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Cover Page Footnote

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Consumers in Shock: How Federal Government Overregulation Led Mylan to Acquire a Monopoly over Epinephrine Autoinjectors

*By: Nicole E. O'Toole**

I. INTRODUCTION

The freedoms and opportunities the United States of America provides allows Americans of any gender, race, religion, ethnicity, education, socioeconomic status, or background to follow their dreams and achieve success. Marco Rubio, the son of a bartender and a housekeeper fleeing the Cuban Revolution in 1956, grew up to become an attorney, published author, United States Senator and Presidential nominee.[1] Oprah Winfrey, born to a single African American teenage mother living in poverty, grew up to be the second-richest self-made woman in the world.[2]

While it is often argued that Republicans and Democrats have the same end goal, the most basic and foundational difference between the parties in present-day American politics is the way in which each party believes Americans are best able to achieve success. Typically, Democrats promote systems such as welfare benefits in order to help citizens who are in a more challenging economic position.[3] On the other side, Republicans usually favor a more limited role of government, including less regulation on business and a *laissez-faire* free market philosophy.[4] Senior research fellow at the Mercatus Center at George Mason University Matthew Mitchell illustrates the idea of similar end goals of opposing parties as it applied to the 2008 financial bailouts:

> Despite the ideological miles that separate them, activists in the Tea Party and Occupy Wall Street movements agree on one thing: both condemn the recent bailouts of wealthy and well-connected banks. To the Tea Partiers, these bailouts were an unwarranted federal intrusion into the free

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[1] *Biography*, MARCO RUBIO, http://www.rubio.senate.gov/public/index.cfm/biography (last visited Mar. 26, 2017).

[2] *Oprah Winfrey Profile,* FORBES, http://www.forbes.com/profile/oprah-winfrey/ (last visited Mar. 26, 2017).

[3] Ryan C. Fuhrmann, *What are the main differences between the Republican and Democratic approaches to regulating the economy?,* INVESTOPEDIA, http://www.investopedia.com/ask/answers/regulating-economy.asp (last visited Mar. 26, 2017).

[4] *Id.*

> market; to the Occupiers, they were a taxpayer-financed gift to the wealthy executives whose malfeasance brought on the financial crisis. To both, the bailouts smacked of cronyism.[5]

The notion that opposing ideologies could have similar views on corruption could be said about the topic of this Note: the effects of the federal government's role on the epinephrine autoinjector market. Both Republicans and Democrats have expressed their disdain over the rapid price increase of epinephrine autoinjectors in recent years, and what it means for those in need of the life-saving drug. Democratic Senator Bernie Sanders said of the issue, "Mylan's near monopoly on the epinephrine autoinjector market has allowed [Mylan] to increase prices well beyond those that are justified by any increase in the costs of manufacturing the EpiPen."[6] Republican Senator Rand Paul penned an op-ed piece on the issue outlining his very similar frustrations: "The controversy over the price of the EpiPen has reached a fever pitch as prices have risen by more than 400% and costing up to $600 for two of the pens. To fully comprehend the outrage of this price…the epinephrine included in the EpiPen costs less than ten dollars retail."[7] While Senator Sanders and Senator Paul are typically in disagreement on most major political stances, their shared frustration over the epinephrine autoinjector market shows how bipartisan the issue is.

Proponents of the fiscally conservative point of view, such as Ann Coulter, have described their support for a free market economy as follows: "everything provided by the free market over time will become better and cheaper...everything provided by the government over time will become more expensive and worse."[8] Many Republicans like to use the example of the Affordable Care Act ("Obamacare") as an example of a "failed" federal attempt to police the marketplace.[9] Once the healthcare industry was regulated by the federal government, Republicans have argued, the cost of insurance premiums have increased the cost of

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[5] Matthew Mitchell, GEORGE MASON U. MERCATUS CTR., *The Pathology of Privilege: The Economic Consequences of Government Favoritism,* 1 (2012), http://mercatus.org/sites/default/files/The_Pathology_of_Privilege-Final_2.pdf.

[6] *Senators Raise Concerns About Mylan's EpiPen Price Hike,* BERNIE SANDERS (Aug. 30, 2016), https://www.sanders.senate.gov/newsroom/press-releases/senators-raise-concerns-about-mylans-epipen-price-hike.

[7] Rand Paul, *Sen. Rand Paul: EpiPen Scandal Is a Perfect Example of Crony Capitalism*, TIME, (Sept. 7, 2016), http://time.com/4482179/sen-rand-paul-epipen-scandal/.

[8] Will Dooling, *Koch's Americans for Prosperity Brings Ann Coulter to Madison in a Last-Minute Push to Stop "Obama's Failing Agenda"*, PRWATCH CTR. FOR MEDIA & DEMOCRACY (Nov. 5, 2012, 8:59 PM), http://www.prwatch.org/news/2012/11/11842/americans-prosperity-brings-ann-coulter-madison-last-minute-push-stop-obamas-fail.

[9] Patient Protection and Affordable Care Act, 111th Cong. (2009)*, H.R.3590*, CONGRESS, https://www.congress.gov/bill/111th-congress/house-bill/3590.

medical services by an estimated twenty-four percent,[10] which caused a number of previously successful carriers to flee the market.[11] Advocates of this theory credit the optimization of quality goods in a given market to healthy competition.[12] As Mitchell describes it: "markets tend to be competitive when, most important[ly], there are no barriers to entering or exiting the industry."[13]

The philosophy that federal government intervention increases costs and decreases options and values available to consumers can be analyzed across a plethora of markets. Specifically, this Note will focus on the epinephrine autoinjector market. An epinephrine autoinjector, more commonly known by Mylan's brand called the "EpiPen,"[14] is most often used for the treatment of anaphylaxis, which is a serious allergic reaction that may cause death.[15] Today, the EpiPen is considered the "Kleenex" of epinephrine autoinjectors as it is estimated to control over ninety percent of the market share.[16] From a Darwinist perspective it would appear that because the EpiPen controls most of the market, it must be the most superior product available to consumers. However, as the succeeding sections will cover, this is likely not the case, and there is ample evidence to prove that EpiPen's market success is largely due to government regulations and mandates. This Note will also focus on the 2014 United States District Court case *JHP Pharmaceuticals v. Hospira,* which dealt with labeling issues surrounding epinephrine autoinjectors.[17] It is quite possible that safer, more efficient, and more affordable versions of the EpiPen may be available to consumers today if it were not for these government interventions.

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[10] Brian Blase, *Overwhelming Evidence That Obamacare Caused Premiums To Increase Substantially*, FORBES (July 28, 2016), http://www.forbes.com/sites/theapothecary/2016/07/28/overwhelming-evidence-that-obamacare-caused-premiums-to-increase-substantially/#36cee92946e3.

[11] *Editorial: Why Obamacare failed,* CHI. TRIB. (Sept. 9, 2016), http://www.chicagotribune.com/news/opinion/editorials/ct-obamacare-fail-health-care-insurance-medicine-0911-jm-20160909-story.html.

[12] Matthew Mitchell, GEORGE MASON U. MERCATUS CTR., *The Pathology of Privilege: The Economic Consequences of Government Favoritism,* 3 (2014), http://mercatus.org/sites/default/files/The_Pathology_of_Privilege-Final_2.pdf.

[13] *Id.*

[14] *Important Safety Information,* EPIPEN, https://www.epipen.com/ (last visited Mar. 26, 2017).

[15] Chitra Dinakar, *Anaphylaxis in Children: Current Understanding and Key Issues in Diagnosis and Treatment,* US NAT'L LIBR. OF MED. NAT'L INSTS. OF HEALTH, (Jul. 20, 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3492692/.

[16] Ben Popken, *Lawmakers Accuse Mylan CEO of 'Rope-a-Doping' on EpiPen Prices,* NBC NEWS (Sept. 21, 2016), http://www.nbcnews.com/business/consumer/lawmakers-grill-mylan-ceo-fda-epipen-price-hike-n651201.

[17] JHP Pharmaceuticals v. Hospira, 52 F.Supp.3d 992 (C.D. Cal. 2014).

As this note will discuss, courts should decline to follow the overall ruling in *JHP Pharmaceuticals v. Hospira*[18] because holding that a court is unable to decide a case based on a separate federal agency simply a waste of litigation. However, courts should consider the line of reasoning that where there is no proof that a non-FDA approved drug is any less safe than an FDA-approved drug, the non-approved drug should not be precluded from entering the market.

II. BACKGROUND

This section provides background information concerning the economic and legal support for the conclusion that the federal government's role in Mylan's monopoly over the epinephrine autoinjectors has created a burden for consumers. The first subsection provides a general background on epinephrine autoinjectors.[19] The second subsection provides a general background on monopolies.[20] The third subsection provides a background on Mylan's monopoly over the epinephrine autoinjector market, and the government's role in the creation of the monopoly.[21] Finally, the fourth subsection provides a background on *JHP Pharmaceuticals* and its legal implications for Mylan's monopoly over the epinephrine autoinjector market.[22]

A. Background on Epinephrine Autoinjectors

Epinephrine is used to treat anaphylaxis, a serious, systemic allergic reaction that is rapid in onset and can cause death.[23] Epinephrine helps relieve the life-threatening symptoms of anaphylaxis (such hypotension, shock, and upper airway obstruction) via its alpha-adrenergic effects.[24] Delayed administration of epinephrine causes an increased risk of death; therefore it is essential for patients at risk for anaphylaxis to be educated regarding the appropriate administration technique for epinephrine autoinjector devices.[25] The most notable users

[18] *Id.*
[19] *See infra* notes 23-46 and accompanying text.
[20] *See infra* notes 47-57 and accompanying text.
[21] *See infra* notes 58-124 and accompanying text.
[22] *See infra* notes 125-139 and accompanying text.
[23] Brice Labruzzo Mohundro and Michael Marlan Mohundro, *Important Considerations When Dispensing Epinephrine Auto-Injector Devices,* PHARMACY TIMES, (Sept. 22, 2010), http://www.pharmacytimes.com/p2p/p2pepinephrine-0910.
[24] *Id.*
[25] *Id.*

of these devices are children with severe food allergies who may be inadvertently exposed to such foods at school.[26]

1. Background on the EpiPen

Presently, the leading brand of epinephrine autoinjectors in Mylan's version called the EpiPen.[27] Mylan has been the subject of much controversy in the past few years, as the price of the EpiPen has drastically increased.[28] Today, a pack of two EpiPens costs about $600.[29] For reference, the amount of epinephrine in the devices only cost about ten dollars[30], and that same two-pack of EpiPens only cost consumers $100 in 2008.[31] Most insurers only cover one pair of EpiPens each year.[32] However, parents with children who have serious food allergies are usually suggested to keep one pair of EpiPens at school, one pair at home, and a pair for each parent to carry with them.[33] Furthermore, the suggested shelf life for an EpiPen in 2016 is about eighteen months, compared to a recommended shelf life of twenty-seven months in 2002.[34] EpiPens must be kept at room temperature, meaning they cannot be left in a vehicle on during extremely hot or cold weather, and must be protected from light and water.[35] If there is even a possibility an EpiPen has been compromised by expiration, temperature, light, or water, it must be thrown away and cannot be used.[36] Taking into consideration all of the associated risks, families could be paying upwards of $2,400 out of pocket per year for this life-saving drug.

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[26] Meghana Keshavan, *Can anyone shake the EpiPen monopoly? Here's one company that's trying,* STATNEWS, (Jul. 7, 2016), https://www.statnews.com/2016/07/07/epipen-monopoly-mylan-windgap-medical/.
[27] *Id.*
[28] *Id.*
[29] *Id.*
[30] Randal H. Paul, *Sen. Rand Paul: EpiPen Scandal Is a Perfect Example of Crony Capitalism*, TIME, (Sept. 7, 2016), http://time.com/4482179/sen-rand-paul-epipen-scandal/.
[31] *Anaphylactic Political Shock,* WALL ST. J., Pg. A10, (Aug. 25, 2016), https://www.wsj.com/articles/anaphylactic-political-shock-1472078239.
[32] Meghana Keshavan, *Can anyone shake the EpiPen monopoly? Here's one company that's trying,* STATNEWS, (Jul. 7, 2016), https://www.statnews.com/2016/07/07/epipen-monopoly-mylan-windgap-medical/.
[33] *Id.*
[34] Carolyn Y. Johnson, *Why EpiPens expire so quickly,* WASH. POST, (Sept. 27, 2016), https://www.washingtonpost.com/news/wonk/wp/2016/09/27/why-epipens-expire-so-quickly/?utm_term=.2068a5e5e357.
[35] *Frequently Asked Questions,* EPIPEN http://www.epipen.ca/en/about-epipen/frequently-asked-questions (last visited Mar. 27, 2017).
[36] *Id.*

2. Alternative Proposals to the EpiPen

Adrenaclick is currently EpiPen's main, and much cheaper, competition, but the product is not always covered by insurance and was prescribed fewer than 1,000 times in the United States last year.[37] CVS Health recently began to market on the drug's behalf and is hoping to price the generic version of the drug at just $110 for a two-pack.[38] Many drug manufacturers have proposed their plans for competing epinephrine autoinjectors. Chris Stepanian, CEO of Windgap Medical, a Boston startup is in the process of creating a smaller, lighter epinephrine autoinjector, called Abiliject, could be ready for review by 2018.[39] Stepanian explained his hope for the Abiliject would make the injector about forty percent smaller than the EpiPen, designed to fit in a pocket.[40] He also says Windgap is working on temperature stability, "so even if you leave it in your car on a hot and sunny day, you don't have to throw away the device."[41] Windgap's other goals for the Abiliject are a longer shelf life than the EpiPen and they are hoping to make the Abiliject more intuitive to use.[42]

As outrage continues to grow over Mylan price increases, several companies have proposed their ideas for alternatives for considerably more affordable options, such as having families obtain syringes that a doctor pre-fills with epinephrine.[43] The drug manufacturer Sanofi introduced its own version of an epinephrine autoinjector, the Auvi-Q, in 2012.[44] The Auvi-Q was novel because it was a "talking autoinjector," in which the device instructed users through the entire process of injection.[45] This aspect of the Auvi-Q was especially beneficial because oftentimes the person suffering an anaphylactic attack is not the one administering a dose of epinephrine. The Auvi-Q allowed a friend, family member, teacher, co-worker, peer, or even complete stranger witnessing somebody who is having an allergic reaction and unable to

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[37] Rand Paul, *Sen. Rand Paul: EpiPen Scandal Is a Perfect Example of Crony Capitalism*, TIME, (Sept. 7, 2016), http://time.com/4482179/sen-rand-paul-epipen-scandal/.
[38] Brad Tuttle, *Sick of $600 EpiPen Prices? A Major Retailer Has an Alternative for Only $10*, TIME, (Jan. 12, 2017), http://time.com/money/4632964/cvs-epipen-alternative-adrenaclick/.
[39] Meghana Keshavan, *Can anyone shake the EpiPen monopoly? Here's one company that's trying,* STATNEWS,, (Jul. 7, 2016), https://www.statnews.com/2016/07/07/epipen-monopoly-mylan-windgap-medical/.
[40] *Id.*
[41] *Id.*
[42] *Id.*
[43] Rand Paul, *Sen. Rand Paul: EpiPen Scandal Is a Perfect Example of Crony Capitalism*, TIME (Sept. 7, 2016), http://time.com/4482179/sen-rand-paul-epipen-scandal/.
[44] Susan Scutti, *Epipen Competitor Alternatives Auvi-Q Returning Soon,* CNN (Oct. 27, 2016), http://www.cnn.com/2016/10/26/health/auvi-q-epinephrine-autoinjector-returns/.
[45] *Id,*

self-inject to help properly administer the dose of epinephrine. However, Auvi-Q was recalled in 2015 amid concerns that the product was not delivering an accurate dosage of epinephrine.[46]

While the EpiPen tackles the most basic purpose of epinephrine autoinjectors (to allow users suffering from an anaphylactic attack to administer a dose of epinephrine), many American companies have tremendous ideas that would specialize, fix, or perfect the current state of epinephrine autoinjectors.

B. General Background on Monopolies

The Encyclopædia Britannica's definition for the Hasbro, Inc. board game "Monopoly" is a great depiction of the economic phenomenon: "Monopoly [is a] real-estate board game…in which the player's goal is to remain financially solvent while forcing opponents into bankruptcy."[47] As players as young as eight years old have discovered, the way to win the game is to acquire all of the properties possible, and leave one's opponents with nothing. This way, the winner can control what players do and how much they pay. This simplistic explanation of a monopoly is critical to understanding the effects of Mylan having significant market power because they are the only – or near only – supplier of a particular product.

There are typically two ways an entity acquires such economic power that they face little or no competition in the territories where they operated: by a *de jure* or a *de facto* monopoly.[48] Most of the great American monopolies of the early nineteenth century were *de jure*, or created by the government.[49] Most twentieth century monopolies were *de facto*, or created by technology, patents, and the marketplace.[50] An example of a *de jure* monopoly is the United States Postal Service ("USPS"). USPS has a monopoly of the letter-delivery industry that dates back to 1775 when Benjamin Franklin was named the first American Postmaster General in order to facilitate the country's need for communication between army commanders, first representatives, and

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[46] *Id.*
[47] *Monopoly Board Game,* ENCYCLOPEDIA BRITANNICA (Jul. 8, 2005), https://www.britannica.com/topic/Monopoly-board-game.
[48] Luis Aníbal Avilés, *Public Utilities And The European Union's "Services Of General Economic Interest": Feudal Origins Of Their Monopoly Powers,* 4 U. P.R. BUS. L.J. 76 (2012).
[49] Herbert Hovenkamp, *Technology, Politics, And Regulated Monopoly: An American Historical Perspective*, 62 TEX. L. REV. 1263, (1984).
[50] *Id.*

constituents.[51] Congress protected USPS's monopoly in 1949 when Congress wrote:

> Whoever establishes any private express for the conveyance of letters or packets, or in any manner causes or provides for the conveyance of the same by regular trips or at stated periods over any post route which is or may be established by law . . .shall be fined . . . or imprisoned . . . or both.[52]

By contrast, true *de facto* monopolies are few and far between. The best example of a *de facto* monopoly is Sirius XM Radio. When rival companies XM Satellite Radio Holdings Inc. and Sirius Satellite Radio merged in 2007,[53] the new company, Sirius XM Radio, acquired a monopoly over the satellite radio market.[54]

Mylan's success in the epinephrine autoinjector market is attributed to some government regulation, such as the FDA approval process and the School Access to Emergency Epinephrine Act, as later sections will explore. While Mylan is not the sole supplier of epinephrine autoinjectors, it does control over ninety percent of the market, therefore it acquires a near-monopoly over the industry, rather than an actual monopoly. This is not uncommon as most other industry leaders are near-monopolies. These companies may not control 100% of the market, but they control a majority of it, so they still reap the benefits of price setting in a given industry.

Such near-monopoly examples are Netflix, having over fifty-percent of the market share for video streaming services, and Google, having seventy-percent of the market share for domestic search engines.[55] The issue then becomes whether companies gain near-monopoly status by their organic success in the market, such as Netflix and Google, or due to some sort of government intervention. For example, many broadband providers and electric utility providers have geographic-specific near-monopolies because of government contracts. An example of this type of quasi-*de jure* near-monopoly is ComEd in the Chicagoland area.[56] While the City of Chicago did not create ComEd to be the sole electric utility

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[51] *Universal Service and the Postal Monopoly: A Brief History,* USPS, (2008), https://about.usps.com/universal-postal-service/universal-service-and-postal-monopoly-history.pdf.

[52] 18 U.S.C. § 1696(a) (1948).

[53] David Ellis & Paul La Monica, *XM, Sirius announce merger,* CNN (Feb 20, 2007), http://money.cnn.com/2007/02/19/news/companies/xm_sirius/index.htm?cnn=yes.

[54] *Id.*

[55] *The Next 7 American Monopolies,* BUS. INSIDER, (Nov. 18, 2010), http://www.businessinsider.com/the-next-7-american-monopolies-2010-11?op=1/#streaming-movies-future-rental-monopoly-opportunity-in-the-making-1.

[56] *City to Return to ComEd for Electricity Contract,* ABC, (Apr. 24, 2015), http://abc7chicago.com/news/city-to-return-to-comed-for-electricity-contract/680651/.

provider, ComEd's contract with the city interferes with other companies' ability to infiltrate the market.[57] Therefore, ComEd's monopoly power in Chicago is due to government intervention rather than organic success in the electric utility market. Now that the general foundation of monopolies has been laid, a more thorough analysis of Mylan's monopoly in the epinephrine autoinjector drug market may be done.

C. Economic Background on Mylan's Monopoly

Mylan recently generated much controversy involving the massive price increase of their allegedly generic brand of the epinephrine autoinjector drug, the EpiPen. There are two factors playing into Mylan's near-monopoly on the epinephrine autoinjector drug market. First, the School Access to Emergency Epinephrine Act ("SAEEA") enacted by Congress in 2013 requiring all elementary and secondary schools in a state to maintain a supply of FDA-approved epinephrine.[58] The mandated purchase of epinephrine drugs by schools and lack of ability for other drug companies to sell their epinephrine drugs essentially created a monopoly for Mylan.[59] This gave Mylan the ability to hike up its prices, creating a burden on consumers to attain an adequate supply of the drug they need. The second is the incredibly tedious United States Food and Drug Administration ("FDA") approval process and subsequent heavy backlog of drugs awaiting approval, which makes it nearly impossible for alternatives to the EpiPen to get approved.[60]

1. The School Access to Emergency Epinephrine Act

The first way Mylan achieved the ability to hike up its price of the EpiPen is through the enactment of the SAEEA. Mylan was under criticism after it was revealed that it spent $4 million to lobby congress for the 2013 Act.[61] "The company's profits soared twenty-two and one

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[57] *Id.*
[58] School Access to Emergency Epinephrine Act, 113th Congress (2014), S.1503, CONGRESS, https://www.congress.gov/bill/113th-congress/senate-bill/1503.
[59] *Id.*
[60] Sydney Lupkin, *FDA Fees On Industry Haven't Fixed Delays In Generic Drug Approvals,* NPR, (Sept. 1, 2016), http://www.npr.org/sections/health-shots/2016/09/01/492235796/fda-fees-on-industry-havent-fixed-delays-in-generic-drug-approvals.
[61] Jacob Maslow, *EpiPen Maker Mylan Flees Overseas to Avoid Taxes After 2013 School Access to Emergency Epinephrine Act,* HUFFINGTON POST, (Aug. 31, 2016), http://www.huffingtonpost.com/entry/epipen-maker-mylan-flees-overseas-to-avoid-taxes-after_us_57c2b82ae4b0b01630df8490.

half percent between 2013 and 2015."[62] Chief Executive Officer of Mylan, Heather Bresch, who was behind the price raise of the EpiPen in 2015 received a $19 million salary.[63] Mylan was also under scrutiny because Bresch is the daughter of Democratic Senator from West Virginia Joe Manchin III, a member of the 113th Congress that passed the SAEEA.[64] While Mylan's efforts in lobbying for the SAEEA were suspicious, the importance of the Act is widely undisputed. Anaphylactic shock is so rapidly-onset and potentially life threatening, so the need to act quickly is very high.[65] Therefore, SAEEA is very important in order to ensure that schools are prepared to treat children who may go into anaphylactic shock.

Just prior to SAEEA's enactment, it was estimated that nine and one-half percent of American children suffered from Asthma, and between four and six percent of American children were affected by food allergies; either of which can strike in an instant, and have life threatening consequences.[66] Congress and drug companies stepped in to address the concern for parents of children with asthma and severe food allergies (among other ailments which may trigger anaphylaxis).[67] In 2012, Mylan announced the *EpiPen4Schools* program, providing the drug for free.[68] To date, Mylan has given away more than 700,000 free EpiPens to schools nationwide.[69] After Mylan's successful lobbying efforts culminated in the passage of the SAEEA in 2013, it has not been reported that Mylan has continued to provide schools with free EpiPens.[70]

Mylan's lobby efforts to increase the availability of epinephrine autoinjectors in United States schools did not go unnoticed.[71] "Although these legislative efforts were not supposed to benefit a particular company, the brand has such a lock on the market that when President Barack Obama signed the School Access to Emergency Epinephrine Act

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[62] *Id.*
[63] *Id.*
[64] *Id.*
[65] *Death From Anaphylaxis is a Reassuringly Unusual Outcome,* AAAAI, (Dec. 13, 2013). https://www.aaaai.org/global/latest-research-summaries/Current-JACI-Research/death-anaphylaxis.
[66] Valerie Jarrett, *President Obama Signs New EpiPen Law To Protect Children with Asthma and Severe Allergies, And Help Their Families To Breathe Easier,* WHITE HOUSE, (Nov. 13, 2013), https://obamawhitehouse.archives.gov/blog/2013/11/13/president-obama-signs-new-epipen-law-protect-children-asthma-and-severe-allergies-an.
[67] Carolyn Y. Johnson and Catherine Ho, *How Mylan, the EpiPen company, maneuvered to create a virtual monopoly,* CHI. TRIB, (Aug. 25, 2016), http://www.chicagotribune.com/business/ct-mylan-epipen-monopoly-20160825-story.html.
[68] *Id.*
[69] *Id.*
[70] *Id.*
[71] *Id.*

in 2013, a news announcement simply called it the 'EpiPen Law,'" an article in the Chicago Tribune explained in August 2016.[72]

Democratic Senator Richard Durbin from Illinois introduced the SAEEA to the Senate on September 12, 2013.[73] Officially, the Act "amends the Public Health Service Act…to give an additional preference to a state that allows self-administration of asthma and anaphylaxis medication."[74] The Act:

> Requires elementary and secondary schools in such a state to: (1) permit trained personnel to administer epinephrine to a student reasonably believed to be having such a reaction, (2) maintain a supply of epinephrine in a secure location that is easily accessible to trained personnel for such treatment, and (3) have in place a plan for having on the school premises during operating hours one or more designated personnel trained in administration of epinephrine.[75]

These "additional preferences" included financial incentives to states that enact their own mandates for schools to stock epinephrine autoinjectors.[76] Many have argued that mandating a state "maintain a supply of epinephrine in a secure location that is easily accessible to trained personnel for such treatment"[77] was the golden ticket for Mylan, because the EpiPen was the most well-known epinephrine autoinjector available, so it was the optimal choice for schools.[78] If schools are required to supply a drug that must be administered by bystanders in emergency situations, it makes the most sense that they would supply a drug that the majority of children and staff are familiar with. "That was a Trojan horse," said David Maris, a Wells Fargo analyst.[79] "That was, 'Let's get it in schools to help people,' but it helps market EpiPen and promote it as the trusted product in schools."[80]

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[72] Carolyn Y. Johnson and Catherine Ho, *How Mylan, the EpiPen company, maneuvered to create a virtual monopoly,* CHI. TRIB, (Aug. 25, 2016), http://www.chicagotribune.com/business/ct-mylan-epipen-monopoly-20160825-story.html.
[73] School Access to Emergency Epinephrine Act, 113th Congress (2014), S.1503, CONGRESS, https://www.congress.gov/bill/113th-congress/senate-bill/1503.
[74] *Id.*
[75] *Id.*
[76] Carolyn Y. Johnson and Catherine Ho, *How Mylan, the EpiPen company, maneuvered to create a virtual monopoly,* CHI. TRIB, (Aug. 25, 2016), http://www.chicagotribune.com/business/ct-mylan-epipen-monopoly-20160825-story.html.
[77] School Access to Emergency Epinephrine Act, 113th Congress (2014), S.1503, CONGRESS, https://www.congress.gov/bill/113th-congress/senate-bill/1503.
[78] Carolyn Y. Johnson and Catherine Ho, *How Mylan, the EpiPen company, maneuvered to create a virtual monopoly,* CHI. TRIB, (Aug. 25, 2016), http://www.chicagotribune.com/business/ct-mylan-epipen-monopoly-20160825-story.html.
[79] *Id.*
[80] *Id.*

R. Adams Dudley, a pulmonologist at the University of California at San Francisco said of the monopoly: "[Mylan's] most brilliant maneuver, clearly, was giving [EpiPens] away to schools and making it the thing that they could say, 'Well, the nurse knows how to use it.'"[81] As evidenced by their decision to use EpiPens, this logic made sense to school administrators, nurses, and parents. NBC News Senior Staff Writer Ben Popken said of the issue: "Mylan has made its crown jewel product ubiquitous…. What are the parents afraid of? Their child will be away from them, and they won't be there to use [an epinephrine autoinjector]…. If they can say the school nurse knows how to use an EpiPen; she's never seen an Adrenaclick.... It's just a fear thing."[82] The combination of this government intervention, the SAEEA, along with the complex and lengthy FDA approval process has allowed Mylan to create a monopoly over the epinephrine autoinjectors.

2. FDA New Drug Approval Process

There are two generally unchallenged facts that are important to clarify in order to accurately lay the foundation for a background into the FDA approval process: (1) a federally-regulated approval process is critical to ensure that patients are receiving safe drugs, and (2), because of this, American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world.[83] The main consumer watchdog for the American pharmaceutical system is the Center for Drug Evaluation and Research ("CDER"), a division of the FDA.[84] The CDER's main role is to evaluate new drugs before they can be sold, in order to prevent quackery and ensure that doctors and patients are provided with the necessary information they need to use medicines wisely.[85]

When a new drug wants to enter the market in the United States, the first step is to test the drug to prove that it is safe and effective for its intended use.[86] In order to do so, the CDER assembles an independent and unbiased team of physicians, statisticians, chemists, pharmacologists, and other scientists to review the company's data and proposed

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[81] *Id.*
[82] Ben Popken, *Lawmakers Accuse Mylan CEO of 'Rope-a-Doping' on EpiPen Prices,* NBC NEWS, (Sept. 21, 2016), http://www.nbcnews.com/business/consumer/lawmakers-grill-mylan-ceo-fda-epipen-price-hike-n651201.
[83] *Development & Approval Process (Drugs),* FDA, (Jan. 29, 2016), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/.
[84] *Id.*
[85] *Id.*
[86] *Id.*

labeling.[87] This CDER team does not actually test the drug itself; rather, it conducts research in the areas of quality, safety, and effectiveness standards to determine if the drug's health benefits outweigh its known risks.[88]

Once the drug's quality, safety, and effectiveness standards have been established, the burden shifts to the drug company, or a sponsor, to perform laboratory and animal tests in order to determine the likelihood that it will be safe and effective in humans.[89] From there, the company can begin to test the drug on humans to determine whether it is safe when used to treat a disease and whether it provides a real health benefit.[90] The need for an agency to regulate the drugs available in the American market to consumers is paramount in order to ensure that Americans are not unknowingly consuming harmful drugs.

i. Generic Drug Approval Process

Many new drugs are frequently under patent protection during development, and oftentimes throughout the approval process.[91] This patent protects the company or sponsor's investment in the drug's development by giving them the sole right to sell the drug while the patent is in effect.[92] A patent usually guarantees market exclusivity for a drug for twenty years.[93] Additionally, this also incentivizes companies to undergo expensive research and design costs since they are likely to recoup the cost through utilizing their patents.[94] In an article on patent protection strategies and market exclusivity in the pharmaceutical industry, leading scholars found that "skyrocketing research costs have resulted in an increased dependence on market exclusivity as a means of maintaining growth and profitability."[95] Without a patent system, such as the one the United States currently employs, it is likely many companies would steal the formulas of newly-approved drugs and manufacture and sell them at a much lower cost. This would create a risk for a black market, the sale of unapproved drugs, and the overall safety of the drugs

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[87] *Id.*
[88] *Development & Approval Process (Drugs),* FDA, (Jan. 29, 2016), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/.
[89] *Id.*
[90] *Id.*
[91] *Id.*
[92] *Id.*
[93] Himanshu Gupta, Suresh Kumar, Saroj Kumar Roy, R.S. Gaud, *Patent Protection Strategies,* J. PHARM. BIOALLIED SCI., (Mar. 2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3146086/.
[94] *Id.*
[95] *Id.*

consumers are able to purchase. That is why once the patent, or some other period of exclusivity, on a brand-name drug expires, manufacturers can then apply to the FDA to sell generic versions of the drug.[96] The purpose of generic drugs is to provide a safe, effective, low-cost alternative to American consumers.[97] A generic drug is comparable to an "innovator" or "brand-name" drug in dosage form, strength, administration, quality, performance characteristics, and intended use.[98]

When generic drug manufacturers apply for FDA approval, their applications are considered "abbreviated" because they are generally not required to include laboratory, animal, and clinical data to establish safety and effectiveness.[99] Instead, generic drug applicants must scientifically demonstrate that their drug is bioequivalent, or performs in the same manner as the brand-name drug.[100] As of February 27, 2017, the FDA held that one way scientists can determine bioequivalence is by measuring the time it takes the generic drug to reach the bloodstream in twenty-four to thirty-six healthy volunteers.[101] The generic drug must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of the time as the brand-name drug in order to be approved.[102] Due to these very stringent requirements, as of July 1, 2016, the FDA had 4,036 generic drug applications awaiting approval and the median time for the FDA to approve a generic drug is forty-seven months.[103] As of 2011, more than seventy percent of prescriptions filled in the United States were for generic drugs.[104] By comparison, the European Medicines Agency (Europe's version of the FDA) has just twenty-four generic drugs waiting approval.[105]

The extreme backlog of drugs waiting FDA approval is not by chance, however. Many companies have been trying to create a generic brand of

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[96] *Id.*

[97] *Abbreviated New Drug Application (ANDA): Generics,* FDA, (Feb. 27, 2017), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm.

[98] *Id.*

[99] *Id.*

[100] *Id.*

[101] *Id.*

[102] *Id.*

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

[104] Bill Mears, *High Court Sides With Generic Drug Makers in Narrow Ruling,* CNN, (June 23, 2011), http://www.cnn.com/2011/HEALTH/06/23/scotus.generic.drugs/.

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

epinephrine auto-injectors at a lower price than EpiPen.[106] In March 2016, generics giant Teva Pharmaceuticals' generic version of EpiPen was rejected by the FDA and that its launch would be significantly delayed. [107] Adamis Pharmaceuticals Corporation proposed an alternative to the EpiPen, an epinephrine injection Pre-filled Single Dose Syringe ("PFS") product, whose approval was delayed by the FDA in June of 2016.[108] Mylan too has expressed a desire to manufacture a generic version of the EpiPen.[109] Mylan has said it will offer a $300 generic version at some point in 2017, however, because Mylan also makes the brand-name product, it won't have to wait in line behind other pending generics.[110]

ii. Generic v. Brand-Name Drug Labeling Issues

In 2011 the Supreme Court of the United States of America ruled that generic drug makers could not be held liable for failing to warn patients about the risks of their products because the companies had no control over what the warning labels said.[111] In the 2011 case *PLIVA v. Mensing,* two similar cases from lower courts were consolidated.[112] Both cases involved consumers who brought suit against generic drug manufacturers, alleging their long-term use metoclopramide (a drug used to treat heartburn) caused them to develop tardive dyskinesia (involuntary movements of the tongue, lips, face, trunk, and extremities).[113] The plaintiffs argued brand-name drug makers have a responsibility to change a label whenever they discover new important information about a drug, and generic manufacturers are required to follow suit.[114] However, in delivering the opinion of the court, Justice Thomas wrote, "it is beyond dispute that the federal…regulations that apply to brand-name drugs…are meaningfully different than those that

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[106] Yaacov Benmeleh, *Mylan's EpiPen Boosted as FDA Sees Holes in Teva Application,* BLOOMBERG (Mar. 1, 2016), https://www.bloomberg.com/news/articles/2016-03-01/mylan-s-epipen-gets-boost-as-fda-spots-holes-in-teva-application?cmpid=yhoo.headline.
[107] *Id*.
[108] Mark Flather & Mark Gundy, *Adamis Pharmaceuticals Receives Complete Response Letter From FDA For Its Epinephrine Pre-Filled Syringe NDA,* CNBC (Jun. 6, 2016), https://www.cnbc.com/2016/06/06/globe-newswire-adamis-pharmaceuticals-receives-complete-response-letter-from-fda-for-its-epinephrine-pre-filled-syringe-nda.html.
[109] Sydney Lupkin, *FDA Fees On Industry Haven't Fixed Delays In Generic Drug Approvals,* NPR, (Sept. 1, 2016), http://www.npr.org/sections/health-shots/2016/09/01/492235796/fda-fees-on-industry-havent-fixed-delays-in-generic-drug-approvals.
[110] *Id.*
[111] PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011).
[112] *Id.* at 610.
[113] *Id.*
[114] *Id.* at 614.

apply to generic drug[s]…. [I]t is the special…regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public."[115] This 2011 decision split along ideological lines and has been highly scrutinized and praised by various parties.[116] Proponents of the ruling appreciate the tradition of limiting the barriers generic drug manufacturers must pass through in order to bring more drugs quickly and cheaply to the market to service the needs of those consumers who cannot wait and cannot afford brand-name drugs.[117] Opponents of the ruling argue it increases the risk of harm to consumers due to inadequate warnings on generic drugs.[118]

In an op-ed piece for Fox News Health, Dr. Jennifer Brokaw, a practicing emergency physician for over fifteen years and founder of C2it, wrote about how she once inadvertently used a generic brand of an epinephrine drug that she was unfamiliar with.[119] When she injected the drug she gave the patient ten times the amount of epinephrine than she had intended to because she assumed the generic brand was diluted, and it was not.[120] This creates an issue as to whose negligent action caused the graver harm: the generic drug's lack of labeling warning users that it is not diluted, or the doctor's failure to check?

This "labeling" issue is directly related to children's use of epinephrine autoinjector drugs. Many children with serious allergies are taught to use the EpiPen, and are often given prescriptions strictly for the use of EpiPens, and not a generic or substitute brand, because they know how to use EpiPens should they ever go into anaphylactic shock.[121] Proponents of policies such as this argue limiting children's use of epinephrine autoinjectors to the EpiPen will limit a child's risk for using the drug the wrong way.[122] Opponents of these policies argue this increases the

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[115] *Id.* at 626.
[116] Bills Mears, *High Court sides with generic drug makers in narrow ruling,* CNN (June 23, 2011), http://www.cnn.com/2011/HEALTH/06/23/scotus.generic.drugs/.
[117] *Id.*
[118] *Id.*
[119] Jennifer Brokaw, *Cheap EpiPen alternative risks patients' lives. I've seen it myself,* FOX NEWS (Oct. 5, 2016), http://www.foxnews.com/health/2016/10/05/cheap-epipen-alternative-risks-patients-lives-ve-seen-it-myself.html.
[120] *Id*.
[121] Gillian Mohney and Dr. Kavita Vakharia, *EpiPen Users Have Few Options for Generic or Alternate Drugs,* ABC NEWS (Aug. 26, 2016), http://abcnews.go.com/Health/epipen-users-options-generic-alternate-drugs/story?id=41667390.
[122]Charles E. Grassley et. al., *United States Senate Letter,* SENATE (Aug. 24, 2016), http://www.grassley.senate.gov/sites/default/files/constituents/upload/2016-08-24%20CEG%20PJ%20AK%20RB%20RJ%20to%20FDA%20%28Mylan%20EpiPen%29_Redacted.pdf.

demand for, and thus the price of, EpiPens, making it unaffordable to many consumers.[123]

As previously mentioned, the concern for the lack of generic competition in the epinephrine autoinjector market encompasses bipartisan support. Five United States Senators, Richard Blumenthal (D-CT), Charles Grassley (R-IA), Rob Johnson (R-WI), Amy Klobuchar (D-MN), and Patrick Leahy (D-VT), wrote to the FDA on August 24, 2016, inquiring as to why generic versions of the EpiPen had been subjected to additional questioning by the FDA and had not yet been approved.[124] This only furthers the contention that the current system is broken. The incredible backlog (of both generic and brand-name) drugs awaiting FDA approval has increased both the risks and prices for consumers.

The combination of these two government regulations – the FDA approval process and SAEEA – created an enormous problem for the very consumers these regulations intended to protect. By mandating that all schools purchase FDA-approved epinephrine drugs, and by creating an invasive and complex approval process for epinephrine drugs, the government has essentially allowed Mylan to obtain a monopoly over the drug. This has enabled Mylan to skyrocket its prices making the life-saving drug very unaffordable.

D. Legal Background on Generic Drug Alternatives

While Mylan, epinephrine autoinjector drugs, and generic drug alternatives have been the subject of much litigation in the United States legal system, this Note will focus on the 2014 United States District Court case *JHP Pharmaceuticals v. Hospira.*[125] However, it is first imperative to understand the nature of recent case law before *JHP,* in respect to the changes to healthcare law after the Obama administration.

On March 23, 2010, President Barack Obama signed into law the Patient Protection and Affordable Care Act ("ACA"), which included an approximately 900-page law relating to sweeping modifications to the health care system as a whole.[126] The law's numerous provisions also brought important changes to particular aspects of the highly regulated

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[123] *Senators Ask FDA to Account for Any Alternatives to the EpiPen Amid Product Cost Increases,* SENATE (Aug. 24, 2016), http://www.grassley.senate.gov/news/news-releases/senators-ask-fda-account-any-alternatives-epipen-amid-product-cost-increases (last visited Apr. 9, 2017).
[124] Grassley, *supra* note 122.
[125] *JHP Pharmaceuticals v. Hospira*, 52 F.Supp.3d 992 (C.D. Cal. 2014).
[126] Carolyne R. Hathaway, John R. Manthei, and Elizabeth D. Meltzer, *A Brave New World: The U.S. Food and Drug Administration's Newfound Authority for Regulation of Follow-on Biologics,* 3 BLOOMBERG FIN. L.P. 5, (2010), https://www.lw.com/thoughtLeadership/fda-new-authority-over-follow-on-biologics.

pharmaceuticals industry, specifically impacting the world of brand and generic drug products.[127] The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") within the ACA was meant to rearrange the landscape for biologic product innovators and companies seeking to market follow-on biologic products.[128] BPCIA attempts to balance the interests of innovators in recouping their large investment in research, testing, and regulatory approval of innovative biologic products, with the public's interest in faster market entry and reduced prices for competing follow-on biologics. BPCIA created a new regulatory pathway, by which the FDA could approve a biologic product as "biosimilar to" a "reference product" [129] that was itself approved under the full, traditional pathway under the FDA.[130] Through this new pathway, Congress established procedures to control and streamline patent litigation between the biosimilar applicant and the reference product, triggered by the filing of an application under the new abbreviated pathway.

On May 5, 2015, Amgen, Inc. ("Amgen") filed an emergency motion for an injunction to prevent Sandoz, Inc. ("Sandoz") from marketing, selling, or importing into the United States ZARXIO®, its biosimilar product.[131] The Northern District of California then issued a panel opinion on July 21, 2015.[132] The parties each filed petitions for en banc review of aspects of that opinion.[133] In its opinion, the Federal Circuit extended the injunction through September 2, 2015.[134] On October 15, 2015 Amgen officially filed suit against Sandoz for the requested injunction.[135] The case involved the first and only approved biosimilar product, Sandoz's drug called Zarxio (a filgrastim product that helps the body make white blood cells after receiving cancer treatments), which referenced Amgen's filgrastim drug called Neupogen in order to be approved.[136] The Northern District of California ruled that BPCIA's

[127] *Id.*
[128] *Id.*
[129] The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 3139(a)(1)(iii)(C), 124 Stat. 119, 804-21 (2010).
[130] Regulation of Biological Products, 42 U.S.C. § 262(k) (2011).
[131] Amgen Inc. v. Sandoz Inc., No. 2015-1499 (N.D. Cal. May 5, 2015) (order granting injunction pending appeal).
[132] Amgen Inc. v. Sandoz Inc., 794 F.3d 1347 (N.D. Cal. 2015).
[133] *Id.*
[134] *Id*. at 1362.
[135] Amgen Inc. v. Sandoz Inc., 2015 WL 10460059 (N.D. Cal.) (Trial Pleading), No. 3:14-cv-04741-RS, (Oct. 15, 2015).
[136] *Id.*

notice of commercial marketing provision is mandatory and can only be given after FDA licensure of a biosimilar.[137]

On March 21, 2016, Amgen filed a brief opposing Sandoz's request that the Supreme Court overturn the Northern District of California's ruling that BPCIA's notice of commercial marketing provision is mandatory and can only be given after FDA licensure of a biosimilar product.[138] Amgen filed a certiorari cross-petition asking that should the Court decide to review the commercial marketing ruling, it should also review and overturn the Northern District of California's ruling that the patent dance information exchange procedures of the BPCIA are optional.[139]

This legal background sets the stage for the other factors that were going on with the law and healthcare industry in general regarding the many changes that occurred during the Obama administration. The ACA, BPCIA, and case law filed during these administrative changes are important to note when analyzing the *JHP Pharmaceuticals* opinion.

III. *JHP PHARMACEUTICALS V. HOSPIRA* OPINION

In *JHP Pharmaceuticals v. Hospira,* [140] Plaintiff JHP Pharmaceuticals, LLC ("JHP"), manufacturer of epinephrine injectable products, brought suit against Defendants Hospira, Inc. and American Regent, Inc. ("Hospira"), a competitor alleging misleading labeling. As previously discussed, labeling is critical to the manufacturing and selling of drugs. This is because companies sacrifice a much greater cost to obtain "brand-name" drug status as opposed to "generic" drug status, which is reflected in the price companies can sell their products at. Therefore, as this section will discuss, the *JHP* opinion further complicates Mylan's monopoly over the epinephrine autoinjector market.

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[137] James C. Shehan, *Amgen Asks the Supreme Court to Reject Challenge to Ruling that Notice of Commercial Marketing is Mandatory, But Asks for Review of Patent Dance Ruling Just in Casei,* FDA L. BLOG, (Mar. 28, 2016), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2016/03/amgen-asks-the-supreme-court-to-reject-challenge-to-ruling-that-notice-of-commercial-marketing-is-mandatory-but-asks-for-rev.html.

[138] *Id.*

[139] *Id.*

[140] JHP Pharmaceuticals v. Hospira, 52 F.Supp.3d 992 (C.D. Cal. 2014).

A. Facts of the Case

JHP submitted a New Drug Application ("NDA") for its one-milliliter and thirty-milliliter injectable epinephrine products to the FDA under the brand name "Adrenalin."[141] On December 7, 2012, the FDA granted JHP approval to market and sell the one-milliliter version of Adrenalin.[142] JHP alleged that it invested millions of dollars in complying with the FDA approval process.[143] JHP also alleged, and Hospira did not dispute, that Hospira was engaged in the business of selling injectable epinephrine products, which were not FDA-approved.[144] The bulk of JHP's complaint alleged that Hospira misled the public in four different ways: (1) by representing that their products were FDA-approved when they were not, (2) by advertising their products as "safe" and "effective," (3) by misleading as to the legality of their products, and (4) by misleading the public into thinking that JHP's product is more dangerous than the generic brands.[145] JHP asserted the claims against Hospira for each of the aforementioned reasons as in violation of the Lanham Act,[146] which forbids false or misleading advertising.[147]

B. Court's Holding

The United Stated District Court held JHP's claim that the competitor's packaging was misleading by saying their non-FDA approved injectable epinephrine products were safer than the JHP's product was not viable. The court wrote:

> [JHP's] fundamental argument with regard to FDA approval is that it is a sort of 'Good Housekeeping Seal' for pharmaceuticals: it is the government's imprimatur on a product, indicating quality, safety, and desirability. Although some drugs may be lawfully sold without FDA approval, if a product has been approved, consumers may take some assurance that it has been properly tested and meets the agency's minimum quality standards. This makes an FDA-approved product a more attractive product, whether at the wholesale, retail, or end user level. But it can also be expensive to get approval for a drug, so a company that chooses to invest in getting approval may operate at a competitive disadvantage if other companies can falsely represent to the

[141] *Id*. at 996
[142] *Id.*
[143] *Id.*
[144] *Id.*
[145] *Id.* at 996-7.
[146] 15 U.S.C. § 1125(a)(1).
[147] JHP Pharmaceuticals v. Hospira, 52 F.Supp.3d 992, 997 (C.D. Cal. 2014).

> public that their unapproved products are FDA-approved. Thus, representations that a drug is approved when it is not undermine the Lanham Act's public policy goals both by confusing consumers and by enabling unfair competition by producers who have not bothered to get FDA approval.[148]

The court dealt with JHP's four allegations regarding the various arguments that Hospira misled the public, in four different ways.[149] Regarding the first instance in which JHP asserts Hospira misled the public, the court held that there is a large difference between a company making an overtly false statement and, merely misleading in context.[150] Regarding the second instance in which JHP asserts Hospira misled the public, the court held that the issue was not that Hospira chose to market their product as "safe" or "effective," rather, that Hospira overtly misled the consumer by labeling their product as "FDA-approved" when it was not.[151] Regarding the third instance in which JHP asserts Hospira mislead the public, the court held this was a claim with regard to legality requirements that is within the primary jurisdiction of the FDA.[152] Finally, the fourth way in which JHP asserts Hospira misled the public was by omitting from the labeling of their product certain injection location and adverse reaction information.[153] JHP's product must carry this labeling as apart of its FDA approval requirements.[154] However, JHP alleges that such labeling misleads the public into thinking that JHP's product is more dangerous than the generic brands.[155] The court dismissed this claim because the Lanham Act requires a showing of facts regarding the labeling that JHP did not properly plead.[156]

IV. ANALYSIS

A. Policy Implications and Legal Analysis

In *JHP Pharmaceuticals v. Hospira* JHP argued Hospira mislead the public by not including on their packaging and labeling all of the warnings that JHP was required to include under the terms of the FDA

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[148] *Id.* at 1000.
[149] *Id.*
[150] *Id.* at 1002.
[151] *Id.* at 1003.
[152] *JHP Pharmaceuticals.* 52 F.Supp.3d at 1005.
[153] *Id.*
[154] *Id.*
[155] *Id.* at 1005-6
[156] *Id.*

approval.[157] Therefore, JHP alleged, Hospira created the impression that their product was less safe than JHP's because it came with more warnings, when in fact, JHP believed, the opposite was true because JHP's drug was approved by the FDA and Hospira's was not.[158] The court dismissed this claim because they believed JHP did not show that this message was actually transmitted to the consumer, and because JHP did not successfully prove that because the FDA did not approve Hospira's product it was somehow less safe.[159] If Hospira's product was actually found to be less safe than JHP's, then the misleading labeling claim would have succeeded. Therefore, the claim was dismissed.[160] While the court never determined whether or not Hospira's drug was "safe," their failure to determine that Hospira's drug was any *less* safe was in itself an endorsement of non-approved drugs. If the court was truly concerned that Hospira was somehow trying to trick the public, it would have found for JHP. Further, if the court had found that Hospira's conduct was in someway unsafe to American consumers, it would have done something to prevent Hospira from continuing this harmful conduct.

With respect to the surviving clams, the court reiterated the Supreme Court decision that the Lanham Act is a discrete regulatory scheme, with neither statute precluding claims made under the other.[161] The court analyzed JHP's surviving allegations with this in mind.[162] With respect to Hospira's alleged misrepresentations of FDA approval, the court found no preclusion, explaining that falsely representing FDA approval may confer a competitive disadvantage upon the approved drug.[163] Thus, false representations of approval "undermine the Lanham Act's public policy goals both by confusing consumers and by enabling unfair competition by producers who have not bothered to get FDA approval."[164]

As for JHP's claim that the Hospira misrepresented the legality of their products, the court explained the evaluation of this claim "directly implicates the FDA's rulemaking authority," and required the expertise of the FDA to resolve.[165] The court noted that "[t]he determination of whether a drug is 'new,' and whether it can be lawfully marketed under

[157] *JHP Pharmaceuticals.* 52 F.Supp.3d at 992.
[158] *Id.* at 996-97.
[159] *Id.* at 1005-6.
[160] *Id.*
[161] *JHP Pharmaceuticals.* 52 F.Supp.3d at 998.
[162] *Id.*
[163] *Id.* at 1000.
[164] *Id.*
[165] *Id.* at 1004.

the United States Federal Food, Drug, and Cosmetics Act ("FDCA"),[166] involves complex issues of history, public safety and administrative priorities that Congress has delegated exclusively to the FDA."[167] Unlike JHP's allegations of misrepresentations of FDA approval, its allegations based on stations of "legality" would be precluded in the absence of prior review by the FDA.[168]

1. FDA-Approved Drugs in the Market

The holding in *JHP Pharmaceuticals*[169] has tremendous impact on the legality surrounding non-FDA approved drugs on the market. The court's finding that there was no sufficient proof to show that an unregulated drug was any less safe than a regulated drug,[170] speaks volumes to the policy issues of FDA approval. The entire purpose of the FDA is to conduct research on a drug's quality, safety, and effectiveness to determine whether a drug's health benefits outweigh its known risks before allowing that drug to enter the market.[171] In *JHP Pharmaceuticals* the court essentially found that an unregulated drug was not any less safe than a regulated drug.[172] This could lead to questions about the actual purpose of the FDA. If an unregulated drug was not necessarily any less safe than a regulated drug, why would any company waste the time and resources to gain FDA approval in the first place?

2. FDA Approval Process Creates a Monopoly

The FDA approval processes for new drugs create a *de facto* monopoly on approved drugs when interfering legislation, such as the SAEEA, complicate the market. It is clearly important to have one consistent governing entity to regulate and evaluate drugs, especially a drug used by so many children. However, if a federal court can undermine the legitimacy of an administrative agency, this presents an issue. Uniformity among different bodies of government is critical to the forefront of democracy. However, uniformity is lacking where the judiciary steps in to make a definitive ruling one way or the other.

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[166] Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997).
[167] *JHP Pharmaceuticals* , 52 F.Supp.3d at 1002.
[168] *Id.*
[169] *Id.* at 992.
[170] *Id.* at 996.
[171] *Development & Approval Process (Drugs),* FDA, (Jan. 29, 2016), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/.
[172] *JHP Pharmaceuticals*, 52 F.Supp.3d at 996.

Courts should follow the reasoning in *JHP Pharmaceuticals* that where there is no definitive proof the non-FDA approved drug should not be considered any less safe. If this reasoning is applied, companies awaiting FDA approval will not be punished for trying to access the market. Hopefully, this would allow a company to sell non-FDA approved epinephrine autoinjectors to consumers that desperately need the life-saving drug.

3. Economic and Legal Effects of Federal Overregulation

Nonetheless, if Mylan's competitors advertise their products as being as safe and as effective as the EpiPen, despite no FDA approval, this could help lower costs for epinephrine autoinjectors across the country. However, federal mandates such as SAEEA that require FDA approval for a very large percentage of epinephrine autoinjector sales, still feed into this *de facto* monopoly issue. Unfortunately, a judicial ruling on this issue can only go so far if the regulations by other branches of government do not reflect the current atmosphere. Even if the Trump Administration were to lift the SAEEA requirements, EpiPen has already accessed the system. Even if schools were no longer required to store epinephrine autoinjectors, it is unlikely they would stop stocking the, since many students' health still rely access to these autoinjectors.

While hindsight is always twenty-twenty, hopefully the Mylan EpiPen monopoly can, at the very least, serve as a lesson to the federal government and advocates for overregulation. It is evident that the government went too far in attempting to fix the problem of children going into anaphylactic shock and needing assistance with an epinephrine autoinjector. Two regulations that, on their face, seem necessary (an FDA approval process that ensures consumers receive safe drugs and mandating that schools carrying epinephrine autoinjectors) thwarted the very success that they were trying to achieve. Four years after the enactment of the SAEEA, EpiPens have quadrupled in price becoming nearly impossible for consumers to purchase. Legislators should be very weary of the long-term effects of legislation, and continue to analyze how pending legislation will be affected by policies and procedures implemented by other branches of government. This only reiterates the importance of the judiciary to answer the call and address the mistakes made by the legislative and executive branches.

V. IMPACT

This section discusses the impact of the court's ruling in *JHP Pharmaceuticals v. Hospira.*[173] First, it explores the impact the case has had on the field of healthcare.[174] Second, it explores the case's impact on field of education.[175]

A. Impact on Healthcare

The holding in *JHP Pharmaceuticals*[176] impacts how business works in the healthcare industry because ensuring that consumers have drugs available to them that are equally safe and affordable is critical, and, arguably, the most important impact of this subject. The ways in which drug manufacturers can manipulate the market through favorable government intervention poses significant problems for consumers. If a drug manufacturer has a monopoly on over ninety percent of the market[177] then a consumer will reasonably believe that this drug is the most superior drug available to them. It is one thing for a manufacturer to use smart business and marketing tactics, such as giving away free products to schools in order to increase brand recognition[178], or by only selling the product in two-packs effectively doubling their price.[179] The most successful companies in American history have used tactical business maneuvers throughout history. Well-known companies from Kraft to General Mills to Proctor & Gamble have adopted this strategy.[180] However, it is an entirely different situation when a manufacturer gains market control because of government favorability. Furthermore, the stakes are even higher when that manufacturer is creating a life-saving drug, rather than when a company is manufacturing macaroni and cheese or toothpaste.

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[173] *Id.* at 992.
[174] *See infra* notes 174-180 and accompanying text.
[175] *See infra* notes 181-185 and accompanying text.
[176] *JHP Pharmaceuticals*, 52 F.Supp.3d at 992.
[177] Ben Popken, *Lawmakers Accuse Mylan CEO of 'Rope-a-Doping' on EpiPen Prices,* NBC NEWS, (Sept. 21, 2016), http://www.nbcnews.com/business/consumer/lawmakers-grill-mylan-ceo-fda-epipen-price-hike-n651201.
[178] Carolyn Y. Johnson and Catherine Ho, *How Mylan, the EpiPen company, maneuvered to create a virtual monopoly,* CHI. TRIB. (Aug. 25, 2016), http://www.chicagotribune.com/business/ct-mylan-epipen-monopoly-20160825-story.html.
[179] Ben Popken, *Lawmakers Accuse Mylan CEO of 'Rope-a-Doping' on EpiPen Prices,* NBC NEWS, (Sept. 21, 2016), http://www.nbcnews.com/business/consumer/lawmakers-grill-mylan-ceo-fda-epipen-price-hike-n651201.
[180] Brad Tuttle, *The Power of Freebies: Why Companies Pay to Give Free Samples to Supermarket Customers,* BUS. TIME, (Feb. 17, 2011), http://business.time.com/2011/02/17/the-power-of-freebies-why-companies-pay-to-give-free-samples-to-supermarket-customers/.

B. Impact on Legislation

The holding in *JHP Pharmaceuticals*[181] impacts how overregulation of a field may thwart the very efforts the proposed legislation is trying to help. The overregulation of epinephrine drugs essentially drove up the price making them nearly unaffordable for those who need them most. Businesses who create the best products deserve the chance to prove that to the market on their own, and not be overshadowed by a regulation-induced monopoly.

In order to ensure that consumers have access to the best, most efficient, most superior, and, in the case of drugs and medicine, most affordable products, the government should not intervene and overregulate the market. In the case of the EpiPen, the government did so in all three branches: the executive, the legislature, and the judiciary. First, the FDA's lengthy and over-complicated approval process makes it nearly impossible for generic drug manufacturers to create safe and affordable alternatives to the EpiPen.[182] Second, the School Access to Emergency Epinephrine Act enacted by Congress in 2013 heavily influenced by Mylan, essentially allowed Mylan to acquire a monopoly over the epinephrine autoinjector market by offering financial incentives to states who required all schools to stock the drug, knowing full well that the majority of schools were only familiar with the EpiPen.[183] Third, a federal court, failed to find that a non-approved FDA drug was any less safe than an FDA-approved drug,[184] essentially undermining the entire legitimacy and purpose behind the agency. The court, essentially deemed the non-FDA approved drug just as safe as FDA-approved drug, yet still did not make it possible for a non-FDA approved drug to enter the market.

The purpose of the federal judiciary system is to evaluate laws – to interpret the meaning of the laws, apply laws to individual cases, and to decide if laws violate the Constitution.[185] The beauty of the system of checks and balances in the United States government is that no one branch of government is sovereign. If the judiciary finds a flaw within a law enacted by Congress when applying that law to a particular case, it

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[181] *JHP Pharmaceuticals*, 52 F.Supp.3d at 992.
[182] *Development & Approval Process (Drugs),* FDA, (Jan. 29, 2016), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/.
[183] Carolyn Y. Johnson and Catherine Ho, *How Mylan, the EpiPen company, maneuvered to create a virtual monopoly,* CHI. TRIB, (Aug. 25, 2016), http://www.chicagotribune.com/business/ct-mylan-epipen-monopoly-20160825-story.html.
[184] JHP Pharmaceuticals v. Hospira, 52 F.Supp.3d 992, 997 (C.D. Cal. 2014).
[185] *Branches of Government,* USA, https://www.usa.gov/branches-of-government (last visited Mar. 27, 2017).

should further analyze whether or not the legislation is inconsistent with the Constitution. While the purpose of the FDA is to ensure only safe drugs enter the market place, the *JHP* ruling found a non-FDA approved drug was no less safe than an FDA-approved drug. Therefore, the court should not have stopped its analysis there. The specifics of the FDA approval process should be called into question and analyzed by the federal court system.

VI. CONCLUSION

In conclusion, the overregulation of the epinephrine autoinjector market by the federal government caused Mylan to acquire a monopoly on the EpiPen, increasing the cost of the product for consumers. This overregulation was caused by the United States Congress in the passing of the SAEEA, by mandating that states must comply with this law, and by the over-stringent FDA approval process for alternative epinephrine autoinjector drugs. Further, this problem has been exacerbated by the United States Federal Court system as seen in *JHP Pharmaceuticals*. If JHP was unable to allege any facts that Hospira's drug was either unsafe or ineffective and therefore the court allowed for its legal sale, then the federal court finding is inconsistent with the purpose of a federal government agency. Drugs that are not found to be unsafe or ineffective should therefore be approved by the FDA, or, at the very least, be approved to market to consumers.

There have been two major proposals to deal with the EpiPen monopoly and price surge. Advocates on the right think the overly stringent FDA regulations and long approval process are to blame. At his first address to a joint session of Congress, President Trump said, "our slow and burdensome approval process at the Food and Drug Administration keeps too many advances…[from] reaching those in need."[186]

Advocates on the left tend to think more government regulation will fix the problems with previous government regulation. When she was running for President, Mrs. Clinton claimed the EpiPen price hikes showed the need for price controls, and she said she would require drug makers to "prove that any additional costs are linked to additional patient benefits and better value."[187]

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[186] Donald J. Trump, *Donald Trump's Congress speech,* CNN, (Mar. 1, 2017), http://www.cnn.com/2017/02/28/politics/donald-trump-speech-transcript-full-text/.

[187] Hillary R. Clinton, *Hillary Clinton Statement on EpiPen Pricing,* HILLARY CLINTON, https://www.hillaryclinton.com/briefing/statements/2016/08/24/hillary-clinton-statement-on-epipen-pricing/ (last visited Mar. 27, 2017).

There are clearly many proposed solutions to this problem, as the problem itself harbors bipartisan support. Both Republican and Democratic lawmakers have the same end goal: to make epinephrine autoinjector drugs more affordable to families who desperately need this life-saving drug. Either loosening the reigns on the FDA approval process, or allowing for other bodies of government (such as the federal courts) to approve the sale of these products are viable alternatives. This would allow for two products containing nearly the same ingredients, intended to be used for the exact same purposes, to be sold with similar labeling. This would allow the free market system to naturally weed out the inferior of the two products based on consumer preferences. So long as all of the products were considered safe and effective by the FDA, then the consumers could drive the market based on their preferences between drug manufacturers and would not be limited only by what the federal government allows them to choose from. Prices would drop and product efficiency would increase.

Based on these reasons, courts should decline to follow the overall ruling in *JHP Pharmaceuticals*.[188] Holding that the court is unable to decide cases based on a separate federal agency is simply a waste of litigation, which could have been used to better their products, which is ultimately better for society. However, courts should consider the line of reasoning employed in *JHP Pharmaceuticals* in that where there is no proof that a non-FDA approved drug is any less safe than an FDA-approved drug, the non-approved drug should not be precluded from entering the market because this will only increase the competition of a healthy market, providing more and better options for consumers.

[188] *JHP Pharmaceuticals*, 52 F.Supp.3d at 992.