IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

Charles Ouellette, *et al.*, **Plaintiffs** **v.** **Janet Mills, in her official capacity as Attorney General of the State of Maine, *et al.*,** **Defendants**	**No. 1:13-cv-00347-NT** **PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS COMPLAINT**

INTRODUCTION

Maine's newly enacted 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. Whereas Congress enacted the Federal Food, Drug, and Cosmetics Act (FDCA) to protect patients from exposure to unapproved, mislabeled, or invalidly prescribed medications, the Importation Law contravenes this closed distribution system and purports to allow unlicensed, unregulated foreign pharmacies and brokers to import prescription drugs into Maine *regardless* of whether those imports comply with federal law.

The Importation Law thus exposes Maine patients to the exact risk of harm from unregulated imports of prescription drugs that Congress sought to eliminate in the FDCA. The Law inflicts this injury by subjecting licensed Maine pharmacists to unlicensed foreign competition, stripping them of their exclusive right to dispense prescription drugs in Maine, and imposing significant obstacles to the discharge of their legal, ethical, and fiduciary duties to their patients. The Law also threatens reputational harm to domestic drug manufacturers, who will

lose consumer confidence and goodwill if Maine consumers receive from a foreign source adulterated, counterfeit, or expired prescription drugs purporting to be genuine. And the Law has frustrated the mission of several trade associations and forced them to divert resources away from other purposes and toward advocating against the Law.

Any one of these injuries in fact is sufficient to invoke the Court's jurisdiction and to allow it to adjudicate Plaintiffs' claims for injunctive and declaratory relief. Defendants' motion to dismiss thus not only overlooks Plaintiffs' well-pleaded allegations, but also fails to address the controlling case law. The Court should deny the motion.

BACKGROUND

The FDCA's comprehensive, "closed" regulatory scheme for protecting patient safety, *Vermont v. Leavitt*, 405 F. Supp. 2d 466, 473 (D. Vt. 2005), prohibits importation of any "new drug" that has not been approved by the Food and Drug Administration ("FDA"), any medication that has not been labeled in accordance with federal law, and any prescription medicine dispensed without a valid prescription issued by a licensed practitioner, *see, e.g.*, 21 U.S.C. §§ 352–355. Moreover, the "American goods returned" provision prohibits any person other than the original manufacturer from importing into the United States a prescription drug that was originally manufactured here and sent abroad. *See* Prescription Drug Marketing Act, Pub. L. No. 100–293 (Apr. 22, 1988), codified at 21 U.S.C. § 381(d)(1). Congress deemed this provision necessary because it found that such imports from another source "are a health and safety risk to American consumers because [the drugs] may have become subpotent or adulterated during foreign handling and shipping." *Id.* § 2.

Congress also enacted the Medicaid Prescription Drug, Improvement, and Modernization Act ("MMA") in 2003, which, in pertinent part, authorizes the Secretary of Health and Human Services to "promulgate regulations permitting pharmacists and wholesalers to import

prescription drugs from Canada into the United States," 21 U.S.C. § 384(b), and to "grant to individuals . . . a waiver of the prohibition of importation of a prescription drug," *id.* § 384(j)(2)(A). To date, however, the Secretary has not certified to Congress that importation will be safe and cost-effective, as required to permit such imports. *See id.* § 384(l).

Congress has enacted a number of statutes that impose duties on domestic pharmacists. The Omnibus Reconciliation Act of 1990 ("OBRA"), Health Insurance Portability and Privacy Act ("HIPAA"), and parallel Maine regulations require licensed pharmacists to record every prescription and issuing practitioner; to perform a drug utilization review ("DUR") for each prescription, including screening for drug-disease contraindications and drug-drug interactions; and to advise patients regarding proper drug use and storage. *See* Compl. ¶¶ 34–41. The Maine Pharmacy Act also imposes several requirements on licensed Maine pharmacists, including educational, training, and fee-payment requirements, and subjects such pharmacists to the oversight of the Maine Board of Pharmacy. *See id.* ¶¶ 30–31.

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." Letter from Randall D. Lutter to Gov. Kenny Guinn (May 20, 2005), *available at* http://www.fda.gov/Drugs/DrugSafety/ucm179414.htm (last visited Oct. 16, 2013); *see* Compl. ¶ 20. At least one federal district court has already concluded that a state plan for importing drugs from Canada violated the FDCA. *See Vermont v. Leavitt*, 405 F. Supp. 2d at 474. Based on serious legal and public-health concerns, 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* Compl. ¶ 54.

Yet the Importation Law purports to authorize such imports. The Law exempts from the Maine Pharmacy Act's licensing requirements 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," and authorizes any such pharmacy to "export prescription drugs by mail or carrier to a resident of this State for that resident's personal use." *Id.* ¶ 47. The Law also exempts from the Maine Pharmacy Act's licensing requirements any "entity that contracts to provide or facilitate the exportation of prescription drugs from" a foreign mail-order pharmacy, and directs that any such entity "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." *Id.* ¶ 48.

The Importation Law thus authorizes unlicensed foreign pharmacies and brokers to import prescription drugs into Maine, even though they are not subject to the patient-health safeguards of the FDCA, OBRA, HIPAA, and other federal and state laws—and, in fact, may not be regulated *at all*. *See id.* ¶ 61. The Importation Law therefore exposes Maine patients to the substantial health risks posed by unapproved, misbranded, mislabeled, adulterated, improperly handled, or counterfeit prescription drugs, and by inaccurate or incomplete information, that Congress sought to eliminate when it enacted the comprehensive, closed system for distribution of prescription drugs in the United States in the first place. *See id.* ¶¶ 60–62.

Plaintiffs filed suit on September 10, 2013, pleading claims that the Importation Law is preempted and violates the Foreign Commerce Clause. *See id.* ¶¶ 68–83. The individual Plaintiffs, Charles Ouellette and Amelia Arnold, are licensed Maine pharmacists who face a loss of market share, loss of their exclusive right to dispense prescription drugs in Maine, and

impairment of the discharge of their legal, ethical, fiduciary duties. *See id.* ¶¶ 6–7, 61–64. The Pharmacist Association Plaintiffs—the Maine Pharmacy Association, Maine Society of Health-System Pharmacists, and Retail Association of Maine—represent licensed pharmacists who face these harms, and have been harmed in their own right by the Importation Law's frustration of their mission and diversion of their resources away from other purposes. *See id.* ¶¶ 8–10, 61–64, 67. Plaintiff PhRMA, like the Pharmacist Associations, also has been harmed in its own right, and it represents domestic drug manufacturers who face reputational harm, a loss of goodwill, and a dilution of their right to import drugs as American goods returned. *See id.* ¶¶ 11, 65–66. All Plaintiffs seek identical injunctive and declaratory relief. *See id.* Prayer.

Defendants have moved to dismiss Plaintiffs' complaint for lack of standing and to dismiss Defendant Commissioner Millett. The Court should deny this motion because Plaintiffs have pled cognizable injuries in fact, and Commissioner Millett is a proper defendant.

STANDARD OF REVIEW

Because Defendants have not "controverted the accuracy . . . of the jurisdictional facts asserted" in the complaint, this Court, in adjudicating Defendants' motion to dismiss under Rule 12(b)(1), "must credit [Plaintiffs'] well-pleaded factual allegations [and] draw all reasonable inferences from them" in Plaintiffs' favor. *Valentin v. Hosp. Bella Vista*, 254 F.3d 358, 364 (1st Cir. 2001) (cited at Mot. at 8). This Court must uphold allegations of competitor standing where its review of the well-pleaded allegations reveals "no insurmountable obstacles to proof" of such standing. *Adams v. Watson*, 10 F.3d 915, 925 (1st Cir. 1993).

To the extent Defendants have moved to dismiss under Rule 12(b)(6), the Court must "take the complaint's . . . well-pled facts as true, drawing all inferences in the pleader's favor, and see if they plausibly narrate a claim for relief." *Schatz v. Republican State Leadership Comm.*, 669 F.3d 50, 55 (1st Cir. 2012).

ARGUMENT

I. PLAINTIFFS HAVE STANDING TO CHALLENGE THE IMPORTATION LAW

Article III's constitutional standing requirement "serves to distinguish a person with a direct stake in the outcome—even though small—from a person with a mere interest in the problem." *United States v. SCRAP*, 412 U.S. 669, 690 n.14 (1973). The prudential limits on standing likewise serve to ensure that courts expend their resources on cases brought by an appropriate plaintiff. *See, e.g.*, *Clarke v. Securities Indus. Ass'n*, 479 U.S. 388, 399–400 (1987).

"So long as one plaintiff has standing to seek a particular form of global relief, the court need not address the standing of other plaintiffs seeking the same relief." *Comfort v. Lynn Sch. Comm.*, 418 F.3d 1, 11 (1st Cir. 2005); *see also Watt v. Energy Action Educ. Found.*, 454 U.S. 151, 160 (1981). Here, because Plaintiffs all easily satisfy the requirements for both constitutional and prudential standing, the Court should deny Defendants' motion to dismiss.

A. Plaintiffs Have Alleged Cognizable Injuries In Fact

To establish constitutional standing, a plaintiff must demonstrate an "injury in fact" that is "fairly traceable to the challenged conduct of the defendant" and likely to "be redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). "'The contours of the injury-in-fact requirement, while not precisely defined, are very generous,'" and require only that the plaintiff allege "'some specific, identifiable trifle of injury.'" *Adams*, 10 F.3d at 918 (quoting *Bowman v. Wilson*, 672 F.2d 1145, 1151 (3d Cir. 1982)).

Defendants do not dispute that causation and redressability are satisfied here if Plaintiffs have adequately pled an injury in fact. *See* Mot. at 10–14. Rather, Defendants argue only that Plaintiffs have failed to identify a cognizable injury, *see id.*—and, thus, ignore Plaintiffs' well-pleaded allegations of injury. The Court should deny the motion to dismiss.

1. The Individual Plaintiffs Have Adequately Pled Competitor Standing

Courts routinely find standing "based on a plaintiff's *status* as a *direct competitor* whose position in the relevant marketplace would be adversely affected by the challenged governmental action." *Adams*, 10 F.3d at 922 (emphases in original); *see also id.* at 922 n.13 (collecting cases); *Ass'n of Data Processing Serv. Orgs. v. Camp*, 397 U.S. 150, 152–54 (1970); *Arnold Tours, Inc. v. Camp*, 400 U.S. 45, 45–46 (1970); *Investment Co. Inst. v. Camp*, 401 U.S. 617, 620–21 (1971). In many such cases, "future injury-in-fact is viewed as 'obvious' since government action that removes or eases only the competitive burdens on the plaintiff's *rivals* plainly disadvantages the plaintiff's competitive position in the relevant marketplace." *Adams*, 10 F.3d at 922 (emphasis in original). Thus, courts frequently "uphold 'competitor standing' based on unadorned allegations of latent economic injury." *Id.* at 921. In other words, to plead competitor standing, a plaintiff need only identify "imminent injury-in-fact based on the laws of economics," such as "the law of supply and demand." *Id.* at 923.

The First Circuit's decision in *Adams* is instructive. At issue in that case was a price stabilization scheme that required milk dealers to pay assessments on all milk marketed in Massachusetts regardless of where it was produced, but that paid disbursements only to in-state producers. *See id.* at 917. A group of out-of-state milk producers challenged the scheme, but did not allege that they had sold less milk, had received a lower price, or had otherwise been "frustrated in their attempt to undersell Massachusetts producers" as a result of the scheme. *Id.*

The First Circuit nonetheless held that the out-of-state producers had alleged sufficient facts to establish standing. *See id.* at 922–25. Indeed, the out-of-state producers' allegation that the price stabilization scheme would give in-state producers a cost advantage and harm the sales of out-of-state producers, *see id.* at 920, comported with "standard principles of supply and demand routinely credited by courts" and, thus, pled an injury in fact, *id.* at 923.

The individual Plaintiffs have pled sufficient facts to establish competitor standing because they have alleged that the Importation Law exposes them to unlicensed and unregulated foreign competitors, and *advantages* those competitors by exempting them from the educational, fee-payment, and oversight requirements of the Maine Pharmacy Act. *See* Compl. ¶¶ 47–48; *see also Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 20 (1st Cir. 1996) (standing where competitors to whom customers would be lost "do not labor under the same handicap" of regulation as the plaintiff). "[S]tandard principles of supply and demand" illustrate that this interjection of unlicensed and unregulated foreign competition "plainly disadvantages the plaintiff's competitive position in the relevant marketplace." *Adams*, 10 F.3d at 922–23. Indeed, the "sponsors of the Importation Law justified it on a cost-savings rationale, arguing that the Law will reduce prices to consumers because foreign prescription drugs can be less expensive than their domestic counterparts." Compl. ¶ 64. "Thus, even the sponsors contemplate that the Importation Law will cause a transfer of market share away from safe, regulated domestic pharmacies and to unsafe, unreliable, and unregulated foreign mail-order pharmacies." *Id.*

For example, a representative of the Maine State Employees Association and Service Employees International Union explained that the State adopted its MaineMeds program, the precursor to the Importation Law, because it "was a valuable program to help save money." Testimony of Lois Baxter, MSEA-SEIU, Local 1989, In Support of L.D. 449 ("Baxter Testimony"), *available at* http://www.mainelegislature.org/legis/bills/getTestimonyDoc.asp?id=3401 (last visited Oct. 16, 2013); *see also* Testimony of Troy Jackson In Support of L.D. 171, *available at* http://www.mainelegislature.org/legis/bills/getTestimonyDoc.asp?id=1095 (last visited Oct. 16, 2013); Testimony of Janice Kimball, Benefits Manager Of The City Of Portland In Support of L.D. 449, *available at* http://www.mainelegislature.org/legis/bills/getTestimony

Doc.asp?id=3397 (last visited Oct. 16, 2013); Testimony of Michael Brennan, Mayor of the City of Portland, In Support of 449, *available at* http://www.mainelegislature.org/legis/bills/get TestimonyDoc.asp?id=3402 (last visited Oct. 16, 2013). And Defendants' own motion actually *repeats* this rationale for the Importation Law, noting that the City of Portland experienced "substantial savings" from its similar PortlandMeds program. Mot. at 7.

Defendants make no mention of the competitor-standing rule, much less any argument as to how the individual Plaintiffs fail to meet it if, as Defendants posit, the Law will result in "substantial savings" from the purchase of drugs from foreign sources. *Id.* Instead, Defendants offer three arguments in an attempt to refute the individual Plaintiffs' standing based on their prospective loss of market share, all of which fail.

First, Defendants' principal refrain is that the Importation Law "does not apply to plaintiffs," who "do not allege that they have engaged, or plan to engage, in conduct covered" by the Law. Mot. at 10. Defendants thus overlook that—as the Supreme Court has made crystal clear—competitor standing may exist even where the challenged statute or rule does not "apply" to the aggrieved competitor. *See, e.g.*, *Ass'n of Data Processing Serv.*, 397 U.S. at 152–54 (data processing servicers "no doubt" had standing to test ruling allowing national banks to sell data processing services); *Arnold Tours*, 400 U.S. at 45–46 (travel agents had "competitor standing" to test ruling allowing national banks to provide travel services); *Investment Co. Inst.*, 401 U.S. at 620–21 (investment companies had "competitor standing" to test ruling authorizing national banks to operate investment funds). Indeed, "government action that removes or eases only the competitive burdens on the plaintiff's *rivals*"—like the Importation Law here—"plainly" inflicts a cognizable injury. *Adams*, 10 F.3d at 922 (emphasis in original). Defendants' cases involving facial First Amendment challenges, *see, e.g.*, *Ramirez v. Sanchez Ramos*, 484 F.3d 92, 99–100

(1st Cir. 2006) (cited at Mot. at 10); *Osediacz v. City of Cranston*, 414 F.3d 136 (1st Cir. 2005) (cited at Mot. at 11), do not so much as address, much less refute, this commonsense point.

Second, Defendants alternatively admit that a plaintiff not "subject to" a statute "'is not precluded'" from establishing standing, but just has a "'more difficult'" case to make. *See* Mot. at 11 (quoting *Lujan*, 504 U.S. at 562–64). Even assuming the veracity of this proposition, the individual Plaintiffs have clearly met this "more difficult" standard by pleading competitive injury flowing from the Importation Law that can be redressed by an injunction in their favor. *See, e.g.*, *Adams*, 10 F.3d at 922; *see also Ass'n of Data Processing Serv.*, 397 U.S. at 152–54; *Arnold Tours*, 400 U.S. at 45–46; *Investment Co. Inst.*, 401 U.S. at 620–21.

Third, Defendants conclusorily assert—without *any* elaboration or substantiation—that the individual Plaintiffs' prospective loss of market share is "indirect and speculative and is not sufficiently imminent and concrete to establish standing." Mot. at 13. Of course, the individual Plaintiffs' loss of market share is no more "indirect," "speculative," or "not sufficiently imminent and concrete" than the basis for the Importation Law itself, which Defendants themselves predict will result in "substantial savings." *Id.* at 7; *see* Compl. ¶ 64. As a matter of "standard principles of supply and demand," those savings from foreign sales will come at the expense of the individual Plaintiffs, who therefore have standing. *Adams*, 10 F.3d at 923.

2. The Individual Plaintiffs Have Adequately Pled Three Other Injuries

In addition to competitor standing, the individual Plaintiffs have adequately pled at least three other cognizable injuries caused by the Importation Law that can be redressed by a judgment in their favor. *First*, standing exists when the challenged government action changes the party's statutory rights. *See, e.g.*, *Clinton v. City of New York*, 524 U.S. 417, 432 (1998) (plaintiff had standing to challenge Line Item Veto Act where exercise of the line-item veto had "depriv[ed]" it of a "statutory bargaining chip"). The Law does precisely that because it

eliminates "the exclusive license of Maine pharmacists to dispense prescription drugs"—to the detriment of patients on whose behalf the exclusive licensing regime was created. Compl. ¶ 63.

Second, and relatedly, standing exists whenever the challenged action increases the cost or difficulty of the plaintiff's compliance with its legal duties. *See, e.g.*, *Ass'n of Private Sector Colleges & Univs. v. Duncan*, 681 F.3d 427, 458 (D.C. Cir. 2012). Congress created a comprehensive and closed system for the distribution of prescription drugs within the United States, and designated pharmacists as integral agents to guaranteeing patient safety and the integrity of that system. *See* Compl. ¶¶ 30–41. The Importation Law tears a hole in this closed system that "creates informational deficits and undermines the ability of licensed Maine pharmacists and pharmacies to discharge their legal, ethical, and fiduciary duties to protect their patients from potentially deadly misuse of prescription drugs." *Id.* ¶ 63. Indeed, patients who receive prescription drugs from a foreign source "may not know or may not communicate to the Maine pharmacist accurate information regarding the prescription drugs they obtained from the foreign source, such as the description, dosage, or the patient's use history." *Id.* ¶ 62. "The Maine pharmacist will have no record of that information because it was not the pharmacist that filled the prescription." *Id.* "Moreover, even if the patient believes she has perfect information regarding the foreign drugs, those drugs may be misbranded, adulterated, counterfeit, mislabeled, or expired." *Id.* "Thus, it may be impossible for the Maine pharmacist to detect and to prevent dangerous drug-disease contraindications or drug-drug interactions, to advise the patient on potential side or adverse effects, or to provide proper instructions regarding drug use." *Id.*

Defendants attempt to brush aside this cognizable injury as a "'sky is falling' argument," arguing that it "defies common sense and good business practice." Mot. at 13. n.4. Defendants are undoubtedly correct that the individual Plaintiffs and other Maine pharmacists "know[] what

[they are] doing," *id.*—but that does not negate the fact that the Importation Law creates information deficits that make the discharge of their legal duties more difficult through no fault of their own, *see* Compl. ¶ 62. Moreover, while foreign pharmacies and brokers may "want to keep customers and not incur bad reputations," Mot. at 13 n.4, this incentive does not bridge the informational chasm between these unregulated entities and licensed Maine pharmacists, or facilitate licensed Maine pharmacists' discharge of *their* legal duties. And this purported incentive has not prevented certain foreign pharmacies from marketing counterfeit Avastin or CanaRx from misleading its customers. *See* Compl. ¶¶ 20–29.

Third, "[w]here a party has established concrete injury in fact, and otherwise has standing to challenge the lawfulness of the statute, it is 'entitled to assert those concomitant rights of third parties that would be diluted or adversely affected should its constitutional challenge fail and the statute remain in force.'" *PhRMA v. Concannon*, 249 F.3d 66, 74 (1st Cir. 2001) (quoting *Craig v. Boren*, 429 U.S. 190, 195 (1976)), *aff'd on other grounds sub nom. PhRMA v. Walsh*, 438 U.S. 644 (2003). "Accordingly, 'vendors and those in like positions have been uniformly permitted to resist efforts at restricting their operations by acting as advocates of the rights of third parties who seek access to their market or function.'" *Id.* (quoting *Boren*, 429 U.S. at 195). Such suits do not run afoul of the general prohibition on asserting the rights of a third party. *See, e.g.*, Mot. at 10, 15 (citing *Ramirez*, 438 F.3d at 98).

The individual Plaintiffs therefore have standing to challenge the Importation Law's infliction of injury on their patients due to the fact that "foreign mail-order pharmacies are not subject to the verification, DUR, recordkeeping, counseling, or privacy requirements of OBRA, Maine law, and HIPAA." Compl. ¶ 61. Thus, "even foreign mail-order pharmacies that dispense genuine prescription drugs may not give Maine patients proper instructions regarding

their use." *Id.* "In addition, such pharmacies may not properly warn Maine patients regarding, or prevent, drug-disease contraindications or drug-drug interactions." *Id.* "Maine patients thus will be exposed to the risk of serious disease or even death from the improper use of prescription drugs or avoidable drug-disease contraindications or drug-drug interactions." *Id.* The Importation Law's infliction of these risks—in contravention of Congress's action to eliminate them—creates a cognizable injury in fact. *See id.* ¶¶ 30–41, 60–62.

3. The Pharmacist Associations Have Pled Sufficient Facts To Establish Standing On Behalf Of Their Members And Themselves

An association has standing to bring suit on behalf of its members so long as "(a) its members otherwise would have standing to sue in their own right; (b) the interests it seeks to protect are germane to its purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Comm'n*, 432 U.S. 333, 343 (1977). Defendants do not dispute that the Pharmacist Associations satisfy the second and third requirements of this test. *See* Mot. at 14. Instead, Defendants contend that the Pharmacist Associations lack standing because their members have not suffered an injury in fact. *See id.* But, as demonstrated, pharmacists in Maine, including the Pharmacist Associations' members, *do* have a cognizable injury. *See supra* Part I.A.

Moreover, the Pharmacist Associations have standing based on their *own* injuries. *See, e.g.*, *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982); *Lujan*, 504 U.S. at 560. In *Havens Realty*, the Supreme Court held that a housing organization had standing to challenge alleged racial steering practices where it alleged that those practices had "frustrated . . . its efforts" to provide "counseling and other referral services" and had required it "to devote significant resources to identify and counteract the defendant's racially discriminatory steering practices." 455 U.S. at 379. The Supreme Court found "no question" that the impairment of the

organization's mission and "consequent drain on [its] resources" constituted "injury in fact." *Id.*

Defendants do not so much as mention *Havens Realty*, *see* Mot. at 14, presumably because the Pharmacist Associations have pled sufficient facts to demonstrate their standing under it. As in *Havens Realty*, the challenged conduct here is "creat[ing] a drain on the organizational plaintiffs' time and resources." Compl. ¶ 67. The Pharmacist Associations are "expending considerable resources and time to educate the public about the health and safety risks posed by the unregulated importation of foreign drugs and importation of American-made drugs," which has included "public advocacy efforts related to the Importation Law and . . . educating their members on the Importation Law and all applicable federal and state laws." *Id.* The Importation Law thus is diverting the Pharmacist Associations' resources away from "serving the public as well as [their] members in other ways." *Id.* These injuries confer standing on the Pharmacist Associations in their own right. *See Havens Realty*, 455 U.S. at 379.

4. PhRMA Has Pled Sufficient Facts To Establish Standing On Behalf Of Itself, Its Members, And Maine Patients

PhRMA also has pled sufficient facts to establish its standing. In fact, Defendants do not even challenge PhRMA's standing to sue based on the frustration of its mission and diversion of resources caused by the Importation Law. *See* Mot. at 14. Thus, like the Pharmacist Associations, PhRMA has standing in its own right. *See supra* Part I.A.3; *see also* Compl. ¶ 67.

PhRMA also has standing to sue on behalf of its members. *See Hunt*, 432 U.S. at 343. Defendants do not contest that this suit is germane to PhRMA's purpose, but instead dispute that PhRMA's members have suffered an injury and that their participation is unnecessary to this suit. *See* Mot. at 14 & n.5. Defendants are wrong on both fronts.

First, PhRMA's members face cognizable "injuries to goodwill and reputation" from the Importation Law. *Ross-Simons*, 217 F.3d at 13–14; *see also Meese v. Keene*, 481 U.S. 465, 473–

77 (1987); *Foretich v. United States*, 351 F.3d 1198, 1210 (D.C. Cir. 2003). Indeed, "[i]n the event that a mislabeled, adulterated, counterfeit, or expired prescription drug reaches a patient in the United States" from a foreign source, "the patient inevitably will blame the manufacturer of the genuine product that the patient expected to receive." Compl. ¶ 66. As a result, "the manufacturer of the genuine product will suffer a reputational loss, loss of goodwill, and loss of consumer confidence, regardless of whether the manufacturer is to blame or could have done anything to block that import." *Id.*

This reputational harm is not "speculative" or "a chain of hypotheticals," as Defendants assert in conclusory terms. Mot. at 14. Indeed, Plaintiffs have documented the myriad safety risks inherent in importation of prescription drugs, including the widespread international counterfeiting of the cancer drug Avastin. *See* Compl. ¶¶ 20–29. Plaintiffs also have documented the FDA's concerns with CanaRx, the Canadian broker used in the MaineMeds program and found by the FDA to have made "misleading assurances to consumers." *Id.* ¶ 27. Thus, there is a *reality* that mislabeled, adulterated, counterfeit, or expired prescription drugs will reach the United States from foreign sources and that the manufacturers of genuine drugs will suffer reputational harm as a result. *See id.* ¶¶ 20–29.

Second, the Importation Law dilutes PhRMA's members' statutory right under the "American goods returned" provision because it purports to permit foreign pharmacies and brokers to import prescription drugs *regardless* of whether they are originally manufactured in the United States. *See* Compl. ¶¶ 18, 60–65; *see also Clinton*, 524 U.S. at 432. The Law thus exposes the public to the very risk of harm from "subpotent or adulterated" drugs that Congress sought to ameliorate with the "American goods returned" provision. *See* Compl. ¶ 18.

Third, Defendants demote to a footnote their conclusory argument—asserted without a

single citation to authority—"that PhRMA has not shown why the participation of individual members would not be required here" because, in their view, "the injury PhRMA is claiming . . . would involve fact-intensive individual inquiry regarding the conduct of particular drug manufacturers." Mot. at 14 n.5. This undeveloped argument is waived. *See, e.g., NFTC v. Natsios*, 181 F.3d 38, 60 n.17 (1st Cir. 1999) ("We have repeatedly held that arguments raised only in a footnote or in a perfunctory manner are waived.") (cited at Mot. at 17), *aff'd on other grounds sub nom. Crosby v. NFTC*, 530 U.S. 363 (2000). It is also meritless because this Court can grant the requested injunctive relief without conducting a "fact-intensive individual inquiry" regarding PhRMA's members. *N.H. Motor Transp. Ass'n v. Rowe*, 448 F.3d 66, 72 (1st Cir. 2006). Indeed, because "defendants' pernicious [acts] harm all" PhRMA members "in the same way," the requested injunctive relief "would inure to the benefit of all" such members "equally, regardless of their individual circumstances." *College of Dental Surgeons of P.R. v. Conn. Gen. Life Ins. Co.*, 585 F.3d 33, 41 (1st Cir. 2009). And if federal law preempts the Importation Law as to one PhRMA member, it does so as to all such members. *See, e.g., N.H. Motor Transp. Ass'n*, 448 F.3d at 72. It would make no sense to subject Defendants to a "patchwork" of responsibilities with respect to the Importation Law depending on which individual PhRMA members "proceeded to litigation." *Id.* Thus, no individual members are necessary to demonstrate that the Importation Law violates federal law. *See id.*

Finally, in all events, like the other Plaintiffs, PhRMA's members, as central actors in Congress's closed scheme for safe distribution of prescription drugs in the United States, have standing to assert the rights of Maine patients who face significant—and unnecessary—health risks from the Importation Law. *Concannon*, 249 F.3d at 74; *see also* Compl. ¶¶ 60–67.

B. Plaintiffs Need Not Satisfy The Zone Of Interest Test, But Do So Anyway

Defendants' challenge to Plaintiffs' prudential standing posits that Plaintiffs' claims do

not "fall within the 'zone of interests' protected by the constitutional provision[s] they invoke." Mot. at 15.[1] The zone of interest test "denies a right to review" only "if the plaintiff's interests are so marginally related to or inconsistent with the purposes implicit" in the constitutional provision the plaintiff invokes. *Clarke*, 479 U.S. at 399. "The test is not meant to be especially demanding," *id.* at 399–400, and Plaintiffs satisfy it here.

1. The Zone-Of-Interest Test Is Inapplicable To Plaintiffs' Preemption Claim But Would Be Satisfied In Any Event

Plaintiffs' preemption claim does not seek "to enforce rights under [a] statute" such as the FDCA, "but rather . . . under the Supremacy Clause." *Concannon*, 249 F.3d at 73; *cf. Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) (private parties have no cause of action under the FDCA) (cited at Mot. at 7). "[A]n entity does not need prudential standing to invoke the protection of the Supremacy Clause" because "'a state or territorial law can be unenforceable as preempted by federal law even when the federal law secures no individual substantive rights for the party arguing preemption.'" *Concannon*, 249 F.3d at 73 (quoting *St. Thomas-St. John Hotel & Tourism Ass'n v. Virgin Islands*, 218 F.3d 232, 241 (3d Cir. 2000)).

Defendants do not so much as mention *Concannon*, let alone attempt to explain it away. Instead, Defendants assume that the zone-of-interest test applies to preemption claims, and argue that Plaintiffs' claims "do not fall within the 'zone of interests'" because, in their view, preemption doctrine protects "only persons and entities having state laws applied to them when those state laws directly conflict with federal law." Mot. at 15. The Supremacy Clause undoubtedly *does* protect such persons, *see, e.g.*, *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (1987) (cited at Mot. at 15), but its protection is not *exclusive* to them. Indeed, in order to satisfy

[1] Defendants repeat their argument that Plaintiffs are "seeking to vindicate the interests of others," Mot. at 15, but Plaintiffs have sufficiently pled their *own* injuries, *see supra* Part I.A.

the "not . . . especially demanding" zone-of-interest test, a plaintiff need show only that it is *harmed* by the challenged government action, not that such action is being *applied* to it. *Clarke*, 479 U.S. at 399 (upholding prudential standing of brokers who challenged a rule benefitting national banks but imposing no requirements on brokers). Moreover, under the doctrine of field preemption—which, as Plaintiffs elsewhere have explained, invalidates the Importation Law, *see* Pls.' Mot. For Prelim. Inj. at 18–20 (DE 9)—"even *complementary* state regulation is impermissible" when "Congress occupies an entire field" and leaves no room for state legislation, *Arizona v. United States*, 132 S. Ct. 2492, 2502 (2012) (emphasis added).

Thus, the zone of interests protected by the Supremacy Clause encompasses parties harmed by a state law that either touches on a field Congress has occupied or conflicts with federal law. *See Clarke*, 479 U.S. at 399; *Arizona*, 132 S. Ct. 2492; *Geier*, 529 U.S. 861. Plaintiffs' preemption claim plainly arises within this zone because Plaintiffs are harmed by the Importation law, *see supra* Part I.A, and the Law touches on the field of drug importation occupied by Congress, conflicts with the FDCA, and obstructs the FDCA's comprehensive and closed distribution scheme, *see* Pls.' Mot. For Prelim. Inj. at 18–26.

2. Plaintiffs' Claim Arises Within The Zone Of Interests Protected By The Foreign Commerce Clause

The Commerce Clause—of which the Foreign Commerce Clause is part—"is specifically targeted to protect" the "economic interests" of individual citizens. *Houlton Citizens' Coal. v. Town of Houlton*, 175 F.3d 178, 183 (1st Cir. 1999). The Foreign Commerce Clause, moreover, "comprehend[s] [that] every species of commercial intercourse between the United States and foreign nations" will be subject to "exclusive and plenary" federal control. *Bd. of Tr. of Univ. of Illinois v. United States*, 289 U.S. 48, 56 (1933). 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'" that speaks "with one voice." *Japan Line, Ltd. v. Los Angeles Cnty.*, 441 U.S. 434, 448, 453 (1979) (quoting *Bd. of Tr.*, 289 U.S. at 59 (emphasis added)).

The Supreme Court held in *Board of Trustees* that the Foreign Commerce Clause prohibited a state from avoiding payment of import duties Congress had levied on foreign goods, even though such avoidance would have *favored* foreign commerce. *See* 289 U.S. at 56. And, of course, there can be no doubt that a state law that purported to permit trade in violation of a federal embargo would be invalid under the Foreign Commerce Clause. *See, e.g.*, *id.* at 57 ("If the Congress saw fit to lay an embargo or to prohibit altogether the importation of specified articles, . . . no State by virtue of any interest of its own would be entitled to override the restriction" and permit such importation).

The interests protected by the Foreign Commerce Clause therefore encompass *both* private economic interests *and* the interest in federal uniformity in international relations, regardless of whether the challenged state law favors or disfavors foreign commerce. *See, e.g.*, *Houlton Citizens' Coal.*, 175 F.3d at 183; *Bd. of Tr.*, 289 U.S. at 56. Plaintiffs' Foreign Commerce Clause claim arises within the zone of these interests. Plaintiffs' own economic interests are implicated because the Importation Law diminishes their market share and inflicts reputational damage on them. *See supra* Part I. Plaintiffs' claim, moreover, implicates the interest in federal uniformity in the important area of drug importation—an area where Congress has created a comprehensive regulatory scheme with Plaintiffs as integral actors. *See* Compl. ¶¶ 30–41; *see also* Pls.' Mot. For Prelim. Inj. at 14–18.

Defendants therefore err when they contend that the Foreign Commerce Clause is concerned only "with state laws that discriminate against foreign commerce or that excessively interfere with foreign affairs." Mot. at 17. While the Foreign Commerce Clause undoubtedly *is*

concerned with such laws, *see, e.g.*, *Antilles Cement Corp. v. Fortuno*, 670 F.3d 310 (1st Cir. 2012) (cited at Mot. at 17); *Natsios*, 181 F.3d 38 (cited at Mot. at 17), it is not *exclusively* concerned with them, *see Houlton Citizens' Coal.*, 175 F.3d at 183; *Bd. of Tr.*, 289 U.S. at 56; Pls.' Mot. For Prelim. Injun. at 14–18.

Defendants, moreover, conflate one of Plaintiffs' arguments on the *merits* with their allegations of injury, and contend that Plaintiffs have no standing to "complain that the [Importation Law] provides that pharmacies from certain countries, but not others, are not subject to the Maine Pharmacy Act's unlawful practice provision." Mot. at 18. But the Importation Law's discrimination *among* foreign commerce is yet another reason for its invalidity. *See* Pls.' Mot. For Prelim. Inj. at 17. The Court should deny the motion to dismiss.

II. The Court Should Not Dismiss Commissioner Millett

Commissioner Millett has been sued in his official capacity because he "oversees the provision of health insurance benefits to state employees and their families" and, thus, "will be responsible for implementing any state-run program to import pharmaceuticals." Compl. ¶ 13. The State recently announced that it is resuming the MaineMeds program, which effectively subsidizes and directs state employees to import drugs from CanaRx, *see* MaineMeds, http://mainemeds.com/ (Ex. BB to Pls.' Reply To Defs. Opp. To Prelim. Inj.), and whose "valu[e] . . . to help save money" for the State itself was a significant impetus in the enactment of the Importation Law, *see* Baxter Testimony. Commissioner Millett therefore is a proper defendant to the preemption and Foreign Commerce Clause claims. *See* Compl. ¶¶ 68–83. And the fact that Plaintiffs could not bring a claim under the FDCA, *see* Mot. at 20, is irrelevant to the fact that Commissioner Millett is a proper defendant to the claims Plaintiffs *did* plead.

CONCLUSION

This Court should deny the motion to dismiss.

Dated: October 16, 2013

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CERTIFICATE OF SERVICE

On October 16, 2013, I filed the foregoing document using the CM/ECF system, which will send notification of such filing to the parties registered with the Court's CM/ECF system.

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