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# Federal Judge Blocks Massachusetts Governor Deval Patrick's Attempts to Limit Access to Potent Opioid Painkiller Zohydro

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On July 8, 2014, Judge Rya Zobel of the United States District Court for the District of Massachusetts rejected newly enacted state regulations limiting the availability of Zohydro, a Food and Drug Administration-approved prescription painkiller manufactured by Zogenix, Inc.[1] Three months earlier, Judge Zobel had rejected Massachusetts Governor Deval Patrick's (D) effort to ban Zohydro outright, finding the state's action preempted by the federal Food, Drug, and Cosmetic Act.[2] Governor Patrick responded to the *Zogenix I* ruling with a series of regulations limiting physicians' prescribing Zohydro and pharmacists' handling and dispensing it. Zogenix argued in its Motion for a Preliminary Injunction against the regulations that Massachusetts was attempting to ''make scarce or altogether unavailable a drug that the FDA, by approving it, has said should be available.''[3] Zogenix claimed, and the Court in essence agreed, that the regulations as written amounted to a de-facto ban on the drug that undermined the FDA's roles to approve drugs for specific uses and purposes and to place safe, effective drugs on the market.[4] Massachusetts implemented modified regulations and sought to vacate the order, and is now opposing Zogenix' attempt to obtain a protective order.

In responding to Zogenix' initial challenge to its regulations, Massachusetts noted that Zohydro would remain available and that the restrictions were not as stringent as plaintiffs contended.[5] The state relied on its police power—the authority to regulate citizens' health and safety—which, it argued, includes policing medical professionals.[6] Massachusetts maintained that because the FDA does not regulate the practice of medicine or the dispensation of drugs, its own exercise of police power was constitutional.[7]

Judge Zobel agreed that the state has broad power to regulate health and safety, but she held that the state must exercise that power consistently with federal law.[8] Because the FDA approved Zohydro, the state's regulations were preempted.[9] Preemption, the judge reiterated, applies even when a state is regulating a matter of special concern, such as a public health crisis.[10] The court determined that one, though perhaps both, of the

[1] *Zogenix, Inc. v. Patrick*, No. 14–11689–RWZ, 2014 WL 3339610, at *4-5 (D. Mass. July 8, 2014) (''*Zogenix II*'').

[2] *Zogenix, Inc. v. Patrick*, No. 14–11689–RWZ, 2014 WL 1454696, at *2-3 (D. Mass. Apr. 15, 2014) (''*Zogenix I*'').

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[3] *Zogenix II*, 2014 WL 3339610, at *3.

[4] *Id.* at *3.

[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] *Id.* at *4.

[9] *Id.*

[10] *Id.* (quoting *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141 (1982)).

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regulations at issue frustrated the objective of the Food, Drug, and Cosmetic Act: to make safe, effective drugs publicly available.[11]

Specifically, Judge Zobel blocked the regulation requiring a physician prescribing Zohydro to issue a Letter of Medical Necessity certifying that alternative pain treatments have failed.[12] Judge Zobel held that the text of the regulation was ambiguous.[13] The state, by attempting to ''make Zohydro a last-resort opioid . . . makes Zohydro less available,'' and by ''requir[ing] a fresh failure [of alternative medication] as a precondition to each 30-day Zohydro prescription, [the state] . . . severely frustrate[s] Zohydro's availability.''[14] Although the judge granted the injunction, she allowed Massachusetts an opportunity to revise the regulation and move to lift the injunction.[15] She asked the state to ''provide adequate and constitutional guidance to physicians regarding the prerequisites for prescribing Zohydro.''[16]

Zogenix also sought to enjoin the state's new regulatory requirement that pharmacists alone—not staff or technicians—dispense Zohydro.[17] Zogenix claimed that major, though unspecified, pharmacy chains declared their intent not to stock Zohydro because the regulation was incompatible with their protocol for dispensing opioids.[18] Conversely, the state submitted a declaration from a pharmacy stating that the regulation neither burdened nor created logistical problems for its dispensation of the drug.[19] Confronted with competing evidence and no clear conflict between state and federal law, Judge Zobel denied the injunction.[20] Although Zogenix had not met its burden of proving irreparable harm, the court gave Zogenix an opportunity to submit more evidence.[21] The court further denied the Massachusetts' Motion to Dismiss on the grounds that plaintiffs had stated a plausible claim for relief.[22]

On July 11, 2014, Massachusetts filed a Motion to Vacate the injunction, arguing that the state had revised the problematic regulations days before Judge Zobel issued *Zogenix II*.[23] Specifically, Massachusetts had redrafted the Letter of Medical Necessity regulation to require prescribers to show that alternative painkillers proved ''inadequate,'' not necessarily a failure.[24] This requirement mirrors the language the FDA requires Zogenix to use on labels of Zohydro itself.[25] The state argues that the revision fulfilled the court's requirement that the new regulations provide adequate and constitutional guidance to physicians.[26]

Zogenix responded that the state's revised regulation neither moots the preemption challenge nor solves the underlying constitutional problem.[27] Regardless of textual changes to the rule, Zogenix argued, it still limits the FDA-approved drug's availability.[28] Zogenix further noted its preparedness to develop a factual record regarding pharmacies' willingness to dispense Zohydro, to schedule discovery, to brief summary judgment, and to move to trial.[29] Zogenix also asked the court to enter a protective order, claiming that eliciting relevant information from pharmacies and customers to create a record would place it at a disadvantage relative to its competitors.[30] At the time of this writing, Judge Zobel has neither ruled on Massachusetts' Motion to Vacate nor addressed Zogenix's concerns.

The *Zogenix* litigation was the result of Governor Patrick's declaration of a public health emergency in April 2014, in response to a 90% increase in the number of heroin and opioid overdose deaths in Massachusetts between 2000 and 2012.[31] By declaring a public health emergency, Governor Patrick granted emergency powers to himself, the Commissioner of Public Health, and the state's Public Health Council.[32] Most controversially, the state prohibited the prescription and dispensation of pure-hydrocodone painkillers until measures were imposed to prevent abuse and misuse of those drugs.[33] Massachusetts targeted prescription painkillers in general, and Zohydro in particular, as a gateway to heroin abuse and overdose in the apparent hope that cutting off this path might assuage the opioid crisis.[34] Because Zohydro is especially long-acting, potent, and not abuse-resistant, Massachusetts believes it poses significant public health risks.[35]

Zogenix sued the Governor and the Public Health Commissioner, arguing that the state's conduct was unconstitutional for three reasons: 1) the FDA's approval of the drug preempted the state's ban, 2) the state's action violated the Dormant Commerce Clause by burdening interstate commerce, and 3) the state's action violated the Contracts Clause by impairing private contracts among Zogenix and other parties.[36] Zogenix argued that banning a single, FDA-approved pharmaceutical harms not only the drug manufacturer, but also patients suffering from chronic pain.[37] A ban would cause patients, physicians, pharmacists, and the public to believe that the drug is unsafe or ineffective, despite FDA approval.[38] Because Zohydro's pure-hydrocodone formulation fills a significant niche in the market—providing relief to patients who cannot tolerate painkill-

[11] *Id.* at *4-5.
[12] *Id.* at *4.
[13] *Id.*
[14] *Id.*
[15] *Id.* at *5.
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] Def.'s Mot. to Vacate Prelim. Inj. 1-3, July 11, 2014, ECF No. 68.
[24] *Id.* at 2.
[25] *Id.* at 2-3.
[26] *Id.* at 3.
[27] Req. of Pl. Zogenix, Inc. for a Scheduling/Status Conference 2-3, July 10, 2014, ECF No. 67.
[28] *Id.* at 1.
[29] *Id.* at 3.
[30] *Id.*
[31] Press Release, Governor Deval Patrick, Governor Patrick Declares Public Health Emergency, Announces Actions to Address Opioid Addiction Epidemic (March 27, 2014) (http://www.mass.gov/governor/pressoffice/pressreleases/2014/0327-governor-declares-public-health-emergency.html).
[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] Pl.'s Mem. of P. & A. in Supp. of Mot. for TRO and Prelim. Inj. 1, Apr. 7, 2014, ECF No. 4.
[37] *Id.* at 19.
[38] *Id.* at 19-20.

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ers containing acetaminophen—Zogenix's commercial viability depends on the drug's success.[39]

Massachusetts responded that a conditional ban, which could be lifted when safeguards against abuse were imposed, fell within its police power to protect its citizens' health and safety; it was appropriate for and necessary to a legitimate public purpose—combatting a public health crisis.[40] The state claimed that its actions did not violate the Dormant Commerce Clause because the ban was directed at a discrete risk posed by a single drug, manufactured and sold by one firm.[41] Massachusetts argued that its actions did not violate the Contracts Clause because Zogenix operates in a highly regulated industry in which it can anticipate limits on contracting.[42]

Judge Zobel ruled in favor of Zogenix, holding: ''When the Commonwealth interposed its own conclusion about Zohydro's safety and effectiveness . . . did it obstruct the FDA's Congressionally-given charge? I conclude that it did. . . . If the Commonwealth were able to countermand the FDA's determinations and substitute its own requirements, it would undermine the FDA's ability to make drugs available to promote and protect the public health. The Commonwealth's emergency order thus stands in the way of 'the accomplishment and execution of' an important federal objective. The Constitution does not allow it to do so.''[43] The judge relied on a preemption analysis to grant injunctive relief to Zogenix, so she did not address the Dormant Commerce Clause or Contracts Clause issues.[44]

**While a federal court rejected efforts of Massachusetts to restrict the market for Zohydro, other states have taken action to regulate the distribution and prescription of Zohydro.**

Judge Zobel's rulings in April and July soundly rejected Governor Patrick's attempts to restrict the market for Zohydro in Massachusetts. Other states, however, have taken action to regulate the distribution and prescription of Zohydro. On April 3, 2014, Vermont's Governor Peter Shumlin issued emergency rules governing the dispensing of Zohydro.[45] Vermont now requires prescribers to conduct patient evaluations before prescribing the drug, requires patients to acknowledge the dangers of Zohydro, and requires physicians to follow up routinely; physicians must obtain patients' informed consent for prescriptions of the painkiller and for specific monitoring protocols (a Controlled Substance Treatment Agreement).[46] Prescribing physicians must also certify that other medications have proven ineffective.[47] On June 18, 2014, Delaware followed suit, imposing emergency regulations that mirror Vermont's.[48] Delaware's rules also impose prescribing conditions that require physicians to, among other actions, conduct patient evaluations, obtain the patient's informed consent to prescription and to specific monitoring protocols, and to engage in routine follow up.[49]

Legislators in Ohio introduced a bill on May 27, 2014, to categorize Zohydro as a Schedule I drug.[50] A substance classified as Schedule I in Ohio has a high potential for abuse, has no accepted medical use, and is considered unsafe to use even under medical supervision; licensed health professionals in Ohio are prohibited from prescribing Schedule I substances.[51] A Schedule I classification effectively criminalizes the use, sale, and prescription of the pharmaceutical.[52] Similarly, on April 28, 2014, a Pennsylvania legislator introduced a bill to ban Zohydro in that state.[53]

States' attempts to ban Zohydro—or any FDA-approved painkiller—outright will likely not succeed in federal courts for the reasons articulated by Judge Zobel in *Zogenix I & II*. Federal legislators, however, also have taken steps to attempt to limit the drug's availability. On March 13, 2014, U.S. Senator Joe Manchin, a Democrat from West Virginia, and U.S. Congressman Stephen Lynch, a Democrat from Massachusetts, introduced bills proposing a federal-level ban on Zohydro.[54] Both bills were referred to subcommittees several days later, and neither has seen movement since.[55] State and federal lawmakers from many states, including New York's Democratic Senator Charles E. Schumer, have written to the Department of Health and Human Services encouraging the FDA to reverse its approval of Zohydro.[56] On March 3, 2014, Schumer wrote to HHS Secretary Kathleen Sebelius, ''I urge you to override the FDA's approval of Zohydro ER and work quickly to stop it from being sold to consumers. It is essential that we stop yet another dangerous drug from playing a role in our country's national drug epidemic, and that we also begin to incorporate abuse-deterrent technologies into

[39] *Id.*

[40] Def.'s Mem. in Opp'n to Appl. for Prelim. Injunctive Relief 8-10, Apr. 11, 2014, ECF No. 20.

[41] Def.'s Supplemental Mem. in Opp'n to Pl.'s Mot. for Prelim. Injunctive Relief 5-10, Apr. 14, 2014, ECF No. 24.

[42] *Id.* at 1-5.

[43] *Zogenix I*, 2014 WL 1454696, at *2.

[44] *Id.* at *2 n.2.

[45] Vermont Department of Health, Agency of Human Services, Rule Governing the Prescription of Extended Release Hydrocodones Manufactured Without Abuse-Deterrent Formulations §§ 4.1-4.8 (http://healthvermont.gov/regs/documents/hydrocodone_emergency_rule.pdf).

[46] *Id.*

[47] *Id.*

[48] Delaware Department of State, Emergency Rule Adoption Placing Requirements on Prescription of ER Hydrocodone (http://dpr.delaware.gov/boards/controlledsubstances/documents/Emergency_Rule.pdf).

[49] *Id.*

[50] H.B. 501, 130th Gen. Assemb. Reg. Sess. (Ohio 2014).

[51] Ohio Legislative Service Commission, Bill Analysis, H.B. 501, 130th Gen. Assemb., at 1 (2014) (http://www.lsc.state.oh.us/analyses130/h0501-i-130.pdf).

[52] *Id.*

[53] H.B. 2203, 2014 Gen. Assemb. Reg. Sess. (Pa. 2014).

[54] S. 2134, 113th Cong. (2014); H.R. 4241, 113th Cong. (2014).

[55] *Id.*

[56] Press Release, United States Senator Charles E. Schumer, Schumer Calls on HHS Secretary to Overturn Confounding FDA Decision Allowing New Super-Drug to Hit Market Without Protections to Prevent Abuse—Urges Nationwide Ban of Powerful Painkiller Zohydro Until it is Abuse-Proof (March 3, 2014) (http://www.schumer.senate.gov/Newsroom/record.cfm?id=349480).

all dangerous opioids as new drugs are introduced to the market.''[57]

The FDA, however, has so far stood by its approval of Zohydro. Although in favor of a continued dialogue about the opioid crisis in America, the FDA has discouraged states from undermining the agency's authority and expertise. Margaret A. Hamburg, M.D., Commissioner of the U.S. Food and Drug Administration, issued a statement on April 29, 2014 addressing the agency's concern for the opioid addiction crisis, states' attempts to manage it, and the need for comprehensive, science-based policies and strategies to tackle the complex problem.[58]

Dr. Hamburg wrote that, while regulations such as Massachusetts' and Vermont's are ''consistent with the essential tenets of . . . appropriate pain management and . . . are precisely what responsible physicians should be doing,'' the misplaced focus on Zohydro leads to ''considerable misinformation'' that ''divert[s] attention from more comprehensive policy solutions that apply to all opioids.''[59] The FDA is adamant that states—and the nation—focus on regulating all opioids by limiting excessive or unnecessary prescribing, prosecuting illegal activity by rogue providers, encouraging proper disposal of unused drugs, and mitigating prescriber and patient ignorance.[60] In the meantime, states' attempts to ban, or even to limit, the availability of FDA-approved drugs should be challenged through federal litigation.

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[57] *Id.*

[58] Dr. Margaret A. Hamburg, M.D., *The Way Forward on Opioid Abuse: A Call to Action for Science-Based, Comprehensive Strategies*, FDAVoice (April 29, 2014), http://blogs.fda.gov/fdavoice/index.php/2014/04/the-way-forward-on-opioid-abuse-a-call-to-action-for-science-based-comprehensive-strategies-2/.

[59] *Id.*

[60] *Id.*

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