UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

CHARLES OUELLETTE, et al., Plaintiffs v. JANET T. MILLS, in her official capacity as Attorney General of the State of Maine, et al., Defendants.	)	Civil No. 1:13-cv-00347-NT

DEFENDANTS' (1) MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR JUDGMENT ON THE PLEADINGS AND (2) CROSS-MOTION FOR JUDGMENT ON THE PLEADINGS

INTRODUCTION

Defendants submit this memorandum in opposition to plaintiffs' motion for judgment on the pleadings with respect to their lawsuit challenging Public Law 2013, Chapter 373, an amendment to the Maine Pharmacy Act (the "2013 Amendment").[1] *See* DE 46. Defendants also hereby move, in their own right, for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c) and submit this memorandum in support of their Cross-Motion.

The 2013 Amendment restricts the reach of the Maine Pharmacy Act by providing that certain conduct will no longer constitute the unlawful practice of pharmacy or otherwise violate the Maine Pharmacy Act. *See* 32 M.R.S. §§ 13731(1), 13799. The 2013 Amendment says nothing about whether such conduct may violate federal law, such as the Food, Drug and Cosmetic Act ("FDCA"). Plaintiffs claim that the 2013 Amendment is preempted by the FDCA.

[1] Pursuant to the Court's order, *see* DE 56, defendants are treating plaintiffs' Motion for Summary Judgment as a Motion for Judgment on the Pleadings pursuant to Rule 12(c).

A bedrock principle of federalism is that states are not required "to enact or administer a federal regulatory program." *Printz v. United States*, 521 U.S. 898, 926, 933 (1997). The 2013 Amendment constitutes nothing more than the State of Maine's exercise of that right. Through that law, the State is leaving to the federal government the enforcement of any federal laws that regulate the sale of prescription drugs to Mainers by certain foreign-based pharmacies. Just as states may decriminalize the possession of marijuana for medical reasons, and leave to federal authorities the enforcement of any federal criminal laws banning marijuana possession, so may Maine choose to get out of the business of regulating – as the unlicensed practice of pharmacy – the activities of pharmacies located in specified foreign countries.

Contrary to plaintiffs' repeated claims, the 2013 Amendment does not affirmatively "authorize" or "permit" anyone to buy prescription drugs from pharmacies located in certain foreign countries. The law simply leaves federal laws as the barrier to such activities, to be enforced by federal authorities if (contrary to current practice) they choose to enforce those laws.

Although plaintiffs contend that the 2013 Amendment is preempted by the FDCA, their real concern seems to be that the 2013 Amendment allegedly "violates" the FDCA. DE 46 at 2. This concern is not well-founded. In any event, it is well-established that only the federal government, not private litigants, may enforce the FDCA. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) (no private right of action to enforce FDCA).

Plaintiffs' action is thus barred for another reason: they lack a private cause of action. The FDCA does not create any privately enforceable rights with respect to state regulation or licensure of pharmacies located in foreign countries. And as four Justices of the Supreme Court recently recognized, "[w]hen Congress did not intend to provide a private right of action to enforce a statute enacted under the Spending Clause, the Supremacy Clause does not supply one

of its own force." *Douglas v. Independent Living Center of Southern Calif., Inc*., 132 S. Ct. 1204, 1215 (Roberts, C.J., dissenting). Although the majority of the *Douglas* Court did not reach that issue, the Court has taken up the question again this Term in *Armstrong v. Exceptional Child Center, Inc*., 567 Fed. App. 496 (9th Cir.), *petition for certiorari granted*, 2014 WL 3107841 (U.S. Oct. 2, 2014). This Court should adopt the position set forth in Chief Justice Roberts' persuasive dissent in *Douglas*.

The Court should deny plaintiffs' Motion and grant defendants' Cross-Motion. The 2013 Amendment is not preempted by the FDCA.

MEMORANDUM OF LAW

Factual allegations. Because the Court has ruled that it intends to "determine whether Plaintiffs are entitled to declaratory relief with respect to their facial preemption challenge, a predicate question the Court may answer as a matter of law, without consideration of facts," Docket Entry ("DE") 56 at 2, defendants do not plan to address plaintiffs' factual allegations in any detail. Defendants have denied many of the allegations in plaintiffs' Complaint. *See* DE 42 at 3-12.

There are five remaining plaintiffs – two Maine-licensed pharmacists (Charles Ouellette and Amelia Arnold) – and three trade associations comprised in whole or in part of pharmacists (the Maine Pharmacy Association, the Maine Society of Health-System Pharmacists, and the Retail Association of Maine).[2] DE 1 at ¶¶ 6-11. No plaintiff alleges it has engaged or plans to engage in conduct covered by the 2013 Amendment, or that this Amendment applies to them.

Plaintiffs have alleged, inaccurately, that (1) the "MaineMeds" program has resumed operations, DE 46 at 11 (relying on Exh. L to Gore Decl.), and (2) the State currently "spends

[2] The claims of a sixth plaintiff, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), have been dismissed. DE 39 at 9-10.

public money to pay CanaRx for foreign prescription drugs and their importation into the United States," DE 46 at 11, 19. The record shows that the MaineMeds program was not "reinstated" after the 2013 Amendment became effective, and that it has not "resumed operations" (assuming *arguendo* that these facts had some relevance to plaintiffs' preemption claim). *See* DE 50-2 (Declaration of Christine Brawn at ¶ 2).

Safety issues raised by plaintiffs. Although plaintiffs seek to portray prescription drugs sold by foreign-based pharmacies as inherently harmful and those sold in this country as uniformly safe, DE 46 at 2-12, the issue is not so clear. The legislative record shows that the City of Portland "did not experience a single incident of prescription error or health risk from utilization of the mail order program" involving CanaRX between 2004 and 2012.[3] DE 9-14. The City also pointed out the substantial savings from its program. *Id*. In contrast, more than 500,000 people died or suffered serious injuries in 2011 as a result of taking FDA-approved drugs. *See* FAERS Reporting by Patient Outcomes by Years, available at http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugeffects/ucm070461.htm (last visited Oct. 10, 2014). That number has increased in 2012 and 2013. *Id*.

Applicable law. As shown below, the FDCA leaves to the states such decisions as whether, and how, to regulate and license pharmacies and pharmacists. In 2013, Maine decided it no longer wanted to be involved in regulating, by means of the Maine Pharmacy Act's unlicensed practice provision, the activities of certain pharmacies located in specified foreign countries, and so it enacted the 2013 Amendment. That decision by Maine leaves it to the federal government to enforce the FDCA or any other federal law that may be applicable to such activities.

[3] Prescription drugs sold in this country are often produced in foreign countries with minimal FDA oversight and then shipped back to the United States. *See* DE 18-1 at 7.

State of Maine regulatory framework. Maine, like many other states, has a Board of Pharmacy ("Board") and a licensing and regulatory program for those persons and businesses seeking to engage in the practice of pharmacy in Maine. *See* Maine Pharmacy Act, 32 M.R.S. §§ 13701-13835. Licensure provides the State with one means of regulation, and it allows for the imposition of discipline and penalties (*e.g.*, license suspension) as to licensees that are found to have engaged in conduct that violates the Maine Pharmacy Act. *See* 32 M.R.S. § 13742-A.

At all relevant times, however, including prior to the enactment of the 2013 Amendment, the Maine Pharmacy Act did not provide for the licensure of pharmacies located in other countries, including Canada. *See* DE 9-11. Plaintiffs do not challenge the correctness of that legal determination made by the Board and the Attorney General. Thus, regardless of the 2013 Amendment, the Maine Pharmacy Act does not – and did not – provide for the licensure of pharmacies based in foreign countries, such as CanaRx. Instead, prior to the 2013 Amendment, the unlicensed practice provision in the Maine Pharmacy Act was the means by which the Board or the State penalized foreign-based pharmacies engaged in the unlicensed practice of pharmacy in Maine. *See* 32 M.R.S. § 13731(1) (2012) ("Unlawful Practice; Penalties; Injunctions").[4]

In 2013, the Maine Legislature chose to reduce the reach of the Maine Pharmacy Act by providing that the conduct of pharmacies located in certain countries would no longer constitute the unlawful practice of pharmacy in Maine. The Legislature effected this change by amending 32 M.R.S. § 13731(1) so that it provides:

[4] Prior to the 2013 Amendment, section 13731(1) provided: "It is unlawful for any person to engage in the practice of pharmacy [in Maine] unless licensed to practice under this Act; provided that physicians, dentists, veterinarians or other practitioners of the healing arts who are licensed under the laws of this State may dispense and administer prescription drugs to their patients in the practice of their respective professions where specifically authorized to do so by law."

> It is unlawful for any person to engage in the practice of pharmacy [in Maine] unless licensed to practice under this Act, except that
>
> A. Physicians, dentists, veterinarians or other practitioners of the healing arts who are licensed under the laws of this State may dispense and administer prescription drugs to their patients in the practice of their respective professions where specifically authorized to do so by law;
>
> B. A licensed retail pharmacy that is located in Canada, the United Kingdom of Great Britain and Northern Ireland, the Commonwealth of Australia or New Zealand that meets its country's statutory and regulatory requirements may export prescription drugs by mail or carrier to a resident of this State for that resident's personal use. A licensed retail pharmacy described in this paragraph is exempt from licensure under this Act; and
>
> C. An entity that contracts to provide or facilitate the exportation of prescription drugs from a licensed retail pharmacy described in paragraph B may provide or facilitate the provision of prescription drugs from that pharmacy by mail or carrier to a resident of this State for that resident's personal use. An entity that provides or facilitates the provision of prescription drugs pursuant to this paragraph is exempt from licensure under this Act.

The 2013 Amendment sought to preserve choices for Maine consumers and reduce the reach of the Maine Pharmacy Act.[5] *See* Public Law 2013, Chapter 373. The law became effective on October 9, 2013.[6]

The 2013 Amendment provides that certain conduct will not constitute the unlicensed practice of pharmacy or otherwise violate the Maine Pharmacy Act. That is all it does. The statute says nothing about whether such conduct may violate the FDCA or other Maine laws.

---

[5] The 2013 Amendment also includes the enactment of 32 M.R.S. § 13799, which provides that "[n]othing in this chapter may be construed to prohibit: (1) An individual who is a resident of the State from ordering or receiving prescription drugs for that individual's personal use from outside the United States by mail or carrier from a licensed retail pharmacy described in section 13731, subsection 1, paragraph B or an entity described in section 13731, subsection 1, paragraph C; or (2) A licensed retail pharmacy described in section 13731, subsection 1, paragraph B or an entity described in section 13731, subsection 1, paragraph C from dispensing, providing or facilitating the provision of prescription drugs from outside the United States by mail or carrier to a resident of the State for that resident's personal use."

[6] Although plaintiffs emphasize the titles to LD 171 and other bills, DE 46 at 1, 8-9, the title to LD 171 is not part of the law. *See* 1 M.R.S. § 71(10).

Contrary to plaintiffs' repeated claims, the 2013 Amendment does not affirmatively "authorize" or "permit" the sale to Maine residents of prescription drugs from pharmacies located in certain foreign countries.[7] DE 46 at 1, 10, 11. To the extent there is any ambiguity on the meaning of the 2013 Amendment, the Court should construe the statute as not purporting to affirmatively authorize activities that are prohibited by federal law. It is a longstanding principle of statutory construction under Maine and federal law that the Court must avoid even a potentially unconstitutional interpretation of a statute if a reasonable interpretation would satisfy constitutional requirements. *See, e.g.*, *Mushero v. Ives*, 949 F.2d 513, 519-520 (1st Cir. 1991) ("statutes should be construed to avoid constitutional problems"); *Redgrave v. Boston Symphony Orchestra, Inc.*, 855 F.2d 888, 909 (1st Cir. 1988) ("a statute must be construed, if fairly possible, so as to avoid not only the conclusion that it is unconstitutional *but also grave doubts upon that score*") (emphasis in original), *cert. denied*, 488 U.S. 1043 (1989); *Anderson v. Town of Durham*, 895 A.2d 944, 951 (Me. 2006) (it is a "basic principle of statutory construction that this Court is bound to avoid an unconstitutional construction of a statute if a reasonable interpretation of the statute would satisfy constitutional requirements") (quoting *Bagley v. Raymond School Dep't*, 728 A.2d 127, 133 (Me. 1999)) (internal quotation marks omitted), *cert. denied*, 549 U.S. 1051 (2006).

[7] Plaintiffs also misconstrue other aspects of the 2013 Amendment. For example, plaintiffs contend that the 2013 Amendment provides that "nothing in Maine law" may be construed to prohibit the conduct addressed by the 2013 Amendment. DE 46 at 11. Instead, the 2013 Amendment provides that "nothing in this chapter" – meaning the Maine Pharmacy Act – "may be construed to prohibit" the conduct at issue. Other Maine laws may apply. Plaintiffs then claim, again incorrectly, that under the 2013 Amendment, "Maine law would no longer prohibit such foreign pharmacies" from engaging in certain conduct. DE 46 at 11. Again, the 2013 Amendment provides that "nothing in this chapter" – meaning the Maine Pharmacy Act – will prohibit foreign pharmacies from engaging in certain conduct.

The 2013 Amendment is a classic example of a state acting to limit the extent of its traditional police powers – deciding not to assert its regulatory authority over certain conduct. The State of Maine has every right to do so. As the Supreme Court has made clear, under the Tenth Amendment to the United States Constitution, Maine has no obligation to enact state laws (or keep such laws on the books) to further the federal policies underlying the FDCA. *See Printz*, 521 U.S. at 933 ("The Federal Government may not compel the States to enact or administer a federal regulatory program."); *New York v. United States*, 505 U.S. 144, 188 (1992) (same). Thus, Maine is free not to regulate the conduct of pharmacies located in other countries – even assuming *arguendo* that those pharmacies may choose to engage in conduct that violates the FDCA. Plaintiffs may not "commandeer state governments into the service of federal regulatory purposes" by compelling Maine to enact laws to enforce the FDCA or further the FDCA's policies. *See Printz*, 521 U.S. at 925; *New York*, 505 U.S. at 175-176.

FDCA. The FDCA generally prohibits the introduction into interstate commerce of any "adulterated" or "misbranded" drug. 21 U.S.C. § 331(a). For each "new drug" introduced into interstate commerce, the FDA approves the manufacturing process, labeling, and packaging. 21 U.S.C. § 355(b).

With respect to the importation of prescription drugs, "[e]xcept as provided in paragraph (2) and section 384 of this title, no drug subject to section 353(b) of this title or composed wholly or partly of insulin which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug." 21 U.S.C. § 381(d)(1). There are at least two exceptions to this rule, however. First, the Secretary of HHS may authorize importation for emergency use. 21 U.S.C. § 381(d)(2). Second, importation may

be permitted under the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), which is part of the FDCA. *See* 21 U.S.C. § 384.

The MMA expressly contemplates both commercial and individual importation of drugs from Canada into the United States. The MMA provides that the Secretary of HHS "shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States." 21 U.S.C. § 384(b). The MMA also provides that the Secretary "may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate." 21 U.S.C. § 384(j)(2)(A). As one court stated, "[t]hese provisions of the MMA appear to become effective only if the Secretary certifies to Congress that importation will be safe and cost-effective" pursuant to 21 U.S.C. § 384(l). *See Vermont v. Leavitt*, 405 F. Supp. 2d 466, 473 (D. Vt. 2004). To date, however, apparently no Secretary of HHS has issued a certification under this subsection. DE 1 at ¶ 29.

The FDA has a policy, however, pursuant to which it typically does not object to personal importation of prescription drugs that the FDA has not approved, under certain circumstances. *See* FDA Regulatory Procedures Manual, Chapter 9-2, "Coverage of Personal Importations," available at http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179266.htm (last visited Oct. 16, 2014).

Moreover, Congress did not address in the FDCA the licensure or regulation of pharmacies, which is the subject of the 2013 Amendment. Thus, the FDCA leaves it to the states to regulate (or not) the activities of pharmacies.

Furthermore, the FDCA does not contain a preemption provision addressing the regulation of the sale of prescription drugs.[8] *See Wyeth v. Levine*, 555 U.S. 555, 567, 574-575 (2012). To the contrary, when Congress amended the FDCA in 1962 to enlarge the FDA's powers, "it took care to preserve state law" by adding a savings clause. *See Wyeth*, 555 U.S. at 567; *see* Pub. L. 87-781, § 202, 76 Stat. 793 ("Nothing in the amendments made by this Act to the [FDCA] shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law").

In *Wyeth*, 555 U.S. at 581, the Supreme Court held in 2012 that the FDCA does not preempt a state's failure-to-warn tort claims against prescription drug manufacturers. The Court found that the FDA had "long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation" of prescription drugs. *Id.* at 578-579.

As the Supreme Court has made clear, the FDCA "leaves no doubt" that only the federal government, not a private litigant, is authorized to file suit for noncompliance with the FDCA's provisions. *See Buckman*, 531 U.S. at 349 n.4. With exceptions not relevant here, "all such proceedings for the enforcement [of the FDCA], or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a).

ARGUMENT

Standard of review. Rule 12(c) allows a party to move for judgment on the pleadings at any time "[a]fter the pleadings are closed but within such time as not to delay the trial." *Id.* "Because such a motion calls for an assessment of the merits of the case at an embryonic stage, the court must view the facts contained in the pleadings in the light most favorable to the

[8] The FDCA expressly preempts certain state laws relating to the regulation of non-prescription drugs. *See* 21 U.S.C. § 379r.

nonmovant and draw all reasonable inferences therefrom to the nonmovant's behoof." *Rivera–Gomez v. de Castro*, 843 F.2d 631, 635 (1st Cir.1988). "There is no resolution of contested facts in connection with a Rule 12(c) motion: a court may enter judgment on the pleadings only if the properly considered facts conclusively establish the movant's point." *G. Fin. Corp. v. Yergara–Nunez*, 446 F.3d 178, 182 (1st Cir. 2006).

A. There is no private cause of action for preemption where Congress has chosen not to provide one in the FDCA or in any other federal statute.

Congress in the FDCA did not create any privately enforceable rights with respect to the states' regulation of pharmacies or their treatment of the sale of prescription drugs. And plaintiffs do not contend otherwise. They do not assert a private right of action under the FDCA. Rather, their private right of action purportedly arises under the Supremacy Clause itself. But the Supremacy Clause cannot be used to create a private right of action to enforce a statute that Congress chose not be privately enforced.

Preemption doctrine protects persons and entities from having state laws applied to them when those state laws conflict with federal law. *See, e.g., Geier v. American Honda Motor Co.*, 529 U.S. 861 (1987). Unlike most litigants seeking to block a state law based on preemption, plaintiffs here do not allege that the 2013 Amendment applies to them or that any plaintiff is planning to engage in conduct that may bring that plaintiff within the reach of the 2013 Amendment. Instead, plaintiffs seek to create a private cause of action under the Supremacy Clause that Congress chose not to provide in the FDCA or any other statute.[9]

The Supreme Court has not decided whether private parties have a cause of action directly under the Supremacy Clause or Section 1983. There is a case likely to be heard this

[9] The Court has ruled against defendants on this argument in its Order on Motion to Dismiss, *see* DE 39 at 14, but defendants wish to preserve it here for purposes of any appellate review.

Term that may resolve this issue. *See Armstrong v. Exceptional Child Center, Inc*., 567 Fed. App. 496 (9th Cir. 2014), *petition for certiorari granted*, 2014 WL 3107841 (U.S. Oct. 2, 2014).

In 2012, the Court was set to decide "whether Medicaid providers and recipients may maintain a cause of action under the Supremacy Clause to enforce a federal Medicaid law – a federal law that, in their view, conflicts with (and pre-empts) state Medicaid statutes that reduce payments to providers." *Douglas*, 132 S. Ct. at 1207. The Court did not reach that issue because, while the case was pending, the state law was approved by the administering federal agency, and the Court remanded the case. *Id*. at 1211. In dissent, however, Chief Justice Roberts, joined by Justices Scalia, Thomas, and Alito, persuasively explained that "[w]hen Congress did not intend to provide a private right of action to enforce a statute enacted under the Spending Clause, the Supremacy Clause does not supply one of its own force." *Id*. at 1215 (Roberts, C.J., dissenting).

Defendants are aware of no case in which the First Circuit explicitly held, as opposed to merely assumed, that a preemption claim may be brought directly under the Supremacy Clause or under Section 1983.[10] The Court should enter judgment in favor of defendants on plaintiffs' preemption claim because there is no private cause of action for preemption here.

B. The 2013 Amendment is not preempted by the FDCA.

The State's sovereign prerogative not to regulate. We start with a basic proposition: a state is not required by the Constitution to regulate any particular industry. A state may simply choose not to regulate. The crux of plaintiffs' lawsuit is the remarkable proposition that they can

[10] In *Pharmaceutical Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 72 (1st Cir. 2001), *aff'd sub nom. Pharmaceutical Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003), the First Circuit and Supreme Court addressed the merits of a preemption claim brought under the Supremacy Clause, but neither Court discussed whether such a cause of action existed. That case is one of many where courts have assumed that preemption claims may be brought directly under the Supremacy Clause. *Concannon* does not control the outcome here.

require the State of Maine to regulate pharmacies in accordance with plaintiffs' view of federal law, where the State has chosen not to regulate these pharmacies. Plaintiffs have not identified any decision that has adopted such an extraordinary principle.

The 2013 Amendment is a classic example of a state acting to limit the extent of its traditional police powers – deciding not to assert its regulatory authority over certain conduct. The State of Maine has the sovereign prerogative to take such steps. To the extent that plaintiffs seek to require Maine to have laws that further the policies underlying the FDCA, plaintiffs run afoul of the Tenth Amendment. *See Printz*, 521 U.S. at 933 (under Tenth Amendment, states may not be compelled "to enact or administer a federal regulatory program"); *New York*, 505 U.S. at 188 (same). Thus, under the Tenth Amendment, the State of Maine is free to choose not to regulate the conduct of pharmacies and pharmacists located in other countries – even if those pharmacies and pharmacists may engage in conduct that violates the FDCA.

There is, in particular, no constitutional principle that requires a state to regulate pharmacies or pharmacists. If the federal government is concerned that foreign pharmacies "may be more likely to violate federal law if the additional deterrent of state liability [for unlicensed practice of pharmacy] is removed," then "the proper response – according to *New York* and *Printz* – is to ratchet up the federal regulatory regime, not to commandeer that of the state." *See Qualified Patients Ass'n v. City of Anaheim*, 187 Cal.App.4th 734, 761 (Cal. App. 2010) (rejecting preemption claim to California Medical Marijuana Program Act's decriminalization provisions) (internal quotations and citation omitted).

Plaintiffs' preemption claim is an attempt to do an end run around the prohibition in *New York* and *Printz* against commandeering states to enact laws in furtherance of federal programs. That is, to say as plaintiffs do that Maine's decision *not* to have laws furthering the FDCA is

preempted by the FDCA is to say that Maine must enforce the FDCA. Yet *Printz* holds just the opposite: that a state cannot be required to enforce the FDCA or its policies. The 2013 Amendment cannot be in conflict with, or an obstacle to, the FDCA, for the FDCA may not – and, indeed, does not by its terms seek to – compel states to enforce its policies.

Preemption. In any event, as shown below, the 2013 Amendment does not conflict with the FDCA and is not preempted. Preemption may be express or implied. Plaintiffs do not claim that the 2013 Amendment is expressly preempted by the FDCA. There are two basic types of implied preemption: (A) "field" preemption, where the federal framework regulating the field at issue is so pervasive as to make reasonable the inference that Congress left no room for states to supplement that area of law, and (B) "conflict" preemption. *See Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992). In turn, there are two basic types of "conflict" preemption – (1) where compliance with both federal and state regulations is a "physical impossibility"; and (2) where state law "stands as an obstacle" to the accomplishment and execution of the full purposes and objectives of Congress ("obstacle preemption"). *Id*.

There is a presumption against preemption: the court must "start[ ] with the basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). The Supreme Court applied this presumption in *Wyeth*, 555 U.S. at 565 n.3, a case involving drug labeling, which both the states and the federal government have long regulated. The fact that Congress has not enacted a preemption provision for prescription drugs cuts strongly against all of plaintiffs' preemption arguments. *See Wyeth*, 555 U.S. at 574-575 ("If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history").

In their Motion, plaintiffs assert three different preemption claims: field preemption (DE 46 at 13-15), what plaintiffs call "conflict" preemption, citing *Gade*, 505 U.S. at 109 (DE 46 at 15-17), and "obstacle" preemption (DE 46 at 17-20). Before addressing plaintiffs' preemption claims, it is worth emphasizing what the 2013 Amendment does and what it does not do. The 2013 Amendment provides that certain conduct will not constitute the unlicensed practice of pharmacy in Maine or otherwise violate the Maine Pharmacy Act. The 2013 Amendment says nothing about whether that same conduct may violate the FDCA or other Maine laws.

Plaintiffs' preemption arguments rely heavily on statements made by FDA officials years ago regarding other states' laws or programs. *See, e.g.*, DE 46 at 7 (referencing a May 20, 2005, letter from an FDA official to the governor of Nevada, which is Exh. B to DE 48, stating: "Licensure of Canadian pharmacies by the State of Nevada" … "would be preempted by federal law" and would "result in violations of federal law."). Such conclusory statements by FDA officials, addressing other states' laws or programs that are unlike the Maine statute at issue here, are entitled to no weight. The Supreme Court held recently that FDA statements about preemption that do not have the force of law – even when made about the particular type of state law at issue in the case – are not entitled to deference. *See Wyeth*, 555 U.S. at 577-581 (Court did not defer to preamble in 2006 FDA regulation stating FDA's view on preemption of state failure-to-warn claims).

In any event, the 2013 Amendment does not authorize the licensure of foreign pharmacies. In fact, the Maine Pharmacy Act did not authorize the licensure of pharmacies located in foreign countries even before the 2013 Amendment. By enacting the 2013 Amendment, Maine simply reduced the scope of its unlicensed practice provision. 32 M.R.S. §

13731(1). Again, Maine has decided that it will not charge these pharmacies with unlicensed practice. Such a law does not conflict at all with the FDCA.

Plaintiffs' preemption arguments prove too much. If Congress truly occupied the field at issue here, as plaintiffs contend, then states would have no authority to charge any pharmacy located in a foreign country with unlicensed practice. *See* DE 46 at 15 ("any state laws addressing this issue" are preempted). Indeed, under plaintiffs' view of preemption, the prior version of Maine's unlicensed practice of pharmacy law – and even the entire Maine Pharmacy Act – would be invalid on the theory that it "addressed" the "issue" of pharmacies located in foreign countries. Such a remarkable result would be unsupported by any case law and directly contrary to the goals of plaintiffs' lawsuit.

1. Field preemption. Field preemption occurs when Congress implicitly withdraws the states' power to regulate in an area by creating a regulatory system so pervasive and complex that it leaves "no room" for the states to regulate the subject matter covered by the federal law. *See Massachusetts Med. Soc'y v. Dukakis*, 815 F.2d 790, 791 (1st Cir. 1987) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). The Supreme Court has long held that courts should not lightly find field preemption: "federal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons – either that the nature of the regulated subject matter permits no other conclusion, or that Congress has unmistakably so ordained." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963).

The "field" at issue here is the regulation and licensure of pharmacies and pharmacists. That is what the 2013 Amendment covers. And that field is primarily and historically a matter of state law. Congress did not address the regulation of pharmacies or pharmacists in the FDCA.

Plaintiffs' field preemption claim fails because Congress has not occupied the field of regulating pharmacies and pharmacists. *See, e.g., Ter Beek v. City of Wyoming*, 846 S.W.2d 531, 536-541 (Mich. 2014) (Michigan Medical Marihuana Act not preempted by federal Controlled Substances Act ("CSA") under field preemption); *County of San Diego v. San Diego NORML*, 165 Cal.App.4th 798, 820-828 (Cal. App. 2008) (California Medical Marijuana Program's identification card laws not preempted by federal CSA). If the state laws in these cases were not preempted, then *a fortiori* plaintiffs' preemption claim here fails.

Plaintiffs allege that Congress has occupied the fields of "commerce with foreign nations" and "pharmaceutical importation." DE 46 at 13, 15. Again, no court of which defendants are aware has ruled that a state ran afoul of field preemption where it chose not to regulate in a particular field, as Maine has done here. Field preemption comes into play only when a state has chosen to affirmatively regulate a particular business or industry sector. *See, e.g., Arizona v. United States*, 132 S. Ct. 2492, 2501-2503 (2012) (portions of Arizona law addressing issues related to unlawful aliens were preempted because Congress has "occupied the field" of alien registration).

Field preemption does not require that Maine regulate or license pharmacies located in foreign countries. The federal government is left to regulate them freely as it sees fit, under the FDCA and any other applicable federal law. Not surprisingly, plaintiffs have identified no case finding field preemption as to a state law that, like the 2013 Amendment, lessened the reach of a state's regulatory authority.

The state laws in the cases relied on by plaintiffs either (A) were held not to be preempted by federal law or (B) bear no resemblance to the 2013 Amendment. Plaintiffs appear to rely on *Massachusetts Medical Society v. Dukakis*, 815 F.2d 790. DE 46 at 13. In that case,

however, which involved a Massachusetts law that prohibited physicians from "balance billing" Medicare patients, the First Circuit rejected plaintiffs' preemption claims, including a field preemption claim. *Id*. at 793-797.

In *Arizona v. United States*, the Court ruled that part of an Arizona law addressing issues related to unlawful aliens was preempted, relying on "field preemption" doctrine. 132 S. Ct. 2492, 2501-2503 (2012). The Court did so because it found that Congress has "occupied the field" of alien registration and thus "even complementary state regulation" was not allowed. *Id*. Here, Congress has not "occupied the field" of licensing pharmacies or pharmacists. Thus, the 2013 Amendment, which lessens the reach of Maine's regulatory authority by providing that certain conduct will no longer constitute the unlawful practice of pharmacy or otherwise violate the Maine Pharmacy Act, cannot possibly be in conflict with the FDCA.

Plaintiff also rely heavily on *National Foreign Trade Council v. Natsios*, 181 F.3d 38, 61-71 (1st Cir. 1999), *aff'd on other grounds sub nom. Crosby v. National Foreign Trade Council*, 530 U.S. 363 (2000). In *NFTC*, the State of Massachusetts had enacted a law that restricted the State government's purchases of goods or services from individuals or companies engaged in business with Burma. The First Circuit held that the state law was preempted by the so-called Federal Burma Law, a federal statute that imposed comprehensive federal sanctions on Burma. The Massachusetts law at issue in *NFTC*, which prohibited the State of Massachusetts and its agencies from contracting with companies that did business with Burma (except in three situations), bears no resemblance to the 2013 Amendment.

Citing the foreign Commerce Clause, plaintiffs also claim the 2013 Amendment excessively interferes with foreign affairs and thus impairs the federal government's ability to

speak with one voice in the area of international pharmaceutical trade.[11] *See* DE 46 at 13-14. The 2013 Amendment does not regulate the international pharmaceutical trade, however; it merely lessens the reach of the State's unlicensed practice of pharmacy law. The 2013 Amendment does not violate any federal uniformity requirement because there is no uniform federal law regarding the regulation of pharmacies with which the 2013 Amendment interferes.

Other cases cited by plaintiffs (DE 46 at 14) involve state tax laws that burdened foreign commerce and were struck down under the foreign Commerce Clause. *See, e.g., Japan Line, Ltd. v. County of Los Angeles*, 441 U.S. 434, 437-438 (1979) (California tax subjected plaintiff to multiple taxation); *Kraft Gen. Foods, Inc. v. Iowa Dep't of Rev. & Fin.*, 505 U.S. 71, 75-76 (1992) (Iowa tax statute to which plaintiff was subject treated dividends received from foreign subsidiaries less favorably than dividends received from domestic subsidiaries). *But see Container Corp. of Am. v. Franchise Tax Bd.*, 463 U.S. 159, 173-175 (1983) (Court upheld California tax law against preemption and foreign Commerce Clause challenges).

In *Container*, 463 U.S. at 194-197, the Court held that a California tax statute that had "foreign resonances" was not preempted by federal law and did not violate the foreign Commerce Clause. The tax treated Container Corp. and all its foreign corporate subsidiaries as a single "unitary business" and imposed California income tax on the aggregate income of all those corporations, including foreign subsidiaries. California's method of taxation differed sharply from the methods used by the federal government in taxing Container Corp. and by the relevant foreign jurisdictions in taxing the various subsidiaries. The Court nonetheless held that the California tax was not preempted, concluding that it did not violate a "clear federal directive" – even though it differed substantially from federal tax law. *Id*. at 196-197.

[11] The Court has already dismissed plaintiffs' foreign Commerce Clause claim. DE 39 at 15-16.

As in *Container*, the 2013 Amendment is not preempted by federal law and does not violate a clear federal directive. There is no uniform federal law regulating the regulation and licensure of the practice of pharmacies or pharmacists – it is primarily a matter of state law.

2. Conflict preemption. Plaintiffs rely on *McCulloch v. Maryland*, 4 Wheat. 316, 427 (1819), and *Gade*, 505 U.S. 88, for the proposition that a state law is preempted when it "directly conflicts with a federal statute." DE 46 at 15. This claim fails because conflict preemption prevents a state from affirmatively regulating in a particular fashion – it does not require a state to regulate. Here, the 2013 Amendment simply leaves certain pharmacies to be regulated by federal law or other Maine laws. Such a statute does not "directly conflict" with the FDCA. *See, e.g., Ter Beek v. City of Wyoming*, 846 S.W.2d at 536-541 (Michigan Medical Marihuana Act not preempted by federal CSA); *People v. Crouse*, 2013 WL 6673708, at **8-10 (Colo. App. 2013) (Colorado Medical Marijuana Amendment not preempted by federal CSA); *County of San Diego*, 165 Cal.App.4th at 820-828 (California Medical Marijuana Program's identification card laws not preempted by federal CSA).

Other cases cited by plaintiffs do not involve preemption. DE 46 at 15-16 (citing *Vermont v. Leavitt*, 405 F. Supp.2d 466 (D. Vt. 2004), and *Montgomery County v. Leavitt*, 445 F. Supp. 2d 505 (D. Md. 2006)). Both cases involved challenges to actions by the Secretary of HHS under the federal Administrative Procedures Act. Neither case addressed the legal issue before the Court: whether a State may choose not to regulate pharmacies in foreign countries.

3. Obstacle preemption. The Supreme Court's "precedents establish that a high threshold must be met if a state law is to be pre-empted for conflicting with the purposes of a federal Act. Any conflict must be 'irreconcilable…. The existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute.'" *Gade*, 505 U.S. at 110

(Kennedy, J., concurrring) (citing *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982)). "Implied preemption analysis does not justify a 'freewheeling judicial inquiry into whether a state statute is in tension with federal objectives'; such an endeavor 'would undercut the principle that it is Congress rather than the courts that preempts state law.'" *Chamber of Commerce of U.S. v. Whiting*, 131 S. Ct. 1968, 1985 (2011) (quoting *Gade*, 505 U.S. at 111 (Kennedy, J., concurring)).

Congress did not address the regulation or licensure of pharmacies or pharmacists in the FDCA, and the 2013 Amendment does not "stand as an obstacle" to the objectives of the FDCA, or interfere with or undermine the federal government's ability to enforce the FDCA in Maine. *See, e.g., Ter Beek*, 846 S.W.2d at 539-540 (Michigan Medical Marihuana Act not preempted by federal CSA under obstacle preemption; immunity provided by state law "does not purport to alter the CSA's federal criminalization of marijuana, or to interfere with or undermine federal enforcement of that prohibition"); *Crouse*, 2013 WL 6673708, at **8-10 (Colorado Medical Marijuana Amendment not preempted by federal CSA under obstacle preemption); *County of San Diego*, 165 Cal.App.4th at 826-828 (California Medical Marijuana Program's identification card laws not preempted by federal CSA under obstacle preemption).

Plaintiffs again rely on *Massachusetts Medical Society*, 815 F.2d at 793-797, DE 46 at 17-18, where the First Circuit rejected plaintiffs' obstacle preemption claim. Plaintiffs also rely on *NFTC*, 530 U.S. 363, which, as shown above, involved a Massachusetts law that prohibited the State of Massachusetts and its agencies from contracting with companies that did business with Burma. The 2013 Amendment is nothing like that Massachusetts law.

The other obstacle preemption cases on which plaintiffs rely involve state laws that, unlike the 2013 Amendment, affirmatively authorized conduct that was prohibited by federal

law. *See, e.g., Michigan Canners & Freezers Ass'n v. Agricultural Marketing & Bargaining Bd.*, 467 U.S. 461, 478 (1984); *Emerald Steel Fabricators, Inc. v. Bureau of Labor & Indus.*, 230 P.3d 518, 519-520, 528-537 (Ore. 2010). As the Supreme Court of Michigan recently explained, "*Michigan Canners* involved a state law that not only permitted what federal law prohibited, but also required that certain federal guarantees be denied." *Ter Beek*, 846 S.W.2d at 540 n.6. Plaintiffs have identified no case in which a court has found obstacle preemption as to a state law that, like the 2013 Amendment, merely lessened the reach of a state's regulatory authority.

CONCLUSION

For the reasons stated above, (A) plaintiffs' Motion for Judgment on the Pleadings should be denied, (B) defendants' Cross-Motion for Judgment on the Pleadings should be granted, and (C) judgment should enter in favor of defendants.

Respectfully submitted,

Dated: October 23, 2014

JANET T. MILLS
Attorney General

/s/Thomas A. Knowlton
PAUL STERN
Deputy Attorney General
THOMAS A. KNOWLTON
Assistant Attorney General
Office of Attorney General
6 State House Station
Augusta, ME 04333-0006
(207) 626-8832

CERTIFICATE OF SERVICE

I hereby certify that on the 23rd day of October 2014, I electronically filed the above document with the Clerk of Court using the CM/ECF system, which will send notification of such filing to the following persons:

DAVID B. MCCONNELL
dmcconnell@perkinsthompson.com

JOHN M. GORE
jmgore@jonesday.com

MICHAEL A. CARVIN
macarvin@jonesday.com

To my knowledge, there are no non-registered parties or attorneys participating in this case.

/s/ Thomas A. Knowlton
THOMAS A. KNOWLTON
Assistant Attorney General
6 State House Station
Augusta, Maine 04333-0006
(207) 626-8832
thomas.a.knowlton@maine.gov