UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 14-11689-RWZ

ZOGENIX, INC.

v.

DEVAL PATRICK,
in his official capacity as
GOVERNOR OF THE COMMONWEALTH OF MASSACHUSETTS, *et al.*

ORDER

April 15, 2014

ZOBEL, D.J.

Plaintiff Zogenix, Inc., filed a three-count complaint alleging that the Commonwealth's emergency order banning the prescription, ordering, dispensing, and administration of Zohydro ER, an opioid analgesic Zogenix developed, is unconstitutional. It seeks a preliminary injunction suspending enforcement of the ban (Docket # 3).[1] Because I conclude that the Commonwealth's emergency order is preempted by federal law, plaintiff's motion is ALLOWED.

I take the facts from the verified complaint and the parties' affidavits. Zogenix manufactures Zohydro ER, the only hydrocodone analgesic on the market whose sole active ingredient is hydrocodone. Other analgesics contain acetaminophen, which can

[1]Zogenix styled its motion to seek a "temporary restraining order and preliminary injunction." At oral argument, the parties agreed that it is appropriate for the court to treat the motion as for a preliminary injunction.

cause liver damage. Zohydro ER is an "extended release" medication, dispensing pain relief over a twelve-hour period. But because Zohydro ER does not have an "abuse-resistant formulation," it can be crushed and inhaled or injected, making the full dose of hydrocodone available immediately. The absence of this "abuse-resistant formulation" has provoked concern that Zohydro ER may lead to opioid addiction and overdose fatalities, a concern especially potent given the recent spike in opioid- and heroin-related deaths in Massachusetts.

The Food and Drug Administration ("FDA") approved Zohydro ER on October 25, 2013. On March 27, 2014, defendant Governor Deval Patrick declared a public health emergency and directed the Department of Public Health ("DPH") to take several steps to respond to increased opioid addiction. The declaration empowered defendant DPH Commissioner Cheryl Bartlett to immediately prohibit the prescribing and dispensing of Zohydro ER until DPH determined that adequate measures to safeguard against diversion, overdose, and misuse had been implemented. Commissioner Bartlett issued an emergency order to that effect the same day. This challenge followed.

To obtain a preliminary injunction, Zogenix must establish (1) it is likely to succeed on the merits; (2) it is likely to suffer irreparable harm in the absence of preliminary injunctive relief; (3) the balance of equities weighs in its favor; and (4) an injunction is in the public interest. Winter v. Natural Res. Def. Council, 555 U.S. 7, 20 (2008).

Zogenix's main claim is that the emergency order is preempted by federal law. The Supremacy Clause provides that the Constitution and the laws of the United States

"shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. For this reason, "state law that conflicts with federal law is 'without effect.'" Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 516 (1992) (quoting Maryland v. Louisiana, 451 U.S. 725, 746 (1981)). As relevant here, state and federal law conflict if state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

The Federal Food, Drug, and Cosmetic Act ("FDCA") created the FDA and charged it with "promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b)(1). Congress required the FDA to "protect the public health" by making sure that "drugs are safe and effective." Id. § 393(b)(2)(B). The FDA endorsed Zohydro ER's safety and effectiveness when it approved the drug. When the Commonwealth interposed its own conclusion about Zohydro ER's safety and effectiveness by virtue of DPH's emergency order, did it obstruct the FDA's Congressionally-given charge?

I conclude that it did. The FDA has the authority to approve for sale to the public a range of safe and effective prescription drugs—here, opioid analgesics. 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. See Geier v. Am. Honda Motor Co., 529 U.S. 861, 881 (2000). The Commonwealth's emergency order thus stands in the way of "the

accomplishment and execution of" an important federal objective. Hines, 312 U.S. at 67. The Constitution does not allow it to do so.

Defendants' arguments in support of the emergency order are without merit. Defendants claim that the Supreme Court has rejected "obstacle preemption" with respect to the FDCA. See Wyeth v. Levine, 555 U.S. 555, 573 (2009). That is not so. Wyeth simply concluded that Congress did not view state tort suits as an obstacle to achieving the FDA's purposes. Id. Defendants also contend that here, as in Wyeth, federal regulation is a floor, not a ceiling; if states wish to regulate over and above federal regulations, they may do so. But Wyeth is a drug labeling case, and defendants present no evidence or persuasive argument that its reasoning should control in this different context. Furthermore, Wyeth assumed the availability of the drug at issue and analyzed whether stronger state labeling requirements obstructed the FDA's objectives. Here, the obstruction is clearer because the 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.

For the reasons described above, Zogenix is likely to prevail on the merits. The remaining three injunctive relief factors are not without doubt. When viewed in the context of the constitutional question at issue, however, the remaining factors favor the grant of the injunction. Plaintiff has shown injury to its reputation by defendants' highly publicized ban of its drug, and the ban also adversely impacts the Congressionally-mandated arrangement for ensuring that drugs are safe and effective for those in need.

As to the equities, although the ban may prevent someone from misusing the drug, the ban prevents all in need of its special attributes from receiving the pain relief Zohydro ER offers. For the same reason, the injunction is in the public interest.[2]

In short, the Constitution mandates that the injunction issue. Plaintiff's motion for preliminary injunctive relief (Docket # 3) is ALLOWED. Defendants' motion to strike the Declaration of Donald M. Fox (Docket # 23) is DENIED AS MOOT.

Accordingly, it is ORDERED that, pending further order of the court, defendants are enjoined from taking any action to implement or enforce the Governor's Declaration of Emergency and the order of the Commissioner of the Department of Public Health banning the sale and distribution of Zohydro™ ER as approved by the FDA.

This order is stayed until April 22, 2014.

April 15, 2014 /s/Rya W. Zobel

DATE RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE

[2]In view of this ruling, I do not consider Zogenix's other arguments that the order violates the Contracts Clause and the Dormant Commerce Clause of the U.S. Constitution.