceutical Companies Need a Dose of Corporate Social Responsibility*, 9 MINN. J. L., SCI. & TECH. 607 (discussing the trend of pharmaceutical companies valuing profit over public health).

[116] *See*, *e.g.*, *id.*; Melody Petersen, *How 4 Drug Companies Rapidly Raised Prices on Life-Saving Drugs*, L.A. TIMES (Dec. 21, 2016, 3:35 PM), http://www.latimes.com/business/la-fi-senate-drug-price-study-20161221-story.html.

[117] *See id.*

[118] *See Phases of Clinical Trials*, *supra* note 107.

[119] *Id.*

[120] Junod, *supra* note 22.

[121] *Id.*

[122] *Id.*

[123] *Id.*

> That just focused attention on these various phases of new drug development and promotion . . . first of all, was it really all that expensive? Were they really doing all that kind of research? And anyone who had looked at any of the New Drug Applications knew, as I knew, that that was all baloney, and what they were saying to us in those early days was essentially a bunch of testimonials. The way drugs were investigated—a physician from the company would go out in the community with some samples and say to the doctor, "I've got this new drug for so-and-so. Here's some samples. Try it out and let us know how you like it." And they would get back a letter from him: "I tried it out on eight patients and they all got along fine." That's the kind of stuff that was coming in for the science. Of course, that was completely unsatisfactory, and as soon as people focused on that, that raised the problem.[124]

The excessive requirements of the FDA lend credence to the pharmaceutical industries' claims, however.[125] The cost of research and development for one potential innovative drug is astronomical.[126] "For companies that have launched more than three drugs, the median cost per new drug is $4.2 billion; for those that have launched more than four, it is $5.3 billion."[127] The sheer cost of research and development has the potential to cripple a company if they get far enough along in the process only to have the FDA deny their application.

While "pharmaceutical greed" is a strong phrase to levy upon a business, there are some that may not be as innocent. Martin Shkreli, Chief Executive Officer of Turing Pharmaceuticals was a headliner in the news for many weeks in late 2015.[128] Shkreli and his company purchased a decades-old AIDS drug (Daraprim) that typically sold for $13.50 per pill, but overnight the price skyrocketed to $750 per pill.[129] Although he raised the price dramatically, Shkreli has said that "while Turing did not develop Daraprim, it will use the money from the price increase to develop new drugs for serious diseases."[130] Shkreli, like all

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[124] *Id.*

[125] Matthew Herper, *How Much Does Pharmaceutical Innovation Cost? A Look At 100 Companies*, FORBES (Aug. 11, 2013, 11:10AM), http://www.forbes.com/sites/matthewherper/2013/08/11/the-cost-of-inventing-a-new-drug-98-companies-ranked/#4480838b1628.

[126] *Id.*

[127] *Id.*

[128] Heather Long & Matt Egan, *Meet the Guy Behind the $750 AIDS Drug*, CNN MONEY (Sep. 22, 2015, 7:50 PM), http://money.cnn.com/2015/09/22/investing/aids-drug-martin-shkreli-750-cancer-drug/.

[129] *Id.*

[130] Andrew Pollack, *Martin Shkreli's Arrest Gives Drug Makers Cover*, N.Y. TIMES (Dec. 17, 2015), https://www.nytimes.com/2015/12/18/business/martin-shkreli-arrest-gives-drug-makers-cover.html?_r=0.

from the pharmaceutical industry, referred to the high costs and expenses that manufacturers must contend with, regarding the requirements associated with research and development, to defend his high cost for the drug.[131] This price gouge is but one example of available drugs receiving a makeover of their sticker price.[132]

Another example of the so-called "pharmaceutical greed" was met in 2008 when Congress held hearings "focusing for instance on Ovation Pharmaceuticals, which acquired a drug to treat a breathing problem in newborns and raised the price to $1,500 per unit from about $100."[133] In that instance, the argument was similar to Shkreli's and surrounded high research and development costs.[134] This defense has been common throughout the industry, where it refers to the high cost of developing drugs "as a reason that high prices are justified."[135]

PRODUCTS LIABILITY CLAIMS IN PHARMACEUTICALS

In its most basic concepts, "product liability" is the liability a seller of a product faces due to a defect in the product's design or manufacture, or damage to its consumer in another capacity.[136] Pharmaceutical companies are no stranger to lawsuits surrounding their products.[137] "In a drug products liability case, all the difficulties of power, 'tort reform,' evasiveness, and preparation are wrapped up in one large package ready to pounce on you as soon as the lid is opened."[138]

Pharmaceutical companies may be held liable under the concept of products liability in a variety of ways, including either strict liability or negligence, depending on jurisdiction.[139] Strict liability comes about when a seller of a product is liable, even without fault, caused by their product if it is sold in a defective condition unreasonably dangerous to its

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[131] *Id.*

[132] *Id.*

[133] *Id.*

[134] *Id.*

[135] *Id.*

[136] Han W. Choi & Jae Hong Lee, *Pharmaceutical Product Liability*, *in* PRINCIPLES AND PRACTICE OF PHARMACEUTICAL MEDICINE 688, 688 (Lionel D. Edwards et al. eds., 3d ed. 2011) (for text of chapter visit http://media.mofo.com/files/Uploads/Images/101200-ch55.pdf).

[137] *See id.*

[138] Linda Turley et al., *Products Liability: Tips and Tactics*, TRIAL (Nov. 1, 1997).

[139] Choi & Lee, *supra* note 136, at 688–90.

user.[140] Against a pharmaceutical company, this would yield a likelihood of damages payouts regardless of the extensive research conducted to support the pharmaceutical company.[141] Redress is available to the pharmaceutical company, however, so long as they can show no less alternative means for the effectiveness of the drug, as well as the presentation of an expert in the field capable of articulating that the defect was not present at the time of manufacture.[142] Essentially, pharmaceutical companies are liable unless they can show that there was no other reasonable method to obtain the effectiveness of the drug (i.e., chemotherapy is a poison that affects that entire body—killing both good cells and bad cells—but it is the most reasonable drug for the disease and no other drug has similar effect to kill the growth of the cells).[143]

Negligence cases of products liability, simply put, arise when there is a breach of duty of care owed to a plaintiff.[144] In this instance, a defendant may be culpable for acts of misfeasance or nonfeasance.[145] So long as a plaintiff can show that the actions or omissions of the pharmaceutical company contain a causal connection between the negligence and the damages incurred, the plaintiff may be compensated.[146]

Possible claims against a pharmaceutical company, under a theory of products liability, can range from manufacturing defect (individual dosage has a problem at time of its manufacture), design defect (the entire lot produced has an issue), or failure to warn (labeling issues).[147] Each of these forms of liability can be employed against a manufacturer throughout the life-cycle of the drug produced.[148] This effectively puts the pharmaceutical company on a lifetime of notice to follow precise protocols and practices.

The New York Court of Appeals in *Enright v. Eli Lilly & Co.*, acknowledged the dangers of exposing a pharmaceutical company to tort

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[140] *Id.* at 689.
[141] *Id.*
[142] *Id.*
[143] *Id.*
[144] *Id.* at 690.
[145] *Id.*
[146] *Id.*
[147] *Id.*
[148] *Id.* at 689.

liability.[149] The court held that an infant had deformities, because her mother had cerebral palsy that was caused by the infant's grandmother's use of Diethylstilbestrol during pregnancy, which was not something for which Eli Lilly could be held liable.[150] Instead, the court expressed the need to limit manufacturer tort liability and opined a case could only be brought by the patients who ingested the drug or were exposed *in utero*.[151]

Another instance of product liability in pharmaceutical cases comes from Bayer's drug, Baycol—which received FDA approval in 1997.[152] Baycol, a cholesterol drug, began causing rhabdomyolysis, a muscle disorder, which prompted Bayer to pull the drug from the markets in 2001.[153] Since Baycol's withdrawal, Bayer has been subjected to more than 9,000 lawsuits.[154] These cases were consolidated and resulted in nearly 3,200 settlements amassing $1,168,233,835.[155] The settlements of these cases, and pharmaceutical company's moral consciousness,[156] present a strong notion that product liability is an avenue for plaintiff redress capable of ensuring the FDA's desired goal of public safety.

A third example of product liability in the pharmaceutical world comes from Merck's Vioxx (a pain killer), which gained FDA approval in 1999.[157] After five years in the world-wide market, on September 30, 2004, Merck announced it was voluntarily withdrawing the drug due to concerns of patients being two-times as likely to suffer a heart attack as those on placebos.[158] Vioxx had experienced $2.5 billion in sales each

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[149] 570 N.E.2d 198, 200 (N.Y. 1991).

[150] *Id.*; Choi & Lee, *supra* note 136, at 695.

[151] *See generally* Choi & Lee, *supra* note 136 (outlining scenarios when a claim could be brought).

[152] *Id.* at 696.

[153] Steve Sternberg, *Bayer Pulls Cholesterol Drug Linked To Deaths*, USA TODAY (Aug. 8, 2011), http://usatoday30.usatoday.com/news/health/2001-08-08-statin-drug.htm.

[154] Choi & Lee, *supra* note 136, at 696.

[155] *Id.*

[156] Here, the moral consciousness is two-fold. Taking the drugs with negative effects off the market to prevent further damage causes pharmaceutical companies to admit to creating the bad drug, and thereby, subjects themselves to likely liability and expense.

[157] Choi & Lee, *supra* note 136, at 697.

[158] Barbara Martinez et al., *Merck Pulls Vioxx From Market After Link To Heart Problems*, WALL ST. J. (Oct. 1, 2004, 12:01 AM), http://www.wsj.com/articles/SB109654671320932405.

year,[159] but was subjected to more than 10,000 lawsuits resulting in settlements totaling $4.85 billion.[160] In January 2016, Merck agreed to pay an additional $830 million, bringing its total culpability for Vioxx to an excess of $6 billion.[161]

PRODUCTS LIABILITY LAWSUITS SHOULD BE THE REGULATORY CHECK ON PHARMACEUTICAL COMPANIES RATHER THAN THE INCREASING FDA OVERSIGHT IN ORDER TO DECREASE THE COST OF DRUGS.

The FDA regulations placed upon the pharmaceutical companies, just so they may obtain the opportunity to have their product approved for advancement in the clinical trials phase places irreparable harm upon the business of pharmaceutical manufacturing. Without the costs associated with the purchase of a drug, the developing company faces a near-impossible uphill battle to profitability.

FDA authority is designed to protect the consumer from dangerous toxins that may be present in a drug, whether prescribed or over-the-counter.[162] However, their overreach pits the individual consumer against health and wealth. The only means of marketing their innovation and serving the purpose of a business—making a profit—is for the pharmaceutical company to sell their drug at a high cost to the individual user.[163]

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[159] Barbara Martinez et al., *Merck's Earnings are Hurt by Vioxx*, WALL ST. J. (Oct. 22, 2004, 12:01 AM), https://www.wsj.com/articles/SB109812872915948303.

[160] Heather Won Tesoriero, Sarah Rubenstein & Jamie Heller, *Merck's Tactics Largely Vindicated as It Reaches Big Vioxx Settlement*, WALL ST. J. (Nov. 10, 2007, 12:01 AM), http://www.wsj.com/articles/SB119461288943387907.

[161] Peter Loftus, *Merck To Pay $830 Million To Settle Vioxx Shareholder Suit*, WALL ST. J. (Jan. 15, 2016, 8:31 PM), http://www.wsj.com/articles/merck-to-pay-830-million-to-settle-vioxx-shareholder-suit-1452866882.

[162] *What Does the FDA Regulate?*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/About FDA/Transparency/Basics/ucm194879.htm (last updated January 17, 2017).

[163] *See* Matthew Herper, *The Cost of Creating a New Drug Now $5 Billion, Pushing Big Pharma to Change*, FORBES (Oct. 11, 2013, 11:10 AM), http://www.forbes.com/sites /matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/#5404d09f6bfc ("A company hoping to get a single drug to market can expect to have spent $350 million before the medicine is available for sale. In part because so many drugs fail, large pharmaceutical companies that are working on dozens of drug projects at once spend $5 billion per new medicine.").

It is the position of this Note that the FDA regulations placed upon the pharmaceutical industry at the outset of research and development place an insurmountable burden on the pharmaceutical companies to charge the very people they work diligently to help an excessive amount of money. More FDA regulation on the front-end of the business requires the pharmaceutical companies to raise their prices in order to cover the costs of not only research and development, but any lawsuit further down the road in the drugs' existence. By limiting FDA regulation and empowering courts and juries to decide an issue of culpability through products liability, prices of drugs will come down, making them more affordable for the very people they are intended to help.

ARGUMENT AGAINST PRODUCTS LIABILITY AS A SOLUTION TO FDA REGULATIONS

The very purpose of the FDA is to ensure the safety of those who ingest, use, inject, or otherwise consume pharmacological innovation.[164] This purpose is within FDA purview with the extensive processes and trials required to ensure the effectiveness of a given drug prior to its entrance into the markets.[165] "Given the soaring costs of prescription drugs, it is not surprising that more than 70 percent of Americans think that drug prices are 'unreasonable' and that 'drug companies put profits before people.'"[166]

The purpose of the extensive drug approval process has been met with a longstanding understanding that the safety of the people is at its core.[167] "The drug approval process needs to strike a careful balance between speed and diligence—patients need safe, effective drugs, and it takes time and clinical trials in order to determine whether a drug meets

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[164] *See generally* Junod, *supra* note 22 (describing the evolution of the FDA's role in monitoring new drugs before they enter the consumer market).

[165] *How Drugs Are Developed and Approved*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ (last updated Aug. 18, 2015) (illustrating the process a new drug undergoes before entering the U.S. consumer market).

[166] Maura Calsyn & Thomas Huelskoetter, *FDA Is Not The Problem: Why Undermining the Drug Approval Process Is Not The Answer to High Drug Prices*, CTR. FOR AM. PROGRESS (Mar. 9, 2016, 2:38 PM), https://www.americanprogress.org/issues/healthcare/report/2016/03/09/132850/fda-is-not-the-problem/.

[167] *See generally* Junod, *supra* note 22 (describing the evolution of the FDA's role in monitoring new drugs before they enter the consumer market).

those standards."[168] "[T]he FDA approves the overwhelmingly majority of new drugs, and does so at a quicker pace than any other nation."[169] Sixty-four percent of new drugs gain FDA approval before its similar approval is obtained around the world.[170]

The ability for the FDA to ensure that the people are being kept safe is their statutorily prescribed responsibility.[171] To do anything against this notion would be a direct violation of the very fight President Theodore Roosevelt and Dr. Harvey Wiley undertook in 1906.[172]

Placing limits, or stripping the FDA of its authority to regulate is arguably contrary to the interests of the people and only advances the economic interests of the pharmaceutical industry.[173] "This approach would lead to additional drugs entering the market with little evidence to support their safety and effectiveness, which can harm patients."[174] By following along with this line of thinking, the FDA would be effective in preventing any and all harmful drugs from entering the market. As noted earlier, this is simply not the case.[175] Baycol and Vioxx were both run through the rigorous course of FDA regulation, yet disastrous effects were prevalent and felt by consumers years later.[176] The FDA did not even get to the gate first and pull the drugs—it was Bayer and Merck that voluntarily withdrew their respective drugs from market.[177]

Removing the front-end hurdles and leaving the potential issues up to products liability could have catastrophic results for thousands of patients before any negative effects are uncovered. Maura Calsyn and Thomas Huelskoetter present the notion that less demanding regulation

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[168] Calsyn & Huelskoetter, *supra* note 166.

[169] *Id. But see* Michael Mezher, *Japan Edges Out FDA For Fastest Approvals*, REGULATORY AFFAIRS PROF'L SOC'Y (Jul. 31, 2015), http://www.raps.org/Regulatory-Focus/News/2015/07/31/22952/Japan-Edges-out-FDA-for-Fastest-Approvals/.

[170] Calsyn & Huelskoetter, *supra* note 166.

[171] *See Legislation*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/RegulatoryInformation/Legislation/ (last updated July 2, 2015).

[172] *See About the FDA: Significant Dates in U.S. Food and Drug Law History*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm (last updated July 2, 2015).

[173] Calsyn & Huelskoetter, *supra* note 166.

[174] *Id.*

[175] *See supra* text accompanying notes 116–27.

[176] *See supra* notes 158–161 and accompanying text (discussing the effects of the FDA's heavy regulation of Baycol, Vioxx and Merck).

[177] *Id.*

in approval of drugs would place patients in an unreasonable state of danger.[178]

> For example, researchers have found that since 1992, when policymakers adopted the priority review and accelerated approval programs, the number of approved prescription drugs that received black-box warnings—which is the most serious safety warning that the FDA can impose on a drug—or that were withdrawn from the market for safety-related reasons has increased 25 percent. The researchers suggest that one reason for this increase is that growing numbers of new drugs are entering the market with more limited data about their safety and efficacy.[179]

By ignoring the positive endgame that products liability offers to the people using these drugs, in favor of strict FDA regulation, prices of drugs are going to become increasingly more expensive, virtually classing out the very people the drug is being developed to help.

ARGUMENT FOR PRODUCTS LIABILITY AS A SOLUTION TO FDA REGULATIONS

The influence and authority the FDA has over the pharmaceutical industry is similar to a big brother controlling a younger sibling. The intended purpose of ensuring the safety of the people from harmful drugs directly contradicts the need for affordability of the drug. The FDA requires each new drug to go through a laborious process just to be lucky enough to have the chance to reach the masses.[180] By allowing tort liability to handle any issues that arise would not only help the people, but it will ensure the pharmaceutical company is absolutely certain their innovation is ready for market.

Removing the authority of the FDA to dictate when a drug can be brought to market, and placing that decision on the pharmaceutical company will have significant positive effects for the people. Instead of finding a way to develop a drug that meets the standards of the FDA, the industry will govern itself. The massive lawsuits that can be levied upon a company are the only necessary deterrent required.[181] These lawsuits will ensure a drug manufacturer has done their due diligence prior to its

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[178] *See generally* Calsyn & Huelskoetter, *supra* note 166 (discussing the risks consumers are likely to face with less demanding FDA regulations and the stringent requirements drugs must go through to satisfy FDA approval).

[179] *Id.*

[180] *Id.*

[181] *See generally* Choi & Lee, *supra* note 136 (discussing the growing number of drugs that have been subject to product liability actions for either dangerousness or ineffectiveness).

release to market—and likely significantly more diligence than presently displayed due to the defense of FDA approval.

Using tort liability as a means to ensure each company develops a drug that they are confident in is vital to the continued growth of the industry. Instead of FDA regulation, the pharmaceutical industry is demanded to govern themselves. Sending a drug to market when it is not ready will lead to disastrous results for the manufacturer because of a greater sense of responsibility, one that the industry has shown in the past to be cognizant of with its voluntary withdrawals of ineffective or dangerous drugs.[182]

As it currently stands, lawsuits typically yield multi-billion dollar settlements.[183] But that is with the slight defense of "the FDA said we were good." Taking away that fallback defense places the full brunt of the burden on the pharmaceutical company. Instead, placing this on the shoulders of the industry, it is likely to result in more aggressive research and testing.[184] Should a drug entered into market be found to be harmful and a products liability lawsuit takes place, only the punitive damages imposed on the negligent company, as well as the compensatory damages, should be much greater. Thus, it will be more crippling to a bad-acting pharmaceutical company.

The threat of the unknown jury verdict is a strong deterrent that places the onus of responsibility on the developer and manufacturer.[185] This threat also gives discretion to the manufacturer to withdraw a drug that may cause some concern for public health.[186] The longer a harmful drug is on the market, the greater number of patients likely to be affected. The greater number of patients affected, the greater the damages ordered to pay in class action lawsuits. Strict FDA regulation takes the view that "pharmaceutical greed" will outweigh any negatives discovered in order to churn out the greatest profits. This simply is not

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[182] *See* Sternberg, *supra* note 153.

[183] *See generally* Michelle Llamas, *Top 5 Big Pharma Verdicts and Settlement of 2015*, DRUGWATCH (Jan. 21, 2016), https://www.drugwatch.com/2016/01/21/top-5-big-pharma-verdicts-settlements-in-2015/ (discussing various lawsuits that have yielded multi-billion dollar settlements as a result of product liability).

[184] *See generally* Herper, *supra* note 125 (providing examples of research and development costs exceeding millions).

[185] Turley et al., *supra* note 138 (discussing tips and tactics used by plaintiff lawyers against pharmaceutical companies that may serve as a deterrent).

[186] *See generally* Martinez et al., *supra* note 158 (providing an example of Merck's voluntary withdrawal).

true. As noted earlier, pharmaceutical companies have voluntarily withdrawn drugs that have negative effects.[187] If this "greed" was as great as believed, pulling a drug would never occur because of the desire to make as much money as possible prior to any lawsuits are brought.

Limiting FDA regulation on the front-end of the business will also open up greater access to innovation, or not stymie innovation.[188] At present, many companies that could find the next great cure are unable to get on the playing field.[189] Burke Therapeutics LLC president Dow Stough, M.D., brought this to light when he spoke about FDA filing fees.[190] "The small pharma companies can't come in because of very high FDA filing fees. Then they are at the mercy of the FDA to process, review, inspect . . . . The filing fees to the FDA for new drug approval [are] more than $1.2 million."[191] These basic entry costs can simply be too much for a small company to undertake without the guarantees that their research has the chance to lead to development. It places a burden on a small company to weigh the cost-benefit analysis of taking a chance on researching a potential drug that may not yield financial security. This provides no incentive for innovation and life-saving drugs.

Alternatively, FDA regulation and process can hold back a vital drug from reaching the market for years. Novartis had spent millions of dollars conducting research and testing what they deemed the "magic cancer bullet," but was required to wait for FDA approval.[192] In his book "Magic Cancer Bullet," Daniel Vasella detailed the immediately clear success of Novartis' cure for a rare form of Leukemia, but also their fights with the FDA to get to market as fast as possible.[193] Eventually

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[187] *See* Sternberg, *supra* note 153.

[188] *See* Calsyn & Huelskoetter, *supra* note 166.

[189] *See* Logan Albright, *Heartbreaking: Experimental Drugs Could Save Lives, If Only Patients Could Get Them*, CONSERVATIVE REV. (May 11, 2016), https://www.conservative review.com/commentary/2016/05/heartbreaking-experimental-drugs-could-save-lives-if-only-patients.

[190] *See* Becky Gillette, *U.S. Drug Prices Highest in the World*, ARK. MEDICAL NEWS (Nov. 11, 2015), http://www.arkansasmedicalnews.com/business/article/20358599/us-drug-prices-highest-in-the-world.

[191] *Id.* (quoting Dow Stough).

[192] *See* DANIEL VASELLA, MAGIC CANCER BULLET: HOW A TINY ORANGE PILL IS REWRITING MEDICAL HISTORY 137–67 (2003) (discussing the path to marketing a drug and FDA pushback).

[193] *Id.* at 25–34, 137–67.

Novartis won out and released Gleevec with an expedited FDA approval in 2001.[194] The success of Gleevec is unparalleled and has helped cure numerous people since its inception.[195] Maintaining strict FDA regulation over the front-end of the industry has the potential to stifle innovation before people have an opportunity to take a potentially life-saving drug.

Additionally, FDA regulation and process completely ignores the reason pharmaceutical companies exist in the first place. These companies are in the business of developing, manufacturing, and marketing drugs that can help people when they are in desperate need. For many people, an experimental drug is their last, or only, chance at life.[196] By maintaining the long path to market the FDA is not helping those in need, but instead effectively delivering a death sentence. For people in dire straits, the risks of taking a drug are far outweighed by the potential benefits.[197] If a pharmaceutical company is willing to send their drug to market, the FDA should not get in the way. Instead, as this article contends, allow the drug to be distributed with any issues uncovered being handled after-the-fact through comprehensive tort liability.

CONCLUSION

The FDA regulations are not in the best interests of the people, defying the actual purpose of the FDA's creation. By demanding astronomical costs incurred, lengthy processes endured, and multiple clinical trial phases undertaken before a drug can even be marketed, the hands of the pharmaceutical companies are tied to a point where prices and costs must be continually raised in order to recoup their expenses.

The FDA has dramatically increased its authority throughout its history with numerous amendments to the Pure Food and Drugs Act of 1906, the Food, Drugs, and Cosmetics Act of 1938, amendments made in 1963, and its current interpretations of the statutory language expressing

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[194] *See* Calsyn & Huelskoetter, *supra* note 166.

[195] *Id.*

[196] *See* Albright, *supra* note 189.

[197] Theo Raynor, *The Benefits of Medicines Outweigh the Risks of Treatment–Says Who?*, THE PHARMACEUTICAL J. (May 22, 2013), http://www.pharmaceutical-journal.com/news-and-analysis/news/the-benefits-of-medicines-outweigh-the-risks-of-treatment-sayswho/11121573.article.

their role.[198] These expansions of power and authority establish a concept of "big government" that the American economic system, and medical system, does not, and cannot, adhere to. The strong-arm nature of the FDA over the pharmaceutical industry is nothing more than a statement to the people that their health and well-being is only achievable so long as they approve. Giving the decision to use a drug to the people, with their redress coming through tort law products liability is the most effective way to "ensure the safety of the people."

By limiting regulation on the front-end and having tort liability handle all aspects on the back-end, the prices of drugs in the United States will begin to recede to a competitive price like the rest of the world. Innovations researched, developed, and marketed with the intent to help the masses would continue to thrive.

AFTERWORD

At the time of submission this was a legal issue on the forefront of my mind. Since then, the issue has found its way to Capitol Hill and nationally televised forums, including Town Hall Debates and Executive Orders.

During his first few days as President-Elect of the United States, Donald Trump released a statement regarding overreaching regulation. President-Elect Trump made the bold proclamation that "I will formulate a rule which says that for every one new regulation, two old regulations must be eliminated."199 On January 30, 2017, President Trump took his first steps toward the reduction of federal regulations by signing an Executive Order designed to reduce regulation and control regulatory costs.[200] Taking this Order into consideration, President Trump has effectively created a pathway for deregulation of the FDA and ensuring, at the very least, conversation regarding FDA oversight and regulation of the pharmaceutical industry and its relation to excessive cost to patients and the public.

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[198] Junod, *supra* note 22.

[199] Clyde Wayne Crews, Jr., *Donald Trump Promises To Eliminate Two Regulations For Every One Enacted,* FORBES (Nov. 22, 2016, 12:12 PM), https://www.forbes.com/sites /waynecrews/2016/11/22/donald-trump-promises-to-eliminate-two-regulations-for-every-one-enacted/#2f84214f4586.

[200] Exec. Order No. 13771, 82 Fed. Reg. 9339 (Jan. 30, 2017).

On February 7, 2017, Senators Ted Cruz and Bernie Sanders engaged in a Town Hall Debate regarding the state of healthcare.[201] During this telecast, Senator Cruz set his sights on the FDA and the high costs of entry to the marketplace.[202] Senator Cruz understands the pressing nature of relieving costs to the patient derives from limiting the FDA. "[I]n particular taking on the FDA. Right now, it takes $2 billion to approve a new drug. Now, I've introduced legislation to reform the FDA process so that new health care -- so that we can be curing diseases and we can be helping people."[203]

Senator Cruz went on to discuss FDA reform, the costs of drug approval, and related it to "Dallas Buyers' Club," and similar real-life stories of the urgency of access to new drugs.[204] "But another fundamental area is FDA reform, where the costs of getting a new drug approved are prohibitively expensive. There are [sic] story after story after story of exactly that happening. Life-saving drugs that are available . . . and the FDA won't allow it."[205] Senator Cruz then explained why FDA reform is vital to affordability. "That's why I think FDA reform is so valuable that if we lift the barriers, to let people try, give you a right to try. . . . Tough FDA barriers to entry benefit the big pharmaceutical companies. Massive complexity in tax laws benefits big corporations."[206]

The idea of affordability emanates directly from easier access to the market. The "big pharmaceutical companies" can afford to let the FDA, as it stands, implement barriers and hurdles to entry into the market. These regulations stymie the small laboratories from delivering a product to market, therefore eliminating the access and affordability of the common man.

President Trump and Senator Cruz are on the right path to limiting the regulatory nature of the FDA. These ongoing conversations are vital to reducing cumbersome regulations that drive up the front-end cost to

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[201] *See* MJ Lee & Eli Watkins, *Cruz, Sanders Face Off on Obamacare*, CNN, http://www.cnn.com/2017/02/07/politics/obamacare-cruz-sanders-highlights/ (last updated Feb. 8, 2017, 4:48 AM).

[202] *Id.*

[203] *CNN Live Event Special*, CNN, (Feb. 7, 2017), http://www.cnn.com/TRANSCRIPTS/1702/07/se.01.html.

[204] *See id.*

[205] *Id.*

[206] *Id.*

the pharmaceutical industry, which levy high costs to the individual. Product liability tort litigation is the answer.