UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

CHARLES OUELLETTE, AMELIA ARNOLD, MAINE PHARMACY ASSOCIATION, MAINE SOCIETY OF HEALTH-SYSTEM PHARMACISTS, and RETAIL ASSOCIATION OF MAINE,	)	
Plaintiffs,	)	
v.	)	Docket No. 1:13-cv-00347-NT
JANET MILLS, in her official capacity as Attorney General of the State of Maine, and RICHARD ROSEN, in his official capacity as Commissioner of Administrative & Financial Services for the State of Maine,[1]	)	
Defendants.	)	

ORDER ON PARTIES' COMPETING MOTIONS ON FACIAL PREEMPTION

Before the Court are the parties' competing motions for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) (ECF Nos. 46, 57). For the reasons stated below, the Plaintiffs' motion is **GRANTED** and the Defendants' motion is **DENIED**.

PROCEDURAL HISTORY

Two licensed Maine pharmacists and three trade organizations representing the interests of Maine pharmacists (the "**Plaintiffs**") bring suit against Janet Mills

[1] Pursuant to Federal Rule of Civil Procedure 25(d), Richard Rosen is substituted as a defendant in this matter.

and Richard Rosen, in their official capacities (the "**Defendants**" or the "**State**"), pursuant to the Supremacy Clause, U.S. Const. art. VI, cl. 2, and 42 U.S.C. § 1983. The Plaintiffs claim that the federal Food, Drug, and Cosmetics Act (the "**FDCA**"), 21 U.S.C. §§ 301-399f, preempts certain amendments to the Maine Pharmacy Act (the "**MPA**"), 32 M.R.S. §§ 13701-13847.

This Court issued an order on the Defendants' motion to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), disposing of the Plaintiffs' Foreign Commerce Clause claim and dismissing the Pharmaceutical Research and Manufacturers of America from this suit. *See* Order on Mot. to Dismiss (ECF No. 39). Shortly thereafter, the Plaintiffs moved for summary judgment (ECF No. 46), and the Defendants responded by asking this Court either to deny the motion or continue the matter so they could conduct limited discovery (ECF No. 50). The Plaintiffs countered by asserting that no discovery was necessary to resolve their "purely legal" challenge to the Maine legislation. Pls.' Summ. J. Reply & Fed. R. Civ. P. 56(d) Opp'n 1, 14 (ECF No. 51).

The Court called a conference of counsel and determined that it could resolve whether the Plaintiffs are entitled to declaratory relief on their facial preemption challenge without discovery. Report of Conf. of Counsel & Order 2 (ECF No. 56).[2] The

[2] The Plaintiffs themselves have not labeled their challenge to the Maine legislation as a "facial" one. However, upon further examination of the relief requested in the Plaintiffs' Complaint, it is clear that they have *only* brought a facial challenge to the Maine legislation. As the First Circuit recently explained, a party brings a facial challenge where the relief sought reaches beyond " 'the particular circumstances' " of that plaintiff. *Showtime Entm't, LLC v. Town of Mendon*, 769 F.3d 61, 70 (1st Cir. 2014) (quoting *John Doe No. 1 v. Reed*, 561 U.S. 186, 194 (2010)). Here, because the Plaintiffs seek to strike down the Maine legislation in its entirety, not just as it applies to the particular plaintiffs in this case, their challenge is facial.

Court also determined that it would treat the Plaintiffs' motion for summary judgment as a motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) and disregard any facts that would be properly considered at summary judgment, after the benefit of discovery. Report of Conf. of Counsel & Order 2.[3] The Defendants thereafter filed their own cross-motion for judgment on the pleadings. Defs.' Mem. in Opp'n to Pls.' Mot. for J. on the Pleadings & Cross-Mot. for J. on the Pleadings (ECF No. 57). The Court now resolves the parties' competing motions on the facial preemption question.[4]

LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a

[3] The Court's instruction that Rule 12(c) was the proper procedural vehicle for the Plaintiff's motion was an error. Because the Plaintiffs had not labeled their challenge to the Maine legislation as "facial" in any of their written submissions, the State understandably resisted responding to a motion for summary judgment before the discovery process had begun. However, now that the Court has identified the Plaintiffs' challenge as facial, summary judgment via Rule 56 is indeed the appropriate mechanism for adjudicating their preemption claim. *See Showtime Entm't, LLC*, 769 F.3d at 69, 71 (resolving a facial statutory challenge through summary judgment); *URI Student Senate v. Town of Narragansett*, 631 F.3d 1, 8, 15 (1st Cir. 2011) (same); *McGuire v. Reilly*, 386 F.3d 45, 59 (1st Cir. 2004) (same); *Abdullah v. Comm'r of Ins. of Mass.*, 84 F.3d 18, 20 (1st Cir. 1996) (same); *N.H. Motor Transp. Ass'n v. Rowe*, 301 F.Supp.2d 38, 40-41 (D. Me. 2004) (same).

[4] The Plaintiffs have cited a variety of agency materials in their filings, including letters from the FDA to state and local officials between 2003 and 2008 opining on the legality of efforts by other states and municipalities to create pharmaceutical importation programs. *See, e.g.*, Compl. ¶ 20 (citing Letter from Randall D. Lutter to Gov. Kenny Guinn (May 20, 2005), *available at* http://www.fda.gov/Drugs/DrugSafety/ucm179414.htm (last visited Feb. 9, 2015)). The Plaintiffs offer no materials from the FDA specifically dealing with the Maine legislation at issue.

The Supreme Court has instructed that the weight given to an "agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness." *Wyeth v. Levine*, 555 U.S. 555, 576 (2009) (internal citations omitted). Even if the Plaintiffs had pointed to an opinion from the FDA on the legality of the Maine legislation or its potential impact on the enforcement of the FDCA, this Court would "not defer[ ] to an agency's *conclusion* that the state law is pre-empted." *Id.* Ultimately, the determination as to preemption belongs to the Court. *Id.* Accordingly, for purposes of the motions at hand, the Court sets these materials aside.

matter of law." Fed. R. Civ. P. 56(a). This standard applies with equal force where parties file cross-motions for summary judgment, in which case the court's role is to " 'determine whether either of the parties deserves judgment as a matter of law on [the] facts that are not disputed.' " *Showtime Entm't, LLC*, 769 F.3d at 69 (quoting *Wightman v. Springfield Terminal Ry. Co.*, 100 F.3d 228, 230 (1st Cir. 1996)). Because this is a facial challenge to the Maine legislation, and no discovery has taken place, the Court decides this matter by the terms of the relevant statutes, without any information about the effects of the Maine legislation or how it is being enforced. *See N.H. Motor Transp. Ass'n*, 301 F.Supp.2d at 41.

DISCUSSION

I. The Statutory Background

A. The MPA Amendments

In 2013, the Maine legislature passed, without the Governor's signature, "An Act To Facilitate the Personal Importation of Prescription Drugs from International Mail Order Prescription Pharmacies." 2013 Me. Legis. Serv. ch. 373 (S.P. 60) (L.D. 171) (West) (effective Oct. 9, 2013) (the "**MPA Amendments**"). The Maine Pharmacy Act generally requires those who "engage in the practice of pharmacy" to be licensed. 32 M.R.S. § 13731(1). The MPA Amendments, which exempt certain entities from the licensing requirement, provide:

> **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.

Id.

The MPA Amendments also include a "Consumer Choice Preserved" provision, which states:

> Nothing in this chapter may be construed to prohibit:
>
> **1. Ordering or receiving prescription drugs.** 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. Dispensing or providing prescription drugs.** 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.

32 M.R.S. § 13799.

The sponsor of the MPA Amendments explained that because "frequently prescriptions from Canada are far less expensive than those from the United States," the purpose of the Act was to "expand[ ] the definition of a 'mail order prescription pharmacy' under the Maine Pharmacy Act to include an entity located outside of the United States that dispenses prescription medications by mail or carrier from a

facility not located in this State to a pharmacy or to a patient who resides in this State." *Testimony from Senator Troy Jackson in Support of L.D. 171, An Act to Facilitate the Licensing of International Mail Order Prescription Pharmacies by the Maine Board of Pharmacy: Hearing on L.D. 171 Before the J. Standing Comm. on Labor, Commerce, Research and Econ. Dev.*, 126th Legis., 1st Sess. (Me. 2013).

B. The FDCA

The FDCA creates a regulatory scheme that sets limits on the importation of prescription drugs from other countries. Specifically, the FDCA prohibits the importation or introduction into interstate commerce of any "new drug" that has not received FDA approval, 21 U.S.C. § 355, of any prescription drug not labeled as required by federal law, 21 U.S.C. § 352, 353, and of any prescription drug dispensed without a valid prescription issued by a licensed practitioner, 21 U.S.C. § 353(b). The FDCA also restricts the importation of "American goods returned," by prohibiting any person other than the original manufacturer from importing a prescription drug that was originally manufactured in the United States and sent abroad. 21 U.S.C. § 381(d)(1).

In 2003, Congress enacted the Medicaid Prescription Drug, Improvement, and Modernization Act (the "**MMA**"), which contemplated the promulgation of "regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States." Pub. L. No. 108-173, § 1121, 117 Stat. 2066, 2464 (codified at 21 U.S.C. § 384(b)). This portion of the MMA only takes effect when the Secretary of Health and Human Services certifies that such importation will be safe and cost-effective. 21 U.S.C. § 384(*l*). No Secretary has supplied that

certification, and thus no regulations permitting such importation have issued. *See* 21 C.F.R. §§ 200-369.

II. The Parties' Positions

A. The State's Position

The State contends that the MPA Amendments simply reduce the reach of the MPA and that it is within its authority as a sovereign to choose not to regulate certain conduct. To hold otherwise, the State asserts, would violate the Tenth Amendment principle that states may not be compelled to administer federal regulatory programs. *Printz v. United States*, 521 U.S. 898, 935 (1997). In other words, "Maine is leaving to the federal government the enforcement of any federal laws that regulate the sale of prescription drugs to Mainers by pharmacies located in certain foreign countries." Defs.' Reply Mem. in Supp. of their Cross-Mot. for J. on the Pleadings 2 (ECF No. 60).[5]

B. The Plaintiffs' Position

The Plaintiffs contend that the FDCA creates a comprehensive and "closed" regulatory scheme, which strictly limits the introduction of prescription drugs into

[5] The State also asserts that where the Plaintiffs have no private right of action under the FDCA, the Supremacy Clause does not create one. Defs.' Mem. in Opp'n to Pls.' Mot. for J. on the Pleadings & Cross-Mot. for J. on the Pleadings 2-3. This Court has already resolved that issue in favor of the Plaintiffs in light of *Pharmaceutical Research and Manufacturers of America v. Concannon*, 249 F.3d 66, 73-74 (1st Cir. 2001). *See* Order on Mot. to Dismiss 14. However, the Supreme Court has granted certiorari on a similar, potentially dispositive question. *See Armstrong v. Exceptional Child Ctr., Inc.*, 567 Fed. Appx. 496 (9th Cir. 2014), *cert. granted*, 83 U.S.L.W. 3077 (U.S. Oct. 2, 2014) (No. 14-15) ("Does the Supremacy Clause give Medicaid providers a private right of action to enforce § 1396a(a)(30)(A) against a state where Congress chose not to create enforceable rights under that statute?"). The grant of certiorari in *Armstrong* does not affect this Court's prior ruling, but does present the possibility that this case will ultimately be dismissable on justiciability grounds, should it be pending on appeal when *Armstrong* is decided.

interstate commerce. The Plaintiffs also point out that Congress contemplated the potential importation of prescription drugs from Canada in the MMA, but that this section has not taken effect because the Secretary has not granted the necessary certification. *See* 21 U.S.C. § 384(*l*). The Plaintiffs assert that the FDCA preempts the MPA Amendments pursuant to the Supremacy Clause. The Plaintiffs offer three distinct theories of preemption—field preemption, direct conflict, and obstacle preemption.

III. The Governing Law

A. Facial Challenges

As plead, the Plaintiffs are only bringing a facial challenge to the MPA Amendments. The Supreme Court has instructed that "[a] facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987); *see also Thayer v. City of Worcester*, 755 F.3d 60, 71 n.3 (1st Cir. 2014) (citing *Salerno* as the applicable standard for non-speech-related facial challenges). "The existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute." *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982). In addition, the Court must avoid declaring the MPA Amendments unconstitutional where a constitutionally permissible construction is available. *See Vaquería Tres Monjitas, Inc. v. Pagan*, 748 F.3d 21, 26 (1st Cir. 2014).

B. Preemption

1. General Framework

To understand the theory behind preemption, it is helpful to step back, as the Supreme Court recently did, and review the basics of federalism:

> Federalism, central to the constitutional design, adopts the principle that both the National and State Governments have elements of sovereignty the other is bound to respect. From the existence of two sovereigns follows the possibility that laws can be in conflict or at cross-purposes. The Supremacy Clause provides a clear rule that federal law "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." U.S. Const. art. VI, cl. 2. Under this principle, Congress has the power to preempt state law.

Arizona v. United States, 132 S. Ct. 2492, 2500 (2012) (citations omitted).

There are a number of ways in which federal law may preempt state law. First, Congress can expressly state that it is preempting state law. *Gade v. Nat'l Solid Wastes Mgmt. Assoc.*, 505 U.S. 88, 98 (1992). Second, the courts may find that although Congress did not expressly preempt state law, preemption can be inferred. *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, No. 14-1290, slip op. at 2 (1st Cir. Feb 20, 2015). There are, it appears, two variants of implied preemption, which have come to be known as "field" and "conflict" preemption. *Id.* Field preemption occurs when "[t]he intent to displace state law altogether can be inferred from a framework of regulation 'so pervasive . . . that Congress left no room for the States to supplement it' or where there is a 'federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.' " *Arizona*, 132 S. Ct. at 2501 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Conflict preemption is sometimes further broken down into

"impossibility" preemption and "obstacle" preemption. Impossibility preemption occurs "where 'compliance with both federal and state regulations is a physical impossibility . . . .' " *Id.* (quoting *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963)). Obstacle preemption occurs where "the challenged state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " *Arizona*, 132 S. Ct. at 2501 (quoting *Hines v. Davidowitz,* 312 U.S. 52, 67 (1941)). However, the Supreme Court has acknowledged that these "pre-emption categories are not 'rigidly distinct.' " *Gade*, 505 U.S. at 104 n.2 (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 n.5 (1990)).

2. Competing Presumptions

The Court must consider two competing presumptions regarding preemption. On the one hand, the Court must begin with the "presumption that the state statute is valid," *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 661 (2003), particularly if it regulates matters of public health, *see Hillsborough Cnty., Fla. v. Automated Med. Lab., Inc.*, 471 U.S. 707, 718 (1985). There is a presumption against preemption "in any field in which there is a history of state law regulation, even if there is also a history of federal regulation." *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 178 (1st Cir. 2009) (citing *Wyeth*, 555 U.S. at 565 n.3). If a state law regulates in an area of traditional local concern, Congress must make its intent to preempt that state law clear. *Nat'l Foreign Trade Council v. Natsios*, 181 F.3d 38, 73 (1st Cir. 1999) (citing *Rice*, 331 U.S. at 230). For example, in *Hillsborough County*, the Supreme Court held that local ordinances regulating blood plasma donation were not preempted by federal standards also governing blood plasma

donation under a theory of field preemption. 471 U.S. at 723. There, the comprehensiveness of the FDA's regulations was not enough to overcome the presumption against preemption for "state or local regulation of matters related to health and safety." *Id.* at 715.

The Plaintiffs, on the other hand, argue that a competing presumption in favor of preemption should apply because the MPA Amendments touch on foreign affairs and thus the state is acting in an area traditionally reserved to the federal government. *Natsios*, 181 F.3d at 73, 77 (finding preemption where state legislation affected foreign affairs), *aff'd on other grounds sub nom. Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363 (2000).[6] This presumption in favor of preemption where a state legislates in the traditional federal area of foreign affairs is based in part on a need for federal uniformity regarding foreign commerce, which is "pre-eminently a matter of national concern." *Japan Line, Ltd. v. Los Angeles Cnty.*, 441 U.S. 434, 448 (1979); *see also Hines*, 312 U.S. at 63 ("Our system of government is such that the interest of the cities, counties and states, no less than the interest of the people of the whole nation, imperatively requires that federal power in the field affecting foreign relations be left entirely free from local interference."). If Congress has spoken with respect to foreign commerce, any state law that compromises the uniformity of that federal directive must be carefully scrutinized.

[6] The Supreme Court affirmed *Natsios* on the basis of obstacle preemption rather than field preemption, but noted that "field pre-emption may be understood as a species of conflict pre-emption." *Crosby*, 530 U.S. at 374 n.8 (2000).

When undertaking preemption analysis, courts may evaluate whether the aim of the state law is to affect an area of federal regulation or interest. For instance, in *Natsios*, the First Circuit was unmoved by Massachusetts' claim that its law restricting trade with Burma was an exercise of its state procurement authority, a traditional area of state power, when the state law was "aimed primarily at effecting change in and expressing disapproval of the current regime in Burma." 181 F.3d at 74; *see also N.H. Motor Transport Ass'n*, 301 F.Supp.2d at 44 (evaluating whether a Maine tobacco delivery law was a "disguised attempt to impose state regulations on interstate trucking.").

IV. Application of the Governing Law

The Plaintiffs have not argued that the FDCA expressly preempts state law, but focus instead on whether the MPA Amendments are preempted under field preemption and conflict preemption principles. The Court begins with the Plaintiffs' contention that the MPA Amendments violate the Supremacy Clause under the theory of field preemption.

A. Defining the Field

In order to decide whether Congress intended to occupy the field, it is important, first, to define the field.[7] The Plaintiffs assert that the relevant field is the

[7] The First Circuit's decision in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 582 F.3d 156 (2009), demonstrates the importance of properly defining the field in preemption analysis. There, the district court found that a pharmaceutical company violated a Massachusetts consumer protection statute by publishing false "average wholesale prices," and therefore injuring those who paid inflated drug prices. *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d at 160. The company appealed and argued that Congress's complex Medicare scheme preempted the Massachusetts law with respect to the computation and reimbursement of claims. *Id.* at 172. Because the consumers' claims did not challenge the government's calculation of reimbursements under Medicare, but instead challenged the pharmaceutical company's publication of

importation of prescription drugs into the United States. The State counters that the relevant field is limited to the regulation and licensure of pharmacies and pharmacists, an area traditionally reserved for the states.

Pharmacist licensure does indeed implicate the traditionally local sphere of public health and safety. Maine, like other states, has a Board of Pharmacy responsible for regulating the licensure of pharmacies and pharmacists. *See* 32 M.R.S. § 13711. The FDCA does not regulate the licensure of pharmacists; it instead leaves that area to individual states. *See, e.g.*, 21 U.S.C. § 360(g) (referencing "pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy."); 21 U.S.C. § 384(a)(2) (defining "pharmacist" as "a person licensed by a State to practice pharmacy."). If the MPA Amendments were truly limited to the regulation of pharmacy licensure, then evidence of "a congressional decision to foreclose any state regulation in the area" would be lacking. *Arizona*, 132 S. Ct. at 2502.

But by its plain language, the MPA Amendments extend beyond the regulation and licensure of pharmacies and pharmacists within Maine. The MPA Amendments do not, as the State asserts, simply repeal state licensure regulations; the MPA Amendments select five countries whose licensed retail pharmacies "may export" prescription drugs to Maine residents. *See* 32 M.R.S. § 13731(1)(B). Unlike the local blood plasma donation law in *Hillsborough County*, the MPA Amendments extend

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inflated prices, the First Circuit held that the field, correctly described, was consumer protection. *Id.* at 177-78.

beyond the traditionally local arena of public health and safety and into the traditionally federal spheres of foreign commerce and affairs. *See id.* The existence of a state interest does not preclude a finding that the field is within the traditional federal sphere of foreign commerce. *See Natsios*, 181 F.3d at 74.

The legislative history of the MPA Amendments indicates that their purpose was to allow the importation of pharmaceuticals from pharmacies abroad. The Act's title—"An Act To Facilitate the Personal Importation of Prescription Drugs from International Mail Order Prescription Pharmacies"—further supports this interpretation of the State's aim. The MPA Amendments did not merely repeal pharmacy licensure laws. Instead, they were the State's attempt to enable importation of certain cheaper foreign pharmaceuticals.

The Court agrees with the Plaintiffs that, properly defined, the field at issue here is the importation of foreign pharmaceuticals. The question, then, is whether the FDCA forecloses the State's foray into the realm of pharmaceutical importation. "[W]hether the regulation of an entire field has been reserved by the Federal Government is, essentially, a question of ascertaining the intent underlying the federal scheme." *Hillsborough Cnty., Fla.*, 471 U.S. at 714.

B. Purpose and Structure of the FDCA

As the Supreme Court has observed, "Congress enacted the FDCA to bolster consumer protection against harmful products." *Wyeth*, 555 U.S. at 574. In furtherance of this purpose, Congress has created a complex regulatory scheme covering the importation of pharmaceuticals into the United States. The FDCA prohibits the importation or introduction into interstate commerce of any "new drug"

that has not received FDA approval. *See* 21 U.S.C. § 355. "New drug applications" require a variety of information, including information on the drug manufacturer, the drug's packaging, and how the drug will be labeled. *See* 21 U.S.C. § 355(b)(1). As such, even if a foreign drug is chemically identical to its domestic counterpart, it is still "unapproved"—and thus cannot be imported legally—unless it is manufactured, packaged, and labeled according to the specifications in its new drug application. *See United States v. 1500 90-Tablet Bottles*, 384 F.Supp.2d 1205, 1218 (N.D. Ill. 2005).

Congress has also legislated explicitly with respect to the importation of drugs from Canada. As discussed above, even though the relevant section has not taken effect, the MMA does provide a path to legally permissible importation. *See* 21 U.S.C. § 384. As the Eighth Circuit has reasoned:

> That Congress created a special procedure for authorizing importation of prescription drugs from Canada supports our conclusion that the pre-existing system established by the [FDCA] does not permit such importation. While it is true that no federal statute by its express terms bans importation of prescription drugs from Canada, such an explicit country-by-country prohibition is unnecessary to accomplish the task. By creating the comprehensive regulatory system described above, Congress has effectively precluded importation of these drugs absent the sort of special authorization contemplated by 21 U.S.C. § 384.[8]

In re Canadian Import Antitrust Litig., 470 F.3d 785, 790 (8th Cir. 2006). The importation contemplated, but not yet allowed, under the MMA, together with the complex regulatory system established by the FDCA's drug approval, labeling, and packaging provisions, demonstrate a clear Congressional intent to tightly control

[8] 21 U.S.C. § 384 contains the MMA's certification provision. It instructs that "[t]his section shall become effective only if the Secretary certifies to the Congress that the implementation of this section will (A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer." 21 U.S.C. § 384(*l*)(1).

prescription drug importation.[9] Based on the foregoing, the Court concludes that the FDCA occupies the field of importation of pharmaceuticals from foreign countries.

The MPA Amendments' singling out of certain countries from which pharmaceuticals may be imported compromises the tightly regulated structure set up by the FDCA and the federal government's ability to "speak with one voice" when it regulates foreign commerce. *Japan Line*, 441 U.S. at 449.

The State's arguments do not convince the Court otherwise. The State argues that it has no obligation to regulate in order to further the policies underlying the FDCA, because it is inconsistent with the Tenth Amendment for the federal government to "compel the States to enact or administer a federal regulatory program." *New York v. United States*, 505 U.S. 144, 188 (1992); *see also Printz*, 521 U.S. at 933. However, this Tenth Amendment principle cannot save a state law that *obstructs* federal law. *Printz*, 521 U.S. at 913. To use the Plaintiffs' example, if the federal government bans coffee for health reasons, the federal government cannot insist that the states follow suit by also banning coffee. But, states may not authorize the purchase of foreign coffee if the federal government institutes an embargo prohibiting its importation. *See* Pls.' Combined Reply in Supp. of Mot. for J. on the

[9] In the past, the State seemed to acknowledge that it owed deference to federal law in the area of prescription drug importation. For example, in 2005 the Maine legislature enacted "An Act to Establish a Program for the Purchase of Prescription Drugs from out of the Country for the Elderly and Disabled." 2005 Me. Legis. Serv. Ch. 165 (H.P. 369) (L.D. 494) (West), codified at 22 M.R.S. § 254-C. Any program pursuant to § 245-C would only be established "when permitted by federal law or by the granting of a waiver by the United States Secretary of Health and Human Services." 22 M.R.S. § 254-C. The "when permitted" language suggests that the Maine legislature did not believe a Canadian importation program was consistent with then-existing federal law. Section 254-C does, however, reflect an optimism that the relevant section of the MMA would someday take effect.

Pleadings & Opp'n to Defs.' Cross-Mot. for J. on the Pleadings 3 (ECF No. 59). Federal law may preempt state law even where the federal government may not compel a state government to enact or administer a federal legislative or regulatory scheme. *See Printz*, 521 U.S. at 913. The Tenth Amendment does not save the MPA Amendments from preemption.

The marijuana cases cited by the State are distinguishable as well. *See* Defs.' Mem. in Opp'n to Pls.' Mot. for J. on the Pleadings & Cross-Mot. for J. on the Pleadings 13, 17, 20, 21 (citing *Ter Beek v. City of Wyoming*, 495 Mich. 1 (2014); *Qualified Patients Ass'n v. City of Anaheim*, 187 Cal. App. 4th 734 (Cal. App. 2010); *Cnty. of San Diego v. San Diego NORML*, 165 Cal. App. 4th 798 (Cal. App. 2008); *People v. Crouse*, No. 12CA2298, 2013 WL 6673708 (Colo. App. Dec. 19, 2013)). None of the marijuana cases involved field preemption because Congress included a "savings clause" in the Controlled Substances Act that expressly provides that Congress did not intend to occupy the field. *See* 21 U.S.C. § 903 ("No provision of this subchapter shall be construed as indicating an intent on the part of Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot stand together.").[10] Accordingly, these cases are not on point.

[10] Congress included a savings clause in the 1962 amendments to the FDCA, which instructs that "[n]othing in the amendments made by this Act . . . 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." Pub. L. No. 87-781,

The Plaintiffs have established that "no set of circumstances exists under which the Act would be valid." *Salerno*, 481 U.S. at 745 (1987). No matter how they are applied, the MPA Amendments regulate within the field of pharmaceutical importation. The State has not suggested any limiting construction which would allow a portion of the law to stand, and the parties have not briefed the issue of severability. It is apparent that removing the portion of the statute that touches on foreign commerce would defeat the purpose of the law. Because they are contrary to clear Congressional intent to occupy the field of pharmaceutical importation, the MPA Amendments violate the Supremacy Clause and are therefore preempted.[11]

CONCLUSION

For the reasons stated above, the Court **GRANTS** the Plaintiffs' motion (ECF No. 46) with respect to Count I and declares that the FDCA preempts the MPA Amendments pursuant to the Supremacy Clause of the United States Constitution. The Court therefore **DENIES** the Defendants' motion (ECF No. 57). The Clerk's Office will schedule a conference of counsel to discuss what remains of this case in light of this Order.

SO ORDERED.

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76 Stat. 793. The State mentions this savings clause in its briefing, *see* Defs.' Mem. in Opp'n to Pls.' Mot. for J. on the Pleadings & Cross-Mot. for J. on the Pleadings 10, but does not develop how it should affect the Court's preemption analysis. In any event, the Court does not view the FDCA's savings clause as affecting field preemption analysis in this case.

[11] The Court does not reach the Plaintiffs' additional theories of preemption because the MPA Amendments are unconstitutional under the theory of field preemption.

/s/ Nancy Torresen
United States Chief District Judge

Dated this 23rd day of February, 2015.