

# Quitting Cold Turkey?: Federal Preemption Doctrine and State Bans on FDA-Approved Drugs

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## QUITTING COLD TURKEY?: FEDERAL PREEMPTION DOCTRINE AND STATE BANS ON FDA-APPROVED DRUGS

Thomas A. Costello\*

### INTRODUCTION

For the past two decades, the United States has struggled to deal with a massive public health crisis stemming from the overprescription and abuse of opioids.<sup>1</sup> Between legally prescribed analgesic pain medications, such as OxyContin®, and illegal drugs, such as heroin, over 29,000 Americans died because of an overdose in 2015.<sup>2</sup> Americans have become increasingly dependent on pain medications, with “more than enough [opioid prescriptions] to give every American adult their own bottle of pills” in 2012.<sup>3</sup> The prescription opioid industry is massive, with an approximate value of \$8.34 billion in 2012.<sup>4</sup>

Given the vast size of this health epidemic, various efforts have been made by state and federal governments. For example, in 2016, the Center for Disease Control (CDC) announced new guidelines for prescribing opioid painkillers that focused on limiting their prescription if possible.<sup>5</sup> Additionally, in 2016, Congress approved and President Obama signed the Comprehensive Addiction and Recovery Act, which largely focused on the symptoms of the epidemic—large numbers of opioid addicts—as opposed to going after the underlying issue.<sup>6</sup> In 2014, the Commonwealth of

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<sup>1</sup> See generally *Understanding the Epidemic*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/drugoverdose/epidemic/index.html> [<https://perma.cc/72VK-8RQ9>] (last updated Aug. 30, 2017) (providing general information on the opioid epidemic and its many facets).

<sup>2</sup> AM. SOC’Y OF ADDICTION MED., OPIOID ADDICTION: 2016 FACTS & FIGURES 1, <http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf> [<https://perma.cc/K43H-4TVG>] (last visited Feb. 21, 2018).

<sup>3</sup> *Id.* at 2.

<sup>4</sup> Barry Meier & Bill Marsh, *The Soaring Cost of the Opioid Economy*, N.Y. TIMES (June 22, 2013), <http://www.nytimes.com/interactive/2013/06/23/sunday-review/the-soaring-cost-of-the-opioid-economy.html>.

<sup>5</sup> See Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain United States, 2016*, 315 JAMA 1624, 1641 (2016) (“[N]onopioid therapy is preferred for treatment of chronic pain. Opioids should be used only when benefits for pain and function are expected to outweigh risks.”).

<sup>6</sup> See generally Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, 130 Stat. 695 (amending Titles 21 and 42 of the United States Code) (frequently referring to opioid addicts as a population). Though the Act passed the Senate 92–2, divergent views

Massachusetts attempted to tackle the opioid epidemic at what it perceived to be its source—the widespread availability of prescription opioids—by illegalizing an FDA-approved opioid before it went to market.<sup>7</sup> Although other states have enacted restrictions on controversial FDA-approved drugs in the past,<sup>8</sup> none have gone as far as to ban the drug outright.<sup>9</sup>

Although that particular drug has not become a street drug of choice as regulators feared,<sup>10</sup> looking at Massachusetts’s public health legislation and the resulting litigation<sup>11</sup> provides a unique opportunity to examine the constitutionality of a state banning an FDA-approved drug without being preempted by federal law under the Supremacy Clause.<sup>12</sup> Using the backdrop of this situation, this Note will review the case law regarding implied preemption and propose a return to a *Wyeth v. Levine*<sup>13</sup> framework for preemption decisions with modifications specifically allowing a state to ban an FDA-approved drug in certain extremely limited conditions. Specifically, this framework would add a value calculation into federal preemption doctrine that would allow a court to factor in information discovered after a drug has been approved by the FDA and a state’s immediate local concerns reflecting unique, exigent circumstances.

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of the bill have emerged. Emmarie Huetteman, *Senate Approves Bill to Combat Opioid Addiction Crisis*, N.Y. TIMES (July 13, 2016), <https://nyti.ms/2kpNE2F>. Compare Jessica Nickel, *Legislation Brings Hope to Those Shattered by Addiction*, THE HILL (June 13, 2016, 8:37 AM), <http://thehill.com/blogs/pundits-blog/healthcare/282908-legislation-brings-hope-to-those-shattered-by-addiction> [<https://perma.cc/D9YY-85NF>] (calling the Senate and House bills “better” and stating that they put us “within reach of tackling this epidemic”), with Presidential Statement on Signing the Comprehensive Addiction and Recovery Act of 2016, 2016 DAILY COMP. PRES. DOC. 1 (July 22, 2016) (expressing deep disappointment that the Act did not “provide any real resources” for addiction aid).

<sup>7</sup> See Susan Heavey, *Massachusetts Bans Sale of FDA-Approved Zogenix Painkiller*, REUTERS (Mar. 28, 2014, 1:35 PM), <https://www.reuters.com/article/us-usa-drugs-opioids-zogenix/massachusetts-bans-sale-of-fda-approved-zogenix-painkiller-idUSBREA2R1F920140328> [<https://perma.cc/X4AD-WPYL>].

<sup>8</sup> See Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 MICH. ST. L. REV. 1, 16–22, 25–26 (reviewing the history of states’ attempts to restrict certain drugs or otherwise circumvent FDA approval or nonapproval decisions).

<sup>9</sup> See generally *id.*

<sup>10</sup> See Michael Specter, *Who’s Afraid of Zohydro?*, NEW YORKER (July 24, 2014), <https://www.newyorker.com/news/daily-comment/whos-afraid-of-zohydro> [<https://perma.cc/92C6-LA5V>].

<sup>11</sup> See generally *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 1454696, at \*3 (D. Mass. Apr. 15, 2014) (upholding an injunction against a Massachusetts law that banned Zohydro); *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 3339610, at \*5 (D. Mass. July 8, 2014) (upholding the Massachusetts ban on preemption grounds), *vacated in part*, No. 14-11689-RWZ, 2014 WL 4273251 (D. Mass. Aug. 28, 2014).

<sup>12</sup> See U.S. CONST. art. VI, cl. 2.

<sup>13</sup> See 555 U.S. 555, 577–81 (2009) (holding a Vermont law was not preempted by federal regulation).

The *Wyeth* framework is superior to the current implied preemption framework, as represented by *Mutual Pharmaceutical Co. v. Bartlett*,<sup>14</sup> as it grants states more leniency in crafting policy attuned to their needs. Such a modified framework would expand on those benefits by allowing rapid responses to urgent state needs that may not have been fully reflected in the FDA's approval process, thereby providing a method for states to force technological progress through economic incentive.

In order to create this modified framework, this Note will first examine the current case law surrounding implied federal preemption under the Supremacy Clause. Part I will discuss the opioid epidemic specifically in the Commonwealth of Massachusetts, as well as the legislation pursued by Governor Patrick and litigation that it prompted. Part II will examine three Supreme Court cases that all play a significant role in current preemption jurisprudence and directly relate to the *Zogenix v. Patrick*<sup>15</sup> litigation. After reviewing the case law, Part III will establish the modified framework and lay out the positives and negatives of allowing that amount of state freedom from preemption. Additionally, this Part will apply the modified framework to the *Zogenix* facts as an example of how a case might turn out under this framework. Finally, Part IV will use the recent immigration case of *Arizona v. United States*<sup>16</sup> to demonstrate that this modification would not significantly hurt object preemption analysis outside the prescription drug context.

Overall, this Note will show that a slight modification to the federal preemption doctrine under the Supremacy Clause of the Constitution is both beneficial and supportable under current case law. And in the case of the opioid epidemic, this modified framework could even be lifesaving.

### I. ZOGENIX V. PATRICK

In October 2013, the Food & Drug Administration (FDA) approved Zohydro ER®, “the first FDA-approved single-entity . . . and extended-release” opioid analgesic available in the United States.<sup>17</sup> Not combined with any other analgesic, Zohydro ER contains pure hydrocodone, a then-standard ingredient contained in opioid painkillers such as Vicodin.<sup>18</sup> Designed to allow doctors flexibility in prescriptions for those requiring “daily, around-the-clock, long-term” pain management,<sup>19</sup> the extended-release nature of Zohydro, along with its pure hydrocodone formula, meant it could

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<sup>14</sup> 133 S. Ct. 2466, 2476–78 (2013).

<sup>15</sup> *Zogenix*, 2014 WL 1454696.

<sup>16</sup> 567 U.S. 387 (2012).

<sup>17</sup> News Release, U.S. Food & Drug Admin., FDA Approves Extended-Release, Single-Entity Hydrocodone Product (Oct. 25, 2013), <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm372287.htm> [<https://perma.cc/RSS8-K9K3>].

<sup>18</sup> *Id.*; see Matthew Perrone, *FDA Approves More Powerful, Pure Hydrocodone Drug*, BOS. GLOBE (Oct. 26, 2013), <https://www.bostonglobe.com/business/2013/10/25/fda-approves-more-powerful-pure-hydrocodone-drug/AGTqSQGTFkkB55h761gnAN/story.html> [<https://perma.cc/K7ML-HR3D>].

<sup>19</sup> News Release, *supra* note 17.

be significantly stronger than comparable opioids on the market.<sup>20</sup> Although this was relatively safe when taken as directed, without abuse-resistant measures, an opioid addict could easily crush and snort the drug, immediately accessing the greater amount of hydrocodone.<sup>21</sup>

The FDA's decision to approve Zohydro explicitly rejected the recommendation of its Anesthetic and Analgesic Drug Products Advisory Committee, which had voted 11–2, with one abstention, against approving another nonabuse-resistant opioid painkiller.<sup>22</sup> The approval brought criticism and condemnation from medical professionals,<sup>23</sup> state attorneys general,<sup>24</sup> and other groups concerned with the ongoing national addiction crisis.<sup>25</sup> A few months after the FDA's approval of Zohydro, Governor Deval Patrick of Massachusetts, fearing an expansion of the opioid epidemic, declared a public health emergency and authorized the Department of Public Health to “prohibit the prescribing and dispensing of Zohydro ER until DPH determined that adequate measures to safeguard against diversion, overdose, and misuse had been implemented.”<sup>26</sup> The case that inspired this Note followed soon after.

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<sup>20</sup> See Matthew Perrone, *28 States Ask FDA to Rethink Painkiller Approval*, NEWSOK (Dec. 12, 2013, 12:09 PM), <http://newsok.com/article/feed/627227> [<https://perma.cc/PKN8-QPGM>] (“The pill uses an extended release formulation that is reportedly five to 10 times more potent than currently available hydrocodone combination pills.”).

<sup>21</sup> See Noah, *supra* note 8, at 5 (discussing difference between taking a pill as directed and crushing it).

<sup>22</sup> CTR. FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., RISK ASSESSMENT AND RISK MITIGATION REVIEW(S): ZOHYDRO ER (HYDROCODONE BITARTRATE) 2 (2013) [hereinafter RISK ASSESSMENT AND RISK MITIGATION REVIEW(S): ZOHYDRO ER]; see also Catherine M. Sharkey, *States v. FDA*, 83 GEO. WASH. L. REV. 1609, 1620–26 (2015) (discussing in greater detail the process the FDA goes through to seek public and professional comments on a potential pharmaceutical). See generally *Advisory Committees: Critical to the FDA's Product Review Process*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143538.htm> [<https://perma.cc/HNT4-AGLH>] (discussing how the FDA employs advisory committees in the drug approval process).

<sup>23</sup> See Peter Loftus, *Doctors Split on Zohydro, a Longer-Lasting Painkiller*, WALL ST. J. (May 26, 2014, 7:49 PM), <https://www.wsj.com/articles/doctors-split-on-zohydro-a-longer-lasting-painkiller-1401137975> [<https://web.archive.org/save/https://www.wsj.com/articles/doctors-split-on-zohydro-a-longer-lasting-painkiller-1401137975/>].

<sup>24</sup> See *Prescription Narcotics Are Potent Painkillers, But They Can Be Deadly*, WASH. POST (Nov. 10, 2014), [https://www.washingtonpost.com/national/health-science/prescription-narcotics-are-potent-painkillers-but-they-can-be-deadly/2014/11/10/2498ffc8-2259-11e4-8593-da634b334390\\_story.html?utm\\_term=.14cd70203504](https://www.washingtonpost.com/national/health-science/prescription-narcotics-are-potent-painkillers-but-they-can-be-deadly/2014/11/10/2498ffc8-2259-11e4-8593-da634b334390_story.html?utm_term=.14cd70203504) [<https://perma.cc/VL4J-YCM5>] (“[A]ttorneys general from 28 states have asked the FDA to reconsider its decision . . .”).

<sup>25</sup> See Barry Meier, *Addiction Specialists Wary of New Painkiller*, N.Y. TIMES (Nov. 15, 2013), <https://nyti.ms/2FNYKJK>; *Critics Question FDA's Approval of Zohydro*, NATIONAL PUBLIC RADIO (Feb. 26, 2014) (transcript available at <https://www.npr.org/2014/02/26/282836473/critics-question-fdas-approval-of-zohydro> [<https://web.archive.org/web/20171013041006/http://www.npr.org/2014/02/26/282836473/critics-question-fdas-approval-of-zohydro>]) (“Forty-two public health groups are urging the FDA to withdraw its support of Zohydro.”).

<sup>26</sup> *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 1454696, at \*1 (D. Mass. Apr. 15,

Zogenix, Inc., a California-based pharmaceutical company, filed a complaint in the District Court of Massachusetts, seeking a preliminary injunction against what it saw as an unconstitutional violation of the Supremacy Clause.<sup>27</sup> Judge Rya Zobel granted the injunction, stating that the ban was likely unconstitutional as it would “obstruct the FDA’s Congressionally-given charge.”<sup>28</sup> By demanding an abuse-resistant formula before it can be sold in Massachusetts, a development that according to the FDA was still in its “nascent stages,”<sup>29</sup> the state was substituting its own judgments for that of the FDA and would require Zogenix to return to the FDA for another approval.<sup>30</sup> Seeing that as an unconstitutional obstruction of the purpose of the FDA, Judge Zobel granted the preliminary injunction.<sup>31</sup>

Instead of challenging the grant, and perhaps allowing a higher court to elucidate if any circumstances would allow a state to ban an FDA-approved pharmaceutical, following the injunction Governor Patrick passed restrictions on when and how a healthcare provider may prescribe Zohydro.<sup>32</sup> Again, Zogenix challenged these restrictions, especially the requirement of a letter of medical necessity stating that other potential drugs had failed, describing them as a “de facto ban” on Zohydro.<sup>33</sup>

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2014) (order granting preliminary injunction); *see also* Brian MacQuarrie, *Governor Declares an Emergency on Opiate Abuse*, BOS. GLOBE (Mar. 27, 2014), <https://www.boston-globe.com/metro/2014/03/27/with-heroin-overdoses-rise-gov-patrick-declares-public-health-emergency-mass/hOajTIJNKnSHKAnWjZ6wYL/story.html> [<https://web.archive.org/web/20170216002323/https://www.bostonglobe.com/metro/2014/03/27/with-heroin-overdoses-rise-gov-patrick-declares-public-health-emergency-mass/hOajTIJNKnSHKAnWjZ6wYL/story.html>].

<sup>27</sup> Complaint at 14, *Zogenix*, No. 1:14-cv-11689, 2014 WL 1454696; *Zohydro Maker Sues to Block Massachusetts Ban*, WBUR (Apr. 8, 2014), <http://www.wbur.org/news/2014/04/08/zohydro-lawsuit-massachusetts-ban> [<https://perma.cc/H78R-BP3K>].

<sup>28</sup> *Zogenix*, 2014 WL 1454696, at \*2.

<sup>29</sup> CTR. FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., SUMMARY REVIEW FOR REGULATORY ACTION: ZOHYDRO ER 32 (2013), [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2013/202880Orig1s000SumR.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/202880Orig1s000SumR.pdf) [<https://perma.cc/J5EY-HERN>] (“[T]he technology used to produce abuse-deterrent opioid formulations is still in the nascent stages . . . . If and when they . . . are able to create an abuse-deterrent formulation that remains safe and effective for patients, we would certainly give serious consideration to assuring that any non-abuse formulations are removed from the market.”).

<sup>30</sup> *Zogenix*, 2014 WL 1454696, at \*2.

<sup>31</sup> *Id.* at \*2–3.

<sup>32</sup> *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 3339610, at \*1–2 (D. Mass. July 8, 2014), *vacated in part*, No. 14-11689-RWZ, 2014 WL 4273251 (D. Mass. Aug. 28, 2014) (describing the required procedures under 243 MASS. CODE REGS. 2.07(25) (2014) and 247 MASS. CODE REGS. 8.05(3) (2014)). These requirements, in relevant part, included a letter of medical necessity before prescribing a pure hydrocodone drug, of which Zohydro ER was the only one available, and restrictions on who may handle pure hydrocodone products, limiting it exclusively to pharmacists or assistants under direct supervision. *Id.*

<sup>33</sup> Verified Third Amended Complaint at 29, *Zogenix*, No. 1:14-cv-11689-RWZ, 2014 WL 1454696.

Once more, Judge Zobel sided with Zogenix, finding that the letter intentionally turned Zohydro into a drug of last resort, and issued a secondary injunction under a similar implied object preemption analysis.<sup>34</sup> This injunction would last until Massachusetts loosened the required statement on the letter, putting the restriction in line with the FDA's recommended use for Zohydro.<sup>35</sup>

Though Judge Zobel believed Zogenix to be the likely winner in a trial on the merits, finding object preemption in both the physical ban and the "de facto ban," this is not definitive.<sup>36</sup> Without an appeal, the issue has not been satisfactorily resolved and deserves a deeper investigation.

## II. CURRENT SUPREME COURT PREEMPTION DOCTRINE

Judge Zobel based her grant of a preliminary injunction in both cases solely on the idea implied object preemption prohibited the state action.<sup>37</sup> Federal preemption doctrine stems from the Supremacy Clause of the Constitution, which states, "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."<sup>38</sup> Under this Clause, the Supreme Court has repeatedly held that state laws in direct conflict with federal laws are "without effect."<sup>39</sup> State laws may either be explicitly preempted by federal law, in the case where a federal statute expressly mentions preemption,<sup>40</sup> or impliedly preempted. Implied preemption arises in three situations: (1) where federal law has entirely occupied a field of law,<sup>41</sup> (2) where compliance with a federal law and a state law are mutually exclusive,<sup>42</sup> and (3) where a state law "stands as an obstacle to the accomplishment and execution of

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<sup>34</sup> *Zogenix*, 2014 WL 3339610, at \*4–5.

<sup>35</sup> *Zogenix*, 2014 WL 4273251, at \*2 (finding that Massachusetts had omitted the troublesome language; instead of "other pain management treatments must have 'failed,' now they must be 'inadequate'" (quoting 243 MASS. CODE REGS. 2.07(25)(a); 263 MASS. CODE REGS. 5.07(12)(a))).

<sup>36</sup> *See Zogenix*, 2014 WL 1454696, at \*2; *Zogenix*, 2014 WL 3339610, at \*2, \*5.

<sup>37</sup> *See Zogenix*, 2014 WL 1454696, at \*1–2; *Zogenix*, 2014 WL 3339610, at \*2, \*4–5.

<sup>38</sup> U.S. CONST. art. VI, cl. 2.

<sup>39</sup> *See, e.g., Maryland v. Louisiana*, 451 U.S. 725, 746 (1981) (citing *McCulloch v. Maryland*, 17 U.S. 316 (1819)).

<sup>40</sup> *See, e.g., Chamber of Commerce v. Whiting*, 563 U.S. 582, 595–96, 600 (2011) (discussing the express preemption provision of 8 U.S.C. § 1324a(h)(2)).

<sup>41</sup> *See, e.g., Hines v. Davidowitz*, 312 U.S. 52, 66–67 (1941) (regarding the field of immigration, the Court stated: "[W]here the federal government, in the exercise of its superior authority in this field, has enacted a complete scheme of regulation and has therein provided a standard for the registration of aliens, states cannot, inconsistently with the purpose of Congress, conflict . . . the federal law, or enforce additional or auxiliary regulations.").

<sup>42</sup> *See, e.g., PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617–18 (2011) (discussing impossibility in a case of federal drug labeling).

the full purposes and objectives of Congress.”<sup>43</sup> In all preemption cases, however, “[t]he purpose of Congress is the ultimate touchstone”<sup>44</sup> in determining the scope of preemption. Finally, the Supreme Court “start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”<sup>45</sup>

Within this wide-spanning doctrine, two seemingly incongruent results have emerged from the Supreme Court in the context of FDA-approved pharmaceuticals.<sup>46</sup> Although these cases focus primarily on state tort liability and FDA labeling, the discussions of implied object and impossibility preemption are essential to a complete understanding of Judge Zobel’s decision in *Zogenix*. This Note, therefore, will examine each case individually, along with a third case outside of the pharmaceutical context, upon which Judge Zobel also seems to base her preliminary injunction.

#### A. *Wyeth v. Levine*

As one of the major cases that the Commonwealth of Massachusetts relied on in defense of its ban, *Wyeth v. Levine* is perhaps the most beneficial case towards the state, even though the Court’s holding deals primarily with state tort law.<sup>47</sup> In that case, an FDA-approved antihistamine for treating nausea, Phenergan®, was given to a patient using a method of injection known as an IV-push.<sup>48</sup> Following the treatment, the plaintiff lost a forearm to gangrene due to a complication that had not been explicitly stated on the warning label.<sup>49</sup> The drug’s manufacturer, Wyeth, now part of Pfizer, claimed that allowing a state tort action against a drug manufacturer whose label had received FDA approval would create an unconstitutional “obstacle to the accomplishment and execution of the full purposes and objectives of Congress,” and thus should be preempted.<sup>50</sup>

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<sup>43</sup> See *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) (finding obstacle preemption in a state tort liability case).

<sup>44</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)).

<sup>45</sup> *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). There is some disagreement between the Supreme Court Justices as to whether this applies strictly to a determination of whether Congress intended preemption or more broadly to the scope of invalidation of state law once preemption is found as well. See *id.* (citing *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 545–46 (1992)).

<sup>46</sup> Compare *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 1454696, at \*1–2 (D. Mass. Apr. 15, 2014) (discussing implied obstacle preemption), with *Mensing*, 564 U.S. at 617–18 (discussing impossibility preemption).

<sup>47</sup> See generally 555 U.S. 555 (2009).

<sup>48</sup> *Id.* at 558–59 (mentioning the difference between an IV-push and other methods of injection).

<sup>49</sup> *Id.* at 559–60.

<sup>50</sup> *Id.* at 563–64 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).



The Court began its analysis with an investigation into the Congressional purpose of the FDA by examining its authorizing legislation and amendments.<sup>51</sup> Among other things, this brief history focused on the expansion of FDA powers in the name of health and safety<sup>52</sup> and the efforts Congress took to maintain state law without expressly preempting it.<sup>53</sup> After a discussion of impossibility preemption, in which the Court maintained that impossibility is “a demanding defense” and found Wyeth able to comply with state warning requirements and the FDA’s label adjustment rules,<sup>54</sup> Justice Stevens began the more relevant discussion of object preemption. Although Wyeth sought to categorize FDA approval as a “‘floor’ and a ‘ceiling’ with respect to drug labeling,”<sup>55</sup> Justice Stevens found that argument to be against Congress’s general unwillingness to provide an alternative remedy in place of state inadequate warning tort suits<sup>56</sup> and unwillingness to enact an express preemption clause like those in place for medical devices,<sup>57</sup> nonprescription drugs,<sup>58</sup> and cosmetics.<sup>59</sup> Further, the Court repeated its judgment that “[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.”<sup>60</sup>

The Court also examined the preamble to an FDA regulation that Wyeth asserted granted preemptive force to the FDA’s approval of labeling.<sup>61</sup> In that preamble, the FDA, not Congress, asserted the preemptive force of its own regulation, calling it a floor and a ceiling.<sup>62</sup> The Court noted that while an agency’s opinion on the

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<sup>51</sup> *Id.* at 566.

<sup>52</sup> *Id.* at 566–67.

<sup>53</sup> *Id.* at 567. Specifically, Congress enacted a savings clause which stated that a state law could only be preempted on a finding of a “direct and positive conflict.” Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793. Additionally, Congress refused to write an express preemption clause for prescription drugs, unlike medical devices and nonprescription drugs. *See Wyeth*, 555 U.S. at 567.

<sup>54</sup> *Wyeth*, 555 U.S. at 573 (finding that Wyeth did have options beyond repititioning the FDA for a new label that could have warned victim).

<sup>55</sup> Brief for Petitioner at 45, *Wyeth*, 555 U.S. 555 (No. 06-1249), 2008 WL 2273067, at \*22 (quoting 71 Fed. Reg. 3935 (2006)).

<sup>56</sup> *See Wyeth*, 555 U.S. at 574 (“Evidently, [Congress] determined that widely available state rights of action provided appropriate relief for injured consumers. It may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings.” (citation omitted)).

<sup>57</sup> 21 U.S.C. § 360k(a) (2012); *see Wyeth*, 555 U.S. at 574.

<sup>58</sup> 21 U.S.C. § 379r(e) (2012).

<sup>59</sup> 21 U.S.C. § 379s(d) (2012).

<sup>60</sup> *Wyeth*, 555 U.S. at 575 (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–67 (1989)).

<sup>61</sup> *Id.*; *see also* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (2006).

<sup>62</sup> *Wyeth*, 555 U.S. at 575.

preemptive power of its own regulation may have some weight, it is certainly not conclusory.<sup>63</sup> Finally, the majority discussed the benefits of state tort claims in finding potentially undiscovered dangers in FDA-approved drugs.<sup>64</sup> When all is said and done, *Wyeth* shows the Court at its most sympathetic with regards to states' rights in the field of pharmaceuticals. If the Commonwealth had any chance of succeeding on the merits in *Zogenix v. Patrick*, it was almost certainly due to this case.<sup>65</sup>

The concurring opinion by Justice Thomas in *Wyeth* is worth briefly mentioning, although an in-depth examination of his argument is beyond the scope of this Note. In his concurrence, Justice Thomas concluded that obstacle preemption itself is not an appropriate analysis when looking for unconstitutional violations of the Supremacy Clause.<sup>66</sup> While Justice Thomas seemed content to allow implied preemption based on impossibility to continue, his concurrence with the majority opinion was not based on agreement with their methodology, but instead rested exclusively on his belief that state tort law cannot be preempted by Congressional object, since no state law can.<sup>67</sup> This would significantly strengthen the case of Massachusetts in *Zogenix*. However, Justice Thomas elaborated that he would also expand impossibility preemption from a true impossibility standard to a clear and direct conflict standard.<sup>68</sup> It appears that this view may have caught on amongst the more conservative Justices, as the majority in *Mutual Pharmaceutical Co. v. Bartlett* did not refer to implied object preemption in any form in its opinion, nor did it cite to *Wyeth* in support of its analysis.<sup>69</sup>

#### B. Mutual Pharmaceutical Co. v. Bartlett

University of Florida law professor Lars Noah notes, in his Article on possible constitutional defenses for the Commonwealth of Massachusetts in *Zogenix*, that Judge Zobel did not even mention *Mutual Pharmaceutical Co.* in her grant of the preliminary injunction against the ban on Zohydro.<sup>70</sup> *Mutual Pharmaceutical Co.*

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<sup>63</sup> *Id.* at 576–77; *see also* *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 883 (2000) (also noting the importance of the agency's interpretation of its own regulation).

<sup>64</sup> *Wyeth*, 555 U.S. at 578–79 (discussing relative abilities to monitor post-approval pharmaceuticals between the FDA and drug manufacturers).

<sup>65</sup> *See infra* Part I.

<sup>66</sup> *Wyeth*, 555 U.S. at 604 (Thomas, J., concurring) (“I can no longer assent to a doctrine that pre-empts state laws merely because they ‘stan[d] as an obstacle to the accomplishment and execution of the full purposes and objectives’ of federal law . . .” (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941))).

<sup>67</sup> *Id.*

<sup>68</sup> *See id.* at 589–94; *see also* Noah, *supra* note 8, at 30 n.114.

<sup>69</sup> *See* *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

<sup>70</sup> Noah, *supra* note 8, at 34–35 (“For some reason, however, Judge Zobel had not cited *Bartlett* to buttress her sense that federal law preempted Massachusetts's effort to ban Zohydro, perhaps because she thought that the case before her raised questions of implied preemption based solely on frustration of purposes rather than impossibility of dual compliance.”).

was sparked when a generic prescription nonsteroidal anti-inflammatory drug known as sulindac, manufactured by Mutual Pharmaceutical, caused a patient to contract toxic epidermal necrolysis.<sup>71</sup> The victim sued under two causes of action offered by the state of New Hampshire: failure-to-warn, which was dismissed by the trial court, and design-defect.<sup>72</sup>

According to the majority, in New Hampshire, the design-defect tort imposes a positive duty on the manufacturer to design a relatively safe product.<sup>73</sup> This in turn places a duty on drug manufacturers to either increase the usefulness of the drug, reduce the risk of danger, or to increase the presence or efficiency of the warning label already on the drug.<sup>74</sup> Being a generic drug manufacturer, however, Mutual Pharmaceutical was subject to strict rules regarding formula and label change, often stricter than those affecting a name-brand drug manufacturer.<sup>75</sup> Both generic and name-brand drugs are not allowed to make any significant changes to the formula of the prescription.<sup>76</sup> However, only generic drug manufacturers are forbidden from unilaterally changing their FDA-approved labeling.<sup>77</sup> Essentially, the generic drug manufacturers were trapped. If they tried to increase the value of the product or minimize the risk, the manufacturer would run into the prohibition against changing the formula.<sup>78</sup> If instead the manufacturer attempted to change the warning labels, it would be stopped by the relevant code provision.<sup>79</sup> Thus, according to the majority, an impossibility had been reached and the state tort claim was preempted.<sup>80</sup>

The Court explicitly rejected a claim made by the plaintiff, which would have significant repercussions in *Zogenix* if Judge Zobel had done an impossibility preemption analysis.<sup>81</sup> The plaintiff claimed that if a company could not change its

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<sup>71</sup> 133 S. Ct. at 2472.

<sup>72</sup> *Id.*

<sup>73</sup> *Id.* at 2473.

<sup>74</sup> *See id.* at 2475 (quoting *Vautour v. Body Masters Sports Indus., Inc.*, 147 N.H. 150, 154 (2001)).

<sup>75</sup> *Id.*

<sup>76</sup> *See id.* at 2471 (quoting 21 C.F.R. § 314.70(b)(2)(i) (2012)). These restrictions specifically limit any qualitative or quantitative change to the formula, including inactive ingredients. 21 C.F.R. § 314.70(b)(2)(i).

<sup>77</sup> *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011) (“Federal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs’ safety labels.”); *see also, e.g.*, 21 U.S.C. § 355(j)(2)(A)(v) (2012) (requiring generic drugs to use the same label as approved for its brand-name equivalent). A fair amount of attention has been paid to *PLIVA*, mostly by detractors arguing against its holding. *See, e.g.*, Stacey B. Lee, *PLIVA v. Mensing: Generic Consumers’ Unfortunate Hand*, 12 *YALE J. HEALTH POL’Y L. & ETHICS* 209, 235–45 (2012) (looking at the potential repercussions in the huge generic pharmaceuticals industry).

<sup>78</sup> *See Mut. Pharm. Co.*, 133 S. Ct. at 2471 (quoting 21 C.F.R. § 314.70(b)(2)(i)); *see also, e.g.*, 21 U.S.C. § 355(j)(2)(A)(v).

<sup>79</sup> *See PLIVA*, 564 U.S. at 617.

<sup>80</sup> *Mut. Pharm. Co.*, 133 S. Ct. at 2470.

<sup>81</sup> *See id.* at 2477.

label, nor could it change its formula, it could avoid its duty entirely by simply not selling in New Hampshire any longer.<sup>82</sup> The Court swiftly rejected this argument, stating:

We reject this “stop-selling” rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be “all but meaningless.”<sup>83</sup>

The majority concluded by reaffirming that there was impossibility preemption here and that a company’s ability to withdraw from a market does not affect the impossibility it faced between state tort liability and federal labeling laws.<sup>84</sup>

In a short dissent, Justice Breyer, joined by Justice Kagan, rejected the impossibility argument of the majority and returned to a *Wyeth v. Levine* true impossibility standard, finding no impossibility in *Mutual Pharmaceutical Co.* with the option to stop selling or pay a fine.<sup>85</sup> The dissent continued, however, that sizeable damages may invoke object preemption.<sup>86</sup> Further, Breyer discussed the amount of leeway that should be given to the FDA’s determinations of preemption, weighing factors such as opportunity for the public to comment,<sup>87</sup> consistency of the FDA’s view of pre-emption, and, most significantly, the fact that “the question of pre-emption may call for considerable drug-related expertise. Indeed, one might infer that, the more medically valuable the drug, the less likely Congress intended to permit a State to drive it from the marketplace.”<sup>88</sup> In this case, Breyer found the FDA and drug manufacturers could not produce a “convincing reason” that forcing the manufacturer to either remove the drug from New Hampshire or be subject to liability would undercut the object of the FDA, and so believed the state tort was not preempted.<sup>89</sup>

In a separate dissent, Justice Sotomayor, joined by Justice Ginsburg, expanded on the Breyer dissent, diving deeper into an analysis of both impossibility and object preemption.<sup>90</sup> Much of this dissent focused on the complementary role that state laws serve in with regards to the federal drug regulation of the FDA.<sup>91</sup>

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<sup>82</sup> *Id.* at 2477.

<sup>83</sup> *Id.* (quoting *PLIVA*, 564 U.S. at 621).

<sup>84</sup> *Id.* at 2477–79 (discussing *PLIVA*).

<sup>85</sup> *Id.* at 2480–81 (Breyer, J., dissenting) (“It is not *literally* impossible here for a company like petitioner to comply with conflicting state and federal law.” (emphasis added)).

<sup>86</sup> *Id.* at 2481.

<sup>87</sup> *Id.*; see also Sharkey, *supra* note 22 (developing a framework for preemption decisions that focused on opportunity for public comment).

<sup>88</sup> *Mut. Pharm. Co.*, 133 S. Ct. at 2481 (Breyer, J., dissenting).

<sup>89</sup> *Id.* at 2482.

<sup>90</sup> *Id.* at 2482–96 (Sotomayor, J., dissenting).

<sup>91</sup> *Id.* at 2483–85 (“Congress’ preservation of a role for state law . . . reflects a realistic

C. Geier v. American Honda Motor Co.

One other case warrants an in-depth look, as it was significantly featured in Judge Zobel's grant of a preliminary injunction.<sup>92</sup> Although *Geier v. American Honda Motor Co.*<sup>93</sup> is not within the prescription drug context, it is an essential case to federal preemption doctrine under the Supremacy Clause. In that case, a defective design suit was brought against American Honda, alleging that Honda was negligent in not installing driver's side airbags in the car.<sup>94</sup> After examining an express preemption clause found in the National Traffic and Motor Vehicle Safety Act of 1966 and finding it inapplicable due to a saving clause,<sup>95</sup> the Court examined a claim of implied object preemption.<sup>96</sup> After a lengthy examination of the legislative history of the standard in question, the Court ruled that there was an actual conflict between the state tort action and the safety standard from the Department of Transportation at issue, resulting in preemption.<sup>97</sup>

The Court held that the legislative history pointed to "the standard deliberately provid[ing] the manufacturer with a range of choices among different passive restraint devices. Those choices would bring about a mix of different devices introduced gradually over time . . . which would promote FMVSS 208's safety objectives."<sup>98</sup> Because the legislation was specifically designed to create a mix of safety measures, requiring a manufacturer to have a driver's side airbag or face a design-defect claim was an obstacle to the object of the federal statute.<sup>99</sup> Although this case is not immediately applicable to the FDA drug approval context, it is extremely relevant to the *Zogenix* case, especially because the FDA explicitly stated one purpose of approving Zohydro ER was to "offer prescribers an additional therapeutic option to treat pain . . . because individual patients may respond differently to different opioids."<sup>100</sup>

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understanding of the limitations of *ex ante* federal regulatory review in this context. On its own, even rigorous preapproval clinical testing of drugs is 'generally . . . incapable of detecting adverse effects that occur infrequently [or] have long latency periods . . .'" (quoting David A. Kessler & David C. Vladcek, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 471 (2008)).

<sup>92</sup> See *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 1454696 (D. Mass. Apr. 15, 2014).

<sup>93</sup> 529 U.S. 861 (2000).

<sup>94</sup> *Id.* at 865.

<sup>95</sup> See *id.* at 867-68.

<sup>96</sup> See *id.* at 874-86.

<sup>97</sup> See *id.*

<sup>98</sup> *Id.* at 875 (citing 49 Fed. Reg. 28962 (1984)).

<sup>99</sup> *Id.* at 881 ("Such a state law . . . would have required manufacturers of all similar cars to install airbags rather than other passive restraint systems . . . . It thereby would have presented an obstacle to the variety and mix of devices that the federal regulation sought.").

<sup>100</sup> Susan Jeffrey, *FDA Okays First Single-Entity Extended Release Hydrocodone*, MEDSCAPE

III. CREATION OF THE MODEL AND APPLICATION TO *ZOGENIX*

Although not completely incompatible, *Wyeth v. Levine*, *Mutual Pharmaceutical Co. v. Bartlett*, and *Geier v. American Honda Motor Co.* could certainly use “Congress’ ‘explicit’ resolution of the difficult pre-emption questions that arise in the prescription drug context. That issue has repeatedly vexed the Court—and produced widely divergent views—in recent years.”<sup>101</sup> Absent such a direct policy statement by Congress, a workable, consistent theory of implied preemption would significantly benefit states, such as Massachusetts in *Zogenix*, looking to avoid preemption moving forward. This Note proposes a return to a *Wyeth* interpretation of implied preemption, abandoning the Justice Thomas concurrence model, which has seemingly become the standard post-*Mutual Pharmaceutical Co.*<sup>102</sup> This model is designed specifically to allow states freedom to enact their particular regulatory schemes through tort liability or, in some cases, a ban on a particular drug.

Before building such a model, it is important to examine why that amount of freedom is beneficial and address possible criticisms. Allowing failure-to-warn and design-defect tort claims against drug manufacturers serves two major purposes: it allows for monitoring beyond the limited scope of the FDA<sup>103</sup> and drives companies to produce safer, more effective drugs.<sup>104</sup> A similar rationale can and should be applied to a ban on an FDA-approved prescription drug. *Zogenix v. Patrick* provides a perfect example of a situation where enforcement of a ban could have pressed technology forward.<sup>105</sup> If the only way a drug manufacturer could sell a pharmaceutical in a certain state was to incorporate abuse-resistant technology, a potentially powerful counter to the ongoing addiction crisis, the manufacturer would almost certainly respond by developing an abuse-resistant formula.<sup>106</sup>

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(Oct. 25, 2013), <https://www.medscape.com/viewarticle/813236> [<https://web.archive.org/web/20150114041016/https://www.medscape.com/viewarticle/813236>].

<sup>101</sup> *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2480 (2013) (citing *Wyeth v. Levine*, 555 U.S. 555 (2009); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011)).

<sup>102</sup> See *supra* notes 66–69 and accompanying text.

<sup>103</sup> See *Wyeth*, 555 U.S. at 578–79 (discussing limited monitoring ability of FDA after approval of a pharmaceutical).

<sup>104</sup> *Id.* at 579 n.12 (“[S]tate tort suits ‘can serve as a catalyst’ by aiding in the exposure of new dangers . . . .” (quoting *Bates v. Dow Agrosciences LLC*, 554 U.S. 431, 451 (2005))).

<sup>105</sup> See No. 14-11689-RWZ, 2014 WL 1454696 at \*2 (D. Mass. Apr. 15, 2014) (order granting preliminary injunction) (“[T]he drug Massachusetts wants *Zogenix* to adopt—Zohydro ER with an ‘abuse-resistant formulation’—has not been approved by the FDA. To satisfy the Commonwealth, *Zogenix* would be required to return to the FDA and seek approval of a drug different from the one the FDA has already deemed safe.”).

<sup>106</sup> See, e.g., News Release, *Zogenix, Zogenix Submits Modified Formulation of Zohydro ER with Potential Abuse Deterrent Properties for FDA Review* (Oct. 1, 2014), <http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&ID=1972777> [<https://perma.cc/3Y6R-G9YE>]. Although the ban in Massachusetts did not last, the public outcry against Zohydro

Beyond this economic incentive towards safer prescriptions, however, a state's ability to ban a drug can reflect local concerns that are not adequately captured by the FDA's risk-benefit analysis. According to the CDC, in 2014, the year of the *Zogenix* litigation, Massachusetts had the thirteenth highest age-adjusted rate of drug overdose, primarily driven by opioids.<sup>107</sup> While it may not have had as acute problems with drug overdose as West Virginia,<sup>108</sup> a state in the position of Massachusetts should be able to respond to certain local conditions that might not exist on the same scale at the national level.<sup>109</sup> Although access to additional opioid options nationwide may be a net benefit under the FDA's decision-making, in these hard-hit areas another opioid may not be the answer. Additionally, a state is better equipped to respond quickly to changing situations and rapidly developing crises than the FDA.

Although it has some strong benefits, allowing states to unilaterally ban a specific FDA-approved pharmaceutical is not a panacea; there are legitimate criticisms from a policy standpoint. Perhaps the most significant concern is that states could use this ability to reject various socially contentious prescriptions, such as contraceptives and abortifacients.<sup>110</sup> However, if a state did try to block these drugs, a constitutional challenge under existing Supreme Court privacy and equal protection jurisprudence would quickly take care of the unconstitutional state legislation.<sup>111</sup>

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ER may have contributed to the rapid submission of an NDA for an abuse-resistant formulation of the drug in October 2014, less than two months after the end of *Zogenix*'s litigation as part of *Zogenix v. Patrick*. See *id.*

<sup>107</sup> See *Drug Overdose Death Data*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/drugoverdose/data/statedeaths.html> [<https://perma.cc/V6NJ-V67A>] (last updated Dec. 19, 2017).

<sup>108</sup> See *id.* (listing West Virginia as the state with the overall highest age-adjusted rate of drug overdose in 2014); see also Noah, *supra* note 8, at 6 ("Although it had not encountered the problems with OxyContin experienced by West Virginia and other states in the Appalachian region, officials in Massachusetts knew of that drug's scourge . . . ." (citations omitted)).

<sup>109</sup> See, e.g., Nadja Popovich, *A Deadly Crisis: Mapping the Spread of America's Drug Overdose Epidemic*, GUARDIAN (May 25, 2016), <https://www.theguardian.com/society/ng-interactive/2016/may/25/opioid-epidemic-overdose-deaths-map> [<https://perma.cc/9EWX-U8MV>] (mapping skyrocketing overdose rates, driven mainly by opioid overdoses, specifically concentrated in Central Appalachia, the Southwest, the Pacific Northwest, Florida, and to a certain extent, New England).

<sup>110</sup> For a discussion of previous attempts to block socially contentious drugs without resorting to an outright post-approval ban, see Noah, *supra* note 8, at 16–27 (detailing state attempts to block FDA-approved drugs and to allow non-FDA-approved drugs such as marijuana).

<sup>111</sup> See, e.g., *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992) (establishing the undue burden test for access to abortion); *Griswold v. Connecticut*, 381 U.S. 479 (1965) (finding a state ban on contraceptives violates the constitutional right to privacy). According to the CDC, approximately 20% of abortions use a combination of FDA-approved mifepristone and misoprostol, probably leading to a finding of undue burden. See KAREN PAZOLET ET AL., CTRS. FOR DISEASE CONTROL & PREVENTION, ABORTION SURVEILLANCE—UNITED STATES, 2012, at 39 tbl.22 (2015), [http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6410a1.htm?s\\_cid=ss6410a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6410a1.htm?s_cid=ss6410a1_e) [<https://perma.cc/2JGL-FGAT>].

Another common contention against allowing states to ban prescriptions is the idea that FDA approval should bring uniformity in access to all states.<sup>112</sup> Although uniformity of drug availability might be of great significance to the manufacturer seeking approval of a new, expensive drug,<sup>113</sup> FDA approval only “represents a necessary but hardly sufficient condition for patient access.”<sup>114</sup>

Another major benefit of uniformity of access in the pharmaceutical context is community immunity from vaccines.<sup>115</sup> If a state were to ban a vaccine solely within its borders, the resulting unvaccinated population could threaten the health of the United States.<sup>116</sup> While this is a valid concern, it is highly unlikely that a state’s local concerns surrounding a vaccine could ever meet the exacting standard this Note recommends before allowing an un-preempted ban. Finally, a critic may claim that, in the case of opioids in particular, trying to ban access to a drug is a moot point due to the sheer size of the pill mill industry.<sup>117</sup> This is easily countered by the idea that even though a prescription is accessible immediately across the border, the state is acting in what it believes is the best interest of its citizens by making it substantially more difficult to obtain. Although allowing states to ban FDA approved drugs has some serious drawbacks, the benefits derived from state self-determination and possible enhanced research and development to meet more exacting standards make the trade-off worth it.

Having established the importance of allowing the states to unilaterally ban at least some FDA-approved drugs, this Note will now formulate a framework for preemption cases under the Supremacy Clause using the precedents found in *Geier*, *Wyeth*, and *Mutual Pharmaceutical Co.* Specifically, it will advocate a *Wyeth* type framework with small modifications to ensure a state’s right to ban drugs in certain

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<sup>112</sup> See, e.g., *Ray v. Atl. Richfield Co.*, 435 U.S. 151, 165–68 (1978) (finding that a Department of Transportation regulation on tanker design preempted more stringent state restrictions, as it “would frustrate the congressional desire of achieving uniform, international standards”).

<sup>113</sup> In the pharmaceuticals case, uniformity and ability to sell in every state might be prompted by the need to recoup losses from excessively high new drug research and development costs. See Jason Millman, *Does It Really Cost \$2.6 Billion to Develop a New Drug?*, WASH. POST: WONKBLOG (Nov. 18, 2014), <https://www.washingtonpost.com/news/wonk/wp/2014/11/18/does-it-really-cost-2-6-billion-to-develop-a-new-drug/> [<https://perma.cc/K56L-B2W2>] (discussing price of research and development and pharmaceutical industry efforts to recoup that amount).

<sup>114</sup> Noah, *supra* note 8, at 10–12 (“[S]ponsors of genuinely promising investigational products can decide not to seek FDA approval; . . . license holders generally have no obligation to commercialize their products, to do so at an affordable price, or in a manner that ensures easy access. Lastly, FDA approval does not invariably guarantee insurance coverage . . . .” (citations omitted)).

<sup>115</sup> *Vaccines Protect Your Community*, U.S. DEP’T OF HEALTH & HUM. SERVS., <https://www.vaccines.gov/basics/work/> [<https://perma.cc/C8JE-ZNQG>] (last reviewed Dec. 2017).

<sup>116</sup> See *id.*

<sup>117</sup> See generally Meier & Marsh, *supra* note 4 (listing various statistics on the opioid economy, including the prevalence of “doctor shopping” and “pill mills”).



contexts. Finally, this Note will apply the framework to *Zogenix v. Patrick* as an example of how a case would turn out. Unlike the majority in *Mutual Pharmaceutical Co.* and the Justice Thomas concurrence in *Wyeth*, this Note will assume that object preemption is still a valuable part of the Supremacy Clause jurisprudence, otherwise “the vast majority—if not all—of the cases in which the Court has found” object “pre-emption, were wrongly decided.”<sup>118</sup>

### A. Object Preemption

As in any discussion of implied object preemption, the starting point for this model is the assumption that the police powers of the state are not preempted, unless that was the clear intent of the federal statute as determined by its purpose and object.<sup>119</sup> Therefore, without developing a uniform statement of intent for the FDA, developing a consistent method of determining preemption of state statutes is nearly impossible. Many different documents and statements have been presented as demonstrating Congress’s intent through the FDA, though most tend to focus on protecting public health, the lack of any opposing statements of intent, and the testimony of FDA employees.<sup>120</sup> Like the Court in *Wyeth*, this framework does not see FDA approval as a “floor and a ceiling” for drug regulation.<sup>121</sup> While Judge Zobel characterized the object of the FDA as “mak[ing] drugs available to promote and protect the public health,”<sup>122</sup> this is an “entirely aspirational . . . mission statement”<sup>123</sup> that ignores the fact that “Congress crafted the current version of the licensing scheme for new drugs in order to *prevent* the introduction of unsafe or ineffective pharmaceutical products.”<sup>124</sup>

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<sup>118</sup> With apologies to Justice Alito in *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466, 2478 (2013) (“Adopting the First Circuit’s stop-selling rationale would mean . . . the vast majority—if not all—of the cases in which the Court has found impossibility preemption, were wrongly decided.”).

<sup>119</sup> See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

<sup>120</sup> See, e.g., *Wyeth v. Levine*, 555 U.S. 555, 566–67, 574–75 (2009) (examining the legislative history of the FDA and, in some cases, lack of legislation as evidence of the Congressional purpose of the FDA); *Mut. Pharm. Co.*, 133 S. Ct. at 2493–94 (Sotomayor, J., dissenting) (once again examining legislative history, but also looking at amici curiae briefs); *Zogenix v. Patrick*, No. 14-11689-RWZ, 2014 WL 1454696, at \*2 (D. Mass. Apr. 15, 2014) (quoting 21 U.S.C. § 393(b) (2012), the mission statement of the FDA); see also Noah, *supra* note 8, at 8–12 (criticizing Judge Zobel’s characterization of the FDA’s purpose and discussing its purpose generally).

<sup>121</sup> See *Wyeth*, 555 U.S. at 573.

<sup>122</sup> *Zogenix*, 2014 WL 1454696, at \*2 (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 881 (2000)).

<sup>123</sup> Noah, *supra* note 8, at 9.

<sup>124</sup> *Id.* at 8.

It can probably be safely assumed that the FDA would not support this interpretation of its preemptive power for any drug it has already approved and would argue that its decision preempts the state ban. This is not an issue, however, even though some weight is given to an agency's view of "federal objectives when 'the subject matter is technical[] and the relevant history and background are complex and extensive.'"<sup>125</sup> While some weight should be given to the FDA's view of its own preemptive power, its conclusion is not deferred to, only its view of how allowing a certain regulation would affect the regulatory scheme.<sup>126</sup> This model acknowledges that some disruption of the federal scheme will be necessary to allow states to ban FDA-approved drugs and so requires less deference to the FDA's position. Wavering opinions of the FDA on its preemptive power,<sup>127</sup> opinions found exclusively in briefs filed for litigation,<sup>128</sup> and views held without any consultation with the public,<sup>129</sup> should all reduce the deference given to the FDA.<sup>130</sup> Thus, under this framework, very little leeway should be given to the FDA's view of preemption absent direct "regulations, preambles, interpretive statements, and responses to

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<sup>125</sup> *Wyeth*, 555 U.S. at 576 (quoting *Geier*, 529 U.S. at 883); see *Mut. Pharm. Co.*, 133 S. Ct. at 2494 (Sotomayor, J., dissenting) (describing the amount of leeway to give federal agencies' view of preemptive effect).

<sup>126</sup> See *Wyeth*, 555 U.S. at 576.

<sup>127</sup> See *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005) (holding that agency inconsistency does not eliminate *Chevron* deference, but it may strengthen the case for arbitrary and capricious change from standard practice).

<sup>128</sup> *Mut. Pharm. Co.*, 133 S. Ct. at 2481 (Breyer, J., dissenting) (refusing to give special weight to FDA's statements because all of its positions were stated in briefs filed in litigation).

<sup>129</sup> See *id.* ("[T]he FDA in developing its views has held no hearings on the matter or solicited the opinions, arguments, and views of the public . . .").

<sup>130</sup> Further, without getting too deep into judicial deference to agency positions, under *King v. Burwell*, the FDA would be entitled to even less deference if the drug's availability can be argued to be a matter of "deep 'economic and political significance.'" See 135 S. Ct. 2480, 2489 (2015) (quoting *Util. Air Regulatory Grp. v. Env'tl. Prot. Agency*, 134 S. Ct. 2427, 2444 (2014)) (refusing to grant *Chevron* deference to the IRS). However, the preemptive effect of the FDA's prescription drug approval does not seem to be the type of regulatory "elephant" that the Supreme Court is concerned with. See *id.* ("[H]ad Congress wished to assign that question to an agency, it surely would have done so expressly."); see also *Whitman v. Am. Trucking Ass'ns.*, 531 U.S. 457, 468 (2001) ("Congress . . . does not, one might say, hide elephants in mouseholes."). Some commentators believe that this may be a death knell for agency deference, especially in combination with the ascension of Neil Gorsuch to the Supreme Court. See, e.g., Kristin E. Hickman, *The (Perhaps) Unintended Consequences of King v. Burwell*, 2015 PEPP. L. REV. 56 (discussing *Chevron* deference post-*King v. Burwell*); Richard J. Pierce, Jr., *The Future of Deference*, 84 GEO. WASH. L. REV. 1293 (2016) (also discussing the tenuous future of *Chevron*); Jonathan H. Adler, *Should Chevron Be Reconsidered? A Federal Judge Thinks So.*, WASH. POST: VOLOKH CONSPIRACY (Aug. 24, 2016), [https://www.washingtonpost.com/news/volokh-conspiracy/wp/2016/08/24/should-chevron-be-reconsidered-a-federal-judge-thinks-so/?utm\\_term=.55e56c1c3d84](https://www.washingtonpost.com/news/volokh-conspiracy/wp/2016/08/24/should-chevron-be-reconsidered-a-federal-judge-thinks-so/?utm_term=.55e56c1c3d84) [<https://perma.cc/45T4-TFPQ>] (discussing Judge Gorsuch's decision against *Chevron* deference).

comments.”<sup>131</sup> Therefore, FDA views of the preemptive power, at least when it comes to the effect on the full federal drug licensing scheme, should be downplayed.

One essential piece of this model, and an area where the FDA’s opinion should be given weight, is the specific inclusion of a medical value component to the FDA’s purpose. Since its founding, the FDA has had as its primary purpose the object of showing whether the benefits of using a product or eating a food is worth the risk.<sup>132</sup> In his dissent to *Mutual Pharmaceutical Co.*, Justice Breyer specifically noted value as important to the calculation of object preemption, writing, “[O]ne might infer that, the more medically valuable the drug, the less likely Congress intended to permit a State to drive it from the marketplace.”<sup>133</sup> Focusing on the FDA’s purpose of proving value in drugs, a court should find no obstacle preemption for a unilateral drug ban where the drug adds little to no value to the medical community. Though simply being an additional treatment option may be valuable in and of itself,<sup>134</sup> as the amount of similar treatments rises, each individual slightly loses some of this “additional option” value. With more and more substitutes that functionally have the same effect (e.g., an opioid pain reliever), the likelihood that Congress intended to have that specific option available in that certain state fails. Critics, including Judge Zobel, will cite to *Geier*,<sup>135</sup> arguing that the FDA’s intent in approving a drug is to expand the arsenal of pharmaceuticals a doctor has at his or her disposal and so is preempted. However, this is an unreasonable expansion of the holding in that case. In *Geier*, the legislative history and comments of the Department of Transportation (DOT) all pointed towards the intention of the DOT that there be a wide variety of safety measures,<sup>136</sup> whereas the FDA has no statements matching this level of extensiveness for any drug.<sup>137</sup>

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<sup>131</sup> *Mut. Pharm. Co.*, 133 S. Ct. at 2481 (Breyer, J., dissenting) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 506 (1996) (Breyer, J., concurring)) (refusing to give special weight to the FDA’s statements because all of its positions were stated in briefs filed in litigation).

<sup>132</sup> *Wyeth v. Levine*, 555 U.S. 555, 566–67 (2009) (“Congress became increasingly concerned about unsafe drugs and fraudulent marketing, and it enacted the Federal Food, Drug, and Cosmetic Act (FDCA). It required every manufacturer to submit a new drug application . . . to the FDA for review. Until its application became effective, a manufacturer was prohibited from distributing a drug . . . In 1962, Congress amended the FDCA and shifted the burden of proof from the FDA to the manufacturer. Before 1962, the agency had to prove harm to keep a drug out of the market, but the amendments required the manufacturer to demonstrate that its drug was ‘safe’ . . .” (internal citations omitted)).

<sup>133</sup> 133 S. Ct. at 2481 (Breyer, J., dissenting).

<sup>134</sup> *See, e.g.*, News Release, *supra* note 17 (“Zohydro ER will offer prescribers an additional therapeutic option to treat pain, which is important because individual patients may respond differently to different opioids.”).

<sup>135</sup> *See* 529 U.S. 861 (2000).

<sup>136</sup> *See id.* at 874–81 (examining the legislative history and contemporaneous comments of the DOT).

<sup>137</sup> *Compare* News Release, *supra* note 17, with *Geier*, 529 U.S. at 874–81 (citing generally 49 Fed. Reg. 28962 (1984)). Although the news release does mention diversity in prescription

This must be a particularly demanding inquiry into the medical value of the drug at issue. Simply because a drug has one or two substitutes or is not as powerful as other drugs on the market does not mean a drug should be at risk to become illegal in a state. In order to succeed on the merits under this modified framework, the state must show that either new information has come to light, which renders the FDA's initial value judgment no longer correct, or that the particular local concerns of the state are substantial enough to justify depriving potential patients who may need that drug. If a state is attempting to show that the FDA's initial value judgment is incorrect due to new information, the state would have a duty to show that this is actually new information about the risks or benefits of a drug that the FDA had no opportunity to consider and the state had no opportunity to alert the FDA before the drug was approved.<sup>138</sup> In weighing the local concerns, courts should take into consideration availability of substitutes, potential benefits and risks of the drug compared to similar products, amount of potential users in that state, and how substantial the local concerns actually are when compared to the rest of the nation.

In the case of *Zogenix, Inc. v. Patrick*, the whole premise of the public health emergency was the overprescription and overavailability of opioids before Zohydro was even approved for sale.<sup>139</sup> It is assumed that, on appeal, the FDA would have submitted a brief in favor of preemption.<sup>140</sup> The FDA's conclusion of preemption would not be taken as fact, however,<sup>141</sup> and its testimony as to the effect of removal of Zohydro ER on the federal scheme would almost certainly not amount to the level needed to find preemption. Although this would aid Massachusetts's argument, the state would not enjoy some of the presumptions that benefitted the plaintiff in *Wyeth*.<sup>142</sup> Namely, unlike in the state tort context considered by *Wyeth*, Congress has not "indicated its awareness of the operation of state law in a field of federal interest"

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opioids as "important," it does not go nearly as far as statements in the legislation as far as deliberate desire for a variety.

<sup>138</sup> Some models of preemption in the drug context have focused almost exclusively on whether the State had any opportunity to make comments to the FDA prior to approval. *See Sharkey, supra* note 22, at 1625–29 ("Judicial deference to the FDA's position is only proper where the FDA can show that it invited states an opportunity to express health and safety concerns during the approval process."); *see also Mut. Pharm. Co.*, 133 S. Ct. at 2481 (Breyer, J., dissenting) ("At the same time, the agency can develop an informed position on the pre-emption question by providing interested parties with an opportunity to present their views. . . . [T]he FDA, in developing its views, has held no hearings on the matter or solicited the opinions, arguments, and views of the public . . .").

<sup>139</sup> *See* No. 14-11689-RWZ, 2014 WL 1454696, at \*1 (D. Mass. Apr. 15, 2014).

<sup>140</sup> *See* James M. Beck, *The FDA's Amicus Curiae Briefs on Preemption—Redux*, DRUG & DEVICE L. (Oct. 19, 2007), <https://www.druganddevicelawblog.com/2007/10/fdas-amicus-curiae-briefs-on-preemption.html> [<https://perma.cc/PG5M-84AX>] (providing examples of the FDA submitting briefs in support of preemption).

<sup>141</sup> *See supra* notes 125–32 and accompanying text.

<sup>142</sup> *See* 555 U.S. 555, 565–66 (2009).

in the case of state bans of prescription drugs.<sup>143</sup> As one of the first attempts to ban a drug after receiving FDA approval, Congress has certainly not indicated an awareness of Massachusetts's power to reject an FDA-approved pharmaceutical. In the future however, this Note recommends that Congress explicitly comment on the preemptive power of FDA approval.

The analysis would then proceed to the question of value. This is not a case where new information has surfaced about a prescription. In fact, the concerns that led Governor Patrick to ban Zohydro are the same concerns that were considered and brought up by the advisory committee and numerous public health officials.<sup>144</sup> Further, Massachusetts did have an opportunity to comment on the decision to approve Zohydro ER and did not send a representative.<sup>145</sup> Because new information is not on the table, the only way for Massachusetts to avoid preemption under this new framework would be to show that its local conditions are substantially bad enough to justify non-preemption. With regards to available substitutes, the backlash to Zohydro ER revolved around the availability of other opioids.<sup>146</sup> Though there was the small benefit of added prescription flexibility, along with the slight benefit of not containing an analgesic,<sup>147</sup> there seem to be no other benefits of Zohydro over other prescription opioid pain medications.<sup>148</sup> Additionally, Zogenix did not have abuse-resistant features at the time, unlike some of its major competitors and substitutes.<sup>149</sup> Although critics today will point out that the risks of a hydrocodone-only drug were overblown,<sup>150</sup> the potential risks of Zohydro were significant at the time, with the outside Advisory Committee's opinion and the reaction in the medical community to Zohydro both extremely concerned with possibility of abuse.<sup>151</sup> Testimony from the FDA would probably be necessary to determine the amount of potential patients affected.

The bulk of the analysis under this framework for cases of states attempting to ban FDA-approved drugs is whether the local conditions of that particular state warrant leeway. In the case of Zohydro ER, Massachusetts most likely would have

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<sup>143</sup> *Id.* at 575 (quoting *Bonito Boats, Inc., v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–67 (1989)).

<sup>144</sup> *See supra* Part I.

<sup>145</sup> *See Sharkey, supra* note 22, at 1625–26 (“The FDA offered state officials the opportunity to attend . . . its public drug advisory committee meetings regarding Zohydro and even to register ahead of time in order to make comments at these events. But not a single state official . . . spoke or even attended the advisory committee’s public meeting.” (citations omitted)).

<sup>146</sup> *See Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 1454696, at \*1 (D. Mass. Apr. 15, 2014); *see also supra* Part I.

<sup>147</sup> *See Noah, supra* note 8, at 5 (discussing the benefits of an opioid without a combined analgesic).

<sup>148</sup> *See News Release, supra* note 17; *see also RISK ASSESSMENT AND RISK MITIGATION REVIEW(S): ZOHYDRO ER, supra* note 22, at 1.

<sup>149</sup> *See Noah, supra* note 8, at 5 (“[I]n contrast to the currently marketed versions of OxyContin, Zohydro failed to incorporate any abuse-resistant features.”).

<sup>150</sup> *See supra* note 10 and accompanying text.

<sup>151</sup> *See supra* notes 23–25 and accompanying text.

succeeded. As stated earlier, Massachusetts ranked thirteenth in most drug overdoses in 2014, a number substantially driven by opioids, legal and illegal.<sup>152</sup> Massachusetts also had 10.9% of its entire population taking some form of Schedule II opioid by prescription alone in 2014, with enough pills sold to give every resident of Massachusetts his or her own bottle.<sup>153</sup> The state would need to show more statistics, including comparisons to the rest of the country at the time of the FDA approval, but overall, under this framework, Massachusetts could meet its standard of a substantial showing.

Taken together, these facts that Governor Patrick could produce would lead to a finding of no preemption. Because the need is so great and the value of the drug is so low compared to other available substitutes, a court should give the Commonwealth of Massachusetts leeway in passing this law, as it does not “stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”<sup>154</sup> Under this new framework, the state law banning hydrocodone-only products without abuse-resistant features would be un-preempted under the Supremacy Clause of the Constitution.<sup>155</sup>

Looking briefly at the other legislation passed by Governor Patrick after the preliminary injunction was granted by Judge Zobel,<sup>156</sup> even if a court found under this modified framework that Massachusetts’s ban was preempted, the requirement of a letter of medical necessity verifying other treatments have failed before receiving a prescription of Zohydro would certainly not be an obstacle to the object of the FDA.<sup>157</sup> In this situation, even with the local conditions of Massachusetts remaining exactly the same,<sup>158</sup> the medical value lost through the legislation is even smaller because the drug is still available, just in a more restricted form.<sup>159</sup> Further, the Commonwealth would benefit from the historic police power of the states to regulate doctor prescriptions.<sup>160</sup>

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<sup>152</sup> See *supra* note 107 and accompanying text.

<sup>153</sup> See MASS. DEP’T OF PUB. HEALTH, MA PRESCRIPTION MONITORING PROGRAM COUNTY-LEVEL DATA MEASURES (CALENDAR YEAR 2014) 2 (2015), <http://www.mass.gov/eohhs/docs/dph/quality/drugcontrol/county-level-pmp/pmp-county-data-2014.pdf> [<https://perma.cc/NMY5-M4XD>] (detailing county by county data on opioid use in Massachusetts in 2014).

<sup>154</sup> *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

<sup>155</sup> See U.S. CONST. art. VI, cl. 2.

<sup>156</sup> *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 3339610, at \*1–2 (D. Mass. July 8, 2014), *vacated in part*, No. 14-11689-RWZ, 2014 WL 4273251 (D. Mass. Aug. 28, 2014) (describing the required procedures under 243 MASS. CODE REGS. 2.07(25) (2014) and 247 MASS. CODE REGS. 8.05(3) (2014)).

<sup>157</sup> See *Zogenix*, 2014 WL 4273251, at \*2.

<sup>158</sup> See *supra* notes 107, 153 and accompanying text.

<sup>159</sup> *Zogenix*, 2014 WL 3339610, at \*3 (“The regulation does not require physicians to prescribe other opioids or subject patients to medically ill-advised treatments before prescribing Zohydro. The regulation gives physicians far more flexibility than plaintiff is willing to admit.” (internal citation omitted)).

<sup>160</sup> See *Gonzales v. Oregon*, 546 U.S. 243, 270–71 (2006) (discussing state power to regulate the health care profession).

Unlike in the analysis for the prescription drug ban, which would be a case of first impression, Congress's awareness and tolerance of the existence of this state power alongside the FDA's drug licensing scheme would bolster Massachusetts's argument against preemption.<sup>161</sup> As Justice O'Connor wrote in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, "The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to 'stand by both concepts and to tolerate whatever tension there [is] between them.'"<sup>162</sup> Taking into consideration that presumption, as well as the smaller loss of medical value by not outright banning the pharmaceutical, under this Note's framework for preemption, the letter of medical necessity would not be preempted by the FDA's approval of Zohydro.

### *B. Impossibility Preemption*

Although Governor Patrick's law may pass muster under object preemption, it must also be non-preempted under implied impossibility preemption. In *Mutual Pharmaceutical Co. v. Bartlett*, the Court seemingly expanded federal impossibility preemption doctrine beyond a true impossibility standard.<sup>163</sup> The Court also seemingly expanded such a definition of impossibility to state positive law as well by equating the tort liability with a positive state law.<sup>164</sup> Unlike the concurrence by Justice Thomas,<sup>165</sup> which is tacitly endorsed by the majority in *Mutual Pharmaceutical Co.*,<sup>166</sup> this Note advocates a true impossibility standard like the one discussed in *Wyeth v. Levine*.<sup>167</sup>

In order for a state to ever have the opportunity to ban an FDA-approved drug, it is necessary that the Court reject the impossibility standard it set in *Mutual Pharmaceutical Co.*, as some commentators have already started to do.<sup>168</sup> Under a true

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<sup>161</sup> See *Wyeth v. Levine*, 555 U.S. 555, 575 (2009).

<sup>162</sup> 489 U.S. 141, 166–67 (1989) (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984)).

<sup>163</sup> See 133 S. Ct. 2466, 2477 (2013) (finding impossibility when a company could accept a tort claim or stop selling in a state to comply with both laws).

<sup>164</sup> *Id.* at 2479 (“[S]tatutory ‘mandate[s]’ do precisely the same thing [as the threat of adverse tort judgments]: They require a manufacturer to choose between leaving the market and accepting the consequences of its actions (in the form of a fine or other sanction)”). Noah seems to believe that the Court's liberal and conservative justices may flip on the issue of state positive law, however. See Noah, *supra* note 8, at 34 n.137 (discussing instances of Sotomayor potentially believing state positive law is preempted).

<sup>165</sup> See *Wyeth*, 555 U.S. at 582–604 (Thomas, J., concurring) (advocating an elimination of object preemption and slightly expanding impossibility preemption).

<sup>166</sup> See 133 S. Ct. at 2470–80 (deciding a preemption case without citing *Wyeth* as precedent or mentioning object preemption at all in support of its analysis).

<sup>167</sup> 555 U.S. at 568–73 (calling impossibility preemption a “demanding defense” and finding no impossibility).

<sup>168</sup> See Noah, *supra* note 8, at 54 (“Because pharmaceuticals run the gamut on these various measures, a state's decision to deprive patients of access to a drug licensed by the FDA would

impossibility standard, it is not physically impossible for a pharmaceutical company to have FDA approval and still have a product banned in a state or two.<sup>169</sup> Like the dissents in *Mutual Pharmaceutical Co.* stated, the company could either stop selling the drug in the state or pay the fine associated with breaking the law against selling the drug.<sup>170</sup> The state attempting to ban the drug would have to keep fines for breaking the ban limited, however, otherwise the case gets closer and closer to being impliedly preempted by impossibility.<sup>171</sup> Without restricting the holding of *Mutual Pharmaceutical Co.* and returning to a standard of strict impossibility in drug ban cases, the whole framework falls apart.<sup>172</sup> It is thus essential that a state trying to ban a drug keeps fines minimal and that the Court draws back part of the holding in *Mutual Pharmaceutical Co.* for this framework to ever find a ban not preempted.

In *Zogenix*, under a true impossibility standard, the ban of Zohydro would not be preempted. In her order granting the preliminary injunction, Judge Zobel based her decision exclusively on implied object preemption, stating that the “emergency order thus stands in the way of ‘the accomplishment and execution of’ an important federal objective.”<sup>173</sup> Judge Zobel does not even mention impossibility preemption in her grant.<sup>174</sup> A true impossibility standard is a “demanding” standard to meet,<sup>175</sup> and only stems from “irreconcilable conflict”<sup>176</sup> between two “irreconcilable affirmative requirements.”<sup>177</sup> A pharmaceutical manufacturer like Zogenix would have to show that it has no options but to violate either the Massachusetts ban or the FDA’s approval of Zohydro. This is simply not the case when Zogenix could simply stop selling in Massachusetts and continue selling in 49 other states.<sup>178</sup>

With a true impossibility standard and the object preemption framework established earlier, Governor Patrick’s order to ban Zohydro ER until it adopted an abuse-resistant formula would be upheld, unlike the actual result in *Zogenix*.<sup>179</sup>

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not invariably run afoul of the Constitution, unless, of course, one takes seriously the Supreme Court’s expansive approach to implied preemption in its latest tort decision, *Mutual Pharmaceutical Co. v. Bartlett*.”)

<sup>169</sup> *Mut. Pharm. Co.*, 133 S. Ct. at 2480–81 (Breyer, J., dissenting).

<sup>170</sup> *Id.*; *id.* at 2482–96 (Sotomayor, J., dissenting).

<sup>171</sup> *Id.* at 2481 (Breyer, J., dissenting) (stating that high damage payments for avoiding conflict between federal and state law may lead to a finding of preemption).

<sup>172</sup> *See id.* at 2469–80 (majority opinion) (finding that a state law subjecting a company to a decision to stop selling their product or face liability is preempted).

<sup>173</sup> *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 1454696, at \*2 (D. Mass. Apr. 15, 2014) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

<sup>174</sup> *See id.*

<sup>175</sup> *See Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

<sup>176</sup> *Mut. Pharm. Co.*, 133 S. Ct. at 2485 (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984)).

<sup>177</sup> *Id.*

<sup>178</sup> *See id.* at 2491–92 (Sotomayor, J., dissenting).

<sup>179</sup> *See* 2014 WL 1454696, at \*1.



## IV. OUTSIDE THE PRESCRIPTION DRUG CONTEXT

Although this modification to the framework for deciding federal preemption cases accomplishes this Note's stated goal of allowing a state to ban an FDA-approved pharmaceutical, object preemption cases do not occur in a vacuum.<sup>180</sup> Under the Supremacy Clause of the Constitution, there is no special exemption allowing for different results in a specific context simply because it is convenient.<sup>181</sup> Although a full examination of the implications of this model outside the prescription drug case is beyond the scope of this Note, it is important that at least some of the ramifications of this model in the greater preemption context be addressed.

In the great majority of cases, this model will result in exactly the same result as the current preemption doctrine without any modification. Take, for example, the world of immigration law. In 2012, the Supreme Court decided the immigration case of *Arizona v. United States*.<sup>182</sup> In relevant part, that case found an Arizona statute that made "knowingly apply[ing] for work, solicit[ing] work in a public place or perform[ing] work as an employee or independent contractor" a punishable misdemeanor<sup>183</sup> to be preempted under implied object preemption.<sup>184</sup> Applying the modified framework, which allows a reflection of the value, as represented through local consideration,<sup>185</sup> of a regulation like Arizona's Section 5(C) to perhaps outweigh the negatives would not make any difference.<sup>186</sup> Although by virtue of being on the southern border Arizona has a larger than average population of illegal immigrants,<sup>187</sup> with an estimated 325,000 unauthorized aliens making up approximately 5% of its total population in 2014,<sup>188</sup> this would not add up to a significant local concern. Around the country, there are states with significantly larger unauthorized immigrant populations, both by percent and as a total number.<sup>189</sup> Further, Section 5(C)

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<sup>180</sup> See, e.g., *id.* at \*1–2 (citing cases in the automobile safety (*Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861 (2000)) and immigration (*Hines v. Davidowitz*, 312 U.S. 52 (1941)) context to decide on a drug preemption case).

<sup>181</sup> U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.").

<sup>182</sup> 567 U.S. 387 (2012).

<sup>183</sup> ARIZ. REV. STAT. ANN. § 13-2928(C) (2010).

<sup>184</sup> *Arizona*, 567 U.S. at 403–07 (finding object preemption even without an explicit Congressional statement forbidding punishment of illegal employees, as to allow punishment would "interfere with the careful balance struck by Congress").

<sup>185</sup> See *supra* Section III.A.

<sup>186</sup> See *Arizona*, 567 U.S. at 403–07.

<sup>187</sup> See *U.S. Unauthorized Immigration Population Estimates*, PEW RES. CTR: HISPANIC TRENDS (Nov. 3, 2016), <http://www.pewhispanic.org/interactives/unauthorized-immigrants/> [<https://perma.cc/P8DF-VKX5>].

<sup>188</sup> *Id.*

<sup>189</sup> *Id.*

would have a massive effect on a large population, subjecting them to criminal liability just for seeking employment.<sup>190</sup> Unlike the case of Zohydro, where there were ample amounts of substitutes and the additional value of having one further opioid was low,<sup>191</sup> there is no easily available income-generating substitute for a job and the value of not punishing immigrants for seeking work is great.<sup>192</sup> Presumably there would not be an issue with changing circumstances in this case, either, as the illegal immigration population had not been increasing significantly in Arizona since 2009.<sup>193</sup> Thus, the addition of a value check would not change the result in a case like *Arizona*.

Indeed, in most cases, local conditions will not rise to the level of significance this framework would require. Absent near-emergency levels of health or safety issues facing one single state, this model will turn out the exact same result as the current preemption framework for decisions does.<sup>194</sup> A state could not hijack this framework by simply claiming exigent circumstances and overruling the federal government. To do so would be a direct violation of the Supremacy Clause.<sup>195</sup> Any court applying this modified framework would require an incredibly significant showing of facts surrounding the value to society of the legislation. Thus, in the vast majority of cases, this modification would not alter the result at all. However, where emergencies call for it, a balancing of the value in protecting the state should be done.

#### CONCLUSION

The *Zogenix v. Patrick* litigation provided an interesting opportunity to reexamine federal preemption doctrine under the Supremacy Clause of the U.S. Constitution.<sup>196</sup> Although the grant of a preliminary injunction and Governor Patrick's subsequent decision not to appeal did not allow any court to examine the merits, the next time a case like this occurs, this Note suggests modifying the federal object preemption doctrine to allow for certain bans when the need is great. This framework would not result in state law replacing federal law as "the supreme Law of the Land,"<sup>197</sup> but would simply allow wiggle room when the need is severe. Where local conditions demand it or a discovery of new information arises, this framework would provide states the

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<sup>190</sup> See *supra* notes 182–83 and accompanying text.

<sup>191</sup> See *supra* Part I and Section III.A.

<sup>192</sup> See *Arizona v. United States*, 567 U.S. 387, 405 (2012) ("IRCA's framework reflects a considered judgment that making criminals out of aliens engaged in unauthorized work—aliens who already face the possibility of employer exploitation because of their removable status—would be inconsistent with federal policy and objectives.").

<sup>193</sup> See *U.S. Unauthorized Immigration Population Estimates*, *supra* note 187 (documenting no significant change in unauthorized population from 2009–2014).

<sup>194</sup> See *supra* Section III.A.

<sup>195</sup> U.S. CONST. art. VI, cl. 2.

<sup>196</sup> See *id.*; *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 1454696, at \*1 (D. Mass. Apr. 15, 2014).

<sup>197</sup> U.S. CONST. art. VI, cl. 2.

much-needed leeway to ban a potentially dangerous pharmaceutical. This would require a return to a *Wyeth* standard instead of the new *Mutual Pharmaceutical Co.* one that is currently in place, but the switch would be worth it to promote states' rights to protect its citizens from problems that perhaps were not reflected in the FDA's calculation. It would also allow the state to place pressure on pharmaceutical companies like Zogenix to improve the safety or efficacy of their drugs.

In the current case of the American opioid epidemic, the need for states to be able to fight on an individual level is severe. Without allowing the states the ability to combat the harsh local conditions they might face, the epidemic may continue to spiral out of control, taking more and more lives with it. By adopting this framework for federal preemption decisions, especially in the pharmaceutical case, lives may be saved and the nation can begin fighting back, one state at a time.