**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MAINE**

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| **Charles Ouellette, *et al*.,**<br><br>**Plaintiffs**<br><br>**v.**<br><br>**Janet Mills, in her official capacity as Attorney General of the State of Maine, *et al*.,**<br><br>**Defendants** | **No. 1:13-cv-00347-NT**<br><br>**PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND INCORPORATED MEMORANDUM OF LAW** |

## INTRODUCTION

Maine's 2013 Public Law Chapter 373 ("the Importation Law") tears a hole in the comprehensive, closed system that Congress created for the safe distribution of prescription drugs in the United States. Congress has occupied the crucial field of prescription drug importation—a quintessential area of federal concern where states have no power to regulate—by enacting the Federal Food, Drug, and Cosmetic Act (FDCA) and related laws to protect patients from exposure to unapproved, mislabeled, or invalidly prescribed medications. Yet the Importation Law invades this federal field and contravenes Congress's closed distribution system by purporting to allow unlicensed, unregulated foreign pharmacies and brokers to import prescription drugs into Maine *regardless* of whether those imports comply with federal law. Indeed, the Law's entire purpose is to exempt foreign vendors from state licensing laws in order to—as the Law's own title puts it—"Facilitate the Personal Importation of Prescription Drugs from International Mail Order Prescription Pharmacies." 2013 P.L. Ch. 373 (Ex. A).

Maine's unauthorized effort to *permit* importation of prescription drugs is plainly preempted by Congress's decision to strictly *limit* such imports. In fact, the conclusion that the

Importation Law fails under the Supremacy Clause could not be more straightforward: the Importation Law not only impermissibly touches on an exclusively federal area where Congress inherently occupies the field, but also conflicts with and obstructs the comprehensive federal scheme that Congress enacted to govern that area.

The Importation Law thus exposes Maine patients to the exact risk of harm from unregulated imports of prescription drugs that Congress sought to eliminate, even though the federal Food and Drug Administration (FDA) has repeatedly warned that similar state importation efforts both violate the FDCA and pose a threat to patient health and safety. At the same time, the Importation Law harms licensed Maine pharmacists by subjecting them to unlicensed foreign competition, stripping them of their exclusive right to dispense prescription drugs in Maine, and impairing the discharge of their legal, ethical, and fiduciary duties.

Maine is no mere passive facilitator of these illegal imports, but now has begun to actively violate federal law and to aid, abet, and subsidize others to do so. Since the filing of this lawsuit, Maine has partnered with an unregulated foreign broker to reinstate the MaineMeds program, which uses State funds to import foreign prescription drugs for state health insurance customers. *See* Plaintiffs' Statement of Material Facts in Support of Mot. for Summ. J. (SMF) ¶¶ 16–19. The Court should grant summary judgment and enjoin Maine from implementing the preempted Importation Law.

## BACKGROUND

### A. A Comprehensive Framework Of Federal Laws Protects The Health And Safety Of American Patients By Prohibiting The Importation Of Unapproved Or Mislabeled Pharmaceutical Products

In the FDCA, Congress created a comprehensive and "closed" regulatory scheme that strictly limits the importation or introduction into interstate commerce of prescription drugs. *Vermont v. Leavitt*, 405 F. Supp. 2d 466, 473 (D. Vt. 2005). *First*, the FDCA prohibits the

importation or introduction into interstate commerce of any "new drug" that has not received FDA approval under an exacting statutory scheme that regulates the manufacturing processes, labeling, and packaging of pharmaceutical products. 21 U.S.C. § 355; *see also* 21 C.F.R. § 314.50. *Second*, the FDCA prohibits importation or introduction into interstate commerce of any prescription medicines that have not been labeled in accordance with federal law, including requirements pertaining to the content of warning labels and use of the English language. *See* 21 U.S.C. §§ 352, 353; 21 C.F.R. § 201.15(c). *Third*, the FDCA prohibits importation or introduction into interstate commerce of any prescription medicine dispensed without a valid prescription issued by a licensed practitioner. *See* 21 U.S.C. § 353(b); *see also id.* §§ 331(a)-(d).

More specifically, in 1988, Congress enacted a special restriction on importation of pharmaceutical products as "American goods returned." *See* Prescription Drug Marketing Act, Pub. L. No. 100–293 (Apr. 22, 1988), codified at 21 U.S.C. § 381(d)(1). That restriction prohibits any person other than the original manufacturer to import into the United States a prescription drug that was originally manufactured in the United States and sent abroad. *See* 21 U.S.C. § 381(d)(1). This restriction was necessary to protect the health and safety of the American public. Indeed, Congress found that "[l]arge amounts of drugs are being reimported into the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping." Prescription Drug Marketing Act, Pub. L. No. 100-293 § 2.

Congress also enacted the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) in 2003, which, in part, authorizes the Secretary of Health and Human Services to "promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada" and to grant individual waivers "of the prohibition of importation of a prescription

drug." 21 U.S.C. §§ 384(b), 384(j)(2)(A). These provisions become effective only when the Secretary certifies to Congress that importation will be safe and cost-effective. *See id.* § 384(l). To date, no such certification or regulations have been issued. *See* 21 C.F.R. §§ 200–369.

### B. The FDA Has Consistently Warned States Not To Authorize Importation Of Foreign Drugs Because Doing So Would Endanger The Public, Violate Federal Law, And Be Preempted Under The Supremacy Clause

As the FDA has repeatedly stated, "virtually all prescription drugs imported for personal use into the United States from Canada" or other countries "violate the FDCA because they are either unapproved new drugs[,] labeled incorrectly[,] or dispensed without a valid prescription." SMF ¶ 2. Indeed, foreign prescription drugs are not subject to the requirements of federal law or FDA oversight. *See id.*; *see also In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 789 (8th Cir. 2006) ("Canadian prescription drugs at issue are not labeled in conformity with federal law" and "are not approved" by the FDA).

The FDA has consistently informed states that importation of pharmaceuticals from Canada can pose safety risks. *See* SMF ¶¶ 1, 8. In a letter to the Governor of Hawaii, for example, the FDA explained that the agency "cannot provide adequate assurance that the drug products delivered to consumers in the United States from any foreign country, including Canada, U.K., Australia, or others are the same as products that the FDA has approved through its rigorous safety and efficacy review process." *Id.* ¶ 4. "In fact," the FDA continued, "many drugs that U.S. consumers purchase from Canada and believe were made in Canada actually are shipped from other countries, such as India and Costa Rica, and originate from dozens of countries around the world." *Id.* "For example," the agency wrote to the Governor of Nevada, "an American consumer recently ordered an FDA-approved anti-seizure medication called Neurontin from a website that purported to operate in Canada and to ship FDA-approved drugs from Canada into the United States. Nevertheless, the drug the consumer actually received had

been manufactured in India, shipped from India, and was not approved by FDA for any use in the United Sates." *Id.* ¶ 3.

The FDA has also supplied examples of the safety risks of pharmaceuticals imported from Canada or elsewhere. In one instance, "a website that purported to operate in Canada mailed insulin into the United States for use by an American with diabetes." *Id.* But while "the drugs originally had been manufactured in the United States," they were "shipped back into the country in a manner that did not satisfy the refrigeration storage conditions specified in FDA-approved labeling and, therefore, could have potentially compromised the safety and effectiveness of the insulin." *Id.* "Because the failure to refrigerate the product may not change its appearance," the agency concluded, "American consumers may have had no way of knowing if their insulin had been mishandled abroad." *Id.*

In some instances, counterfeit medicines have entered the United States through unauthorized importation, placing patient safety at risk. One widely reported instance involved the cancer medicine Avastin. In recent years, Canadian, British, Turkish, and other foreign pharmaceutical suppliers have arranged the unauthorized importation of what purported to be cut-rate Avastin into the United States. These products turned out to be counterfeit. *See* SMF ¶ 5. As the FDA explained, "The counterfeit version of Avastin does not contain the medicine's active ingredient, bevacizumab, which may have resulted in patients not receiving needed therapy." *Id.*

The FDA has repeatedly emphasized the need to adhere to its strict labeling requirements in order to protect consumers from fraudulent products shipped from overseas. *See id.* The FDA has had to issue additional warnings about imported drugs, including with regard to even more unauthorized importation of fake Avastin. *See id.* ¶ 6.

The FDA has also been specifically concerned with CanaRx—the very Canadian company that Maine insurance plans have now partnered with for the illegal importation of pharmaceuticals. *See id.* ¶¶ 7, 16–19. The FDA has concluded "that CanaRx . . . illegally causes the shipment of prescription drugs from a Canadian pharmacy into the U.S., thereby exposing U.S. consumers to risky imported drug products" and that "[t]his potential risk is compounded by the fact that CanaRx makes misleading assurances to consumers about the safety of its drugs." *Id.* ¶ 7. The agency also "has evidence demonstrating that CanaRx shipped insulin, a product that should be stored under refrigeration, in a manner that did not satisfy the storage conditions specified in FDA approved labeling, and which could potentially compromise the safety and effectiveness of the insulin." *Id.*

In some instances, states have attempted to support illegal pharmaceutical importation, with unfortunate results. Most saliently, then-Governor of Illinois Rod Blagojevich helped create and promote the so-called "I-SaveRx Program," which contracted with CanaRx to facilitate medical importation from Canada and other countries. *See* REPORT OF THE ILLINOIS AUDITOR GENERAL i, xii, xvi (September 2006), *available at* http://www.auditor.illinois.gov/Audit-Reports/Performance-Special-Multi/Performance-Audits/FY06-Flu-Vaccine-ISaveRX-MGMT-digest.pdf (last visited June 19, 2014) (Ex. B). Unlike Maine's Importation law, the Illinois program imposed at least some nominal safeguards to secure patient safety, such as by purporting to limit the range of specific foreign pharmacies that could participate. But that program nonetheless became the subject of a scathing critique from the Illinois Office of Auditor General because it was "in violation of federal law" regarding pharmaceutical importation. *See id.* at i, xii, xvi. Moreover, despite the state's efforts to guarantee patient safety, the imported medicines were actually subject to no effective monitoring

whatsoever by state health authorities. As the Auditor General put it: "The State does not monitor whether prescriptions are being filled only by approved pharmacies," and "[p]articipants not knowing if their prescription was filled at an approved pharmacy question the safety aspect of the I-SaveRX Program." *Id.* at xii, xix. The Illinois program fell into decline, particularly after its main supporter, then-Governor Blagojevich, was impeached and removed from office.

Based on the serious legal and public-health concerns outlined above, the FDA has advised officials in at least 15 states that local laws purporting to authorize the importation of prescription drugs from Canada or other foreign countries—including state laws limiting such importation to private individuals for their personal use—run afoul of the FDCA and are preempted. *See* SMF ¶¶ 1, 8.

As the FDA has reasoned: "Clearly, Congress enacted [the] import provisions in the FDCA with the goal of controlling the types of drugs that could be legally imported into the United States." *Id.* ¶ 2. This federal scheme "is comprehensive in that it promulgates national standards that are to be applied equally to all ports of entry, regardless of the states in which they are situated." *Id.* "By definition, the scheme cannot allow the individual states to enact laws that erode the federal standards; otherwise, importers could simply circumvent the federal law by routing all their unapproved drugs into the state (or states) that allowed such imports." *Id.* "Licensure of Canadian" or other foreign "pharmacies by [a] State . . . would be inconsistent with the plain objectives of the FDCA if such licensure authorized those . . . pharmacies to ship into the United States drugs that violate the provisions of the FDCA." *Id.*

Finally, federal district courts have already concluded that a state plan for importing drugs from Canada violated the FDCA, *see, e.g.*, *Vermont v. Leavitt*, 405 F. Supp. 2d at 474, and the FDA has subsequently cited and endorsed those rulings.

### C. Maine's Importation Law Authorizes And Encourages Foreign Pharmacies To Import Prescription Drugs Into The United States In Defiance Of The Safety Standards Imposed By Federal Law

Despite the long history of FDA opposition to the importation of dangerous and illegal foreign pharmaceuticals, Maine enacted its Importation Law to cut costs, without providing any safeguards for patient safety. In 2012, Maine attempted to cut its healthcare costs by adopting the MaineMeds program. *See* SMF ¶ 10. This program provided financial incentives to state health insurance customers—and used the State money—to purchase prescription medications from foreign pharmacies through CanaRx, the non-pharmacy "broker" about whom the FDA has publicly expressed concerns. *See id.* ¶¶ 7, 10, 19. But CanaRx and the foreign pharmacies with which it contracted were not licensed under state law and so were not subject to any of the safety regulations that protect the health of Maine patients. *See id.* ¶ 11.

Recognizing this problem, the Maine Board of Pharmacy contacted the Maine Attorney General's office for an opinion regarding the legality of the MaineMeds program. *See id.* Assistant Attorney General Carney advised the Board that CanaRx's participation in the program constituted unlicensed practice, and that state law prohibited the Board from licensing any foreign pharmacy. *See id.* Then-Attorney General William Schneider subsequently issued a cease-and-desist letter to CanaRx on the basis that MaineMeds violated state law. *See id.* ¶ 12. CanaRx thereafter terminated the MaineMeds program, as well as the similar "PortlandMeds" program operated by the City of Portland, and the "HardwoodsMeds" program operated by Hardwood Products Company, a Maine employer.

In response to the actions of the Attorney General, supporters of the MaineMeds, PortlandMeds, and HardwoodsMeds programs began to lobby the Maine Legislature to amend state law to permit those programs to resume operation. In particular, two pieces of legislation were proposed: L.D. 171, originally entitled "An Act To Facilitate the Licensing of International

Mail Order Prescription Pharmacies by the Maine Board of Pharmacy," and L.D. 449, which was entitled "An Act To Ensure Consumer Choice in the Purchase of Prescription Drugs." Both measures were promoted primarily on cost-cutting grounds. *See, e.g.*, Testimony of Troy Jackson (Ex. C), *available at* http://www.mainelegislature.org/legis/bills/getTestimonyDoc.asp?id=1095 (last visited June 19, 2014) ("Jackson Testimony"); Testimony of Janice Kimball, Benefits Manager Of The City Of Portland (Ex. D), *available at* http://www.mainelegislature.org/legis/bills/getTestimonyDoc.asp?id=3397 (last visited June 19, 2014); Testimony of Michael Brennan, Mayor of the City of Portland (Ex. E), *available at* http://www.mainelegislature.org/legis/bills/getTestimonyDoc.asp?id=3402 (last visited June 19, 2014). For example, a representative of the Maine State Employees Association and Service Employees International Union explained that "[w]hen the Legislature flat-funded the budget for the State Employee Health Plan for FY '12 and FY '13, the Commission found it necessary to implement approximately $40 million dollars [sic] in savings" and that "CanaRx was a valuable program to help save money." Testimony of Lois Baxter, MSEA-SEIU, Local 1989 (Ex. F), *available at* http://www.mainelegislature.org/legis/bills/getTestimonyDoc.asp?id=3401 (last visited June 19, 2014).

The Maine Legislature responded by passing the Importation Law. *See* SMF ¶ 14. Maine's Governor declined to sign the Law out of his "concern" regarding "the safety aspect of these drugs," since "Maine does not have the ability to regulate these drugs, or even confirm the location where these drugs were made, how they are dosed, or how they have been stored." *Id.* ¶ 15. The measure nonetheless became law on June 27, with an effective date of October 9, 2013. *Id.* ¶ 14. As originally proposed, the law would have created at least the theoretical hope of maintaining minimal safety standards by authorizing the Board of Pharmacy to enter into

"reciprocal inspection arrangements" with countries whose pharmacies exported pharmaceuticals into Maine. *See* L.D. 171 (Ex. G). But the measure's sponsor "d[id] not believe that part needs to be in there," *see* Jackson Testimony (Ex. C), and it was omitted from the final law.

The Importation Law amends Maine's pharmacy licensing statute in three key ways.

*First*, the Importation Law provides that any "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 or regulatory requirements" is exempt from Maine's pharmacy licensing requirements and "may export prescription drugs by mail or carrier to a resident of this State for that resident's personal use." 2013 P.L. Ch. 373 § 1 (Ex. A). Importantly, however, the location of a *pharmacy* does not control the source of its *pharmaceuticals*. International pharmaceutical vendors in Canada and Great Britain routinely acquire their medicines from Asia, Africa, and elsewhere before shipping them to the United States. *See* SMF ¶¶ 3, 4.

*Second*, the measure further provides that any "entity that contracts to provide or facilitate the exportation of prescription drugs from" a foreign pharmacy to Maine is also exempt from state licensing requirements and "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." 2013 P.L. Ch. 373 § 1. This regulation is designed to authorize *pharmaceutical brokers*, including (but not limited to) CanaRx, to move foreign pharmaceuticals into the United States. However, such intermediaries are not "licensed" in *any* country. They instead fall within a regulatory no-man's land because their home countries, including Canada, have no interest in even attempting to regulate the shipment of pharmaceuticals to consumers located in the United States, and the United States has no ability to do so. SMF ¶ 9. In fact, the Canadian government

has disavowed any effort to police international shipments of pharmaceuticals through Canada. *See id.*

*Third*, the Importation Law provides that nothing in Maine law "may be construed to prohibit" a resident of the State "from ordering or receiving prescription drugs for that individual's personal use from" a pharmacy from the identified countries. 2013 P.L. Ch. 373 § 2. The law also provides that Maine law would no longer prohibit such foreign pharmacies "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." *Id.*

Notably, the Importation Law does *not* condition the importation of prescription drugs on compliance with the FDCA's approval or labeling provisions or the MMA's certification or waiver provisions. *See id.* The Law thus purports to permit such imports and to license foreign pharmacies without regard to the requirements Congress imposed under federal law.

### D. Maine Recently Reinstated The MaineMeds Program And Is Actively Encouraging Maine Residents To Import Foreign Prescription Drugs

Following the filing of this lawsuit, Maine announced that "the MaineMeds program through CanaRx has been reinstated." SMF ¶ 16. The program thus is once again available to members of "group health insurance plans sponsored by the State of Maine," including "State of Maine employees, ancillary employees, non-Medicare retirees and all covered dependents." *Id.* The State has advised that "[a]ll member co-payments have been **waived** for this program **only**," and not for any other prescription drug program it offers. *Id.* ¶ 18 (emphases in original). The State thus touts the "annual savings" available to Maine residents who use MaineMeds rather than a "local purchase plan" to obtain prescription drugs. *Id.* Through the MaineMeds program, the State spends public money to pay CanaRx for foreign prescription drugs and their importation into the United States. *See id.* ¶ 19. The City of Portland also recently reinstated its

PortlandMeds program, and Hardwood Products has reinstated its HardwoodMeds program. *See id.* ¶¶ 22, 23.

On November 12, 2013, the Board of Pharmacy wrote a public letter to the Governor regarding the Importation Law. *See id.* ¶ 20. The Board conveyed its view that the Law's exemption of foreign pharmacies and brokers from the Board's "regulatory oversight and compliance requirements causes great concern in an area of significant risk." *Id.* Indeed, "[w]ith no regulatory oversight of these entities and drugs that they provide to Maine citizens, the Board will be unable to respond to complaints or to assure that standards for purity and quality of drugs have been met." *Id.* Moreover, "[n]either the Board nor Maine citizens will know where the drugs received from the exempt entities were manufactured. Nor will there be anyone in Maine that can confirm that they have received the correct drug and strength." *Id.* "Not until after something goes wrong will our citizens discover that the Board does not have authority to address their concerns, or that the importation of their drugs may violate federal law. . . . Sadly, some Maine citizens will not have the Board's protection." *Id.*[1]

## ARGUMENT

### I. THE IMPORTATION LAW IS PREEMPTED

The Importation Law is preempted by federal law for at least three independent reasons: (i) it touches on the exclusively federal field of foreign commerce; (ii) it conflicts with federal law, and (iii) it stands as an obstacle to achieving the full goals of the federal scheme. The Court should grant summary judgment and enjoin Maine from implementing the Law.

[1] In a prior order, this Court rejected Defendants' challenge to the standing of Plaintiffs Charles Ouellette, Amelia Arnold, Maine Pharmacy Association, Maine Society of Health-System Pharmacists, and Retail Association of Maine. *See* Order On Motion to Dismiss at 7 (DE 39). Declarations establishing these Plaintiffs' standing are available at docket entries 9-20, 9-21, 9-22, 9-23, and 9-24.

### A. The Federal Government Has Occupied The Field Of Prescription Drug Importation And Foreclosed The Importation Law

State laws are preempted under the doctrine of field preemption when they "touch a field in which the federal interest is so dominant that" federal law "will be assumed to preclude enforcement of state laws on the same subject." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). In other words, where the "federal government, in the exercise of its superior authority . . . enact[s] a complete scheme of regulation" in such a field, "states cannot," among other things, even "*complement* the federal law, or enforce additional or auxiliary regulations." *Hines v. Davidowitz*, 312 U.S. 52, 66–67 (1941) (emphasis added). Field preemption thus "reflects a congressional decision to foreclose any state regulation in the area, even if it is parallel" or "complementary" to "federal standards." *Arizona v. United States*, 132 S. Ct. 2492, 2502 (2012); *see also Crosby v. NFTC*, 530 U.S. 363, 372 (2000); *Mass. Med. Soc'y v. Dukakis*, 815 F.2d 790, 791 (1st Cir. 1987); *Good v. Altria Group*, 501 F.3d 29, 47 (1st Cir. 1987).

Here, the conclusion that federal law occupies the field is particularly straightforward because commerce with foreign nations is *exclusively* a federal concern in which states have *no* power, and federal laws governing foreign commerce thus do not displace any traditional state power. *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 178 (1st Cir. 2009) (preemption is to be inferred much more readily in "exclusive" federal areas than in areas "in which there is a history of state law regulation"). The Constitution vests *Congress* with power to "regulate Commerce with foreign Nations." U.S. CONST. art. I, § 8 cl. 3. This broad grant of authority "comprehend[s] every species of commercial intercourse between the United States and foreign nations." *Bd. of Tr. of Univ. of Illinois v. United States*, 289 U.S. 48, 56 (1933).

"It is an essential attribute of the power that it is exclusive and plenary" and so "may not be limited, qualified, or impeded to any extent by state action." *Id.* at 56–57. The reason is

plain: non-uniform treatment of foreign commerce by individual states "may create problems, such as the potential for international retaliation, that concern the Nation as a whole." *Kraft Gen. Foods, Inc. v. Iowa Dep't of Rev. & Fin.*, 505 U.S. 71, 79 (1992). Thus, "'with respect to foreign intercourse and trade the people of the United States act through a *single* government with unified and adequate national power.'" *Japan Line, Ltd. v. Los Angeles Cnty.*, 441 U.S. 434, 448 (1979) (quoting *Bd. of Tr.*, 289 U.S. at 59) (emphasis added)). In other words, when the federal government legislates on matters of foreign commerce, it inherently *occupies* the field because it is the *only* government *operating* in the field.

The First Circuit's decision in *NFTC v. Natsios*, 181 F.3d 38 (1st Cir. 1999), *aff'd on other grounds sub nom. Crosby*, 530 U.S. 363, confirms this commonsense point. The "Massachusetts Burma Law" restricted the Massachusetts state government's purchase of "goods or services from individuals or companies" engaged in business with Burma. *Id.* at 45. Congress, however, had enacted legislation that imposed different restrictions, including sanctions, on trade with Burma. *See id.* at 47–48. Even though the state law, like federal law, sanctioned Burma, the First Circuit, invoking the federal government's plenary authority over foreign affairs and commerce, struck down the Massachusetts Law under, *inter alia*, the doctrine of field preemption. *See id.* at 76. As the First Circuit reasoned, "when Congress legislates in an area of foreign relations, there is a strong presumption that it intended to preempt the field, in particular where the federal legislation does not touch on a traditional area of state concern." *Id.*[2]

*A fortiori,* the Importation Law is preempted "[u]nder this standard." *Id.* Federal laws which prohibit importation of foreign prescription drugs—including the FDCA and the MMA—

[2] The First Circuit also held that the plaintiffs—who were United States citizens objecting to a state law—had established that the Burma Law violated the Foreign Commerce Clause. *See* 181 F.3d at 61–71.

exercise the federal government's plenary authority over foreign commerce, and do "not touch on a traditional area of state concern." *Id.* As the FDA has observed, this federal scheme "is comprehensive in that it promulgates national standards that are to be applied equally to all ports of entry, regardless of the states in which they are situated." SMF ¶ 2. Through the FDCA, the MMA, and innumerable regulations, federal law has erected a "closed" nationwide system for pharmaceutical regulation, to ensure that all pharmaceuticals sold domestically are subject to uniform FDA regulation. *Vermont v. Leavitt*, 405 F. Supp. 2d at 473. As the Eighth Circuit has recognized: "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." *In re Canadian Imports*, 470 F.3d at 790-91. This comprehensive congressional scheme in an area of exclusive federal concern has thus occupied the field of pharmaceutical importation, thereby wholly precluding *any* state laws addressing this issue, particularly those like the Importation Law (but unlike the Massachusetts Burma Law) announcing a policy *contrary* to the federal regulation.

**B. Maine's Importation Law Directly Conflicts With Federal Statutes**

The most basic form of preemption arises when a state law directly conflicts with a federal statute. *See McCulloch v. Maryland*, 4 Wheat. 316, 427 (1819); *see also Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 109 (1992); *Crosby*, 530 U.S. at 372. The Importation Law is preempted under this test: indeed, the Law's sole purpose and effect, as its very title indicates, is to "Facilitate" the illegal importation of foreign drugs. *See* 2013 P.L. Ch. 373 (Ex. A). And, as the legislative history confirms, the Importation Law's origins lie in an effort by several state healthcare insurers to illegally obtain less expensive pharmaceutical products from abroad. *See supra* pp. 8–10. Clearly, Maine seeks to aid and abet the illegal introduction of foreign pharmaceuticals into domestic commerce.

Unsurprisingly, federal courts have consistently found violations of federal law when states have sought to facilitate the private importation of prescription drugs. *See Vermont v. Leavitt*, 405 F. Supp. 2d at 474; *see also Montgomery Cnty. v. Leavitt*, 445 F. Supp. 2d 505, 512 (D. Md. 2006); *United States v. Rx Depot, Inc.*, 290 F. Supp. 2d 1238, 1245 (N.D. Okla. 2003). In *Vermont v. Leavitt*, for example, the state of Vermont petitioned the FDA for permission to allow Vermont patients to forward U.S. prescriptions to Canadian physicians for fulfillment. *See* 405 F. Supp. 2d at 471. But even though Vermont's proposal—unlike the Importation Law—included steps to protect the safety of U.S. patients, the FDA rejected the petition as a violation of federal law. The district court agreed, ruling that "[t]here is no question that Vermont's proposed program would violate the FDCA" because it would "cause[]" the importation of American-manufactured drugs other than by the original manufacturer in violation of § 331(t). *Id*. at 474. Vermont's program also was "highly likely" to violate § 381(d)(1) and § 331(a) by "causing" the importation of unapproved, adulterated, or misbranded drugs. *Id.*

There likewise can be "no question" that the Importation Law "violate[s] the FDCA" because it "cause[s]" the illegal importation of prescription drugs. *Id.*; *see also United States v. Rx Depot*, 290 F. Supp. 2d 1238, 1245 (N.D. Okla. 2003). Indeed, the entire purpose of the Importation Law is to violate federal law, and to aid and abet others' violations of federal law, by "Facilitat[ing] the Personal Importation of Prescription Drugs from International Mail Order Pharmacies." 2013 P.L. Ch. 373 (Ex. A). And the State's FDCA violations do not end with aiding, abetting, or "causing" Maine residents to import drugs illegally. *See, e.g.*, 21 U.S.C. § 331. Indeed, the State now is wielding the Importation Law to *actively* violate federal law: through the reinstated MaineMeds program, the State spends public money to secure banned foreign pharmaceuticals from CanaRx, and has waived co-payments for state health insurance

customers who illegally import drugs from CanaRx rather than legally purchase them from a licensed Maine pharmacist. *See, e.g.*, *Vermont v. Leavitt*, 405 F. Supp. 2d at 471–74 (holding that proposed state health insurance plan for importing drugs from Canada violated FDCA).

The Importation Law is even more indefensible than the unlawful Vermont program, since Maine makes no pretense of imposing any safety requirements or other restrictions on importation by foreign mail-order vendors. Indeed, Maine's own Governor declined to sign the Law out of his "concern" regarding "the safety aspect of these drugs," since "Maine does not have the ability to regulate these drugs, or even confirm the location where these drugs were made, how they are dosed, or how they have been stored." SMF ¶ 15. This laissez faire approach to patient safety is contrary to the core principles of the FDCA—particularly because some foreign countries do not even attempt to monitor the safety of pharmaceuticals shipped through or from their countries and into the United States. For example, the Canadian government "does not assure that products being sold to U.S. citizens are safe, effective, and of high quality, and does not intend to do so in the future." *Id.* ¶ 9.

Consistent with its rejection of Vermont's petition, the FDA has repeatedly and forcefully stated that federal law preempts any and all state laws that would facilitate the private importation of foreign pharmaceutical products. *See, e.g., id.* ¶¶ 1, 2, 8. If permitted, state programs like Maine's Importation Law would open a Pandora's box that, under federal law, must remain closed.

### C. Maine's Importation Law Has The Purpose And Effect Of Obstructing Federal Law By Authorizing Circumvention of The FDCA's Comprehensive And "Closed" Pharmaceutical Delivery System

The Importation Law indisputably—indeed, intentionally—subverts the federal regime of excluding improperly labeled and potentially dangerous foreign pharmaceuticals from the United States. The law is therefore plainly invalid under "obstacle preemption." *See Mass. Med. Soc'y,*

815 F.2d at 791 ("[E]ven in the absence of a direct conflict, a state law violates the Supremacy Clause when it 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" (quoting *Hines*, 312 U.S. at 67)); *see also Crosby*, 530 U.S. at 373 (holding that Massachusetts Burma Law was preempted because it stood "as an obstacle to the accomplishment of Congress's full objectives" in the federal act).

The entire purpose of the FDCA, MMA, and related statutes is to protect the American people by establishing a comprehensive, "closed" system in which only prescription drugs subject to the requirements of federal law and oversight by the FDA are available for use by American patients. *See, e.g.*, *Canadian Import*, 470 F.3d at 790; *Vermont v. Leavitt*, 405 F. Supp. 2d at 473; *see also Coleman v. State Supreme Court*, 697 F. Supp. 2d 493, 512 (S.D.N.Y. 2010). Congress deemed this closed system necessary because foreign prescription drugs present unacceptable health and safety risks to U.S. patients. As the FDA has repeatedly explained, foreign drugs never comport with even the most basic federal standards for the manufacture, labeling, transportation, storage, and use of pharmaceuticals. *See, e.g.*, SMF ¶ 2. It is therefore unsurprising that, to date, the Secretary of Health and Human Services has declined to certify that *any* prescription drug imports, from Canada or elsewhere, meet Congress's safety and effectiveness standards. 21 C.F.R. §§ 200–369. Similarly, even American-manufactured drugs that are shipped abroad may be mishandled or become unsafe while in foreign hands. SMF ¶ 3.

The Importation Law obviously stands as an obstacle to effective implementation of the federal effort to *maintain* a closed system by *breaching* that closed system. Moreover, "[b]ecause the [Maine] Act authorizes [foreign pharmaceutical vendors] to engage in conduct that the federal Act forbids, it stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Michigan Canners & Freezers Ass'n v. Agric. Mktg.*

*& Bargaining Bd.*, 467 U.S. 461, 478 (1984). For example, in *Michigan Canners*, after federal law had established certain regulations governing farmers' formation of *voluntary* cooperative associations, Michigan enacted a law authorizing certain private farmers to *impose* obligations on other farmers through cooperative associations. *Id.* at 477–78. Michigan defended its law on the ground that it was "cast in permissive rather than mandatory terms," such that "an association *may*, but need not," impose obligations on farmers in violation of federal law. *Id.* at 478 n.21. The Supreme Court flatly rejected that argument and held that the state law was preempted because it *authorized* what federal law *forbade*. *See id.* at 478.

The Importation Law is likewise preempted because it "authorizes" prescription drug imports that federal law "forbids." *Id.* In the process, the Law impedes the accomplishment of Congress's objectives because it purports both to deem acceptable the health and safety risks that Congress deemed unacceptable and to create an end-run around Congress's comprehensive scheme for eliminating those risks. And it does not end there: through the MaineMeds program, Maine spends public money to import foreign prescription drugs in direct violation of federal law. *See* SMF ¶ 2 (state law cannot "erode the federal standards; otherwise, importers could simply circumvent the federal law by routing all their unapproved drugs into the state (or states) that allowed such imports"); *see also Crosby*, 530 U.S. at 373; *Emerald Steel Fabs., Inc. v. Bureau of Labor & Indus.*, 348 Or. 159, 178 (2010) ("Affirmatively authorizing [what] federal law prohibits stands as an obstacle to the implementation and execution of the full purposes and objectives of" the federal law); Laurence H. Tribe, *American Constitutional Law* 1181 (3d ed. 2000) ("state action" is preempted when its goes "so far as to prohibit the very acts that federal law requires (or vice versa)"); Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 261 (2000) ("If

state law purports to authorize something that federal law forbids[,] the Supremacy Clause requires courts to apply the federal rule.").

* * * * * *

In sum, this is not a case where, in an exercise of its traditional, overlapping police power, a state has simply failed to proscribe certain conduct that federal law prohibits. *Cf. Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 75 (1st Cir. 2001); *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d at 173. Rather, Maine has *exceeded* its jurisdiction by injecting itself into the exclusive *federal* preserve of international commerce, for the sole purpose and effect of undermining the "closed" system erected by the comprehensive federal regime. This is plainly preempted because states may not enact laws that merely *differ* from federal statutes occupying the field of foreign commerce, much less those that are avowedly designed to evade and undermine this exclusive and plenary national regime.

**CONCLUSION**

This Court should enjoin Maine's Importation Law (2013 P.L. Ch. 373) and order that Defendants may not encourage, authorize, or subsidize individuals engaged in the unlawful importation of pharmaceutical products.

Dated: June 20, 2014

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**CERTIFICATE OF SERVICE**

On June 20, 2014, I filed the foregoing document and its attachments using the CM/ECF system, which will send notification of such filing to the parties registered with the CM/ECF system.

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