UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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HEALTHCARE DISTRIBUTION ALLIANCE,

Plaintiff,

-against- 18 CV 6168 (KPF)

HOWARD A. ZUCKER, in his official capacity as Commissioner of Health of New York; and BARBARA D. UNDERWOOD, in her official capacity as the Attorney General of New York,

Defendants.

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REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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Preliminary Statement

Defendants Howard A. Zucker, as Commissioner of the New York State Department of Health ("DOH") and Barbara D. Underwood, as Attorney General of the State of New York (collectively, the "Defendants"), respectfully submit this reply memorandum of law in further support of their motion to dismiss the Amended Complaint ("A.C.") for lack of subject matter jurisdiction and failure to state a claim upon which relief may be granted.

The Opioid Stewardship Act ("the Act"), challenged by Healthcare Distribution Alliance, imposes a surcharge of up to $100 million per year on the sale and distribution of opioids in New York State in order to fund programs designed to combat the epidemical abuse of these drugs. The gravamen of plaintiff's case is that the Act's purpose is to punish plaintiff's members for their supposed responsibility for the national opioid epidemic. Plaintiff's position falls apart immediately, however, because on its face the Act is clearly a taxing measure whose intent is to raise revenue to fund critically important public health programs. Moreover, the rationality of imposing the surcharge on pharmaceutical manufacturers and distributors, rather allowing it to be passed down to the patients, is abundantly self-evident - - the annual revenues of the wholesale pharmaceutical distributors plaintiff represents exceed $379 billion annually (more than twice New York's own budget of approximately $168 billion[1]).

As the Act has all the indicia of a tax, it should be treated as such[2] and this case must be dismissed under the Tax Injunction Act, "TIA", 28 U.S.C. § 1341, as well as

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[1] See "New York Passes $168 billion budget," Albany Times Union, April 1, 2018, https://www.timesunion.com/state/article/Following-impasse-New-York-passes-168-billion-12794136.php.

[2] Plaintiff's contention in its "Combined Opposition to Defendants' Motion to Dismiss and Reply in Support of Plaintiff's Motion for Summary Judgment dated November 7,

broader principles of comity. Moreover, Pullman abstention would apply in any event because the Act is capable of interpretation consistent with the Constitution (such as by allowing the surcharge to be passed down to all non-opioid customers, whether located in or outside of New York State, which would largely avoid the economic harm of which plaintiff complains). Upon discarding plaintiff's counterintuitive notion that the purpose of the Act is punishment rather than funding opioid abuse programs, the rest of plaintiff's challenges fall away. Accordingly, Defendants' motion to dismiss should be granted.[3]

ARGUMENT

I. THE TAX INJUNCTION ACT BARS THIS CASE

A. The Tax Injunction Act

As argued in moving papers (Memorandum in Support of Motion to Dismiss, Docket # 44, "Mem.") the TIA provides that: "The district courts shall not enjoin, suspend or restrain the assessment, levy or collection of any tax under State law where a plain, speedy and efficient remedy may be had in the courts of such State." See cases cited in Mem. at 4-9. "Two conditions need be present before the TIA will strip a federal court of jurisdiction: (a) the payment at issue must constitute a 'tax' and (b) the state must provide an available

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2018, Docket #49 , "Opp." at 5, FN 6, to the effect that the prescription drug monitoring registry which receives funding pursuant to the Act is somehow intended to regulate plaintiff's members (and thereby the surcharge provided by the Act is a user fee rather than a tax) is incorrect. The prescription drug registry, provided for by Public Health Law §3343-a regulates physicians and pharmacists with respect to their prescription and dispensing of controlled substances, and does not regulate the pharmaceutical manufacturing or distribution industries.

[3] If this case is thus dismissed, plaintiff's motion for summary judgment would become academic. Plaintiff's position, Opp. at 15-17, that Defendants are foreclosed from arguing that discovery may be required to respond to its summary judgment is erroneous: the case law cited by Plaintiff did not involve a plaintiff's motion for summary judgment prior to answer or a rule 16 conference, as is the case here, and in any event, Defendants' factual declaration more than "hinted" that discovery would be required to fully address the issues raised by plaintiff in its summary judgment motion.

remedy to plaintiff that is 'plain, speedy and efficient.'" United Food and Commercial Workers Unions and Food Employees Benefit Fund v. DeBuono, 101 F. Supp. 2d 74, 77 (N.D.N.Y. 2000) (citing Travelers Ins. Co. v. Cuomo, 14 F.3d 708, 713 (2d Cir. 1993), rev'd on other grounds, 514 U.S. 645 (1995).

Here, plaintiff does not contest that New York courts can provide a plain, speedy and efficient remedy for its members. Accordingly, if the surcharge provided by the Act is a tax, then the TIA will apply and this case must be dismissed.

B. The Opioid Surcharge is a "Tax" for Purposes of the TIA

It is not disputed that as a matter of nomenclature the Act's surcharge is not called a tax, it is not administered by the Department of Taxation and Finance, and the revenue collected will be deposited in a special fund (the Opioid Stewardship Fund), one of a number of funds maintained pursuant to the State Finance Law. However, plaintiff's claim (Opp. at 2-9) that these factors are dispositive under the TIA is simply incorrect.

"[T]here is no bright line between assessments that are taxes and those that are not." Travelers, 14 F.3d at 713. However, "courts 'have tended . . . to emphasize the revenue's ultimate use, asking whether it provides a general benefit to the public, of a sort often financed by a general tax, or whether it provides more narrow benefits to regulated companies or defrays the agency's costs of regulation.'" Gasparo v. City of New York, 16 F. Supp. 2d 198, 218 (E.D.N.Y. 1998) (citation omitted). "[T]he heart of the inquiry centers on function, requiring an analysis of the purpose and ultimate use of the assessment." Id. (quoting Collins Holding Corp. v. Jasper Country, S.C., 123 F.3d 797, 800 (4th Cir. 1997)) (emphasis added).[4]

[4] See American Landfill, Inc. v. Stark/Tuscarawas/Wayne Joint Solid Waste Management District, 166 F.3d 835, 837 (6th Cir. 1999) (Ohio law solid waste disposal assessments

Thus, "exactions", "surcharges" and "penalties" have been found to be taxes, where the ultimate purpose was to raise public revenue for the benefit of the public. See, e.g., cases cited in Mem. at 6-9.

Here, the Act's clear purpose is to use the surcharge for the benefit of the general public in New York State: ". . . to provide opioid treatment, recovery and prevention and education services; and to provide support for the prescription monitoring program registry." See State Finance Law § 97-aaaaa(4). The fact that DOH administers the funding does not change its essential revenue-raising nature. Gasparo, 16 F. Supp. 2d at 220-21 (licensing charge imposed upon newsstand vendors by the Department of

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were "taxes" for TIA purposes where assessments were placed in fund separated from general fund but were still used for a public purpose benefiting the entire community). That case, in turn, cites factors first cited in San Juan Cellular Tel. Co. v. Public Service Comm'n, 967 F.2d 683, 685 (1st Cir. 1992), and Bidart Bros. v. Calif. Apple Comm'n, 73 F.3d 925, 931 (9th Cir. 1996), as the test for TIA application, to wit, "(1) the entity that imposes the assessment; (2) the parties upon whom the assessment is imposed; and (3) whether the assessment is expended for general public purposes or used for the regulation or benefit of the parties upon whom the assessment is imposed." See also Wright v. McClain, 835 F.2d 143, 144-45 (6th Cir. 1987) (assessments that parolees were required to make on monthly basis to supervision fund and victim's compensation fund were taxes for TIA purposes, even though earmarked only for Corrections Department budget and not "general funds," as defraying cost to public of monitoring/supervising convicted offenders and victim compensation were to the general welfare of citizens of Tennessee even though dedicated to particular aspect of the commonwealth and administered by Corrections Dept.); Lavis v. Bayless, 233 F.Supp.2d 1217, 1222 (D. Ariz. 2001) (assessments under an Arizona statute imposing a ten percent surcharge on civil and criminal fines to create a fund for financing political campaigns held to be a "tax" for TIA purposes, citing Bidart test); Independent Coin Payphone Ass'n v. City of Chicago, 863 F.Supp. 744, 755 (N.D. Ill. 1994) (payphone franchise fee found to be a tax for TIA purposes where ordinance providing for franchise fee was intended as revenue generating mechanism); Butler v. State of Maine Supreme Judicial Ct., 767 F.Supp. 17 (D. Me. 1991) (nonrefundable jury fee to be paid by litigants seeking jury trial held to be a tax for TIA purposes); American Trucking Ass'ns v. Conway, 514 F.Supp. 1341, 1343 (D.Vt. 1981) (permit fees charged to out of state interstate motor carriers found to be tax for TIA purposes.) See also New York Tax Law § 482(b) and Public Health Law § 2807-v, providing that cigarette taxes are held in designated funds and then applied to various public health purposes.

Transportation was a tax for purposes of the TIA). That a limited number of entities will pay the surcharge does not avoid the TIA, notwithstanding plaintiff's argument (Opp. at 3). See Entergy Nuclear Vermont Yankee, LLC, 737 F.3d at 233 (a surcharge payable by nuclear plant operators was still a tax though it affected only one entity in Vermont.)

Here, the plain intent of the Act is to fund programs for opioid abuse prevention, treatment and education available to the general public, including the prescription drug monitoring registry, which is a public health program and does not regulate the pharmaceutical manufacturing or distribution industry. See Public Health Law § 3343-a.

Regardless of nomenclature, because the Act provides general revenue for the public benefit, it is analogous to a tax and this case is subject to the TIA. See also United Food and Comm'l Workers Un., 101 F.Supp.2d at 78 (HCRA surcharge for patient care on licensed providers administered and collected by DOH and deposited in special fund still a tax: purpose of fund was to benefit the general public by offsetting costs of uncompensated care for indigent.) And as we argued (Mem. at 8-9), the Act's penalty provisions are closely related to its revenue-generating purpose and therefore are similarly covered by the TIA's bar against federal suit. See cases cited at id.

Plaintiff's assertion that the purpose of the Act is not to raise revenue but instead to "prejudge the guilt" of licensees in advance of the resolution of various enforcement actions (Opp. at 6-9, A.C. at ¶ 49) misses the mark: nothing in the Act suggests such purpose (and plaintiff's selective reading of statements by public officials is of no moment). Any reasonable reading of the Act and its Legislative History shows the basic intent to raise revenue to fund critical opioid treatment and education programs for the general benefit of the public. Moreover, the entities subject to the Act are established through general and open-ended criteria, such as that found to be permissible even though applicable only against a single entity in Entergy, 737 F.3d at 233.

Hence, for TIA purposes, the Act is a "tax" and this case must be dismissed.

II. COMITY PRINCIPLES ALSO BAR THIS CASE

As we showed (Mem. at 10-12) this Court should also dismiss this case under the Comity Doctrine, because the relief sought by plaintiff would interfere with New York's administration and collection of revenue.

"The comity doctrine instructs federal courts to refrain from granting relief to taxpayer-plaintiffs in suits that contest taxpayer liability in a manner that interferes with a state's administration of its tax system." Abuzaid v. Mattox, 726 F.3d 311, 315 (2d Cir 2013) (citing Levin v. Commerce Energy, Inc., 560 U.S. 413, 417 (2010)). "[C]omity is '[m]ore embracive' than the TIA because it restrains federal courts from hearing not only cases that decrease a state's revenue, but also those that 'risk disrupting state tax administration." Joseph v. Hyman, 659 F.3d 218-21 (2d Cir. 2011), citing Levin, 130 S.Ct. at 2328.

Here, as in Levin, 560 U.S. at 426-28, plaintiff's members clearly are challenging their own liability under the Act and there is a process available in state court to redress their claims. Simply put, an injunction here would disrupt the state's collection of revenue. See Abuzaid, 726 F.3d at 316. Moreover, plaintiff errs in contending that the Act's pass-through bar is not part of the tax for comity purposes (Opp. at 10). Because the surcharge is a state tax, comity bars this Court's adjudication of the penalty provisions enacted to assist in the enforcement of that tax. Cf., Piedmont Gardens, LLC v. LeBlanc, 733 Fed.Appx. 576 (2d Cir. May 11, 2018) (unpublished) (comity barred federal suit against 15% marshal fee imposed for collecting delinquent property taxes).

III. THE COURT SHOULD ABSTAIN UNDER PULLMAN

The Pullman abstention doctrine also mandates dismissal of this case, as it requires that Plaintiff seek relief in the first instance in the State courts. Contrary to plaintiff's contentions (see Opp. at 10-11), its claims inovlve the resolution of various unsettled and important issues concerning the Act, requiring abstention in favor of state proceedings. R.R. Comm'n of Texas v. Pullman Co., 312 U.S. 496, 499 (1941) (See Mem. at 13-15).

At the outset, Plaintiff's Commerce Clause claim clearly depends, at least in part, on whether the pass-through prohibition extends to extraterritorial purchasers or only to intrastate purchasers. Indeed, plaintiff misconstrues defendant's argument (Opp. at 20) -- plaintiff would have no standing to claim injury to out-of-state purchasers if the pass-through bar is only applied to intrastate purchasers. Further, the Act also can be interpreted to only prohibit "pass-throughs" to opioid customers, thus permitting distributors (and manufacturers) to pass their surcharges down to all other pharmaceutical customers, whether in or outside New York. In such circumstances, it is difficult to conceive how the Commerce Clause would be implicated.[5] The essential point is that the Act "is susceptible to an interpretation that would avoid or modify the federal constitutional question presented." Planned Parenthood of Dutchess-Ulster, Inc. v. Steinhaus, 60 F.3d 122, 126 (2d Cir. 1995)

Similarly, as we showed (Mem. at 14), Plaintiff's claim of unconstitutional vagueness and its interpretation of the severability clause both warrant abstention to permit state courts to pass on these issues (and potentially avoid unconstitutional

[5] See Memorandum in Support of Motion to Dismiss in SpecGX v. Underwood, 18 Civ. 9830 (KPF) docket # 30 at 16-17 (copy attached as Appendix 1 hereto for the Court's convenience).

interpretations), as do its various other substantive challenges to the Act. For all of these reasons, Pullman abstention is warranted here.

IV. PLAINTIFF'S CHALLENGE TO THE PASS-THROUGH PROHIBITION IS NOT RIPE FOR REVIEW

As we showed the Court (Mem. at 16-18), Plaintiff's challenge to the Act's pass-through bar fails because that portion of the Act has not yet been applied and plainly could not be applied until at least next year. Any as-applied challenge to it is simply not ready for adjudication by the courts.

For its part, plaintiff argues (Opp. at 13) that "Licensees are obligated to pay $100 million in a few weeks and upon doing so are immediately barred from passing any of that cost to downstream customers." (emphasis in original). Nonetheless, this allegation still falls short of the requirement that an alleged threat of harm be "concrete and particularized and actual and imminent, not conjectural or hypothetical." See cases cited in Mem. at 16-17. Plaintiff acknowledges that the pass-through penalty cannot presently be applied to it.[6] As the penalty can not be applied until at least next year, plaintiff's challenge to the pass-through prohibition is still speculative and unripe for review.

V. PLAINTIFF'S SUBSTANTIVE CHALLENGES TO THE ACT FAIL

Contrary to plaintiff's claim, on its facial challenge it is required to "establish that no set of circumstances exists under which the Act would be valid." Copeland v. Vance,

[6] Inasmuch as Plaintiff's members' annual revenue is over $379 billion (see Declaration of Robert Handfield, "Handfield Decl.," Docket #35, ¶10, Table 1), and the ratable shares of the three largest distributors represent approximately $47 million and the remainder of all distributors and manufacturers is approximately $53 million (see Bassiri Decl., Docket # 43 at ¶ 6), plaintiff's claim that its main members face "a direct and immediate dilemma" from the threat of a penalty for avoiding the cost of the annual surcharge is unconvincing, to say the least.

893 F.3d 101, 110-11 (2d Cir. 2018) (citing U.S. v. Salerno, 481 U.S. 739, 745 (1987). Plaintiff has not met that standard.

Among other things, the Act can be easily construed so as not to violate the Commerce Clause by reading the pass-through prohibition only as to opioid purchasers, and no other pharmaceutical customers (whom obviously represent the vast majority of distribution). Similarly, the Bill of Attainder claim fails because plaintiff fails to point to anything in the statute suggesting anything other than revenue raising, let alone a determination of guilt and punishment. Plaintiff's suggestion that the Act is indistinguishable from the statute in Consolidated Edison Co. of New York, Inc. v. Pataki, 292 F.3d 338 (2d Cir. 2002), (Opp. at 23), only emphasizes the lack of merit to its case. In Con Ed, the law at issue made specific findings that the plaintiff "operate[d] steam generators known to be defective . . . thereby increasing the risk of a radioactive release and/or an expensive plant outage [and thus] failed to exercise reasonable care on behalf of the health, safety and economic interests of its customers," leading the Court to hold that the legislature "in a single stroke, found guilt on the facts of Con Ed's case." 292 F.2d at 344, 349. The Act here contains nothing remotely similar.

Nor can plaintiff prevail on its substantive due process claim, as there plainly is at least a rational basis for imposing a surcharge on the distributors of opioid pharmaceuticals to fund prevention and treatment programs targeting addiction to and abuse of these drugs, especially given their relative ability to pay the surcharge as compared with patients. Contrary to plaintiff's claims, basing the surcharge on market share is a reasonable proxy - - plaintiff's hypothetical case of there only being one licensee who sells one pill in New York in a given year is absurd on its face (Opp. at 31).

The vagueness challenge fails because, as set forth above and in Mem., the Act can easily be construed in a reasonable manner.[7] As to its retroactivity claim, plaintiff argues that the case Defendants cite (Canisius College v. United States, 799 F.2d 18, 25-27 (2d Cir. 1986)) is distinguishable, but it is not. There is simply no rule at law that a state cannot under any circumstances impose a new liability on a past act, or must always impose a tax on prospective activity only. In any event, the approximately one year "retroactivity" is hardly so egregious as to be unconstitutional.

As to plaintiff's takings claim, because the Act provides for a tax, then no takings claim lies. See Planavsky v. Broome County, 2014 WL 6885928 at *2 (N.D.N.Y. Dec, 8, 2014), and Jones v. Safi, 2011 WL 5524674 at *4 (E.D.N.Y. Nov. 10, 2011) ([a] tax sale is not a taking for a public purpose because such sale is pursuant to a state's taxing power and not its power of eminent domain,") (both quoting In re Murphy, 331 B.R. 107, 128 (Bankr. S.D.N.Y. 2005)). Further, the takings also fails because plaintiff does not claim the complete loss of its members' pharmaceutical business (even as limited to New York). Cf. Sierra Medical Services Alliance v. Kent, 883 F.3d 1216, 1225-26 (9th Cir. 2018) (rejecting per se takings claim where plaintiffs only showed a loss when serving one segment of the population, rather than the overall economic impact of the challenged statute on their "bottom line"). Accordingly, as plaintiff's substantive challenges to the Act also fail, its Amended Complaint should be dismissed on this basis as well.

CONCLUSION

[7] In Opp., at 27, FN 34, plaintiff claims it sought "clarification from the Department to no avail." In fact, the Department has responded to the request of which it has knowledge. See Seth Farber Reply Declaration dated November 16, 2018 at Ex. A. Plaintiff does not appear to claim that since its members received their ratable share assessments on or about October 15, 2018 that they have availed themselves of available procedures to challenge their ratable shares or contend that they have been arbitrarily calculated.

For the foregoing reasons, Defendants respectfully submit that their motion to dismiss should be granted and that the Amended Complaint should dismissed in its entirety.

Dated: New York, New York
November 16, 2018

Respectfully submitted,

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Appendix 1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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SPECGX, LLC,

Plaintiff,

v.

No. 18 CV 9830 (KPF)

BARBARA D. UNDERWOOD, in her official capacity as the Attorney General of the State of New York; and HOWARD A. ZUCKER, in his official capacity as Commissioner of Health of the State of New York,

Defendants.

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DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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Preliminary Statement

Defendants Barbara D. Underwood, as Attorney General of the State of New York and Howard A. Zucker, as Commissioner of the New York State Department of Health ("DOH") (collectively, the "Defendants"), submit this memorandum of law (1) in support of their motion to dismiss the Complaint ("Compl.") pursuant to Fed. R. Civ. P. 12(b)(1) and (6) for lack of subject matter jurisdiction and failure to state a claim upon which relief may be granted, and (2) in opposition to the motion for preliminary injunction brought by Plaintiff SpecGx, LLC ("Plaintiff").

Plaintiff, a generic pharmaceutical manufacturer, brings this 42 U.S.C. § 1983 action seeking judgment declaring unconstitutional and enjoining the enforcement of the recently enacted New York State legislation entitled "the Opioid Stewardship Act" ("the Act" or "OSA"). Plaintiff claims that the Act violates the Supremacy Clause of the Constitution because it conflicts with federal law, specifically the Food, Drug and Cosmetic Act ("FDCA") and the Drug Price Competition and Patent Term Restoration Act or "Hatch-Waxman Amendments" pertaining to generic pharmaceutical regulation. Plaintiff further claims that the Act violates the Commerce Clause as an illegal restraint on interstate commerce.

The Act, simply stated, functions as a tax. It imposes a surcharge upon pharmaceutical companies that sell or distribute opioids in New York State for the purpose of creating an Opioid Stewardship Fund that will provide for treatment, recovery, prevention and education programs to combat the growing epidemic of abuse of these drugs. The Act also contains a "pass-through prohibition" that enables DOH to impose penalties of up to $1 million "per incident" if those subject to the Act pass the surcharge to their customers and end users (including patients). Although plaintiff seeks to enjoin the Act in its entirety, the complaint in this case appears to be directed at the pass-through bar, rather than the surcharge itself or other provisions of the law.

As a law duly passed by the state legislature for the purpose of raising revenue to fund critically important public health programs, the Act, for all relevant purposes must be treated as a state taxing scheme. Moreover, the pass-through prohibition is an important part of the Act because it prevents companies from charging a portion of their surcharges back to the State-funded Medicaid program, which covers opioid medications, thereby undermining the revenue-raising purposes of the law. Consequently, the relief sought by Plaintiff in this action is barred by the Tax Injunction Act 28 U.S.C. § 1341 ("TIA"), which precludes federal lawsuits that interfere with state tax schemes. Similarly, principles of comity (which are broader than the TIA) bar plaintiff's challenge to the Act, including its imposition of penalties incident to the collection of revenue thereunder. Further, this Court should abstain under the *Pullman* doctrine from hearing this action, as it concerns a critical matter of State policy and New York courts have not yet had an opportunity to pass on the issues raised herein concerning the Act's interpretation.

As a further matter, plaintiff lacks standing to bring all or some of its claims. Although plaintiff's legal corporate address is in Missouri, it apparently maintains a large manufacturing operation in Hobart, New York (a fact not set forth in its papers). Hence, any sales or distributions that plaintiff makes from such facility to customers in New York, and thus are subject to the Act, will not take place in interstate commerce (or be subject to the Commerce Clause). To the extent that such facility sells its opioid products to out-of-state distributors, such transactions would then not be subject to the surcharge (much less to the pass-through penalty), as the surcharge is only imposed on the "first sale in New York." Further, plaintiff appears to be basing its Commerce Clause claim, at least in part, on purported injuries that would be suffered by consumers in other states if the pass-through prohibition is limited to New York purchasers – an injury it does not have standing to assert.

Additionally, plaintiff's challenge to the pass-through prohibition is not ripe for determination because that portion of the Act has not yet been applied to plaintiff, or any entity, nor could it be as the first payment of the surcharge is not due until January 1, 2019. Any imposition of penalties under the pass-through prohibition could not be imposed until a much later date, and such injury is plainly remote and speculative at this early stage.

Nor can plaintiff show that it is entitled to a preliminary injunction. As set forth above, plaintiff cannot demonstrate a probable success on the merits of its claims due to the threshold jurisdictional defenses applicable to this action, including the TIA, principles of comity, abstention, standing and ripeness. Moreover, because plaintiff's claimed injury arises solely from a potential loss of a revenue from a single product line, which likely amounts to a rounding error when compared with the plaintiff's entire revenues, its claims of imminent irreparable harm in the absence of injunctive relief are less than convincing. Finally, because the manifest purpose of the Act is to provide funding for critical health and education programs to address the opioid crisis, a balancing of the hardships as well as the public interest heavily favors denying plaintiff's motion for preliminary injunction.

The Opioid Stewardship Act

The New York State legislature passed the Act in 2018 in response to the opioid addiction crisis that is gripping the State (and the nation as a whole). It creates a fund of $600 million to be devoted to opioid treatment and education programs and thus to advance the protection of public health. The relevant legislation, codified at Public Health Law ("PHL") § 3323 and State Finance Law § 97-aaaaa, provides for the creation of an "Opioid Stewardship Fund" ("the Fund") to be financed by the collection of up to $100 million per year in surcharges from pharmaceutical manufacturers and distributors that sell or distribute opioid products in New

York ("the licensees"). The Act does not permit the surcharge to be passed directly on to patients or to end users. However, DOH has issued regulatory guidelines to the effect that this provision is not intended to penalize the licensees for recovering their operating costs in their overall pricing scheme.

The amount of the surcharge will be computed by DOH based upon reports filed by the licensees, and will represent each one's proportionate share of opioid sales in New York calculated so that the total surcharge will not exceed $100 million per year for six years. The first set of reports from the licensees were filed with DOH on or about August 1, 2018, DOH notified licensees of their preliminary ratable shares on October 15, 2018, and those licensees are required to make their first payments by January 1, 2019. As set forth in the Act, DOH may in its discretion issue penalties to licensees for failing to file reports, failing to make surcharge payments and/or for avoiding the surcharge by passing it on to end users such as patients.

Here, DOH has advised plaintiff that its estimated ratable share of the surcharge under the Act for 2019 is $1,256,326.33 (to be paid quarterly). Compl. at ¶¶ 42, 43.

STANDARD OF REVIEW

Pulse Creations, Inc. v. Vesture Group, Inc., 154 F.Supp.3d 48, 52-53 (S.D.N.Y. 2015), sets forth the standard for granting a Rule 12(b)(1) motion:

> [A] district court may properly dismiss a case for lack of subject matter jurisdiction under Rule 12(b)(1) if it lacks the statutory or constitutional power to adjudicate it." Aurecchione v. Schoolman Transp. Sys., Inc., 426 F.3d 635, 638 (2d Cir.2005) (internal quotation marks omitted); accord Sokolowski v. Metro. Transp. Auth., 723 F.3d 187, 190 (2d Cir.2013). A "plaintiff asserting subject matter jurisdiction has the burden of proving by a preponderance of the evidence that it exists." Makarova v. United States, 201 F.3d 110, 113 (2d Cir.2000).
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> [I]n resolving a Rule 12(b)(1) motion to dismiss, "[t]he court must take all facts alleged in the complaint as true and draw all reasonable inferences in favor of [the] plaintiff, but jurisdiction must be shown affirmatively, and that showing

> [may] not [be] made by drawing from the pleadings inferences favorable to the party asserting it." Morrison v. Nat'l Austl. Bank Ltd., 547 F.3d 167, 170 (2d Cir.2008) (internal citation and quotation marks omitted). Moreover, where subject matter jurisdiction is contested, a district court is permitted to consider evidence outside the pleadings, such as affidavits and exhibits. See Zappia Middle East Constr. Co. v. Emirate of Abu Dhabi, 215 F.3d 247, 253 (2d Cir.2000); accord Tandon v. Captain's Cove Marina of Bridgeport, Inc., 752 F.3d 239, 243 (2d Cir.2014).
>
> In deciding a motion to dismiss for failure to state a claim under Rule 12(b)(6):
>
> [a] court should "draw all reasonable inferences in [the plaintiff's] favor, assume all well-pleaded factual allegations to be true, and determine whether they plausibly give rise to an entitlement to relief." Faber v. Metro. Life Ins. Co., 648 F.3d 98, 104 (2d Cir.2011) (internal quotation marks omitted). Thus, "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)) . . . "[T]he tenet that a court must accept a complaint's allegations as true is inapplicable to threadbare recitals of a cause of action's elements, supported by mere conclusory statements." Id. at 663, 129 S.Ct. 1937.
>
> "In considering a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), a district court may consider the facts alleged in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint." DiFolco v. MSNBC Cable LLC, 622 F.3d 104, 111 (2d Cir.2010).

Pulse, 154 F.Supp.3d at 52-53.

Parties seeking a preliminary injunction must establish four elements to prevail on their motion: "(i) a likelihood of irreparable harm; (ii) either a likelihood of success on the merits or sufficiently serious questions as to the merits plus a balance of hardships that tips decidedly in their favor; (iii) that the balance of hardships tips in their favor regardless of the likelihood of success; and (iv) that an injunction is in the public interest. See Salinger v. Colting, 607 F.3d 68, 79–80 (2d Cir.2010); id. at 78 (noting that this standard defines "the traditional principles of equity" and should apply broadly across different contexts)." Marblegate Asset Mgt. v. Education Mft. Corp., 75 F.Supp.3d 592, 604 (S.D.N.Y. 2014).

Particularly because a preliminary injunction "is an extraordinary and drastic remedy," where (as here) a party seeks to enjoin a governmental regulation, it must demonstrate "a likelihood of success on the merits" to satisfy the second factor. Grand River Enterprise Six Nations, Ltd. v. Pryor, 481 F.3d 60, 66 (2d Cir. 2017) (internal quotation marks omitted).

ARGUMENT

I.

THIS ACTION IS PRECLUDED BY THRESHOLD JURISDICTIONAL DEFENSES INCLUDING THE TIA, COMITY PRINCIPLES, THE PULLMAN DOCTRINE, LACK OF STANDING AND RIPENESS

A. The Same Threshold Defenses Applicable to the Healthcare Distribution Alliance and The Association For Accessible Medicines Cases Apply Here

As the Court is aware, this is the third case recently brought challenging the Act. In the two prior cases, currently pending before this Court, the defendants have raised the same or very similar jurisdictional defenses (see Healthcare Distribution Alliance v. Zucker, Case No. 18-CV-6168, Docket # 44 at 4-25 and Association for Accessible Medicines v. Underwood, No. 18 CV 8180 (see Docket # 25 at 5-19)). Indeed, in Association for Accessible Medicines v. Underwood ("AAM"), Defendants briefed a number of arguments in moving to dismiss that are virtually the same as they assert here. In the interest of judicial economy, we respectfully refer the Court to that Memorandum (annexed hereto as "Appendix 1" for the Court's convenience), and supplement those arguments with matters specific to the plaintiff's claims in this action.

B. Plaintiff Lacks Standing to Bring a Commerce Clause Claim as an In-State Manufacturer Selling to New York Customers

Plaintiff's second and third counts (see Compl., ¶¶ 76-89) assert that the Act violates the Commerce Clause because the practical effect of the pass-through prohibition is to shift the direct burden of the applicable regulation to interstate commerce, "by externalizing the costs imposed by the OSA onto out-of-state purchasers." (Id., ¶ 80). This claim fails for two separate reasons. As discussed in our brief in AAM, as a manufacturer of pharmaceuticals, plaintiff lacks standing to assert claims on behalf of pharmaceutical customers because it does not represent them. Cf. L.A.M. Recovery, Inc. v. Department of Consumer Affairs, 184 Fed.Appx. 85, 88 (2d Cir. 2006) (dismissing Commerce Clause which"fail[ed] to satisfy the prudential standing requirement that [plaintiff] 'generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties'").

Moreover, to the extent plaintiff's manufacturing facilities are based in New York, it cannot bring a Commerce Clause challenge to a New York regulation that applies solely to its New York, thus intrastate, sales.

It is well-established that Article III standing requires, among other things, an *injury-in-fact,* which is a "concrete and particularized" harm to plaintiff's "legally protected interest." Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-1 (1992). Although plaintiff's papers do not disclose this fact, its principal manufacturing facility is located in Hobart, New York. (see Declaration of Seth Farber dated November 7, 2018, "Farber Decl." at ¶ 2, Exs. A-C, Declaration of Amir Bassiri dated November 7, 2018, "Bassiri Decl. at ¶ 7). Moreover, on its face the Act does not apply to opioid sales made by a New York manufacturer to distributors or purchasers located in other states (See Public Health Law §3233(5)(a) and (b)). Accordingly, any "injury" that plaintiff's New York facility would be subjected to as a result of the Act (*e.g.*, anything that would result in imposition of the opioid surcharge on it) would result *only* if it sold opioid products to a customer *in New York*, which is an entirely intra-state transaction.

In Coalition for Competitive Electricity, Dynergy, Inc. v. Zibelman, 906 F.3d 41 (2d Cir. 2018), affirming 272 F.Supp.3d 554 (S.D.N.Y. 2017), the Second Circuit held that to "to show standing for their dormant Commerce Clause claim, plaintiffs must demonstrate that their alleged injuries are traceable to (the "result of," or "a consequence of") discrimination against interstate commerce." Id., 906 F.2d at 41.

Here, to the extent that plaintiff manufactures its opioid products and sells them in New York State, it cannot assert a Commerce Clause injury based on such action because its injuries would not be traceable to its participation in interstate commerce (see Zibelman, 906 F.3d at 41). Perhaps in anticipation of such a standing problem, plaintiff tries to assert a claim based on its sale of opioids to an out-of-state distributor which then re-sells them into New York (see Plaintiff's Memorandum in Support of Preliminary Injunction, "P.I. Memo.," Docket # 8, at 12-13). Plaintiff asserts that it is harmed because the latter purportedly requires plaintiff to reimburse it for any surcharge for re-selling the product into New York. At the outset, Plaintiff in effect concedes that whether it sells its product directly to New York customers, or through an out-of-state distributor, the net effect is the same - - it pays the surcharge. However, inasmuch as plaintiff's intrastate and interstate transactions have the same outcome, the Act hardly discriminates against interstate commerce. Further, plaintiff's claimed injury due to the actions of a distributor is too remote to confer it standing, as it is "th[e] result [of] the independent action of some third party not before the court." Lujan, 504 U.S. at 560 (internal citation omitted). Moreover, as it is premature for any pass-through penalty to be imposed, and there is significant controversy as to what constitutes an "incident" within the meaning of the Act, such an injury is clearly not "actual or imminent" but "conjectural or hypothetical" at this point. Id.

Accordingly, Plaintiff lacks standing to bring its Commerce Clause claims.

II.

PLAINTIFF'S SUPREMACY CLAUSE CLAIM FAILS BECAUSE THE ACT IS NOT PREEMPTED BY THE HATCH WAXMAN AMENDMENTS OR OTHER FEDERAL LAW

Unlike the plaintiffs in the two prior cases, plaintiff here contends that the Act violates the Supremacy Clause because it is expressly or impliedly preempted by the language of the Hatch Waxman Amendments, which *generally* provide for regulation of generic pharmaceuticals. This claim is meritless because the federal laws raised by plaintiff concern patent issues, drug approvals, labelling and similar matters, and do not even address, let alone preclude, state governments from imposing taxes on generic drugs.

Under the Supremacy Clause, "State action may be foreclosed by express language in a congressional enactment, by implication from the depth and breadth of a congressional scheme that occupies the legislative field, or by implication because of a conflict with a congressional enactment." Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 541 (2001). Here, Plaintiff has not cited any portion of the FDCA or the Hatch Waxman Amendments that expressly forecloses New York from taxing opioid sales in order to raise revenue to fund public health and education programs that target the abuse of those medications. Plaintiff's reliance on In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 191 (2d Cir. 2006) for the proposition that "Congress enacted the Hatch-Waxman Amendments 'in order to accelerate the approval process for [*and availability of*] low-cost generic versions of established drugs'" (emphasis supplied), is unavailing. Tamoxifen was an anti-trust case, discussing the uncontroversial proposition that the Hatch-Waxman Amendments accelerated the federal approval process for generic pharmaceuticals. As the Act is simply a taxing measure, and does not in any way interfere with the federal approval process for generic drugs, that case is off the point.

In the absence of an express statutory preemption clause, conflict preemption may be implied "where it is impossible for a private party to comply with both state and federal requirements." English v. General Electric Co., 496 U.S. 72, 79 (1990). And field preemption occurs when Congress creates a regulatory scheme so pervasive in a particular subject area as to demonstrate that it "intends federal law to occupy the field." Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372 (2000). Here, Plaintiff contends (Compl. ¶ 69) that the Act "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of the Hatch-Waxman Amendments and is therefore preempted." See also P.I. Mem. at 16. Plaintiff's argument ostensibly is that requiring it to pay the opioid surcharge—a tax—is so inconvenient *to it*, based on *its* pricing and profit structure of its opioid products, that it would likely lose money on the sale of these products if it continued to sell them in New York.

In Marentette v. Abbott Laboratories, Inc., 886 F.3d 112, 117 (2d Cir. 2018), the Second held, with respect to "obstacle" preemption:

> The presumption against federal law preempting state law is particularly strong when Congress legislates in a field traditionally occupied by states. See Wyeth, 555 U.S. at 565, 129 S.Ct. 1187; In re MTBE, 725 F.3d at 96. In this context, the Court should only find preemption if the conflict between state law and federal policy is "a sharp one." Marsh v. Rosenbloom, 499 F.3d 165, 178 (2d Cir. 2007) (internal quotation marks and citation omitted). "[F]ederal law does not preempt state law under obstacle preemption analysis unless 'the repugnance or conflict is so direct and positive that the two acts cannot be reconciled or consistently stand together.' " In re MTBE, 725 F.3d at 102 (quoting Madeira v. Affordable Hous. Found.. Inc., 469 F.3d 219, 241 (2d Cir. 2006)). "[T]he purpose of Congress is the ultimate touchstone" of conflict preemption analysis. In re MTBE, 725 F.3d at 101 (quoting Wyeth, 555 U.S. at 565, 129 S.Ct. 1187).

When preemption is invoked to prevent a state or municipality from wielding its traditional police powers, congressional intent to displace that authority must be "'clear and manifest.'" California v. ARC Am. Corp., 490 U.S. 93, 101 (1989) (citation omitted). The Supreme Court has held that where "federal law is said to bar state action in fields of traditional state regulation ... we have worked on the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." De Buono v. NYSA-ILA Med. and Clinical Servs. Fund, 520 U.S. 806, 813 n.8 (1997) (citations and internal quotation marks omitted). See also New York v. F.E.R.C., 535 U.S. 1, 17-18 (2002) ("presumption against preemption" arises most often in deciding whether state authority conflicts with and is hence displaced by federal government authority); Cf., Canale v. Colgate Palmolive Co., 258 F.Supp.3d 312, 329 (S.D.N.Y. 2017) (when Congress *has* expressly manifested intent to preempt state law, no preemption against preemption arises; rather, courts focus on the plain wording of the relevant clause in legislation as the best evidence of Congress' preemptive intent, citing Chamber of Commerce of U.S. v. Whiting, 563 U.S. 582 (2011)).

As explained by the Supreme Court in determining whether a statute mandating the collection of taxes from health care providers was preempted by ERISA's language:

> [w]e begin by noting that the historic police powers of the State include the regulation of matters of health and safety. Hillsborough County v. Automated Medical Laboratories, Inc., 471 U.S. 707, 715 ... (1985). While the [statute at issue] is a revenue raising measure, rather than a regulation of hospitals, it clearly operates in a field that "'has been traditionally occupied by the States.'" Ibid. (quoting Jones v. Rath Packing Co., 430 U.S. 519, 525 ... (1977)). Respondents therefore bear the considerable burden of overcoming "the starting presumption that Congress does not intend to supplant state law." [New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 654 (1995)]
> ....

De Buono, 520 U.S. at 813-14 (footnote omitted). See also Richmond Boro Gun Club, Inc. v. City of New York, 97 F.3d 681, 687 (2d Cir. 1996) (presumption against federal preemption of state and local legislation "is especially strong in areas traditionally occupied by the states, such as health and safety measures") (citing English, 496 U.S. at 79).

Here, Plaintiff claims that the FDCA and Hatch Waxman Amendments express Congress's intent to provide inexpensive, generic pharmaceuticals to patients, and that the Act is an insurmountable "obstacle" to that end. However, the Act, by its own terms, is intended to generate revenue for opioid abuse public health and education programs, which is entirely consistent with another recently passed Congressional law. See Opioid Crisis Response Act of 2018. Furthermore, the Act, by its pass-through prohibition, expressly precludes manufacturers and distributors from increasing the prices for opioid products to their customers and ultimate users (including patients). Plaintiff offers the Court no express authority in the federal statute that the Act is preempted. At bottom, Plaintiff argues that anything that might interfere with *its own pricing structure and business model*, rather than an actual impediment to doing business (such as actual conflicting legal requirements) results in federal preemption. Plaintiff is incorrect.

In effect, Plaintiff confuses a general Congressional intent to provide affordable generic pharmaceutical products *to patients* with a specific intent to benefit the manufacturers and distributors of such products, such as itself, by exempting them from state taxation schemes that might reduce their profits. Plaintiff, however, has not overcome its "considerable burden" to show that this was Congressional intent, and accordingly, fails to establish its preemption or Supremacy Clause claim.

III.

PLAINTIFF FAILS TO MEET THE REQUIREMENTS FOR OBTAINING THE EXTRAORDINARY REMEDY OF A PRELIMINARY INJUNCTION

To establish entitlement to preliminary injunction, Plaintiff must establish "(i) a likelihood of irreparable harm; (ii) either a likelihood of success on the merits or sufficiently serious questions as to the merits plus a balance of hardships that tips decidedly in their favor; (iii) that the balance of hardships tips in their favor regardless of the likelihood of success; and (iv) that an injunction is in the public interest." Salinger, 607 F.3d at 79–80.

As set forth below, Plaintiff cannot make that showing, and therefore its motion for preliminary injunction should be denied. In the interest of judicial economy, because a number of the arguments raised by Plaintiff here in support of its motion for preliminary injunction are similar or identical to those raised by plaintiff in the related AAM case (see Docket # 26 at 4-13), we respectfully refer the Court to defendants' memorandum submitted in opposition to that motion (also annexed hereto as "Appendix 2" for the Court's convenience).

A. Plaintiff Does Not Have A Likelihood of Success on the Merits of its Claims

As discussed in Point I, supra, this action is barred by the TIA and/or principles of comity, the Court should abstain pursuant to the Pullman doctrine, Plaintiff's claims are barred by lack of ripeness or standing and Plaintiff has failed to set forth a claim for relief with respect to certain causes of action. For those reasons, Plaintiff cannot show probable success on the merits and therefore is not entitled to a preliminary injunction. Turley v. Giuliani, 86 F.Supp.2d 291, 295 (S.D.N.Y.2000) ("Because the violation of a constitutional right is the irreparable harm asserted here, the two prongs of the preliminary injunction threshold merge into one: in order to show irreparable injury, plaintiff must show a likelihood of success on the merits.")

National Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 110-2 (2d Cir 2001), is particularly instructive. There, lamp manufacturers claimed that Vermont's requirements for the labelling of mercury bulbs constituted a Commerce Clause violation because they would necessarily erode their profit margins. This is essentially the argument that plaintiff makes here: the Act will substantially reduce, if not eliminate their profits and thereby damage their ability to compete in interstate commerece. However, in Sorrell the Court observed that "manufacturers will rarely be able to fully pass through to consumers the costs of a new tax or regulation" and that any risk that such a requirement would "erode manufacturers' profits and thus encourage them to abandon the state is an appropriate consideration for the [state] legislature, not the federal courts." Id., 272 F.3d at 111-12 (vacating preliminary injunction). While Plaintiff in this case challenges the wisdom of the Act, and claims economic hardship, that is insufficient to establish probable success on the merits of the case.

B. Plaintiff Cannot show Imminent Irreparable Harm in the Absence of the Relief It Seeks

Plaintiff similarly fails to meet the key requirement for obtaining preliminary injunctive relief, i.e., that it faces imminent irreparable harm.

"[I]rreparable harm is the single most important prerequisite for the issuance of a preliminary injunction," thus, "the moving party must first demonstrate that such injury is likely before the other requirements for the issuance of an injunction will be considered." Freedom Holdings, Inc. v. Spitzer, 408 F.3d 112, 114 (2d Cir.2005) (internal quotation marks and citations omitted). Further, "[t]o satisfy the irreparable harm requirement, Plaintiffs must demonstrate that absent a preliminary injunction they will suffer 'an injury that is neither remote nor speculative, but actual and imminent,' and one that cannot be remedied 'if a court waits until the end of trial to resolve the harm.'" (id). Plaintiff cannot make that showing here.

Here Plaintiff argues, erroneously, that it will suffer irreparable harm (1) as a result of its alleged constitutional injuries ostensibly as a *per se* matter, and (2) it specifically contends that the potential loss of the New York market for its opioid products constitutes "irreparable harm." (P.I. Mem. at 23-24). Both of these propositions are erroneous. As to its constitutional injury claim, there mere assertions of a constitutional injury is insufficient to automatically trigger a finding of irreparable harm unless *both* a constitutional deprivation can be shown *and* the violation involves non-compensable injuries *in addition* to money damages. Smith v. Fredrico, No. 12-cv-4408 (ADS)(ETB), 2013 WL 122954 at *5-6 (E.D.N.Y. Jan. 8, 2013) citing Savage v. Gorski, 850 F.2d 64, 68 (2d Cir. 1988). The court in Smith held that "[w]here a plaintiff alleges a violation of his constitutional rights such a preliminary injunction for what is, 'at its core, a single plaintiff's claim for money damages, a preliminary injunction should not issue," 2013 WL 122954 at *5, citing Pinckney v. Bd. of Ed. of Wesbury Union Free Sch. Dist., 920 F.Supp. 393, 400 (E.D.N.Y. 1996).

Similarly baseless is plaintiff's claim that its loss of access to the New York market will be "irreparable." This argument appears predicated on the assumption that the Act flatly prohibits manufacturers and distributors from any "passing on" of their ratable shares, and that they will be penalized unless they bear the entire cost of the surcharge (see e.g., Compl. at ¶¶ 48, 56). However, there is considerable uncertainty regarding the circumstances under which the pass-through penalty may be imposed. Indeed, a plausible if not likely reading of the statute is that the anti pass-through provision only applies to purchasers of opioid medications used to compute the surcharge, since that is the focus of the Act (see PHL § 3323[c][2]: "No licensee shall pass the cost of their ratable share amount to a purchaser, including the ultimate user of the opioid") (emphasis supplied). See Matter of Anonymous v. Molik, 32 N.Y.3d 30, 37 (2018) (All parts of a statute are to be given effect and it must be construed as a whole).

Under that interpretation, plaintiff and other pharmaceutical manufacturers/distributors could distribute their ratable shares amongst all other drug purchasers (i.e., non-opioid sales), both in and outside New York, thereby minimizing if not rendering insignificant any purported economic harm or conflict with federal law. Hooper v. California, 155 U.S. 648 (1895) ("The elementary rule is that every reasonable construction must be resorted to in order to save a statute from unconstitutionality"). Cf. Freedom Holdings, Inc. v. Cuomo, 624 F.3d. 38, 66 (2d Cir. 2010) (rejecting claim that statutes had impermissible extraterritorial effect where "nothing prevents manufacturers from recouping increased costs imposed by New York law from New York consumers"). Brown & Williamson Tobacco Corp. v. Pataki, 320 F.3d 200, 212 (2d Cir. 2003) ("interstate commerce is not subjected to an impermissible burden simply because an otherwise valid regulation causes some business to shift from one interstate supplier to another") (quoting Exxon Corporation v. Maryland, 437 U.S. 117, 127 [1978]).

Consequently, plaintiff's claim that it automatically suffers irreparable harm based upon its mere allegation of a constitutional violation falls short. Cf. Latino Officers Assoc. v. Safir, 170 F.3d 167, 171 (2d. Cir. 1999) (A merely theoretical or conjectural First Amendment injury is "not sufficient to establish real and imminent irreparable harm"). See also Smith, Sorrell, supra.

Indeed, even if the pass-through bar eventually results in a limited loss of a line of products in one state's market for plaintiff - - a company with between $500 million and $1 billion in sales that is in turn a subsidiary of a Fortune 500 multinational corporation with sales of several billion dollars (see Farber Decl., at ¶ 2, Exs. D-E) - - that is not a showing of imminent, irreparable harm. Further, as discussed in our prior motion papers, whether this provision is given such a broad interpretation as to have that consequence, or may be narrowed in order to avoid constitutional issues, is a matter that should be resolved initially by the state courts, under the Pullman abstention doctrine.

In Symquest Group, Inc. v. Canon U.S.A., Inc., No, 15-cv-4200 (LDW)(SIL), 2015 WL 6813599 at *6-*7 (E.D.N.Y. Aug. 7, 2015), the Court held that:

> A movant may establish irreparable harm by making a clear showing that it will suffer a "loss of reputation, goodwill, and business opportunities...." Register.com, Inc. v. Verio, Inc., 356 F.3d 393, 404 (2d Cir.2004).
>
> However, when "the facts demonstrate no loss of goodwill, but only provable monetary damages from the loss of a profitable line of business," a movant is unable to establish irreparable harm. Tom Doherty Assocs., Inc., 60 F.3d at 37 (citing Jack Kahn Music Co. v. Baldwin Piano & Organ Co., 604 F.2d 755, 763 (2d Cir.1979)) (internal citation omitted); see also Fox Ins. Co. v. Envision Pharmaceutical Holdings, Inc., No. 09–cv–237, 2009 WL 790312, at *7 (E.D.N.Y. Mar.23, 2009) ("[T]here is no irreparable harm where the loss of goodwill is doubtful and the loss of a profitable line of business is compensable by monetary damages.").
>
> Courts have also found irreparable harm "where the applicant for a preliminary injunction is threatened with the loss of a product that 'is essential to the life of [its] business.' " Envt'l Servs ., Inc. v. Recycle Green Servs., Inc., 7 F.Supp.3d 260, 279 (E.D.N.Y.2014) (quoting Tom Doherty Assocs., Inc., 60 F.3d at 37). Nevertheless, the loss of a product or service that is neither unique nor irreplaceable does not constitute irreparable harm. See Smith v. Fedrico, No. 12–cv–4408, 2013 WL 122954, at *4 (E.D.N.Y. Jan.8, 2013) (denying preliminary injunction where there was "no evidence that [the products] at issue are in anyway unique or irreplaceable").

At bottom, Plaintiff claims that one of many product lines it offers for sale in New York may prove unprofitable as a result of the Act, and hence, it may have to cease selling them in New York. Simply put, while potentially inconvenient to Plaintiff (and to its multinational corporate parent) this simply does not constitute irreparable harm. See Rex Medical L.P. v.

Angiotech Pharmaceuticals, Inc., 754 F.Supp. 2d 616, 621 (S.D.N.Y. 2010) ("a party seeking a preliminary injunction must show evidence of damage that cannot be rectified by financial compensation," quoting Tucker Anthony Realty Corp. v. Schlesinger, 888 F.2d 969, 975 (2d Cir. 1989)); see also Smith, Sorrell, supra. Absent a showing of irreparable harm, Plaintiff's motion for preliminary injunction should be denied.

C. Plaintiff Cannot Show that the Balance of Hardships Tilts in Favor of the Injunction or that the Injunction Will Further the Public Interest

Plaintiff also argues (P.I. Mem., 24-25), without merit, that it will suffer irreparable harm from operation of the Act, whereas Defendants will *no* injury from the injunction (because the Act is allegedly unconstitutional).

The Act, however, is intended to fund critically needed opioid treatment and education services. Plaintiff cannot reasonably dispute the value of such programs. Moreover, the pass-through prohibition is an important part of the legislative scheme, as its purpose is to secure compliance with and protect the Act's funding provisions. Under these circumstances, Plaintiff's contention that the Defendants (and the people of New York) will suffer no injury if the Act in its entirety is enjoined is clearly erroneous, and its motion for preliminary injunction falters for that reason as well.

Similarly, plaintiff cannot show that the injunction will further the public interest. Plaintiff's contention that enjoining the Act will further the public interest is based on a highly speculative contention that it will undermine the ability of Plaintiff and other pharmaceutical manufacturers and distributors to supply generic opioids to the New York market, and that this will result in reduced availability of such products (P.I. Mem., 25).

In contrast to plaintiff's claims, granting its requested injunction would suspend the funding for critically needed opioid treatment and education services, a result that is not based on speculation but the inevitable result of enjoining the Act. Indeed, although plaintiff's case is essentially against the pass-through prohibition, the injunction it seeks would prohibit any enforcement of the statute's terms against plaintiff, including collection of the surcharge itself, notwithstanding the existence of a severability clause in the statute (at § 4 of the Act) (See plaintiff's Proposed Order Granting Preliminary Injunction). Thus, plaintiff seeks relief that would bar the state from obtaining over one million dollars in funding for these vital programs, even if plaintiffs were able to pass down all, or some of that cost to purchasers, and thereby suffer no economic harm at all. Plaintiff utterly fails to establish that the public interest would be served if its motion were to be granted.

CONCLUSION

For the foregoing reasons, the Defendants respectfully request that the Complaint be dismissed in its entirety and the motion for preliminary injunction denied in all respects.

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Respectfully submitted,
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