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Compounding Drugs: Using Market-Based Solutions to Respond to Patient Needs

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INTRODUCTION

Off-patent drug costs have soared over the past several years, causing patients to urge federal and legislative policy makers to create fast and cheap solutions.[1] For instance, drugs and medical devices such as Mylan's EpiPen surged in price from $10 to $600 after the company acquired the product in 2007.[2] In 2015, Turing Pharmaceutical's Daraprim increased in price from $13.50 to $750 seemingly overnight.[3] Though pharmaceutical companies are under scrutiny by lawmakers and the public for the soaring off-patent drug costs, the companies have not lowered their prices.[4] Off-patent prescription drug price increases are attracting national attention since the profits of these pharmaceutical companies come at the expense of the general health and welfare of the public.[5]

To better respond to patient needs and increase patient access to affordable medicine, the legal industry should examine the controversial process of drug compounding with proper safety regulation and examine new law implementation as an alternative source of obtaining essential medicines. Market-based solutions may be the easiest, most affordable way to combat

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1. Naren P. Tallapragada, *Off-Patent Drugs at Brand-Name Prices: A Puzzle for Policymakers*, J. L. & BIOSCIENCES 1, 2 (2016).
2. *Id.*; Rita Rubin, *EpiPen Price Hike Comes Under Scrutiny*, 388 LANCET 1266, 1266 (2016).
3. Tallapragada, *supra* note 1.
4. *Id.*
5. *Id.*

rising prescription drug costs.

This article will first provide an overview of the current drug compounding legal framework. It will then discuss controversies surrounding drug compounding and the adverse health effects that have occurred from the use of compounded drugs. Finally, this article will advocate for and propose changes to current drug compounding laws to better ensure patient safety and provide an affordable medicine alternative.

I. THE RISING COSTS OF MEDICALLY NECESSARY DRUGS

New inventions are granted patents, or a property right to the product.[6] This right includes the right to exclude others from making, using, offering for sale or selling the invention in the United States.[7] The development of new inventions is risky, expensive and time-consuming.[8] The right to exclude thus allows a monopolization of a drug or invention to permit inventors and businesses to recoup their research and development costs.[9] A patent encourages innovation by supplying inventors with a reward when they undergo risks in developing a drug or product.[10] Without generic competition, patients can expect newly patented brand-name drugs to be more expensive until the patent expires and generic competition enters the market.[11] However, older, off-patent drugs typically have generic competitors which lower the cost of the drugs.[12] Thus, recent price hikes for older, off-patent drugs has policymakers confounded.[13]

Off-patent drug companies have raised their prices through two avenues.[14]

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6. U.S. PATENT & TRADEMARK OFFICE, *General Information Concerning Patents*, (Oct. 2015) https://www.uspto.gov/patents-getting-started/general-information-concerning-patents.
7. *Id.*
8. *Id.*
9. *Id.*
10. *Id.*
11. Tallapragada, *supra* note 1.
12. *Id.*
13. *Id.*
14. *Id.*

First, by increasing rates for single-source drugs, pharmaceutical companies are able to monopolize the market.[15] In other words, with no generic competitors, companies for off-patent drugs are able to exponentially raise their prices since generic companies offer no cheaper alternatives.[16] Second, multisource drugs, and the companies that manufacture them, have undergone manufacturer mergers and manufacturing disruptions.[17]

Furthermore, some off-patent drugs with astronomical prices are classified by the World Health Organization (WHO) as "essential medicines."[18] The WHO recommends essential medicines be available in health systems at all times in adequate amounts, in appropriate dosage forms, with quality and at a price that the community can afford to pay.[19] Unfortunately, the WHO's recommendations have not been carried out. Included on the WHO's list of essential medicines for 2015 are off-patent epinephrine and Daraprim, both of which are monopolized by companies that have raised their prices to an unaffordable cost.[20]

The EpiPen, an off-patent auto-injector used to administer epinephrine for life-threatening allergic reactions, increased in price nearly 400 percent over the last three years.[21] While the auto-injector used to administer epinephrine is forty years old, and epinephrine itself is 100 years old, one EpiPen costs a patient over $600 today.[22] Efforts by generic companies to acquire FDA

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15. *Id.* at 3 (defining single source drugs as those with only one manufacturer as opposed to multi-source drugs with multiple manufacturers).

16. *Id.*

17. *Id.* (discussing how mergers can lead to single source drugs and further monopolization).

18. *Id.* at 5.

19. *Id.*; WORLD HEALTH ORG., *Essential Medicines*, http://www.who.int/medicines/services/essmedicines_def/en/. (last visited Mar. 31, 2017) (defining essential medicines as "those that satisfy the priority health care needs of the population").

20. *See generally* WORLD HEALTH ORG., *WHO Model List of Essential Medicines*, http://www.who.int/medicines/publications/essentialmedicines/EML_2015_FINAL_amended_NOV2015.pdf?ua=1. (last updated Nov. 2015).

21. Rubin, *supra* note 2.

22. *Id.*

approval have proved futile.[23] In October, 2015, the Auvi-Q injector was voluntarily recalled by Sanofi because of worries over inaccurate dosage delivery.[24] Another attempt by Israeli drug company Teva to produce an epinephrine auto-injector failed due to "major deficiencies" in its application.[25] Concerns over EpiPen's lack of competition led President Barack Obama to sign into law the School Access to Emergency Epinephrine Act to ease parents' anxiety about children with severe allergies going into anaphylactic shock while at school.[26] Although the Act is aimed at keeping children safe while at school, the President's endorsement of EpiPen may further monopolize the market, labeling EpiPen as the only trusted auto injector and discouraging new generic attempts to enter the market.[27]

II. DRUG COMPOUNDING AND THE ENDANGERMENT OF PUBLIC HEALTH

Physicians suggest that if worse comes to worse, a doctor can instruct patients how to use a simplified version of the EpiPen, a needle, a syringe and epinephrine.[28] Doctors can put these packs together for less than four dollars, although it carries risks of not meeting the "current standards of medicine."[29] A 2012 study on physician characteristics associated with off-label prescribing in primary care revealed that off-label prescribing is common, accounting for up to twenty-one percent of prescribed drugs.[30] This

23. *Id.*
24. *Id.*
25. *Id.*
26. *Id.* (statement of presidential adviser Valerie Jarrett) ("Under the law, the Department of Health and Human Services will give funding preferences to states for asthma-treatment grants if they maintain an emergency supply of epinephrine (EpiPens) and develop a plan to ensure that school personnel are trained and available to administer it."); *see also* School Access to Emergency Epinephrine Act, S. 1503, 113th Cong. (2013); Part of the reason for the price increase of Mylan's EpiPen may be due to its' program that offers free EpiPens to schools. Mylan, *EpiPen4Schools*, (2016), https://www.epipen4schools.com/.
27. *See generally* Rubin, *supra* note 2.
28. *Id.*
29. *Id.*
30. Tewodros Eguale et al., *Drug, Patient, and Physician Characteristics Associated with Off-Label Prescribing in Primary Care*, 172 ARCH INTERN MED 781, 781 (2012).

alarmingly cheap alternative begs the question of what the legal repercussions and risks would be if doctors were to make their own drugs and devices, otherwise known as "drug compounding" or "pharmacy compounding."[31]

Physicians have compounded drugs for patients well before the rise of mass-produced pharmaceuticals.[32] Compounded drugs represent one to three percent of all pharmaceuticals and are an important aspect for public health.[33] Pharmacy compounding refers to the process by which pharmacists combine drug ingredients to produce medicines tailored to the individual needs of each patient.[34] Often, drugs are modified to a lower dosage or are modified to omit an ingredient to which the patient is allergic.[35] Drug compounding can also take place when physicians produce drugs that are otherwise unavailable or are not being manufactured.[36] "Office-use" drugs that are produced in advance, without a prescription when physicians need them on-hand, are also considered compounded drugs.[37]

Over the past twenty to thirty years, drug compounding has seen significant growth and certain companies have begun producing drugs on a much larger scale.[38] Thus, the traditional role of compounding that occurred for centuries between doctor and patient has been blurred with the process of drug manufacturing.[39] However, because drug compounding is not required

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31. Carey B. Nuttall, *Pharmacy Compounding Issues in Today's Marketplace*, ASPATORE 1, 1 (2013).

32. T.R. Goldman, *Regulating Compounding Pharmacies*, HEALTH AFF. (May 1, 2014), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=114.

33. *Id.*

34. Nuttall, *supra* note 31, at 1 (discussing modifying a drug based on a patient's allergies or need for a different dosage or form).

35. *Id.*

36. *Id.*

37. Goldman, *supra* note 32 (including dermatologists' salves and creams and cardioplegic surgical solution pumped into heart valves).

38. Nuttall, *supra* note 31, at 1.

39. Thomas Smith et al., *There Is No Such Thing as a Compounding Manufacturer! (Or Is There?)*, 27 HEALTH L. 1, 2-3 (2015).

to undergo the premarket approval process by the Food and Drug Administration (FDA), there have been various incidents of mass-manufacturing drug compounding pharmacies endangering patient health.[40]

In 2007, the Centers for Disease Control and Prevention reported a compounding pharmacy in Texas that did not adhere to the correct dosage for intravenous colchicine.[41] The incident resulted in three deaths from cardiac arrest and a recall of the medication.[42] Another adverse event occurred in Florida of August of 2011 when intravitreal injections of bevazicumab were used to treat macular degeneration.[43] Twelve patients were infected with Streptococcus and some lost their remaining vision.[44] In 2012, the worst compounding incident occurred when the New England Compounding Company (NECC) caused more than 438 cases of fungal meningitis and thirty-two deaths.[45] The NECC manufactured and sold vials of a bacterially contaminated steroid solution to physicians that were used on patients nationwide.[46] This tragedy led Congress to enact the Drug Quality and Security Act (DQSA).[47]

III. THE DRUG QUALITY AND SECURITY ACT

The NECC outbreak prompted the FDA and states to conduct inspections at compounding pharmacies which revealed objectionable conditions at more than sixty facilities.[48] House and Senate Committee hearings ensued to formulate a law that would prevent such a disaster from happening again.[49]

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40. Tyler Dinkelaker, *A False Sense of Safety: How The Drug Quality and Security Act Fails to Protect Patients from Harm*, 9 ST. LOUIS U. J. HEALTH L. & POL'Y, 329, 330 (2016).
41. Jennifer Gudeman et al., *The Potential Risks of Pharmacy Compounding*, 13 DRUGS IN R & D 1, 5 (2013).
42. *Id.*
43. *Id.*
44. *Id.*
45. Dinkelaker, s*upra* note 40, at 330.
46. *Id.*
47. *Id.* at 332-33.
48. Goldman, supra note 32.
49. *Id.*

On November 27, 2013, President Obama signed into law the DQSA to clarify FDA oversight of compounding pharmacies and to ensure the FDA could take action against compounding pharmacies that were not up to the standard of practice.[50]

The DQSA amends Section 503B of the Food and Drug Cosmetic Act (FDCA) to allow compounding pharmacies to voluntarily register as "outsourcing facilities" and subjects pharmacies to enhanced FDA regulation.[51] "Outsourcing facilities" can produce medications for patients without prescriptions.[52] Under the DQSA, these facilities may not make drugs that are "essentially a copy" of a drug commercially available and must undergo FDA inspections only if there is a health risk.[53] Outsourcing facilities also must submit information to the FDA about compounded products every six months, report product adverse events and pay an annual fee for inspection.[54] Compounders are permitted to produce products and sell unlimited quantities of drugs on the FDA's drug shortage list without requiring a preexisting prescription.[55] However, if a drug compounding

50. Dinkelaker, s*upra* note 40, at 349.

51. *Id.* at 350. (including the requirement to report adverse events); *see also* The Drug Quality and Security Act, H.R. 3204, 113th Cong. (2013).

52. *Id.*

53. *Id.* at 352. ("Essentially a copy" is defined by section 503B as "(A) a drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 503(b) . . .," not on a list of drug shortages "at the time of compounding, distribution, and dispensing; or (B) a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to 503(b) and not subject to approval in an application submitted under Section 503(b), unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner. "Health Risk" is based on the Secretary's inspection of outsourcing facilities "according to the known safety risks of such outsourcing facilities, which shall be based on the following factors: (i) The compliance history of the outsourcing facility. (ii) The record, history, and nature of recalls linked to the outsourcing facility. (iii) The inherent risk of the drugs compounded at the outsourcing facility. (iv) The inspection frequency and history of the outsourcing facility, including whether the outsourcing facility has been inspected pursuant to section 704 within the last 4 years. (v) Whether the outsourcing facility has registered under this paragraph as an entity that intends to H. R. 3204—6 compound a drug that appears on the list in effect under section 506E. (vi) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.").

54. *Id.*

55. *Id.*

company chooses not to register as an "outsourcing facility," the company is subject to all the requirements of the FDCA.[56] These requirements include seeking drug approval and including adequate directions for patient use.[57]

Although Section 503B attempts to ensure the safety of compounding manufacturers, concerns remain.[58] For example, the DQSA only applies to facilities that engage in the compounding of sterile drugs. Further, the DQSA allows outsourcing facilities producing sterile drugs to be compounded with or without a patient name and Section 503B's registration requirement is completely voluntary.[59] By not regulating non-sterile drugs, the FDA misses an opportunity to engage in strict oversight of a compounding drug company.[60] In addition, because these compounding facilities may still produce drugs without a patient name, manufacturers can produce drugs off-label without a patient prescription.[61] Further, since registration is voluntary, dangerous compounding companies may not register because of the requirements to which they must adhere.[62] This voluntary registration theory is contingent on two premises.[63] The first is that hospitals will only choose to buy from FDA approved outsourcing facilities and thereby provide an economic incentive for companies to register under Section 503B.[64] The second is the use of payment policies where insurers will only reimburse for compounded drugs from registered facilities.[65] These incentives are yet to be

56. *Id.* at 351.
57. *Id.*
58. *See* i*d.*
59. *Id*.
60. *Id.*
61. *Id.*
62. *Id.*
63. Erika Lietzen, *Pharmacy Compounding After the Drug Quality and Security Act*, 26 HEALTH L. 1, 5-6, 8 (2014).
64. The FDA has engaged in substantial outreach efforts to governors, health departments, boards of pharmacy and hospital purchasers asking that they support the FDA's goal to encourage outsourcing facilities to register. However, whether outsourcing facilities will continue to register remains unseen. If outsourcing facilities stop registering it could prompt additional legislation. *Id.*
65. *Id.*

proven effective in encouraging registration.[66]

Finally, one interpretation of the DQSA is that it actually undermines the authority the FDA had before the Act was enacted.[67] Not only is the registration voluntary, but one reading of the DQSA suggests that the FDA already had authority over these large scale pharmacy compounders prior to the enactment of the law.[68] This authority is evident by the agency's actions in response to the meningitis outbreak.[69] The DQSA may simply have made it completely legal for compounding companies to not register and continue to operate facilities that are not up to quality standards while simultaneously regulating the companies that were most likely already in close compliance with FDA requirements.[70] Companies with resources to comply with FDA safety requirements are likely to voluntarily sign up, while those who have not voluntarily signed up are likely non-compliant and free to compound, risking patients' health.

IV. ENHANCED PATIENT SAFETY MEASURES: MAKING COMPOUNDED DRUGS A VIABLE OPTION

Before compounded drugs can be a viable option for producing alternative,

66. *Id.*; FOOD & DRUG ADMIN., *Registered Outsourcing Facilities*, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm (last updated Dec. 2, 2016); As of December 2, 2016, sixty-seven compounding pharmacies have registered as "outsourcing facilities." Although this may seem like a lot, there may be many more eligible to register. It is unknown how many there are and there is no way to track because there is no federal licensing required. *Checking in on 503B: To Register or Not to Register?*, AM. PHARMACISTS ASS'N (Sept. 1, 2015) https://www.pharmacist.com/checking-503b-register-or-not-register-0.

67. Lietzen, *supra* note 63.

68. *Id.*

69. *Id.*; *The Fungal Meningitis Outbreak: Could It Have Been Prevented? Hearing before the Subcomm. on Oversight and Investigations of the Comm. On Energy and Commerce*, 112th Cong. (Nov. 14, 2012) (statement of Margaret A. Hamburg) http://www.fda.gov/NewsEvents/Testimony/ucm327664.htm (explaining that the FDA's far-ranging response to the outbreak includes, but is not limited to, coordinating with the state to conduct an investigation of the facility, conducting an investigation of NECC on October 1, 2012, issuing a MedWatch Safety Alert to health professionals, making available lists of customers who purchased NECC products on or after May 21, 2012 and conducting recall audit checks of NECC's customers).

70. Lietzen, *supra* note 63.

less expensive medication, there must be changes to the law to correct the serious public safety issues. For example, to ensure patient safety, the FDA could implement transparency in the drug supply chains of pharmacy compounders.[71] This would allow consumers to access information about the components and the final production of the prescription drug.[72] In addition, the FDA could rate compounding plants A, B, C, and D, for example, based on FDA inspections and any warning letters issued to the plant.[73] Consumers should then have access to this grading scale when purchasing prescription drugs.[74]

Although grading would be a valuable resource for consumers, there are of course drawbacks. Supply chain transparency, or the availability of information concerning the various levels of the supply chain, is critical for manufacturers to gain and maintain knowledge about their sources of supply and thus better control the quality of the drugs that are manufactured and sold to consumers.[75] Each supplier may have manufacturing sites around the world and manufacture in facilities that are run by subcontractors leading to a complex supply chain structure.[76] This complex structure, although important because it can identify risks when suppliers or subcontractors fail to meet regulatory requirements concerning product quality, is highly difficult to monitor. Furthermore, it is not simply sufficient to gather supplier information once, but it must be continually updated which requires time and resources.[77]

Another concern is that the FDA has limited resources, and requiring it to

71. MARK L. BAUM, PHARMACEUTICAL COMPOUNDING: AN ESSENTIAL PIECE OF THE HEALTHCARE REFORM PUZZLE 48 (2016).
72. *Id.*
73. *Id.*
74. *Id.*
75. *Id.*
76. *Id.*
77. *Id.*

take on additional tasks may be unrealistic.[78] Therefore, the FDA should acquire more funding to better monitor supply chain transparency. In addition, defining factors to create a grading system could prove difficult with such a vast amount of information that would take extensive time to gather and categorize. For instance, determining what factors would separate an A from a B pharmacy may be hard to distinguish. In addition, even an A graded pharmacy may not meet or exceed every FDA requirement or guideline, so there could still be potential safety risks associated with an A-rated pharmacy.

Further, Section 503B could be applied to non-sterile medications.[79] Non-sterile compounds, which include hormone, pain and pediatric medications are commonly used throughout the country and have the ability to be just as dangerous as sterile compounds when ill-prepared.[80] For example, a dose higher than three times the normal amount for non-sterile thyroid medication could result in cardiac arrest.[81] In addition, failure to monitor all aspects of a compounding pharmacy could result in facilities continuing their normal outsourcing practices without stricter scrutiny.[82]

This is the simplest solution to implement, although the FDA may struggle with resources to conduct screening of all non-sterile compounds as well. Another concern with making compounding drugs safer while simultaneously trying to provide a cheaper alternative is fear of making the compounding drug approval process just as long as the FDA's current approval procedures.[83] Currently, priority review takes about twelve

78. *Addressing the FDA's Resource Challenges,* NAT'L CTR. FOR BIOTECHNOLOGY INFO. (2007), https://www.ncbi.nlm.nih.gov/books/NBK52926/.
79. Dinkelaker, *supra* note 40, at 358.
80. *Id.*
81. *Id.*
82. *Id.*
83. *Id.*

months,[84] but if all drugs at compounding facilities are required to undergo thorough inspection, the same timing problem experienced with generic approval could undermine the alternative solution to lowering drug costs. However, considering that many high-priced prescription drugs are essential medicines, the solution is worth pursuing.

V. MOVING TOWARDS AFFORDABLE PRESCRIPTION DRUGS: PROPOSED AMENDMENTS TO THE DRUG QUALITY AND SECURITY ACT

Compounding companies have begun to take active steps to enter the pharmaceutical market which could aid in lowering prescription drug costs.[85] For example, Imprimis Pharmaceuticals, Inc. is taking affirmative steps to break down monopolized markets for Daraprim, a drug that fights a parasitic infection that affects HIV patients.[86] In December 2015, Imprimis announced a deal with Express Scripts Holding Co. to make a new version of Daraprim for just one dollar a capsule to compete with the current market price established by Turing Pharmaceuticals' Daraprim of more than $750 a capsule.[87] Imprimis operates facilities for individual patients and is building two outsourcing facilities.[88] The company fills prescriptions for patients every day and reports high regulation by the FDA.[89]

Although Imprimis may be able to provide a cheaper alternative, the option is not without its obstacles. First, in July 2016 the FDA provided further guidance on the statutory language in the DQSA which states that no compounded drug may be "essentially a copy" of a drug that is currently on

84. Michael Hiltzik, *The FDA Can Single-Handedly Reduce Drug Price Gouging. Why is it Waiting?*, L.A. TIMES (Jan. 5, 2016, 12:31 PM), http://www.latimes.com/business/hiltzik/la-fi-mh-the-fda-can-single-handedly-stop-20160105-column.html.

85. Steve Sternberg, *Can Compounding Pharmacies Circumvent Big Pharma?*, U.S. NEWS (Dec. 15, 2015, 2:14 PM), http://health.usnews.com/health-news/hospital-of-tomorrow/articles/2015-12-15/can-compounding-pharmacies-circumvent-big-pharma.

86. *Id.*

87. *Id.*

88. *Id.*

89. *Id.*

the market.[90] This makes it difficult for Imprimis to produce its version of Daraprim when the current monopolized drug is on the market.[91] Alternatively, the FDA could amend its definition of "essentially a copy" to better align a vision towards affordable prescription drugs. This provision is directly at odds with discouraging monopolized markets and could be amended to "exact copy" so that compounding pharmacies can alter a drug slightly, either by dosage or route of administration, and provide a cheaper and safe alternative.[92] However, if safety measures are not first implemented, then compounding companies will be free to produce a copy of a drug that without adequate standards of safety and efficacy.

Second, the FDA could redefine the term "drug shortages" in the DQSA.[93] The FDA defines a drug shortage as "a period of time when the demand or projected demand for a medically necessary drug in the United State exceeds its supply."[94] However, this definition is too narrow to allow compounding companies to compete with monopolized markets.[95] The definition could be construed more broadly to include economic factors.[96] By including economic factors in the definition, compounding pharmacies will be able to produce drugs that are off-patent on the "drug shortage list" due to lack of competition.[97] This is a simple market-based solution without resorting to price controls or more policy implementation.[98]

A major drawback to allowing compounding companies to make exact

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90. *Id.*

91. BAUM, *supra* note 71, at 26 (defining "essentially a copy" as a compounded drug that has the same active pharmaceutical ingredient, excipients, dosage form and strength and route of administration as a commercially available drug or FDA-approved drug).

92. *Id.*

93. *Id.* at 49.

94. U.S. FOOD & DRUG AMIN., *CDER Conversation: FDA's Drug Shortages Prevention Strategies*, http://www.fda.gov/drugs/newsevents/ucm432474.htm (last updated Feb. 5, 2015).

95. BAUM, *supra* note 71, at 49.

96. *Id.*

97. *Id.*

98. *Id.*

copies of a drug on the market is the negative effect such manufacturing could have on the generic market.[99] For example, allowing compounded drug products to be sold without full FDA approval could provide a disincentive for companies to take drugs through the generic drug approval process.[100] While generic drug manufacturers must go through a lengthy and expensive approval process, compounding companies need not go through bioequivalence trials or comply with significant safety standards, saving time and costs.[101] Therefore, amending the definition of "drug shortages" could provide a short term solution but in the long term may actually undermine affordability goals.[102]

Lastly, the FDA could allow drugs that have been off-patent for more than ten to twenty years to be compounded in 503B outsourcing facilities.[103] The Hatch-Waxman Act was implemented to bring competition for off-patent drugs but it has only been partially successful.[104] One consequence of the act has been to protect markets for old off-patent drugs whose markets are overlooked.[105] Interpreting the DQSA to permit outsourcing facilities to produce these off-patent drugs with no generic competition to make safe copies of the drugs would lower drug prices and permit companies to safely produce the drugs without fear of being shut down.[106]

One disadvantage is that expanding compounding beyond what is prescribed in the statute could weaken oversight.[107] Compounded drugs have

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99. *Why Drug Compounding is Not a Solution to High Drug Prices*, PEW CHARITABLE TR. (Feb. 4, 2016), http://www.pewtrusts.org/en/research-and-analysis/analysis/2016/02/04/why-drug-compounding-is-not-a-solution-to-high-prices [hereinafter *Not a Solution*].

100. *Id.*

101. *Id.*

102. *Id.*

103. BAUM, *supra* note 71, at 58.

104. *Id.* (enacting the Hatch-Waxman Act to encourage the manufacturing of generic drugs by pharmaceutical companies).

105. *Id.*

106. *Id.*

107. *Not a Solution*, *supra* note 99.

historically played a vital role in the nation's health care system, most notably by allowing a physician to order specialized medicines for patients.[108] This need for efficient, specialized medicine has exempted compounders from the normal drug approval process when compounding provides a significant difference to the patient.[109] Allowing compounded drugs for the sole purpose of providing a lower cost-alternative may go beyond the scope intended by the industry.[110] Essentially, compounding exemptions could eliminate the very competition for lower drug prices that it seeks to implement.[111] Efforts to facilitate patient access to affordable medicine should not undermine the significance of bioequivalence testing and quality standards that uphold the patient safety and drug efficacy that consumers rely on.[112]

VI. CONCLUSION

The high prices of off-patent, medically necessary drugs require innovative legal solutions. The controversial drug compounding industry may be a viable solution to increase patient access to affordable medicines. However, after the NECC meningitis controversy and other health incidents throughout the nation, addressing patient safety concerns should be the first priority for lawmakers and the FDA. The FDA should address patient safety issues by implementing transparency in drug supply chains and applying the DQSA rules to both sterile and non-sterile compounds. With improved safety, drug compounding using market-based solutions may be an effective way to address rising drug costs for off-patent, affordable prescription drugs. To address high-costs, several terms in the DQSA should be re-defined and

108. *Id.*
109. *Id.*
110. *Id.*
111. Rob Wright, *What is the Solution to the "High-Price" Drug Sticker Shock*, LIFE SCI. LEADER (Feb. 2, 2016), http://www.lifescienceleader.com/doc/what-is-the-solution-to-high-price-drug-sticker-shock-0001.
112. *Id.*

drugs that have been off-patent for ten to twenty years should be permitted to be produced in compounding facilities. However, none of these solutions are without obstacles. Encouraging compounding drugs, for example, could lead to decreased competition by eliminating the generic market. Drug compounding as a solution to high drug costs of off-patent drugs may be a great option, but actual viability is yet to be seen.