

APPENDICES

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APPENDIX A

**UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT**

Nos. 19-183-cv(L), 19-199-cv(CON), 19-201-cv(CON)

ASSOCIATION FOR ACCESSIBLE MEDICINES,
HEALTHCARE DISTRIBUTION ALLIANCE,
SPECGX LLC,

Plaintiffs-Appellees,

v.

LETITIA JAMES, IN HER OFFICIAL CAPACITY AS
ATTORNEY GENERAL OF THE STATE OF NEW
YORK, HOWARD A. ZUCKER, IN HIS OFFICIAL
CAPACITY AS COMMISSIONER OF HEALTH OF
THE STATE OF NEW YORK,

Defendants-Appellants.

Before: CABRANES and LOHIER, *Circuit
Judges*, and REISS, *District Judge*.*

LOHIER, *Circuit Judge*:

To address the substantial costs imposed by the national opioid public health crisis as it struck New York, the New York State Legislature enacted the Opioid Stewardship Act (OSA). See 2018 N.Y. Sess. Laws,

* Judge Christina Reiss, of the United States District Court for the District of Vermont, sitting by designation.

ch. 57, pt. NN (codified at N.Y. Pub. Health Law § 3323 and N.Y. State Fin. Law § 97-aaaaa). Part of the Act requires opioid manufacturers and distributors to pay an annual “opioid stewardship payment.” The proceeds must be used to support statewide programs that provide opioid treatment, recovery, prevention, and education services. Another part of the Act, known as the “pass-through prohibition,” bars manufacturers and distributors of opioids from passing the costs of the opioid stewardship payment through to their customers.

Healthcare Distribution Alliance (HDA) and Association for Accessible Medicines (AAM) are trade associations that represent manufacturers and distributors of pharmaceutical products, including opioids, while SpecGx develops, manufactures, and sells opioids. The three plaintiffs filed separate actions challenging the OSA and seeking declaratory and injunctive relief against the New York Attorney General and the New York Commissioner of Health in their official capacities (collectively “New York”). In a consolidated decision, the United States District Court for the Southern District of New York (Failla, J.) concluded that the OSA’s pass-through prohibition violated the dormant Commerce Clause. After determining that the prohibition was not severable from the rest of the Act, the District Court invalidated the Act in its entirety.

The New York State Legislature subsequently amended the OSA so that its provisions expired in December 2018. See 2019 N.Y. Sess. Laws ch. 59, pt. XX, § 5. It then enacted a new payment mandate, effective July 2019, that does not include a pass-through prohibition. See 2019 N.Y. Sess. Laws ch. 59, pt. XX (codified at N.Y. Tax Law § § 497–99) (the “2019 Act”). In light of this legislative development, the State has elected not to seek reversal of the District Court’s invalidation

of the pass-through prohibition. On appeal, therefore, New York asks us only to reverse the District Court's invalidation of the remainder of the Act, including the opioid stewardship payment requirement. We conclude that the payment is a tax within the meaning of the Tax Injunction Act (TIA), 28 U.S.C. § 1341, thus depriving the District Court of subject matter jurisdiction to adjudicate the plaintiffs' challenges to the payment. We therefore **REVERSE** the judgment of the District Court insofar as it invalidated the stewardship payment and the remainder of the Act, with the exception of the pass-through prohibition, the legality of which is not before us on appeal.

BACKGROUND

Opioids are a class of drugs that include prescription pain relievers, synthetic opioids like fentanyl, and heroin. While prescription opioid medications can treat and manage pain when properly prescribed by a physician, they also pose serious risks of addiction and abuse. Starting in 1999, the United States experienced a rapid rise in prescription opioid overdose deaths, followed by spikes in heroin and synthetic opioid overdose deaths. The death toll was accompanied by steep economic costs estimated to total \$78.5 billion each year. In 2017 the United States Department of Health and Human Services declared the opioid epidemic a nationwide public health emergency.¹ That same year,

¹ These background facts about opioids and the national opioid epidemic are taken from the Centers for Disease Control and Prevention, the National Institute on Drug Abuse, and the Department of Health and Human Services. See Ctrs. for Disease Control and Prevention, *Opioid Basics*, <https://www.cdc.gov/drugoverdose/opioids> (last updated Mar. 19, 2020); Nat'l Inst. on Drug Abuse, Opioid Overdose Crisis, <https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis> (last updated May 27, 2020);

the New York State Department of Health reported that the rate of overdose deaths involving opioids in New York had doubled between 2010 and 2015.² The associated financial cost to New York of addressing the opioid crisis was over \$200 million in 2017 alone—a twofold increase from the amount spent in 2011.

The New York State Legislature enacted the OSA to raise \$600 million over six years to address the costs of dealing with the crisis. See N.Y. Pub. Health Law § 3323(3); N.Y. State Fin. Law § 97-aaaaa(4); 2018 N.Y. Sess. Laws, ch. 57, pt. NN, § 5. The OSA thus imposes an annual fixed \$100 million “opioid stewardship payment” collectively on all licensed opioid manufacturers and distributors that sell or distribute opioids in the State (“licensees”). N.Y. Pub. Health Law § 3323(2)-(3). Each licensee is responsible for paying a portion of the \$100 million total based on its market share of opioid sales in New York. Id. § 3323(5). The Department of Health, which collects the funds, annually calculates the amount of each licensee’s payment based on reported opioid sales from the previous year. Id. § 3323(4)–(6). Based on 2017 reports, the Department determined that 97 licensees owed stewardship payments in 2018.³

U.S. Dep’t of Health and Human Servs., What is the U.S. Opioid Epidemic?, <https://www.hhs.gov/opioids/about-the-epidemic> (last updated Sept. 4, 2019); see also Fed. R. Evid. 201(b)(2).

² N.Y. State Dep’t of Health, Opioid Annual Report 8 (Oct. 2017), available at https://health.ny.gov/statistics/opioid/data/pdf/nys_opioid_annual_report_2017.pdf (last visited June 26, 2020); see Fed. R. Evid. 201(b)(2).

³ The 2019 Act amended the OSA to provide that the OSA will apply only to opioid sales on or before December 31, 2018. 2019 N.Y. Sess. Laws ch. 59, pt. XX, § 5. Sales after that date are subject to the new assessment. Id. § 6.

The revenues from the opioid stewardship payments are deposited into the “opioid stewardship fund,” a special revenue fund established in the joint custody of the State Comptroller and the Commissioner of Taxation and Finance. *Id.* § 3323(2); N.Y. State Fin. Law § 97-aaaaa(1). New York law requires that “[m]oneys in [the] opioid stewardship fund shall be kept separate and shall not be commingled with” New York State’s general fund or “any other moneys” in the custody of the Comptroller or the Commissioner. N.Y. State Fin. Law § 97-aaaaa(2). New York law also strictly limits how money in the sequestered fund can be used. It may only support programs sanctioned by the State Office of Alcoholism and Substance Abuse Services (OASAS)⁴ to “provide opioid treatment, recovery and prevention and education services,” and to “provide support for the prescription monitoring program registry” that doctors must consult before prescribing opioids and certain other controlled substances. *See id.* § 97-aaaaa(4); N.Y. Pub. Health Law § 3343-a(2); *see also id.* § 3306.

The OSA contains two other provisions of significance to our resolution of this appeal. First, it has a “pass-through prohibition” that bars licensees from passing the costs of their opioid stewardship payments on to purchasers, including the ultimate consumers of opioids. *Id.* § 3323(2). Licensees that violate the Act’s pass-through prohibition are subject to a penalty of up to \$1 million for each violation. *Id.* § 3323(10)(c). Second, the Legislature added a severability clause, which provides that the invalidation of any part of the Act will not “affect, impair, or invalidate” the remainder of the Act. 2018 N.Y. Sess. Laws, ch. 57, pt. NN, § 4 (“If any . . . section of this act shall be adjudged by any

⁴ In 2019 OASAS changed its name to the Office of Addiction Services and Supports.

court . . . to be invalid, such judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the . . . section directly involved in the controversy in which such judgment shall have been rendered. It is hereby declared to be the intent of the legislature that this act would have been enacted even if such invalid provisions had not been included herein.”).

HDA and SpecGx challenged both the opioid stewardship payment and the pass-through prohibition, while AAM challenged only the pass-through prohibition. As relevant here, the plaintiffs argued that the pass-through prohibition violates the dormant Commerce Clause. HDA moved for summary judgment of its claims, while AAM and SpecGx both moved for preliminary injunctions. New York moved to dismiss each case on jurisdictional grounds, arguing, as relevant here, that the TIA, 28 U.S.C. § 1341, barred the District Court from hearing the plaintiffs’ claims because the opioid stewardship payment is a tax. New York also defended both the stewardship payment and the pass-through prohibition on the merits.

In a consolidated Opinion and Order, the District Court denied New York’s motions to dismiss, granted HDA’s motion for summary judgment, and granted AAM’s and SpecGx’s motions for preliminary injunctions. The District Court concluded that the TIA did not apply to plaintiffs’ claims because neither the opioid stewardship payment nor the pass-through prohibition is a tax that triggers the TIA. The District Court also concluded that the separate pass-through prohibition violates the dormant Commerce Clause. Relying on the legislative history rather than the text of the OSA, the District Court held that the stewardship payment requirement could not survive without the pass-through prohibition. Accordingly, the District

Court declared the OSA invalid in its entirety and enjoined its enforcement.⁵

This appeal followed.

DISCUSSION

On appeal, New York asks us to reverse the District Court's invalidation of the OSA, including the opioid stewardship payment, but it no longer defends the pass-through prohibition. The validity of the pass-through prohibition thus is not before us on appeal. The only remaining issue is whether the District Court lacked jurisdiction to invalidate or enjoin the State's collection of the opioid stewardship payment because the payment is a tax within the meaning of the TIA, as opposed to a regulatory fee or a punitive fine. We conclude that it is a tax and that the District Court should have dismissed the challenges to the payment requirement for lack of subject matter jurisdiction. Because New York does not challenge the District Court's invalidation of the pass-through prohibition, we need not and do not address whether the prohibition is severable.

⁵ The District Court entered various orders and judgments from which New York appeals: a December 19, 2018 Opinion and Order denying New York's motion to dismiss, granting HDA's motion for summary judgment, and granting AAM's and SpecGx's motions for preliminary injunctive relief; a December 19, 2018 Judgment to the same effect; a December 21, 2018 Amended Judgment entered at HDA's request, expressly stating the declaratory and permanent injunctive relief granted to HDA; and a January 2, 2019 Order Granting Injunction entered at AAM and SpecGx's request. The AAM and SpecGx actions are stayed pending this appeal.

I

The TIA provides that “[t]he 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.” 28 U.S.C. § 1341. It “prohibits declaratory as well as injunctive relief.” California v. Grace Brethren Church, 457 U.S. 393, 411 (1982). The statute “has its roots in equity practice, in principles of federalism, and in recognition of the imperative need of a State to administer its own fiscal operations.” Franchise Tax Bd. V. Alcan Aluminium Ltd., 493 U.S. 331, 338 (1990) (quotation marks omitted). Congress intended the TIA “first and foremost [as] a vehicle to limit drastically federal district court jurisdiction to interfere with so important a local concern as the collection of taxes.” Id. (quotation marks omitted).

“Two conditions must be satisfied to invoke the protection of the TIA: first, the surcharges must constitute ‘taxes,’ and second, the state remedies available to plaintiffs must be ‘plain, speedy and efficient.’” Travelers Ins. Co. v. Cuomo, 14 F.3d 708, 713 (2d Cir. 1993) (footnote omitted), rev’d on other grounds sub nom. N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645 (1995). The parties do not dispute the sufficiency of state remedies, and “[t]he Supreme Court has previously determined in other litigation related to the TIA that New York does provide ‘plain, speedy and efficient’ forums for individuals to bring constitutional challenges to its tax laws.” Abuzaid v. Mattox, 726 F.3d 311, 316 (2d Cir. 2013) (citing Tully v. Griffin, Inc., 429 U.S. 68, 76–77 (1976)). So we turn immediately to whether the opioid

stewardship payment is a “tax,”⁶ a question that we review *de novo*. See Luessenhop v. Clinton County, 466 F.3d 259, 264 (2d Cir. 2006).

A

“Although there is no bright line between assessments that are taxes and those that are not, most courts agree that [a]ssessments which are imposed primarily for revenue-raising purposes are ‘taxes,’ while levies assessed for regulatory or punitive purposes, even though they may also raise revenues, are generally not ‘taxes.’” Travelers, 14 F.3d at 713 (quotation marks omitted).

In San Juan Cellular Telephone Co. v. Public Service Commission, the First Circuit devised a three-factor test, which we have cited with approval, for distinguishing taxes from regulatory fees.⁷ See 967 F.2d

⁶ The plaintiffs maintain that the TIA did not deprive the District Court of jurisdiction even if the stewardship payment is a tax because the District Court’s invalidation of the stewardship payment requirement flowed entirely from its severability and constitutional analyses of the pass-through prohibition. But the TIA plainly bars federal courts from “enjoin[ing], suspend[ing] or restrain[ing] the assessment, levy or collection of any tax under State law” so long as state remedies are adequate. 28 U.S.C. § 1341. Thus, if the stewardship payment is a tax, then the District Court should have dismissed all of the plaintiffs’ challenges to the opioid stewardship payment—including on severability grounds—because plaintiffs’ claims are barred by the TIA.

⁷ Several sister circuits have adopted the San Juan Cellular factors in analyzing whether an assessment is a tax within the meaning of the TIA. See Hill v. Kemp, 478 F.3d 1236, 1245-46 (10th Cir. 2007) (Gorsuch, J.); Hedgepeth v. Tennessee, 215 F.3d 608, 612 (6th Cir. 2000); Valero Terrestrial Corp. v. Caffrey, 205 F.3d 130, 134 (4th Cir. 2000); Home Builders Ass’n of Miss., Inc. v. City of Madison, 143 F.3d 1006, 1011 & n. 14-15 (5th Cir. 1998); Bidart Bros. v. Cal. Apple Comm’n, 73 F.3d 925, 931-33 (9th Cir. 1996).

683, 685 (1st Cir. 1992) (Breyer, C.J.); see also Entergy Nuclear Vt. Yankee, LLC v. Shumlin, 737 F.3d 228, 232–33 (2d Cir. 2013) (citing San Juan Cellular with approval); Travelers, 14 F.3d at 713 (same). The three factors are: (1) the nature of the entity imposing the assessment, (2) the population subject to the assessment, and (3) the ultimate allocation or use of the revenues generated by the assessment. See Entergy, 737 F.3d at 232–33. To put these factors in context, the First Circuit helpfully described “a spectrum with a paradigmatic tax at one end and a paradigmatic fee at the other”:

The classic “tax” is imposed by a legislature upon many, or all, citizens. It raises money, contributed to a general fund, and spent for the benefit of the entire community. . . . The classic “regulatory fee” is imposed by an agency upon those subject to its regulation. . . .

It may serve regulatory purposes directly by, for example, deliberately discouraging particular conduct by making it more expensive. . . .

Or, it may serve such purposes indirectly by, for example, raising money placed in a special fund to help defray the agency’s regulation-related expenses.

San Juan Cellular, 967 F.2d at 685.

In Entergy, we focused largely on the third San Juan Cellular factor. See Entergy, 737 F.3d at 232–33 (discussing the other two factors with approval but finding it unnecessary to adopt them at the time). Our sister circuits appear to agree that this factor is the most significant. See Hill v. Kemp, 478 F.3d 1236, 1245 (10th Cir. 2007) (Gorsuch, J.) (“[T]he critical inquiry focuses on the purpose of the assessment and the ultimate use of funds.” (quotation marks omitted)); Hedgepeth v. Tennessee, 215 F.3d 608, 612 (6th Cir. 2000)

(describing the revenue’s ultimate use as “the predominant factor” (quotation marks omitted)); Collins Holding Corp. v. Jasper County, 123 F.3d 797, 800 (4th Cir. 1997) explaining that “the heart of the [TIA] inquiry centers on function, requiring an analysis of the purpose and ultimate use of the assessment”); San Juan Cellular, 967 F.2d at 685 (noting that courts “have tended . . . to emphasize the revenue’s ultimate use” in cases falling in the middle of the tax–regulatory fee spectrum).

“[T]he principal identifying characteristic of a tax, as opposed to some other form of state-imposed financial obligation,” therefore, “is whether the imposition serve[s] general revenue-raising purposes,” which “in turn depends on the disposition of the funds raised.” Entergy, 737 F.3d at 231 (quotation marks omitted); see id. at 232 (“[C]ourts applying the San Juan factors . . . have . . . concluded that whether the purported tax is directed to general public purposes is the most salient factor in the decisional mix.” (quotation marks omitted)). If the “revenue’s ultimate use” is to “provide[] a general benefit to the public, of a sort often financed by a general tax,” then the imposition is likely to be a tax. Id. at 232 (quoting San Juan Cellular, 967 F.2d at 685). By contrast, if the funds are allocated to “provide[] more narrow benefits to regulated companies or defray[] [an] agency’s costs of regulation,” the assessment is more likely to be seen as a regulatory fee that does not implicate the TIA. Id. (quoting San Juan Cellular, 967 F.2d at 685).

B

As we have described, faced with rising costs associated with mounting statewide opioid addiction and opioid-related deaths, the State Legislature crafted the opioid stewardship payment to raise \$600 million to re-

spond to the State's public health crisis. New York's allocation of revenues from the payment thus strongly suggests that the stewardship payment requirement serves general revenue-raising purposes without a regulatory or punitive aim.

Funds from the stewardship payment are statutorily directed to support programs that are operated or authorized by OASAS "to provide opioid treatment, recovery and prevention and education services" and to support the State's prescription monitoring program registry. N.Y. State Fin. Law § 97- aaaaa(4). Both the OASAS programs and the registry reflect broad public health initiatives that undoubtedly provide a "general benefit" to New York residents "of a sort often financed by a general tax." Entergy, 737 F.3d at 232 (quotation marks omitted); see, e.g., N.Y. Tax Law § 482(b); N.Y. Pub. Health Law § 2807-v (funding public health programs with the proceeds from New York's cigarette excise tax).

The OSA also effectively bars using any revenue generated from the stewardship payment to deliver "narrow benefits" to opioid manufacturers and distributors. Entergy, 737 F.3d at 232 (quotation marks omitted); cf. Bidart Bros. v. Cal. Apple Comm'n, 73 F.3d 925, 927 (9th Cir. 1996) (holding that an assessment imposed on apple producers was not a tax where proceeds were "used predominantly to promote the sale of . . . apples"). The revenue generated from the stewardship payment also does not "defray" the Department of Health's "costs of regulat[ing]" manufacturers and distributors. Entergy, 737 F.3d at 232 (quotation marks omitted); cf. Gov't Suppliers Consolidating Servs., Inc. v. Bayh, 975 F.2d 1267, 1271 n.2 (7th Cir. 1992) (holding that fees imposed on waste-hauling trucks were not taxes because the proceeds were used for the "regulatory" purpose of "implement[ing] the waste disposal

regulatory system to which registrants are subject”). For example, the proceeds from the stewardship payment cannot be diverted to cover the agency’s costs of licensing opioid manufacturers and distributors; those costs are paid pursuant to a regulatory scheme funded by an entirely separate assessment authorized under New York’s Public Health Law. See N.Y. Pub. Health Law § 3310 (imposing a fee for a license to manufacture or distribute controlled substances in the State).

Consideration of the other two San Juan Cellular factors only reinforces the view that the opioid stewardship payment is a tax. “The first of these additional factors, the nature of the entity imposing the charge, cuts strongly in favor of classifying the [stewardship payment] as a tax.” Entergy, 737 F.3d at 232. The payment was clearly imposed by the Legislature, which wields the taxing power, and not by a “limited-purpose” agency.⁸ Id. The agency appears to have played little substantive role in imposing it.

The plaintiffs argue that the remaining factor cited in San Juan Cellular, the population subject to the charge, suggests that the stewardship payment is not a tax because it falls on a narrow set of only 97 companies. But this argument, like the plaintiff’s failed argument in Entergy, is “too simplistic” insofar as it asks us to just tally the number of entities subject to an assessment. Id. at 233. With respect to this factor, our task is to consider whether “[t]he category of persons or

⁸ We note that the District Court mistakenly believed that the Department of Health imposed the payment. Special App’x 24. In fact, however, the Department of Health only collects the annual \$100 million payment; the Legislature imposed the payment and determined how it would be apportioned among licensees. N.Y. Pub. Health Law § 3323(3), (5); see also Hedgepeth, 215 F.3d at 610, 612.

entities subject to [a] tax[] is defined by general and open-ended criteria, even if only a few entities, or one entity alone, are subject to the tax.” Id. When viewed properly in that light, the population subject to the stewardship payment consists of “[a]ll manufacturers and distributors . . . that sell or distribute opioids in the state of New York.” N.Y. Pub. Health Law § 3323(2). So defined, the category is broad and general enough to qualify the payment at issue in this appeal as a tax.

II

A

Urging a contrary conclusion, the plaintiffs insist that the payment is a regulatory fee, not a tax, because the public health programs supported by the payment serve “not a general revenue-raising purpose” but a “narrow” and “specific one.” HDA Br. 29 (emphases in original); see id. at 35 (contrasting purportedly “narrow” industry-related programs funded by the opioid stewardship fund” with the “lengthy catalogue of general public health programs” funded by the New York cigarette excise tax). They claim that the specific purpose of the programs is to “defray[] . . . expenses associated with regulating the opioid supply chain as well as . . . expenses for mitigating externalities associated with that supply chain.” Id. at 30.

But the public health programs that the stewardship payment funds “relate directly to the general welfare of the citizens of [New York,] and the assessments to fund them are no less general revenue raising levies simply because they are dedicated to a particular aspect of the commonwealth.” Hedgepeth, 215 F.3d at 613 (quotation marks omitted); see id. at 612–13 (holding that a disabled parking placard fee was a tax even though its proceeds went primarily to the state’s high-

way fund). In New York, the statewide OASAS programs benefit the broader New York population through “prevention and education services,” as well as New Yorkers struggling with opioid addiction. N.Y. State Fin. Law § 97-aaaaa(4). The prescription monitoring program registry similarly extends well beyond the opioid crisis to include several categories of non-opioid controlled substances that have debilitated countless New Yorkers. N.Y. Pub. Health Law § 3343-a(1), (2); id. § 3306.

Moreover, the assessment would be a tax even if it helped to alleviate only the social and other costs to New Yorkers caused by the sale and manufacture of opioids by the assessed entities. “[T]axes imposed on industries believed to impose unusual costs on the state or its residents”—like the opioid manufacturers and distributors subject to the OSA—“are common, and are unquestionably taxes.” Entergy, 737 F.3d at 233 n.2; see also Home Builders Ass’n of Miss., Inc. v. City of Madison, 143 F.3d 1006, 1012 (5th Cir. 1998) (reasoning that a building permit fee imposed on residential builders was a tax because it raised revenue to maintain public services strained by rapid residential development).

Directing us to Entergy, the plaintiffs separately contend that the deposit of the opioid stewardship payment proceeds in a “special revenue” fund, rather than in New York’s general fund, cuts strongly against recognizing the payment as a tax. They point to our assertion in Entergy that “[i]f the proceeds [of a measure] are deposited into the state’s general fund (rather than directly allocated to the agency that administers the collection, for the purpose of providing a narrow benefit to or offsetting costs for the agency), the imposition will generally be seen as serving the general benefit of the state, and thus as a tax.” Entergy, 737 F.3d at 231; see

also Travelers, 14 F.3d at 713 (concluding that surcharges imposed on health insurers were taxes because they were “paid into the State’s general fund”).

But Entergy does not suggest the converse, namely, that depositing the proceeds of an assessment in a special fund invariably cuts against finding that the assessment is a tax. Determining whether proceeds are held in the general fund or a special revenue fund does not end our inquiry. In Entergy, we used a more functional approach, contrasting proceeds deposited in a State’s general fund with those proceeds that are “directly allocated to the agency that administers the collection, for the purpose of providing a narrow benefit to or offsetting costs for the agency.” Entergy, 737 F.3d at 231. In Valero Terrestrial Co. v. Caffrey, the Fourth Circuit adopted a similarly flexible, functional approach that considers whether revenue that “is placed in a special fund . . . is used to benefit regulated entities, . . . to defray the cost of regulation (making it resemble a ‘fee’) or else to benefit the general public.” See 205 F.3d 130, 135 (4th Cir. 2000) (quotation marks omitted). In line with this approach, we consider the nature of the fund, and how the money in the fund is ultimately used, to determine if the fund holds the proceeds of a tax.

Recall that the proceeds from the opioid stewardship payment are deposited in a separate, “special revenue” account in the state treasury. See N.Y. State Fin. Law § 97-aaaaa(1). The New York State Finance Law defines “special revenue funds” as “[f]unds which are used to account for the proceeds of specific sources that are specifically restricted by law from being deposited in the general fund of the state.” See N.Y. State Fin. Law § 2. The Commissioner of the Department of Taxation and Finance and the Comptroller alone share custody over the account and exercise significant con-

trol over the funds in the opioid stewardship account. The proceeds are not “directly allocated” to any agency, let alone to the Department of Health, “the agency that administers the collection” of the stewardship payment. Entergy, 737 F.3d at 231. And any money that is paid out of the fund is used primarily to support the work of OASAS in its opioid-related public health initiatives for the benefit of the public at large. As noted, none of the funds from the account offset the Department of Health’s regulatory costs or benefit regulated entities. The only Department of Health program that the funds can support is the prescription monitoring program registry.

We agree with a number of our sister circuits that “even assessments that are segregated from general revenues” may be taxes “under the TIA if expended to provide a general benefit to the public.” Bidart Bros., 73 F.3d at 932 (quotation marks omitted); see also Hill, 478 F.3d at 1244–45; Am. Landfill, Inc. v. Stark/ Tuscarawas/Wayne Joint Solid Waste Mgmt. Dist., 166 F.3d 835, 839 (6th Cir. 1999) (holding that a solid waste disposal assessment was a tax because, although the proceeds were “placed in a fund . . . separate from the general fund, [they] serve[d] public purposes benefiting the entire community”). Indeed, any number of reasons might spur a legislature to place specific tax revenues in an account that is separate from the general fund. The Seventh Circuit has said, for example, that separate accounts may be “created to hold revenues generated by specific taxes, in order to avoid annual appropriations battles.” Empress Casino Joliet Corp. v. Balmoral Racing Club, Inc., 651 F.3d 722, 730 (7th Cir. 2011) (en banc). In short, that the proceeds of the opioid stewardship payment are deposited in a special fund rather than the State’s general fund in this

case does not mean that the payment is a regulatory fee rather than a tax.

We now turn to the remaining Entergy factors. Although the designation to the general treasury of the tax in Entergy was the “principal” characteristic supporting its status as a tax, Entergy, 737 F.3d at 233, we also observed that the statute imposing the tax (1) directed that its proceeds be paid to the Commissioner of the Department of Taxes, (2) did not reserve its proceeds for any particular purpose, and (3) labeled it a “tax,” id. at 231.

The plaintiffs claim that all three of these remaining factors weigh against recognizing the stewardship payment as a tax. The OSA, they point out, directs the payment to be paid to the Department of Health, not the Department of Taxation and Finance; it reserves the payment for a specific purpose; and it does not refer to the payment as a “tax.”

While it is true that the Department of Health is tasked with collecting proceeds of the stewardship payment, the OSA requires that the proceeds be remitted to the special revenue fund jointly held by the State Comptroller and the Commissioner of Taxation and Finance. In other words, the funds are functionally and legally maintained by the State’s taxing authorities, a fact that strongly favors New York’s argument that the payment is a tax.

Nor is the payment a regulatory fee merely because the OSA reserves the proceeds to support public health programs in New York. Such a broad, statewide purpose is not “particular” in the way Entergy contemplates. To the contrary, it constitutes precisely the kind of general public purpose that supports New York’s characterization of the payment as a tax.

As for the final factor, we recognize that the OSA does not call the stewardship payment a “tax” *per se*. But “[t]axation’ is unpopular these days, so taxing authorities avoid the term.” Empress Casino, 651 F.3d at 730. It may well be significant, sometimes even dispositive, that the legislature affirmatively attaches the label “tax” to a required payment. But the legislature’s silent refusal to call a tax a tax, even though it raises revenue to provide a clear general public benefit, is less significant to our inquiry.

For these reasons, we can safely conclude that the stewardship payment is not a regulatory fee.

B

The plaintiffs’ final argument, that the opioid stewardship payment is a punitive fine, fares no better. In assessing the argument, we note that the legislature is entitled to require an industry to pay a tax to support public programs designed to address a widespread problem caused by the industry. See Entergy, 737 F.3d at 233 n.2. Even if we assume, as the plaintiffs claim, that the State Legislature here imposed the stewardship payment to hold opioid manufacturers and distributors responsible for the “unusual costs” of the opioid epidemic, we would not construe it as a fine for that reason. Id.

The plaintiffs also argue that the stewardship payment is a fine because it is a “fixed sum” of \$100 million per year. HDA Br. 38. While fines are “typically” fixed sums, the plaintiffs say, taxes are “usually” calculated as a percentage of each sale. HDA Br. 38. But the TIA is not limited to taxes that a State assesses based on a “usual” method of calculation. The statute broadly bars federal court interference with the “assessment, levy or collection of any tax.” 28 U.S.C. § 1341 (emphasis added). That language does not sug-

gest that the method of assessment bears at all on the jurisdictional inquiry. Likely for that reason, we have never proposed that the method of assessment is relevant to whether a state-imposed payment is a tax within the meaning of the TIA, and we decline to do so now.

The plaintiffs alternatively emphasize that the OSA's pass-through prohibition places the entire burden of the payment on manufacturers and distributors by barring them from passing the costs on to purchasers. This, they contend, is a telltale feature of a punitive fine. But the pass-through prohibition is a separate and distinct element of the OSA that New York no longer defends. On appeal, therefore, our focus is entirely on the stewardship payment. And without the accompanying pass-through provision, the stewardship payment functions much like other tax burdens that a company can choose to pass on to its consumers through price increases. No other provision prevents the plaintiffs from passing on the costs of the payments levied against them.

GenOn Mid-Atlantic, LLC v. Montgomery County, 650 F.3d 1021 (4th Cir. 2011), to which the plaintiffs point us, is not to the contrary. There, the Fourth Circuit held that a county legislature's charge on carbon dioxide emissions was a punitive fee. In determining that the charge was a fee, the court relied in significant part on two facts: first, that the burden of the charge fell on the plaintiff "alone," and second, that GenOn, the electricity plant subject to the charge, would "likely be unable to pass the cost of the charge on to its customers" because it lacked the market power to do so. Id. at 1024. GenOn's inability to pass on the cost of the charge was critical to the county council's decision to impose the charge. See id. at 1025. Neither of these concerns are factors in this case. Here, the burden imposed by the stewardship payment is more generally

borne. And because New York no longer defends the OSA's pass-through prohibition, nothing prevents the plaintiffs and other similarly situated licensees from passing on the costs of the stewardship payment to their customers.

In summary, after considering the factors in En-tergy and San Juan Cellular, we conclude that the primary purpose of the opioid stewardship payment is to raise revenue, not to punish or regulate the plaintiffs and other licensees who are required to make the payment. For this reason, we hold that the payment is a tax within the meaning of the TIA. The District Court therefore lacked jurisdiction to declare it invalid or to enjoin its enforcement.⁹

III

Because New York has “elected not to seek reversal of the district court’s invalidation of the pass-through prohibition, and seeks reversal only of the district court’s invalidation of the remainder of the OSA, including the opioid stewardship payment,” New York Br. 2–3, we need not further address the validity and severability of the prohibition.

⁹ Having concluded that the TIA barred the District Court from enjoining the stewardship payment, we do not reach New York’s alternative argument that the District Court should have abstained under the doctrine of tax comity. See Joseph v. Hyman, 659 F.3d 215, 218-19 (2d Cir. 2011) (explaining that the doctrine 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” (quotation marks omitted)).

CONCLUSION

For the foregoing reasons, we **REVERSE** the District Court's judgment invalidating and enjoining enforcement of the opioid stewardship payment and all other provisions of the OSA except for the pass-through prohibition, the invalidation of which is not before us.

APPENDIX B

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

<p>HEALTHCARE DISTRIBUTION ALLIANCE,</p> <p>Plaintiff,</p> <p>v.</p> <p>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,</p> <p>Defendants.</p>	<p>18 Civ. 6168 (KPF)</p>
<p>ASSOCIATION FOR ACCESSIBLE MEDICINES,</p> <p>Plaintiff,</p> <p>v.</p> <p>BARBARA D. UNDERWOOD, in her official capacity as the Attorney General of New York; and HOWARD A. ZUCKER, in his official capacity as Commissioner of Health of New York,</p> <p>Defendants.</p>	<p>18 Civ. 8180 (KPF)</p>

<p>SPECGX LLC,</p> <p style="text-align: center;">Plaintiff,</p> <p style="text-align: center;">v.</p> <p>BARBARA D. UNDERWOOD, in her official capacity as the Attorney General of New York; and HOWARD A. ZUCKER, in his official capacity as Commis- sioner of Health of New York,</p> <p style="text-align: center;">Defendants.</p>	<p>18 Civ. 9830 (KPF)</p>
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OPINION AND ORDER

KATHERINE POLK FAILLA, District Judge:

New York State — like the rest of our Nation — is in the grips of an opioid epidemic. To counter that epidemic, New York has taken proactive measures to treat existing opioid addiction, to prevent future addiction, and to educate New Yorkers about the dangers of opioid dependence. The centerpiece of these efforts is the Opioid Stewardship Act (the “OSA” or the “Act”), effective July 1, 2018, which established a \$600 million “stewardship fund” to further these goals. The plaintiffs in these three related cases do not contest the existence of the epidemic or the wisdom of countermeasures, but instead take issue with the particular means that New York has chosen.

Plaintiff Healthcare Distribution Alliance (“HDA”) initiated the first action on July 6, 2018, seeking (i) a declaratory judgment that the Act was unconstitutional and (ii) a permanent injunction prohibiting its implementation. On September 12, 2018, HDA moved for summary judgment on its claims. Two other plaintiffs,

the Association for Accessible Medicines (“AAM”) and SpecGx LLC (“SpecGx”), have presented a more surgical approach, challenging provisions of the OSA that forbid opioid distributors and manufacturers from passing on the costs of the OSA to downstream purchasers (the “pass-through prohibition”) as unconstitutional and moving for injunctive relief.

New York¹ has moved to dismiss all three cases on jurisdictional and prudential grounds. Proceeding from the foundational premise that assessments for OSA’s stewardship fund constitute a tax, New York argues that the Court is foreclosed from hearing Plaintiffs’ challenges pursuant to the Tax Injunction Act (the “TIA”), or, in the alternative, that the Court should abstain from so hearing under principles of comity or *Pullman* abstention. As further fallback positions, New York asks the Court to find the OSA constitutional, either in its current state or, if need be, after the excision of the pass-through prohibition.

A review of the record in these cases² confirms that while the animating concerns of the OSA are plainly valid, the method by which the Act extracts payments from opioid manufactures and distributors to redress those concerns violates the Dormant Commerce Clause of the United States Constitution. The OSA is not a tax, but is rather a regulatory penalty on opioid manufacturers and distributors. And as currently structured, it improperly burdens interstate commerce. Furthermore, the record demonstrates that New York did

¹ The Court uses “New York” or the “State” in the remainder of this Opinion to refer to Defendants in each of the three actions, who are state officials.

² New York has acknowledged that the record in each of the three cases may be considered in all three cases. (Transcript of December 10, 2018 Oral Argument (“December 10 Tr.”) at 10:1-13).

not intend the OSA to survive absent the pass-through prohibition. Accordingly, and for the reasons discussed in the remainder of this Opinion, HDA's motion for summary judgment is granted, as are AAM's and SpecGx's motions for preliminary injunctive relief.

BACKGROUND³

A. Factual Background

1. The Plaintiffs

The plaintiffs in the three lawsuits occupy different links within the opioid distribution chain. Plaintiff HDA is the national trade association for pharmaceuti-

³ For ease of reference, the docket entries referred to in this Opinion are distinguished according to the docket number of the particular action. The facts alleged herein are drawn from the complaints in the three actions, referred to as "HDA Compl." (6168, Dkt. #1), "AAM Compl." (8180, Dkt. #1), and "SpecGx Compl." (9830, Dkt. #1). Additional facts have been taken from the parties' submissions in connection with the instant motions, including HDA's Local Rule 56.1 Statement of Undisputed Facts ("HDA 56.1" (6168, Dkt. #29)), and New York's response thereto ("NY 56.1 Response" (6168, Dkt. #46)).

For convenience, the parties' briefs in connection with HDA's motion for summary judgment and New York's cross-motion to dismiss are referred to as "HDA Br." (6168, Dkt. #28); "NY-HDA Opp." (6168, Dkt. #45); "NY-HDA Br." (6168, Dkt. #44); "HDA Reply" (6168, Dkt. #49); and "NY-HDA Reply" (6168, Dkt. #52). The parties' briefs in connection with AAM's motion for a preliminary injunction and New York's cross-motion to dismiss are referred to as "AAM Br." (8180, Dkt. #9); "NY-AAM Opp." (8180, Dkt. #26); "NY-AAM Br." (8180, Dkt. #25); "AAM Reply" (8189, Dkt. #30); and "NY-AAM Reply" (8180, Dkt. #32). The parties' briefs in connection with SpecGx's motion for a preliminary injunction and New York's cross-motion to dismiss are referred to as "SpecGx Br." (9830, Dkt. #8); "NY-SG Opp." (9830, Dkt. #30); "SpecGx Reply" (9830, Dkt. #32); and "NY-SG Reply" (9830, Dkt. #34).

cal wholesale distributors. Its members do not manufacture, produce, or prescribe opioids. Instead, they are responsible for coordinating receipt and delivery between and among manufacturers and pharmacies, hospitals, and other dispensers of pharmaceuticals to consumers. (HDA Compl. ¶ 9). By contrast, Plaintiff AAM is an association representing the leading manufacturers and distributors of generic and biosimilar medicines, manufacturers and distributors of bulk active pharmaceutical ingredients, and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. (AAM Compl. ¶ 9). Plaintiff SpecGx is a limited liability company organized and existing under the laws of the State of Delaware, which develops, manufactures, and sells pharmaceutical products and therapies, including generic opioid medications. (SpecGx Compl. ¶ 13).

HDA represents distributors of opioids, while SpecGx and members of AAM are manufacturers of generic opioids. None of the Plaintiffs is a manufacturer of brand-name opioids. As explained by SpecGx:

[G]eneric prescription drugs are sold by two primary paths: (i) the manufacturer sells the products to wholesale distributors under terms of a negotiated contract, after which the wholesale distributor then re-sells the product to retail pharmacies or other providers; and (ii) the manufacturer may also sell to national or regional pharmacy chains, hospitals, and other healthcare facilities.

(SpecGx Compl. ¶27).

2. New York's Opioid Stewardship Act

The parties' submissions present divergent views of the OSA's legislative history. Ultimately, the Court's decision rests on the text of the OSA itself; the legisla-

tive history is largely irrelevant to the constitutional problems the Court has identified. However, given the parties' arguments concerning severability, the Court provides a brief discussion of the legislative history in order to illuminate the intentions of OSA's sponsors and supporters.

a. The OSA's Introduction and Passage

As deaths continued to mount from abuse of opioids,⁴ Governor Andrew M. Cuomo announced that the crisis would be a priority in his State of the State Address before the New York State Legislature. (HDA 56.1 ¶¶ 1-2). To that end, on January 16, 2018, the Governor introduced his proposed budget, which included the proposal that would eventually become the OSA: "Opioid manufacturers have created an epidemic. We would have an opioid surcharge, 2 cents per milligram will be paid by the manufacture[rs] and would go to offset the costs that we're spending to fight opioid abuse[,] which are multiples of the \$170 million." (*Id.* at ¶¶ 3-4).

As the New York State Assembly debated the bill, Assemblywoman Helene Weinstein, the Chair of the Ways and Means Committee, stated that the OSA's cost would be borne by distributors and manufacturers of opioid medications. (Declaration of Seth Farber dated October 17, 2018 ("Farber Decl." (6168, Dkt. #42)), Ex. K at 21). In response to concerns that the cost would ultimately be borne by downstream pharmacies

⁴ See, e.g., Lenny Bernstein, *U.S. Life Expectancy Declines Again, A Dismal Trend Not Seen Since World War I*, Wash. Post. (Nov. 29, 2018), https://www.washingtonpost.com/national/health-science/us-life-expectancy-declines-again-a-dismal-trend-not-seen-since-world-war-i/2018/11/28/ae58bc8c-f28c-11e8-bc79-68604ed88993_story.html?utm_term=.8b338916a747 (last visited Dec. 18, 2018)

(and, by extension, their customers), Member Weinstein further declared that it was “certainly not the [drafter’s] intention [to have pharmacies pay the OSA’s surcharge].” (*Id.* at 23). In subsequent discussion with Assemblyman Richard N. Gottfried, who was and remains Chair of the Assembly Health Committee, Defendant Commissioner Howard Zucker confirmed that the OSA was structured to ensure that payment would *not* “get filtered down to the end-user[.]” (Declaration of Andrew Kratenstein dated September 12, 2018 (“Kratenstein Decl.” (6168, Dkt. #37)), Ex. K at 174-76). In the OSA’s final form, this payment was given a name: the “opioid stewardship payment.” (HDA. 56.1 ¶ 6). On April 12, 2018, the Governor signed the legislation into law. 2018 N.Y. Sess. Laws 57, S.7507-C. (*Id.* at ¶ 7). The OSA was codified in two places, at New York Public Health Law § 3323 and New York State Finance Law § 97-aaaaa.

b. The OSA’s Text and Structure

The OSA creates a \$600 million fund (the “Opioid Stewardship Fund” or the “Fund”) that is derived from annual assessments on pharmaceutical manufacturers and wholesale distributors that are licensed to sell or distribute opioid products in New York (collectively, the “Licensees”). (HDA Compl. ¶ 13). The assessment will be spread out over six years, with \$100 million paid annually from 2019 through 2024; each year’s assessment is calculated based on sales made the previous year and is payable the following year. (HDA 56.1 ¶¶ 11-12). The assessment for each Licensee is expressed in terms of a “ratable share” and is calculated as follows:

- a) The total amount of [Morphine Milligram Equivalents (“MMEs”)] sold or distributed in the state of New York by the licensee for the preceding calendar year, as reported by the li-

licensee pursuant to subdivision four of this section, shall be divided by the total amount of MME sold in the state of New York by all licensees pursuant to this article to determine the licensee payment percentage. The licensee payment percentage shall be multiplied by the total opioid stewardship payment. The product of such calculation shall be the licensee's ratable share. The department shall have the authority to adjust the total number of a licensee's MMEs to account for the nature and use of the product, as well as the type of entity purchasing the product from the licensee, when making such determination and adjust the ratable share accordingly.

(b) The licensee's total amount of MME sold or distributed, as well as the total amount of MME sold or distributed by all licensees under this article, used in the calculation of the ratable share shall not include the MME of those opioids which are:

(i) manufactured in New York state, but whose final point of delivery or sale is outside of New York state;

(ii) sold or distributed to entities certified to operate pursuant to article thirty-two of the mental hygiene law, or article forty of the public health law;

(c) The department shall provide to the licensee, in writing, on or before October fifteenth, two thousand eighteen, the licensee's ratable share for the two thousand seventeen calendar year. Thereafter, the department shall notify the licensee in writing annually on or before

October fifteenth of each year based on the opioids sold or distributed for the prior calendar year.

N.Y. Pub. Health Law § 3323(5). The New York State Department of Health (“DOH”) is both calculator and payee of each Licensee’s ratable share. *Id.*

The pass-through prohibition that is at the heart of many of Plaintiffs’ challenges is contained in two sections of the OSA. In the provision defining stewardship payments, the OSA states, “No licensee shall pass the cost of their ratable share amount to a purchaser, including the ultimate user of the opioid, or such licensee shall be subject to penalties pursuant to subdivision ten of this section.” N.Y. Pub. Health Law § 3323(2). Later, in the penalties provision, the Act notes that “[w]here the ratable share, or any portion thereof, has been passed on to a purchaser by a licensee, the commissioner may impose a penalty not to exceed one million dollars per incident.” *Id.* § 3323(10)(c).

The ratable share payments are directed to the Opioid Stewardship Fund. N.Y. Pub. Health Law § 3323(2). Of potential significance to the instant motions, the Fund is separate and not comingled with New York State’s general fund. N.Y. State Fin. Law § 7-aaaaa(2). The OSA provides for the use of the Fund as follows:

Moneys of the opioid stewardship fund, when allocated, shall be available, subject to the approval of the director of the budget, to support programs operated by the New York state office of alcoholism and substance abuse services or agencies certified, authorized, approved or otherwise funded by the New York state office of alcoholism and substance abuse services to provide opioid treatment, recovery and prevention and education services; and to provide

support for the prescription monitoring program registry as established pursuant to section thirty-three hundred forty-three-a of the public health law.

At the request of the budget director, the state comptroller shall transfer moneys to support the costs of opioid treatment, recovery, prevention, education services, and other related programs, from the opioid stewardship fund to any other fund of the state to support this purpose.

Id. § 97-aaaaa(4)-(5).

Also of potential significance, the OSA includes a severability provision that states in relevant part:

If any clause, sentence, paragraph, subdivision, or section of this act shall be adjudged by any court of competent jurisdiction to be invalid, such judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, subdivision, or section directly involved in the controversy in which such judgment shall have been rendered. It is hereby declared to be the intent of the legislature that this act would have been enacted even if such invalid provisions had not been included herein.

N.Y. Sess. Laws ch. 57, pt. NN, § 4 (McKinney).

c. The DOH Guidance

On June 15, 2018, DOH issued its guidance concerning interpretation of certain provisions of the OSA (the “Guidance”). (HDA 56.1 ¶ 9; NY 56.1 Response ¶ 9). The Guidance provided that the stewardship payments would be assessed on the “initial transaction in the distribution chain when opioids are first sold or

distributed within, or into, New York.” (HDA 56.1 ¶ 21; NY 56.1 Response ¶ 21). The Guidance further explained that the pass-through prohibition was “not intended to apply to price increases that are attributable to other ordinary changes in manufacture or distribution costs.” (HDA 56.1 ¶ 25; NY 56.1 Response ¶ 25).

d. The 2018 Assessments and the Industry’s Response

DOH has already issued the ratable share assessments for 2018 — which, as noted, are based on 2017 sales and are payable to DOH on January 1, 2019. (SpecGx Br. 9). SpecGx relates that its ratable share payment is “\$1,256,326.33 ... based on 115,037,682 MMEs first sold and distributed by SpecGx into New York.” (*Id.* at 10). SpecGx further relates, and New York does not dispute, that the ratable share payment per qualifying MME exceeds the average manufacturer price (or “AMP”) of several generic opioids covered by the OSA. (*Id.* at 10-11). In other words, on several of the opioids it manufactures, SpecGx has to pay more in assessments to the Fund than it makes in margins.

The record also contains evidence that distributors are dealing with the OSA’s pass-through prohibition by passing the costs of their ratable shares back up the supply chain to manufacturers. SpecGx reports, again without dispute, that

AmerisourceBergen Corp., one of the three national distributors of prescription medications, advised SpecGx on October 10, 2018, that it would, effective October 12, 2018, “no longer accept opioid product shipments at the National Distribution Center in Columbus, Ohio intended for redistribution to AmerisourceBergen distribution centers” in New York. The letter further stated that “[i]f you would like to continue shipping opioid products to the

[National Distribution Center] to New York ... you agree to pay any tax, duty, levy, fee, assessment, tariff or any other charge of any nature imposed by any government authority on the sale or transfer of those opioid products” — e.g., the OSA’s Ratable Share.

(SpecGx Br. 12). At oral argument, Plaintiffs each declared that the economic consequence of the OSA could force them to abandon the generic opioid market in New York entirely. (Dec. 10 Tr. 33:9-13, 56:11-16, 92:1-93:24).

B. Procedural Background

HDA filed its complaint on July 6, 2018, asking the Court to strike down the OSA as unconstitutional on eight grounds, arguing that it was: (i) an unconstitutional Bill of Attainder; (ii) unconstitutionally retroactive; (iii) a violation of the Takings Clause; (iv) a violation of Substantive Due Process; (v) a violation of the Dormant Commerce Clause based on its extraterritorial effects; (vi) a violation of the Dormant Commerce Clause based on its creation of an undue burden on interstate commerce; (vii) unconstitutionally vague as to the calculation of the surcharge; and (viii) unconstitutionally vague as to the calculation of the pass-through prohibition. (6168, Dkt. #1). On September 12, 2018, HDA filed its motion for summary judgment on substantially the same grounds. (6168, Dkt. #27, 28). On October 17, 2018, New York filed its opposition to the motion for summary judgment, and a cross-motion to dismiss HDA’s complaint on five grounds: (i) the TIA barred this Court from hearing the case; (ii) principles of comity warranted abstention in this case; (iii) the *Pullman* abstention doctrine warranted abstention in this case; (iv) the dispute lacked ripeness; and (v) HDA’s complaint lacked plausibility. (6168, Dkt. #41,44, 45). On November 7, 2018, HDA filed its joint

opposition to the motion to dismiss and reply in support of summary judgment. (6168, Dkt. #49). On November 16, 2018, New York filed its reply in support of the motion to dismiss. (6168, Dkt. #52).

On September 7, 2018, AAM filed its complaint challenging the OSA along with a motion for a preliminary injunction on the grounds that the OSA's pass-through prohibition violated the Dormant Commerce Clause. (8180, Dkt. #1, 8, 9). Unlike HDA, AAM did not ask the Court to strike down the entirety of the OSA. (*Id.*). On September 18, 2018, this Court accepted this case as related to HDA's challenge, and on September 20, 2018, it ordered the parties to follow the same briefing schedule. (8180, Dkt #15). On October 17, 2018, New York filed its opposition to AAM's motion for a preliminary injunction, and a cross-motion to dismiss the complaint that echoed the motion filed in the HDA matter but added an argument that AAM lacked standing. (8180, Dkt. #22, 25, 26). On November 7, 2018, AAM filed its opposition to the motion to dismiss and its reply in support of a preliminary injunction. (8180, Dkt. #29, 30). On November 16, 2018, New York filed its reply in support of the motion to dismiss. (8180, Dkt. #32).

On October 14, 2018, SpecGx filed a complaint and a motion for a preliminary injunction. In addition to the Dormant Commerce Clause issues that had been raised by others, SpecGx further argued that the OSA was preempted by the Drug Price Competition and Patent Term Restoration Act, Pub. Law No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Amendments ("Hatch-Waxman"). (9830, Dkt. #1, 7, 8). On November 5, 2018, this Court accepted this case as related to the prior two OSA challenges and set a briefing schedule. (9830, Dkt. #25). On November 7, 2018, New York filed its opposition to the motion, and a cross-motion to dismiss the complaint on substantially the same

grounds as the previous cases. (9830, Dkt. #27, 30). On November 15, 2018, SpecGx filed its joint opposition to the motion to dismiss and reply in support of a preliminary injunction. (9830, Dkt. #32). On November 27, 2018, New York filed its reply in support of the motion to dismiss. (9830, Dkt. #34)

The Court held oral argument on December 10, 2018, and informed the parties thereafter that a decision from the Court would issue before payments were due at the start of 2019, leaving the parties with time to appeal.

DISCUSSION

A. The Court Denies New York's Motions to Dismiss

This Court will begin with an examination of New York's motions to dismiss each of the actions, as the motions address the Court's power to hear these cases. New York has proffered arguments that are both jurisdictional and prudential, but as detailed in the remainder of this section, the Court has identified factual and legal deficiencies as to each. Accordingly, the Court denies New York's motions to dismiss.

1. Applicable Law

a. Motions to Dismiss Under Federal Rule of Civil Procedure 12(b)(1)⁵

"It is a fundamental precept that federal courts are courts of limited jurisdiction and lack the power to dis-

⁵ In its first motion to dismiss, New York raised a Rule 12(b)(6) argument for dismissal due to lack of plausibility. (NY-HDA Br. 15-25). Perhaps tellingly, New York does not raise it in its second and third motions. Given that the cases are considered collectively and the issues raised in the Rule 12(b)(6) motion overlap substantially with the issues in HDA's motion for summary judgment, the Court will dispense with that aspect of the State's briefing.

regard such limits as have been imposed by the Constitution or Congress.” *Durant, Nichols, Houston, Hodgson & Cortese-Costa, P.C. v. Dupont*, 565 F.3d 56, 62 (2d Cir. 2009) (internal quotation marks omitted). In that regard, “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 Solowski 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. U.S.*, 201 F.3d 110, 113 (2d Cir. 2000). In 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 is not made by drawing from the pleadings inferences favorable to the party asserting it.” *Morrison v. Nat’l Bank Ltd.*, 547 F.3d 167, 170 (2d Cir. 2008) (internal citation and quotation marks omitted). 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 E. Constr. Co. v. Emirate of Abu Dhabi*, 215 F.3d 247, 253 (2d Cir. 2000) (“On a Rule 12(b)(1) motion challenging the district court’s subject matter jurisdiction, the court may resolve the disputed jurisdictional fact issues by referring to evidence outside of the pleadings, such as affidavits, and if necessary, hold an evidentiary hearing.”); *accord Tandon v. Captain’s Cove Marina of Bridgeport, Inc.*, 752 F.3d 239, 243 (2d Cir. 2014) (“[W]here jurisdictional facts are placed in dispute, the court has the power and obligation to decide issues of fact by refer-

ence to evidence outside the pleadings, such as affidavits.”).

b. Issues of Justiciability

As New York’s motions to dismiss make clear, several concepts of justiciability are implicated by Plaintiffs’ arguments, including the Tax Injunction Act, the doctrine of tax comity, the doctrine of *Pullman* abstention, ripeness, and Article III standing. The Court outlines the law as to each in this section.

i. The Tax Injunction Act

The TIA provides a straightforward prohibition on federal courts hearing challenges to state tax laws: “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.” 28 U.S.C. § 1341. “Two conditions must be satisfied to invoke the protection of the TIA: first, the surcharges must constitute taxes, and second, the state remedies available to plaintiffs must be plain, speedy and efficient.” *Travelers Ins. Co. v. Cuomo*, 14 F.3d 708, 713 (2d Cir. 1993), *rev’d on other grounds*, 514 U.S. 645 (1995) (internal quotation marks omitted). As the parties do not here dispute the question of state remedies, the Court focuses on the first element, whether the OSA can be classified as a tax.

The last word from the Second Circuit on what constitutes a tax for TIA purposes came in *Entergy Nuclear Vermont Yankee, LLC v. Shumlin*, where the Court held that “the principal identifying characteristic of a tax, as opposed to some other form of state-imposed financial obligation, is whether the imposition ‘serve[s] general revenue-raising purposes.’” 737 F.3d 228, 231 (2d Cir. 2013). The Circuit contrasted this with other state-mandated payments, which are “di-

rectly allocated to the agency that administers the collection, for the purpose of providing a narrow benefit to or offsetting costs for the agency.” *Id.*

The leading case from outside the Circuit, which the Second Circuit cited favorably in *Entergy*, is the First Circuit’s decision in *San Juan Cellular Tel. Co. v. Pub. Serv. Comm’n of Puerto Rico*, 967 F.2d 683, 685 (1st Cir. 1992). Then- Chief Judge Breyer explained that taxes and fees existed on a continuum and, further, that distinguishing payment systems along this continuum requires an examination of the revenue’s ultimate use:

Courts have had to distinguish “taxes” from regulatory “fees” in a variety of statutory contexts. Yet, in doing so, they have analyzed the legal issues in similar ways. They have sketched a spectrum with a paradigmatic tax at one end and a paradigmatic fee at the other. The classic “tax” is imposed by a legislature upon many, or all, citizens. It raises money, contributed to a general fund, and spent for the benefit of the entire community.... The classic “regulatory fee” is imposed by an agency upon those subject to its regulation.... It may serve regulatory purposes directly by, for example, deliberately discouraging particular conduct by making it more expensive.... Or, it may serve such purposes indirectly by, for example, raising money placed in a special fund to help defray the agency’s regulation- related expenses[.]

Courts facing cases that lie near the middle of this spectrum have tended (sometimes with minor differences reflecting the different statutes at issue) 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.

Id. (citations omitted). The Second Circuit in *Entergy* described the *San Juan Cellular* factors as: (i) the revenue's ultimate use; (ii) the nature of the entity imposing the charge; and (iii) the population subject to the charge. 737 F.3d at 232-33.

Courts are also guided by the law governing the TIA's federal analogue, the Anti-Injunction Act ("AIA"), when determining whether a revenue-raising measure is a tax. *See Direct Mktg. Ass'n v. Brohl*, 135 S. Ct. 1124, 1129 (2015) ("We assume that words used in both Acts are generally used in the same way[.]"). With reference to federal taxes, the AIA provides that "no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person, whether or not such person is the person against whom such tax was assessed." 26 U.S.C. § 7421(a). On the specific issue of what constitutes a tax, the Supreme Court has instructed lower courts to examine how Congress labels the payment in the legislation: "label[ing] this exaction a 'penalty' rather than a 'tax' is significant because the Affordable Care Act describes many other exactions it creates as 'taxes.' Where Congress uses certain language in one part of a statute and different language in another, it is generally presumed that Congress acts intentionally." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 544 (2012). Notably, the Court determined that the "exaction" in *Sebelius* was a "tax" for purposes of its underlying constitutional analysis, even as it declined to find it a "tax" for AIA purposes. *Id.* at 561-63.

ii. The Tax Comity Doctrine

New York's second argument for dismissal relies on the doctrine of tax comity. Unlike the TIA, tax comity is a prudential bar to standing, rather than a jurisdictional one. *See Brohl*, 135 S. Ct. at 1134. "[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 215, 218-19 (2d Cir. 2011).

The ordinary case in which courts rely on comity rather than the TIA is one in which the challenge to a tax scheme would result in increased revenue to the state, as the Supreme Court has limited the TIA to cases where a challenge would limit state tax collection rather than expand it. *Joseph*, 659 F.3d at 218-19. The Supreme Court's decision in *Levin v. Commerce Energy, Inc.*, 560 U.S. 413 (2010), provides the key case for understanding the distinction. While the plaintiffs, a group of natural gas marketers, did not seek to block enforcement of an Ohio tax, the remedy they sought would require either a reduction in their tax liability or a reshaping of the Ohio tax code. *Id.* at 429. The Court held that comity counseled against federal jurisdiction even though the TIA did not bar the claim. No party in *Levin* disputed that the case was related to Ohio's tax code. Here, in sharp contrast, no Plaintiff concedes that the OSA is a tax or that any of its provisions is designed to enforce a tax.

iii. The *Pullman* Abstention Doctrine

New York's third argument for dismissal relies on the doctrine of *Pullman* abstention. *Pullman* abstention is proper when a state court determination of a question of state law might moot or alter a federal constitutional question: "Abstention under the *Pullman*

doctrine may be appropriate when three conditions are met: [i] an unclear state statute is at issue; [ii] resolution of the federal constitutional issue depends on the interpretation of the state law; and [iii] the law is susceptible ‘to an interpretation by a state court that would avoid or modify the federal constitutional issue.’” *Vermont Right to Life Comm., Inc v. Sorrell*, 221 F.3d 376, 385 (2d Cir. 2000). However, even if all three conditions are satisfied, *Pullman* does not require abstention. “The doctrine of abstention ... is an extraordinary and narrow exception to the duty of a District Court to adjudicate a controversy properly before it.” *Id.* (citing *Colorado River Water Conservation Dist. v. United States*, 424 U.S. 800, 813 (1976)). “If the state statute in question, although never interpreted by a state tribunal, is not fairly subject to an interpretation which will render unnecessary or substantially modify the federal constitutional question, it is the duty of the federal court to exercise its properly invoked jurisdiction.” *Harman v. Forssenius*, 380 U.S. 528, 534-35 (1965).

iv. The Requirement of Ripeness

New York’s arguments for dismissal consider not only the propriety of the court, but also that of the putative litigants. “To be justiciable, a cause of action must be ripe — it must present ‘a real, substantial controversy, not a mere hypothetical question.’” *Nat’l Org. for Marriage, Inc. v. Walsh*, 714 F.3d 682, 687 (2d Cir. 2013) (quoting *AMSAT Cable Ltd. v. Cablevision of Conn.*, 6 F.3d 867, 872 (2d Cir. 1993)). “Ripeness ‘is peculiarly a question of timing.’” *Id.* (quoting *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580 (1985)). Claims are not ripe if they depend upon “contingent future events that may not occur as anticipated, or indeed may not occur at all.” *Id.* at 580-81. The ripeness doctrine’s principal purpose is “to prevent the

courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements.” *Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967).

“There are two forms of ripeness: constitutional and prudential.” *Vullo v. Office of Comptroller of the Currency*, No. 17 Civ. 3574 (NRB), 2017 WL 6512245, at *8 (S.D.N.Y. Dec. 12, 2017) (citing *Simmonds v. INS*, 326 F.3d 351, 356-57 (2d Cir. 2003)). The former is “a specific application of the actual injury aspect of Article III standing.” *Walsh*, 714 F.3d at 688. It “prevents courts from declaring the meaning of the law in a vacuum and from constructing generalized legal rules unless the resolution of an actual dispute requires it.” *Simmonds*, 326 F.3d at 357. Prudential ripeness, by contrast, is a tool a court may employ, in its discretion, when “the case will be *better* decided later and [] the parties will not have constitutional rights undermined by the delay.” *Id.* “Prudential ripeness [is employed by courts] to enhance the accuracy of their decisions and to avoid becoming embroiled in adjudications that may later turn out to be unnecessary or may require premature examination of ... issues that time may make easier or less controversial.” *Id.*

v. The Requirement of Standing

Article III of the Constitution limits federal courts’ jurisdiction to “cases” and “controversies.” U.S. Const., art. III, § 2. “The doctrine of standing gives meaning to these constitutional limits by ‘identify[ing] those disputes which are appropriately resolved through the judicial process.’” *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 156 (2014) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). The Supreme Court has “established that the ‘irreducible constitutional minimum’ of standing consists of three elements.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016)

(quoting *Lujan*, 504 U.S. at 560). “The plaintiff must have [i] suffered an injury in fact, [ii] that is fairly traceable to the challenged conduct of the defendant, and [iii] that is likely to be redressed by a favorable judicial decision.” *Id.*

“To establish injury in fact, a plaintiff must show that he or she suffered an invasion of a legally protected interest that is concrete and particularized and actual or imminent, not conjectural or hypothetical.” *Spokeo*, 136 S. Ct. at 1548 (internal quotations marks and citation omitted). “[T]hreatened injury must be *certainly impending* to constitute injury in fact,’ and ... ‘[a]llegations of *possible* future injury’ are not sufficient.” *Clapper v. Amnesty Intern. USA*, 568 U.S. 398, 409 (2013) (quoting *Whitmore v. Ark.*, 495 U.S. 149, 158 (1990)) (emphases in *Clapper*).

2. Analysis

a. The TIA Does Not Bar a Challenge to the OSA

Several of New York’s arguments in favor of dismissal depend upon a finding that the ratable share assessment is a tax, and so the Court begins its analysis with this antecedent issue. While the OSA does raise revenue, an examination of the relevant law makes clear that the OSA is not a tax.

“[T]he principal identifying characteristic of a tax, as opposed to some other form of state-imposed financial obligation, is whether the imposition ‘serve[s] general revenue-raising purposes.’ Whether a measure serves ‘general revenue-raising purposes’ in turn depends on the disposition of the funds raised.” *Entergy*, 737 F.3d at 231. Given that the OSA expressly segregates the revenue generated from the surcharge from the State’s general fund, *see* N.Y. Fin. Law § 97-aaaaa(2), New York must argue around the “disposi-

tion of the funds.” It attempts to do so by stating that the surcharge contributes to general revenue, as it secures “funding for opioid abuse prevention, treatment and education programs available to the general public[.]” (NY-HDA Br. 8).

The Second Circuit has clarified, however, that “general revenue” does not merely mean that the funds provide some public benefit, and that courts must consider the state’s actual disposition of the funds in the TIA analysis. *See, e.g., Entergy*, 737 F.3d at 231 (“Nothing in the statute reserves the proceeds of the Generating Tax for any particular purpose.”); *Travelers Ins. Co.*, 14 F.3d at 713 (“Notwithstanding the primary purposes ascribed to the surcharges by the State, [the surcharges] raise revenue which is ultimately paid into the State’s general fund.”); *Keleher v. New England Tel. & Tel. Co.*, 947 F.2d 547, 549 (2d Cir. 1991) (the word “tax” under the TIA “encompasses any state or local revenue collection device,” including a city-assessed public utility “franchise fee” because the money raised was treated as part of the city’s “general revenue”). Here, the OSA charges a regulated industry to create a segregated fund that is directed toward specific purposes closely intertwined with the industry in question. These straightforward facts undercut any argument that the OSA is a tax.

When additional factors from the *San Juan Cellular* and *Sebelius* cases are considered, the weaknesses inherent in the State’s arguments are amplified. *San Juan Cellular* requires consideration of both the nature of the entity imposing the charge and the population subject to the charge. 967 F.2d at 685. Under the OSA, DOH is the collector of the ratable share. N.Y. Pub. Health Law § 3323(5). “Here, as in most cases, this factor is closely linked to the ultimate destination of the revenue[.]” *Entergy*, 737 F.3d at 232. Examining

the population subject to the charge provides the State a slightly better argument, as *Entergy* suggested that an exaction on one entity could remain a tax, and in this case there are many entities subject to the tax. However, the Second Circuit also suggested that “[t]he category of persons or entities subject to such taxes ... be defined by general and open-ended criteria, even if only a few entities, or one entity alone, are subject to the tax.” *Id.* at 233. In this case, at least as regards the 2018 ratable share assessments due on January 1, 2019, the class of entities is not general, but rather is a specific and defined group that can do nothing to change a preexisting (and, it bears noting, retroactively imposed) liability. The *San Juan Cellular* factors provide further evidence that the OSA is a regulatory fee, not a tax.

The Supreme Court’s guidance in *Sebelius*, in the analogous context of the AIA, also counsels against applying the TIA on these facts. *Sebelius* looked primarily at the statutory text, which did not define the Affordable Care Act’s mandate as a tax in rejecting an AIA argument. 567 U.S. at 543-46. The OSA studiously avoids the use of the word “tax” throughout its provisions, referring exclusively to “ratable shares,” “stewardship payments,” and “penalties.” While the use of the word “tax” is certainly not dispositive, the language of the OSA is another factor that weighs against the State. If the line between taxes and fees is “a spectrum with a paradigmatic tax at one end and a paradigmatic fee at the other,” *San Juan Cellular*, 967 F.2d at 685, the OSA is indisputably closer to the fee end.

Even if OSA’s stewardship payments were to be considered a tax, its pass-through prohibition, on which AAM and SpecGx focus their attacks, would not be. New York acknowledged during oral argument the weakness of the TIA arguments when applied to the

pass-through prohibition. (Dec. 10 Tr. 18:20-19:6). It did so with good reason, as the Second Circuit has previously determined that a pass-through prohibition engrafted upon a revenue-raising measure is not a tax for TIA purposes:

As we have indicated the tax purpose of the legislation was to raise funds for the mass transit system. However, the purpose of the anti-pass through provision was not to raise taxes but “to do nothing that will contribute to further increases in the price of petroleum products to (New York) consumers” and “to prevent such gross receipts tax from fueling inflation by prohibiting the pass through of such tax to the consumers of this state.” N.Y. Act, ch. 272, s 1.

This objective is certainly not an exercise of a taxing power but a police power affecting the price structure of petroleum products. We agree that the State has the right to place the legal incidence of the tax upon the oil companies; it has selected its target. But in barring the targets of the tax from recovering their costs from the consumer directly or indirectly, the State has gone beyond its taxing powers and has employed its police powers

Mobil Oil Corp. v. Tully, 639 F.2d 912, 918 (2d Cir. 1981).

New York proffers a distinction based on its role as a purchaser of opioids through Medicaid and, somewhat curiously, suggests that the holding in *Mobil Oil* rested at least in part on the statute’s goal of fighting inflation. (NY-HDA Br. 8). In point of fact, the Circuit made clear that its decision rested on the nature of pass-through prohibitions themselves: “No one questions the right of the State of New York to place the le-

gal incidence of the tax upon the oil companies but it is an entirely different matter for the legislature to instruct the person taxed that he cannot raise the resources to pay the tax by increasing the price of his product.” 639 F.2d at 918. In short, a challenge to the pass-through prohibition is clearly not barred by the TIA.

b. Comity Is Not Relevant to Consideration of the OSA

As this Court does not consider either the OSA stewardship payments or its pass-through prohibition to be a tax, its analysis of tax comity is brief. While it is true that comity sweeps more broadly than the TIA, it does not encompass regulatory fees or penalties. Comity merely provides expanded grounds for federal courts to stand down in the tax context.

New York points to comity to argue that even if portions of the Act were classified as penalties rather than taxes, this Court must still refrain from hearing the case as it could disrupt the administration of state taxes. (NY-HDA Br. 23:22-24:4). For this proposition, it relies on the Second Circuit’s holding in *Abuzaid v. Mattox*, where comity was invoked to bar a challenge to the penalty provision of New York’s cigarette tax: “Regardless of whether assessments made under N.Y. Tax Law § 481(1)(b)(i) might be regarded as penalties imposed under the state’s tax laws designed to encourage payment of taxes, rather than as taxes, they are indisputably part of the state’s tax system.” 726 F.3d 311, 315-16 (2d Cir. 2013). Significantly, however, the parties in *Abuzaid* conceded that the underlying scheme that the State sought to enforce was a tax.

Had this Court agreed that the stewardship payments were a tax, comity would be only slightly more relevant, inasmuch as New York focuses its comity arguments on the pass-through prohibition. Even then,

the comity doctrine would not counsel this Court from abstaining from consideration of the pass-through prohibition. As noted, *Abuzaid*, on which New York principally relies, rested on a challenge to the enforcement of New York’s criminal tax law, which makes it a felony to “willfully attempt[] in any manner to evade or defeat ... [cigarette] taxes’ and to ‘willfully possess[] ... for the purpose of sale’ unlawfully stamped cigarette.” *Id.* at 313. As AAM correctly points out, a taxpayer challenging the enforcement by the taxing authority of a criminal provision of the state tax code clearly poses a threat to state taxing power, in a way that a challenge to the pass-through prohibition does not. (AAM Br. 13 (“[T]his case does not involve ‘state taxing authorities,’ does not involve taxpayer-plaintiffs, does not involve criminal tax violators, and does not pose a threat to the state’s taxing apparatus.”)). Striking down the OSA’s pass-through prohibition would allow New York to collect the exact same amount of money from the exact same parties through the exact same means; all that would change is those bearing the cost of the tax. The tax comity doctrine is designed to protect a state’s taxing apparatus, not the state’s contemplation (or hopes) as to how market forces will respond to that apparatus. As such, even if the OSA stewardship payments were a tax, comity would not bar a challenge to the pass-through prohibition.

c. *Pullman* Abstention Is Not Appropriate to Consideration of the OSA

Pullman abstention is not appropriate in this case, as no construction of the OSA would render it constitutional. As with the question of comity, New York’s *Pullman* claim is largely focused on the pass-through prohibition. (See NY-HDA Br. 12-15). And as HDA points out, such a narrow focus overlooks many of HDA’s direct challenges to the stewardship payments.

(HDA Reply 11 (“As to Counts 1 (bill of attainder), 2 (retroactivity), 3 (takings), 4 (substantive due process), 5 (discrimination against out-of-state distributors), and 7 (undue burden), the State has not identified an ‘unclear state law issue’ whose resolution would inform a federal issue.”)). The facts that (i) abstention “is an extraordinary and narrow exception to the duty of a District Court to adjudicate a controversy properly before it[,]” *Colorado River*, 424 U.S. at 813; (ii) all parties have an interest in a speedy and efficient resolution to the case; and (iii) certain claims fall outside of New York’s arguments for abstention, compel the Court to hear these cases. However, even as to the counts where New York alleges statutory ambiguity, the Court does not find *Pullman* abstention to be appropriate.

While the Court discusses the issue at greater length in its discussion of the Dormant Commerce Clause, *see infra*, it notes at this juncture that the OSA’s text regarding the pass-through prohibition is straightforward. *First*, “No licensee shall pass the cost of their ratable share amount to a purchaser, including the ultimate user of the opioid, or such licensee shall be subject to penalties pursuant to subdivision ten of this section.” N.Y. Pub. Health Law § 3323(2). *Second*, “Where the ratable share, or any portion thereof, has been passed on to a purchaser by a licensee, the commissioner may impose a penalty not to exceed one million dollars per incident.” *Id.* § 3323(10)(c). Any plausible reading of these provisions prohibits the seller from passing “*any portion*” of the costs of the OSA downstream to New York opioid purchasers. But it is naïveté to believe that the Licensees will simply absorb the additional costs, particularly given the record evidence of economic turmoil faced by manufacturers of generic opioids if they were to do so. If companies cannot pass the costs to consumers anywhere, the OSA raises is-

sues of extraterritoriality. If companies cannot pass the costs on to New York consumers of opioids, but can pass them on to non-New York opioid purchasers, the OSA raises issues of interstate discrimination.

New York's predicament is placed in sharp relief in its memorandum in support of its motion to dismiss the case brought by AAM, which case only raised Commerce Clause arguments, though of two types. In relevant part, New York argued:

Pullman abstention is also appropriate because a state court could moot plaintiff's First Cause of Action by interpreting the pass-through provision to apply solely to opioid sales or distributions occurring in New York. Similarly, plaintiff's Second Cause of Action could be mooted by a broader interpretation that applies the provision to all sales and distributions.

(NY-AAM Br. 13-14). Fatal to New York's argument is its inability to offer a plausible reading of the OSA that would moot *both* challenges, and indeed there is no reading that would moot all Dormant Commerce Clause problems. New York's attempt to find some reading of the pass-through prohibition that could eliminate the effect on interstate commerce is akin to a search for a chemical reaction that destroys energy; costs in a single market, like energy in a closed system, do not simply disappear, but must be absorbed elsewhere.

New York also attempts to argue around this problem by pointing to the undefined term "incident" for what violates the pass-through provision, suggesting that "incident" may be defined narrowly to minimize problems. However, no matter how broadly or narrowly New York defines an incident, so long as the monetary penalty exists, it would raise questions under the Com-

merce Clause. Any minor ambiguity “cannot avoid the necessity for constitutional adjudication.” *Naprstek v. City of Norwich*, 545 F.2d 815, 818 (2d Cir. 1976).

d. The Challenges to the OSA Are Ripe for Review

As noted, New York’s arguments include those that posit inadequacies of the Court and those that posit inadequacies of the litigants. The first argument in the latter category, New York’s ripeness challenge, is undercut by the payment requests it has already sent to the Licensees. Claims are not ripe if they depend upon “contingent future events that may not occur as anticipated, or indeed may not occur at all.” *Union Carbide*, 473 U.S. at 580-81. The stewardship payment is certainly not a contingent future event, as the payments are due in a few short weeks. Therefore, a challenge with respect to the stewardship payments is certainly ripe for review.

Here as well, New York’s argument is targeted primarily at the challenges to the pass-through prohibition. It argues that since “the Act’s pass-through prohibition cannot be applied until at least next year, Plaintiff[s] can hardly claim that any potential harm is imminent.” (NY-AAM Br. 16). However, “[a]n allegation of future injury may suffice if the threatened injury is ‘certainly impending,’ or there is a ‘substantial risk’ that the harm will occur.” *Susan B. Anthony List*, 573 U.S. at 158 (citation omitted). Such is the case here.

Beginning January 1, 2019, Plaintiffs face a substantial risk that on each opioid sale they make, New York will impose a penalty of \$1 million. Counsel for New York did not disavow an intention to enforce the pass-through prohibition at oral argument. (*See* Dec. 10 Tr. 64:5-13). And there are further financial consequences: AmerisourceBergen Corp. has informed the

manufacturers with which it deals that they will be required to take on the full cost of the stewardship payments if they intend to continue making sales to New York, and SpecGx has announced its plans to exit the New York market. (SpecGx Reply 19). As with other aspects of its case, New York is not just arguing against Plaintiffs, but is also arguing against fundamental precepts of economics. Once the pass-through prohibition goes into effect on January 1, 2019, if not sooner, the harm is already present and no longer imminent. Therefore, the challenge is ripe for review.

e. AAM and SpecGx Have Standing to Bring Their Claims

New York does not challenge HDA's standing, but does challenge AAM's and SpecGx's standing to bring Dormant Commerce Clause claims on several bases. (See NY-AAM Br. 17-18; NY-SG Opp. 6-9). The Court rejects these challenges.

In evaluating standing, "the court must be careful not to decide the questions on the merits for or against the plaintiff and must therefore assume that on the merits the plaintiffs would be successful in their claims." *City of Waukesha v. EPA*, 320 F.3d 228, 235 (D.C. Cir. 2003); see also *Parker v. Dist. of Columbia*, 478 F.3d 370, 377 (D.C. Cir. 2007), *aff'd by Dist. of Columbia v. Heller*, 554 U.S. 570 (2008). "While standing and merits questions frequently overlap, standing is fundamentally about the propriety of the individual litigating a claim irrespective of its legal merits[.]" *Lyons v. Litton Loan Servicing LP*, 158 F. Supp. 3d 211, 220 (S.D.N.Y. 2016) (citation omitted).

If the Court assumes, as it must in this setting, that Plaintiffs will prevail on their claims of discrimination in violation of the Commerce Clause, then the injury is clear: Plaintiffs are forbidden from taking a constitutionally permissible action, i.e., raising the

price of their drugs, by unconstitutional means, i.e., the unconstitutional pass-through prohibition. To prove standing, Plaintiffs need to prove they are

under threat of suffering “injury in fact” that is concrete and particularized; the threat must be actual and imminent, not conjectural or hypothetical; it must be fairly traceable to the challenged action of the defendant; and it must be likely that a favorable judicial decision will prevent or redress the injury.

Summers v. Earth Island Inst., 555 U.S. 488, 493 (2009). Here, the injury is a million-dollar-per-incident penalty that could hit Plaintiffs on January 1, 2019, if not sooner. Striking the provision would remove the challenged action and redress the injury. The injury here is clear, and AAM’s standing follows. (AAM Reply 2).

New York’s second standing argument is directed toward SpecGx alone, and it relates to the manufacturer’s New York factory. “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[.]” (NY-SG Opp. 8). New York relies on *Coalition for Competitive Electricity, Dynergy, Inc. v. Zibelman*, which held that “[t]o 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.” 906 F.3d 41, 58 (2d Cir. 2018). However, the standing portion of the *Zibelman* decision made clear that “Plaintiffs’ injuries ‘would continue to exist even if the [legislation] were cured’ of the alleged discrimination.” *Id.* Here, by contrast, SpecGx *could* recover the costs of the OSA through passing on the

price in its in-state sales and receive redress for its injuries, were it not for the pass-through prohibition. SpecGx has placed uncontested evidence into the record that the pass-through prohibition will make its sales to the New York market economically infeasible. (SpecGx Reply 17). In this litigation, New York seeks to shift the blame for this consequence onto third parties, such as AmerisourceBergen, that choose to charge back the costs, but the New York legislature clearly intended this precise result when it included the pass-through prohibition. New York cannot now claim that its actions are not causing injury to manufacturers like SpecGx, and SpecGx has standing to bring its claims.

As the above analysis explains, the Court has rejected New York's challenges to its ability to hear Plaintiffs' claims, as well as its challenges to each Plaintiff's respective ability to bring such claims. Because, as demonstrated in the next section, at least one claim common to all Plaintiffs succeeds, New York's motions to dismiss are denied as to all parties.

B. The Court Grants HDA's Motion for Summary Judgment

As the Court considers the merits of Plaintiffs' claims, it begins with HDA's motion for summary judgment. It does so because were HDA to be successful with any of its claims, it might impact the Court's resolution of AAM's and SpecGx's motions for preliminary injunctions. More specifically, the Court begins with a discussion of the Dormant Commerce Clause, as all three Plaintiffs allege that the pass-through prohibition violates the Dormant Commerce Clause. The Court agrees and holds the pass-through prohibition unconstitutional. The Court then discusses severability, as an examination of the OSA absent the pass-through prohibition is unnecessary, if the prohibition is not severable. The Court finds that the provision is not

severable and thus grants HDA's motion for summary judgment.

1. Applicable Law

a. The Standard for Summary Judgment Motions

Under Federal Rule of Civil Procedure 56(a), a “court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).⁶ A fact is “material” if it “might affect the outcome of the suit under the governing law,” and is genuinely in dispute “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *see also Jeffreys v. City of New York*, 426 F.3d 549, 553 (2d Cir. 2005) (citing *Anderson*).

The moving party bears the initial burden of demonstrating “the absence of a genuine issue of material fact.” *Celotex*, 477 U.S. at 323. The movant may discharge its burden by showing that the nonmoving party has “fail[ed] to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the

⁶ The 2010 Amendments to the Federal Rules of Civil Procedure revised the summary judgment standard from a genuine “issue” of material fact to a genuine “dispute” of material fact. See Fed. R. Civ. P. 56, advisory comm. notes (2010 Amendments) (noting that the amendment to “[s]ubdivision (a) ... chang[es] only one word — genuine ‘issue’ becomes genuine ‘dispute.’ ‘Dispute’ better reflects the focus of a summary-judgment determination.”). This Court uses the post-amendment standard, but continues to be guided by pre-amendment Supreme Court and Second Circuit precedent that refer to “genuine issues of material fact.”

burden of proof at trial.” *Celotex*, 477 U.S. at 322; see also *Selevan v. N.Y. Thruway Auth.*, 711 F.3d 253, 256 (2d Cir. 2013) (finding summary judgment appropriate where the non-moving party failed to “come forth with evidence sufficient to permit a reasonable juror to return a verdict in his or her favor on an essential element of a claim” (internal quotation marks omitted)).

If the moving party meets this burden, the non-moving party must “set forth specific facts showing that there is a genuine issue for trial” using affidavits or otherwise, and cannot rely on the “mere allegations or denials” contained in the pleadings. *Anderson*, 477 U.S. at 248; see also *Wright v. Goord*, 554 F.3d 255, 266 (2d Cir. 2009). In other words, the nonmoving party “must do more than simply show that there is some metaphysical doubt as to the material facts,” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986), and cannot rely on “mere speculation or conjecture as to the true nature of the facts to overcome a motion for summary judgment,” *Knight v. U.S. Fire Ins. Co.*, 804 F.2d 9, 12 (2d Cir. 1986).

“When ruling on a summary judgment motion, the district court must construe the facts in the light most favorable to the non-moving party and must resolve all ambiguities and draw all reasonable inferences against the movant.” *Dallas Aerospace, Inc. v. CIS Air Corp.*, 352 F.3d 775, 780 (2d Cir. 2003). However, in considering “what may reasonably be inferred” from witness testimony, the court should not accord the non-moving party the benefit of “unreasonable inferences, or inferences at war with undisputed facts.” *Berk v. St. Vincent’s Hosp. & Med. Ctr.*, 380 F. Supp. 2d 334, 342 (S.D.N.Y. 2005) (citing *County of Suffolk v. Long Island Lighting Co.*, 907 F.2d 1295, 1318 (2d Cir. 1990)).

b. The Dormant Commerce Clause

The Supreme Court has consistently held that in addition to providing an affirmative grant of authority to Congress, the Commerce Clause encompasses an implicit or “dormant” limitation on the authority of the States to enact legislation affecting interstate commerce. *See, e.g., Hughes v. Oklahoma*, 441 U.S. 322, 326 (1979); *H.P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 534-535 (1949). As mentioned above in the discussion of *Pullman* abstention, New York offers two readings of the OSA. One raises issues of extraterritoriality and the other issues of discrimination against out-of-state opioid transactions.

i. Extraterritorial Application of State Law

The absolute constitutional prohibition on state regulation of commerce occurring beyond the state’s borders is clear: “Taken together, ... cases concerning the extraterritorial effects of state economic regulation stand ... for the following proposition[]: ... the ‘Commerce Clause’ ... precludes the application of a state statute to commerce that takes place wholly outside of the State’s borders[.]” *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989). “[A] statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State’s authority and is invalid regardless of whether the statute’s extraterritorial reach was intended by the legislature.” *Id.*

The Constitution is concerned with the maintenance of a national market for interstate commerce. Therefore, even if a statute “may not in explicit terms seek to regulate interstate commerce, it [can do] so nonetheless by its practical effect and design.” *C & A Carbone, Inc. v. Town of Clarkstown, N.Y.*, 511 U.S. 383, 394 (1994).

ii. Discrimination Against Interstate Commerce

The Dormant Commerce Clause also contains an antidiscrimination principle. This principle “follows inexorably from the basic purpose of the Clause’ to prohibit the multiplication of preferential trade areas destructive of the free commerce anticipated by the Constitution.” *Maryland v. Louisiana*, 451 U.S. 725, 754 (1981) (internal citations omitted).

“The paradigmatic example of a law discriminating against interstate commerce is the protective tariff or customs duty, which taxes goods imported from other States, but does not tax similar products produced in State.” *W. Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 193 (1994). However, as the Supreme Court has recognized, states are aware of the obvious constitutional problems of tariffs, and so few cases address clear tariffs. “Instead, the cases are filled with state laws that aspire to reap some of the benefits of tariffs by other means.” *Id.*

In examining whether regulatory actions amount to impermissible tariffs, the Supreme Court has looked at whether they constitute “economic protectionism — that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors.” *New Energy Co. of Indiana v. Limbach*, 486 U.S. 269, 273 (1988). The Second Circuit also provides for an examination of whether the challenged action “shifts the costs of regulation onto other states, permitting in-state lawmakers to avoid the costs of their political decisions.” *Brown & Williamson Tobacco Corp. v. Pataki*, 320 F.3d 200, 208 (2d Cir. 2003). If a regulation “unambiguously discriminates in its effect, it almost always is ‘invalid per se.’” *Id.* at 209.

iii. The *Pike* Balancing Test

Finally, even where a statute does not discriminate on its face, it may violate the Dormant Commerce Clause under the balancing test offered in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). The *Pike* test evaluates whether the statute’s burdens on interstate commerce are “clearly excessive in relation to the putative local benefits.” *Brown & Williamson*, 320 F.3d at 209. Although *Pike* allows for invalidation of statute statutes that are facially neutral, it does not invite a court to undertake its own analysis of the wisdom of legislation by analyzing the benefits and goals of legislation. Instead, for a statute to fail the *Pike* test, it “at a minimum, must impose a burden on interstate commerce that is qualitatively or quantitatively different from that imposed on intrastate commerce.” *National Elec. Mfrs. Ass’n v. Sorrell*, 272 F.3d 104, 109 (2d Cir. 2003). “Under *Sorrell*, a burden that seems incommensurate to the statute’s gains survives *Pike* as long as it affects intrastate and interstate interests similarly — the similar effect on interstate and intrastate interests assuaging the concern that the statute is designed to favor local interests.” *Brown & Williamson*, 320 F.3d at 209.

2. Analysis

a. The Pass-Through Prohibition Violates the Dormant Commerce Clause Under Any Interpretation

i. The Plainest Reading of the Pass-Through Prohibition Would Require the Extraterritorial Application of State Law

New York does not seriously dispute that the most natural reading of the OSA’s pass-through provisions violates the Commerce Clause’s prohibition on extra-

territorial state legislation. Instead, it argues that it does not intend to apply the OSA to penalize wholly out-of-state transactions: “[T]here is nothing in the record suggesting that DOH intends to take that expansive an approach to the Act. Notably, the Legislative History reflects a concern that New York impose the surcharge only to the extent that it can be done so constitutionally.” (NY-AAM Opp. 10). However, New York’s position is seriously, if not mortally, wounded by the fact that the text of the OSA places no such limitation on the pass-through prohibition, stating merely: “Where the ratable share, or any portion thereof, has been passed on to a purchaser by a licensee, the commissioner may impose a penalty not to exceed one million dollars per incident.” N.Y. Pub. Health Law § 3323(10)(c). Indeed, at other points, the OSA specifically references sales made within New York State. *See, e.g., id.* § 3323(4) (“Each manufacturer and distributor licensed under this article that sells or distributes opioids in the state of New York shall provide to the commissioner a report detailing all opioids sold or distributed by such manufacturer or distributor in the state of New York.”). As AAM points out, New York nowhere concedes that it will never charge the penalty for out-of-state sales, only that it has displayed no current intention to do so. (AAM Reply 4 (“Defendants could obviate AAM’s First Cause of Action simply by agreeing that an out-of-state transaction is not subject to the Act’s anti-pass-through provisions and accepting a consent decree to that effect.”)).

If OSA’s provisions are given their clearest meaning, the Dormant Commerce Clause violation is clear. An opioid manufacturer based in Maine that wished to pass on the surcharge it paid on New York transactions by selling opioids at a markup to a pharmacy in New Mexico could face a million-dollar penalty from

New York State. While the statute “may not in explicit terms seek to regulate interstate commerce,” that it does so “nonetheless by its practical effect and design” is abundantly clear. *C & A Carbone*, 511 U.S. at 394. However, despite the clear constitutional problems evidenced by this example, the Court does not end its analysis there, as “the elementary rule is that every reasonable construction must be resorted to in order to save a statute from unconstitutionality.” *Hooper v. People of State of Cal.*, 155 U.S. 648, 657 (1895). The Court turns to an examination of the OSA under the Dormant Commerce Clause, where the penalty provision is assumed to apply only in-state, and where the text is understood to mean, “Where the ratable share, or any portion thereof, has been passed on to a *New York* purchaser by a licensee, the commissioner may impose a penalty not to exceed one million dollars per incident.”

ii. If Limited to New York, the Pass-Through Prohibition Discriminates Against Out-of-State Purchasers

If the OSA pass-through prohibition applies only to in-state purchasers, New York would clearly “reap some of the benefits of tariffs by other means.” *Healy*, 512 U.S. at 193. New York opioid customers would be protected from any price increases in their purchases, and New York would receive a source of funding subsidized by the out-of-state purchasers of opioids. New York could completely avoid the political consequences of its action, as no New York-based business or taxpayer would face a higher cost. Rather, out-of-state drug purchasers, with no representation in New York’s legislature or executive, would bear the cost of New York’s policy program. This shifting of burdens and benefits is antithetical to the idea of intra-national free trade and demonstrates why the Dormant Commerce Cause ex-

ists, i.e., to prohibit discrimination as to “any part of the stream of commerce — from wholesaler to retailer to consumer.” *Id.* at 192.

New York attempts to argue around this clear problem by proffering alternative constructions of the OSA. It suggests that the pass-through prohibition could be limited to cases where the cost would otherwise be filtered back through the state through Medicaid, or to situations where a company “contractually offloads the surcharge onto customers or expressly imposes the surcharge as a component of the price for opioid product”; alternatively, it suggests that companies “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.” (NY-AAM Opp. 8-10; NY-SG Opp. 17). The first and most obvious problem with these arguments is that the text of the Act offers no support for any of these interpretations. Indeed, the legislature specifically included the term “*any portion thereof*” in the statutory text. N.Y. Pub. Health Law § 3323(10)(c). New York essentially asks the Licensees, including Plaintiffs, to trust that DOH will not enforce the statute as written. The Court will not force these entities to serve as test subjects in New York’s evolving effort to address constitutional issues that could easily have been remedied at the drafting stage.

What is more, no matter what construction New York provides, the Act would still have the effect of discriminating between the purchasers of opioids in New York and those outside it. If the penalty is limited to situations where New York would pay through Medicaid, New York Medicaid would gain a discount that other states’ Medicaid programs would not. If the charge could be passed contractually outside New York

but not within, New York customers would gain an advantage unavailable to their out-of-state counterparts. Even if New York purchasers of non-opioid pharmaceuticals could be forced to pay a percentage of the surcharge, this would still not remedy the problem, inasmuch as the Act still treats New York customers of opioids differently than out-of-state customers of the same product. New York's problem remains the same throughout: the Supreme Court has expressly held that the Constitution prohibits "legislation that has the practical effect of establishing 'a scale of prices for use in other states.'" *Healy*, 491 U.S. at 336.

The cases that New York cites in its defense only underscore the problem. New York cites *Freedom Holdings, Inc. v. Spitzer*, 357 F.3d 205 (2d Cir. 2004), which upheld New York's cigarette contraband statutes, but the Second Circuit began its discussion in that case by pointing out that the plaintiffs "[could not and did] not identify any in-state commercial interest that [was] favored, directly or indirectly, by the Contraband Statutes at the expense of out-of-state competitors. *Id.* at 218. Here, the distinction between in-state and out-of-state commercial actors is clear. New York also points to *National Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001). However, *Sorrell*, which allowed Vermont to require lamps containing mercury bulbs to bear labels, is a particularly weak case for New York, considering the following distinction advanced by the Court: "In cases like *Healy*, the state necessarily prevented firms from recouping any of the costs imposed by the state statute from the residents of the state itself. Here, the manufacturers remain free to charge higher prices only to Vermonters without risking violation of the statute." 272 F.3d at 110. The OSA's pass-through prohibition places this case far closer to *Healy* than *Sorrell*.

This analysis of the pass-through prohibition requires no factual findings. Because the question of *Pike* balancing requires additional factual development, and because the OSA either regulates extraterritorially or discriminates in its effects, the Court does not believe it is necessary to address *Pike*. Rather, it is clear from the legislation itself that the pass-through prohibition cannot be applied in a constitutional manner.

3. The Pass-Through Prohibition Cannot be Severed From the OSA

What remains is the question of severance — can the pass-through prohibition be severed from the OSA? Here, alliances are switched, in that all parties but HDA believe the provision can be severed. The Court agrees with HDA.

a. Applicable Law

“Severability is a question of state law[.]” *Concerned Home Care Providers, Inc. v. Cuomo*, 783 F.3d 77, 88 (2d Cir. 2015). “The question is ... whether the legislature ... would have wished the statute to be enforced with the invalid part excised.” *Nat’l Advert. Co. v. Town of Niagara*, 942 F.2d 145, 148 (2d Cir. 1991) (internal citations omitted). “In the absence of evidence that the Legislature would have intended that [a law] remain effective if the primary purpose of the act ... could not be given effect, there is no basis to sever[.]” *City of N.Y. v. Patrolmen’s Benev. Ass’n of City of N.Y., Inc.*, 89 N.Y.2d 380, 394 (1996).

Courts generally presume severability, in accordance with the admonition of then-Judge Cardozo that: “Our right to destroy is bounded by the limits of necessity. Our duty is to save unless in saving we pervert.” *People ex rel. Alpha Portland Cement Co. v. Knapp*, 230 N.Y. 48, 62-63 (1920), *cert. denied*, 256 U.S. 702 (1921). “The preference for severance is particularly strong

when the law contains a severability clause.” *Nat’l Advert. Co.*, 942 F.2d at 148. However, “severance is inappropriate when the valid and invalid provisions are so intertwined that excision of the invalid provisions would leave a regulatory scheme that the legislature never intended.” *Id.* A court may also abstain from considerations of severability and seek (or wait for) guidance from the state. *Cf. Exxon Corp. v. Eagerton*, 462 U.S. 176, 197 (1983) (“Since the severability of the pass-through prohibition from the remainder of the 1979 amendments is a matter of state law, we remand to the Supreme Court of Alabama[.]”).

b. Analysis

This case exemplifies the second line of Judge Cardozo’s admonition; “saving” the OSA absent the pass-through prohibition would clearly “pervert” it. As HDA points out,

Governor Cuomo assured legislators that “[l]anguage in the budget ensures the costs are borne by industry, not by consumers.”... [I]n a legislative hearing, after an assemblyman expressed that “a lot of us are concerned on how this surcharge could go to the consumer,” Commissioner Zucker promised that the Surcharge will not “get filtered down to the end-user.”

(HDA Br. 25). Assembly Member Weinstein, who presented and defended the law before the Assembly, declared similarly that it was “certainly not the [draft-er’s] intention [to have pharmacies pay the OSA’s surcharge].” (Farber Decl., Ex. K at 23).

New York’s response is not to debate the legislative history, which makes clear the State’s desire to place the surcharge directly on distributors and manufacturers. Instead, New York points to the revenue-raising

goals of the law. Its discussion of severability strikes the Court as half-hearted, if not defeatist:

[E]ven if the pass-through provision were struck down judicially, the remainder of the Act could potentially remain in force. Though the Act's revenue-raising purpose would be seriously impaired, conceivably alternative funding for the programs at issue could be supplied through subsequent legislation.

(NY-HDA Opp. 22). When New York suggests that subsequent legislation would be necessary to ensure the OSA achieves its goals absent the prohibition, it is not fairly grappling with a standard that requires examination of whether severance “would leave a regulatory scheme that the legislature never intended.” *Nat'l Advert. Co.*, 942 F.2d at 148.

The severability analysis does not ask whether a state can wring some benefit from the dregs of a discarded statutory scheme. The Court understands that New York prefers to have \$100 million in anticipated stewardship charges in its budget, but the Governor, Commissioner, and legislators explicitly pledged that the costs of the bill would *not* flow to end-users and pharmacies. This clearly suggests that a bill that merely imposed a surcharge, without any mechanism for preventing the costs of that surcharge from flowing to the consumer, was “never intended.”

To be sure, the OSA contains a severability clause. However, the Second Circuit has spoken to the somewhat limited utility of such clauses:

The presence of such a clause ... is not dispositive. See *New York State Superfund Coalition, Inc. v. New York State Dep't of Environmental Conservation*, 75 N.Y.2d 88, 94 (Ct. App. 1989) (holding that objectionable sections were not

severable from entire statute despite presence of a severability clause); *see also United States v. Jackson*, 390 U.S. 570, 585 n.27 (1968) (the ultimate determination of severability will rarely turn on the presence or absence of a severability clause). We should not, for example, treat a severability clause as an invitation from the legislature to write whatever statute we can fashion from the constitutional remnants as augmented by our imagination.

Nat'l Advert. Co., 942 F.2d at 148.

The legislative history of the OSA evinces a clear assessment by the legislature as to where it expected this money to come from, and New York does not so much as hint that it ever considered other sources than the Licensees. In other cases, contested legislation may consist of multiple regulatory actions with unconnected elements and diverse goals. *See, e.g., Concerned Home Care Providers*, 783 F.3d at 88 (“[W]e agree with the district court that, without subdivision four, the Wage Parity Law will still accomplish the legislative purpose of aligning home care aide compensation in the New York City metropolitan area.”). However, the OSA clearly rests on the twin pillars of a surcharge and a pass-through prohibition. With one pillar knocked out for constitutional reasons, the OSA cannot stand. The Court does not sever the pass-through prohibition; it rules that the OSA is unconstitutional its entirety. For this reason, it grants HDA’s motion for summary judgment.

As the Court has determined that the OSA is unconstitutional under the Dormant Commerce Clause, it declines to address HDA’s arguments concerning Substantive Due Process, Bills of Attainder, the Takings Clause, and vagueness. The Dormant Commerce Clause prevents New York from enforcing the OSA, but

unlike HDA's remaining challenges, the Dormant Commerce Clause does not speak to the ability of the federal government to pass similar legislation. Keeping in mind that "[i]t is not the habit of [a] court to decide questions of a constitutional nature unless absolutely necessary to a decision of the case[.]" *Ashwander v. Tennessee Valley Auth.*, 297 U.S. 288, 347 (1936) (Brandeis, J., concurring), the Court will refrain from addressing these issues.

Similarly, the Court declines to address the preemption arguments raised by SpecGx. "[T]he Supreme Court has cautioned against preempting state action in fields of traditional state regulation, and has assumed that the historic police powers of the States were not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress." *Concerned Home Care Providers*, 783 F.3d at 88 (internal quotations omitted). As many of the issues raised in the preemption argument fit more neatly into a Dormant Commerce Clause argument, the Court will heed the warning of the Supreme Court and Second Circuit and will demur on the issue of preemption.

C. The Court Grants AAM's and SpecGx's Motions for Preliminary Injunction

To review, AAM and SpecGx brought more surgical applications for relief from this Court, each seeking a preliminary injunction against enforcement of the pass-through prohibition rather than summary judgment. A preliminary injunction "is an extraordinary and drastic remedy" that a district court should grant only if "the movant, by a clear showing, carries the burden of persuasion." *Grand River Enter. Six Nations, Ltd. v. Pryor*, 481 F.3d 60, 66 (2d Cir. 2007) (quoting *Moore v. Consol. Edison Co. of N.Y.*, 409 F.3d 506, 510 (2d Cir. 2005)). This burden requires the movant to "establish [i] irreparable harm; [ii] either (a) a likeli-

hood of success on the merits, or (b) sufficiently serious questions going to the merits of its claims to make them fair ground for litigation, plus a balance of the hardships tipping decidedly in favor of the moving party; and [iii] that a preliminary injunction is in the public interest.” *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 650 (2d Cir. 2015), (internal quotation marks omitted) (quoting *Oneida Nation of N.Y. v. Cuomo*, 645 F.3d 154, 164 (2d Cir. 2011)).⁷

The Court has found that the pass-through prohibition violates the Dormant Commerce Clause, and AAM and SpecGx have thereby satisfied the “likelihood of success” requirement. The other requirements are also met. Irreparable harm in this setting is defined as “certain and imminent harm for which a monetary award does not adequately compensate.” *Wisdom Imp. Sales Co. v. Labatt Brewing Co.*, 339 F.3d 101, 113 (2d Cir. 2003). It exists “where, but for the grant of equitable relief, there is a substantial chance that upon final resolution of the action the parties cannot be returned to the positions they previously occupied.” *Brenntag Int’l Chem., Inc. v. Bank of India*, 175 F.3d 245, 249-50 (2d Cir. 1999) (citing *American Hosp. Supply Corp. v. Hospital Prods. Ltd.*, 780 F.2d 589, 594 (7th Cir. 1986)). And it is often presumed in cases involving a constitutional violation. *See Jolly v. Coughlin*, 76 F.3d 468, 482 (2d Cir. 1996) (“The district court therefore properly relied on the presumption of irreparable inju-

⁷ And where a movant seeks a preliminary injunction under the “serious questions” standard, the movant “must not only show that there are ‘serious questions’ going to the merits, but must additionally establish that ‘the balance of hardships tips decidedly’ in its favor,” and thus the “overall burden is no lighter than the one it bears under the ‘likelihood of success’ standard.” *Citigroup Glob. Mkts., Inc. v. VCG Special Opportunities Master Fund Ltd.*, 598 F.3d 30, 35 (2d Cir. 2010) (internal citation omitted).

ry that flows from a violation of constitutional rights.”). Here, AAM and SpecGx have presented credible evidence that the OSA, and in particular its pass-through prohibition, will cause them to alter dramatically, if not eliminate altogether, their sales of opioid medications in New York. Such wholesale restructuring, undertaken in response to credible threats of million-dollar penalties, suffices to demonstrate irreparable harm.

The Court also finds that the balance of equities favors the grant of injunction. In so finding, the Court reiterates that the underlying goals of the OSA are commendable. However, the Court cannot permit New York to achieve these goals through unconstitutional means. In other words, New York’s interest in the public health of its residents cannot trump the Commerce Clause. Additionally, the perhaps-unforeseen consequence that the OSA could well *reduce* the availability of opioid medications for those who need them also runs counter to the public interest.

For all of these reasons, AAM’s and SpecGx’s motions for preliminary injunction are granted.

CONCLUSION

For the foregoing reasons, New York’s motions to dismiss in all three cases are DENIED; HDA’s motion for summary judgment in Case No. 18 Civ. 6168 is GRANTED; AAM’s motion for preliminary injunctive relief in Case No. 18 Civ. 8180 is GRANTED; and SpecGx’s motion for preliminary injunctive relief in Case No. 18 Civ. 9830 is GRANTED.

As to Case No. 18 Civ. 6168, the Clerk of Court is directed to terminate all pending motions, adjourn all remaining dates, and close the case.

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As to Case No. 18 Civ. 8180, the Clerk of Court is directed to terminate the motions at docket entries 8, 10, and 22.

As to Case No. 18 Civ. 9830, the Clerk of Court is directed to terminate the motions at docket entries 7 and 27.

The parties in each of Case Nos. 18 Civ. 8180 and 18 Civ. 9830 are directed to submit letters to the Court regarding next steps in the case on or before **January 31, 2019**.

SO ORDERED.

Dated: December 19, 2018
New York, New York



KATHERINE POLK FAILLA

United States District Judge

APPENDIX C

**UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT**

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 18th day of December, two thousand twenty.

Association for Accessible Medicines,
Healthcare Distribution Alliance,
SpecGx LLC,

Plaintiffs – Appellees,

v.

Letitia James, in her official capacity as Attorney General of the State of New York, Howard A. Zucker, in his official capacity as Commissioner of Health of the State of New York,

Defendants – Appellants.

ORDER

Docket Nos:

19-183 (Lead)

19-199

(Con)

19-201 (Con)

Appellees filed a petition for panel rehearing, or, in the alternative, for rehearing en banc. The panel that determined the appeal has considered the request for panel rehearing, and the active members of the Court have considered the request for rehearing en banc.

IT IS HEREBY ORDERED that the petition is denied.

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FOR THE COURT:

Catherine O'Hagan
Wolfe, Clerk

 Catherine O'Hagan Wolfe

APPENDIX D

**UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT**

At a Stated Term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 12th day of February, two thousand twenty-one.

Before: José A. Cabranes,
Raymond J. Lohier, Jr.,
Circuit Judges,
Christina Reiss,
*District Judge.**

Association for Accessible Medicines,
Healthcare Distribution Alliance,
SpecGx LLC,

Plaintiffs – Appellees,

v.

Letitia James, in her official capacity as Attorney General of the State of New York, Howard A. Zucker, in his official capacity as Commissioner of Health of the State of New York,

Defendants – Appellants.

ORDER

Docket Nos:

19-183 (Lead)

19-199

(Con)

19-201 (Con)

* Judge Christina Reiss, of the United States District Court for the District of Vermont, sitting by designation.

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Appellees move to stay the mandate pending the filing and disposition of a petition for a writ of certiorari. Appellants oppose the motion.

IT IS HEREBY ORDERED that the motion is GRANTED.

FOR THE COURT:

Catherine O'Hagan
Wolfe, Clerk

 Catherine O'Hagan Wolfe

APPENDIX E

Tax Injunction Act (TIA), 28 U.S.C. § 1341 provides as follows:

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.

The Opioid Stewardship Act (OSA), provides in relevant part as follows:

**Public Health Law § 3323
Opioid stewardship fund**

1. Definitions:

- (a) “Opioid stewardship payment” shall mean the total amount to be paid into the opioid stewardship fund for each state fiscal year as set forth in subdivision two of this section.
- (b) “Ratable share” shall mean the individual portion of the opioid stewardship payment to be paid by each manufacturer and distributor licensed under this article that sells or distributes opioids in the state of New York.
- (c) Notwithstanding any inconsistent provision of law to the contrary, “distribute” shall mean to deliver a controlled substance other than by administering or dispensing to the ultimate user, including intra-company transfers between any division, affiliate, subsidiary, parent or other entity under complete common ownership and control. For purposes of this section, “distribute” shall not include con-

trolled substances surrendered to reverse distributors, or donated to recipient entities or third-party intermediaries pursuant to the unused prescription drug donation and redispensing program of section two hundred eighty-b of this chapter.

2. Opioid stewardship payment imposed on manufacturers and distributors.

All manufacturers and distributors licensed under this article (hereinafter referred to as “licensees”), that sell or distribute opioids in the state of New York shall be required to pay an opioid stewardship payment. On an annual basis, the commissioner shall certify to the state comptroller the amount of all revenues collected from opioid stewardship payments and any penalties imposed. The amount of revenues so certified shall be deposited quarterly into the opioid stewardship fund established pursuant to section ninety-seven-aaaaa of the state finance law. No licensee shall pass the cost of their ratable share amount to a purchaser, including the ultimate user of the opioid, or such licensee shall be subject to penalties pursuant to subdivision ten of this section.

3. Determination of opioid stewardship payment.

The total opioid stewardship payment amount shall be one hundred million dollars annually, subject to downward adjustments pursuant to subdivision nine of this section.

4. Reports and records.

Each manufacturer and distributor licensed under this article that sells or distributes opioids in the state of New York shall provide to the commissioner a report detailing all opioids sold or distributed by such manufacturer or distributor in the state of New York. Such

report shall include:

- (a) the manufacturer's or distributor's name, address, phone number, federal Drug Enforcement Agency (DEA) registration number and controlled substance license number issued by the department;
- (b) the name, address and DEA registration number of the entity to whom the opioid was sold or distributed;
- (c) the date of the sale or distribution of the opioid;
- (d) the gross receipt total, in dollars, of all opioids sold or distributed;
- (e) the name and National Drug Code (NDC) of the opioid sold or distributed;
- (f) the number of containers and the strength and metric quantity of controlled substance in each container of the opioid sold or distributed;
- (g) the total number of morphine milligram equivalents (MMEs) sold or distributed; and
- (h) any other elements as deemed necessary by the commissioner.

4-a. Initial and future reports.

- (a) Such information shall be reported annually to the department in such form as defined by the commissioner, provided however that the initial report provided pursuant to subdivision four shall consist of all opioids sold or distributed in the state of New York for the two thousand seventeen calendar year, and must be submitted by August 1, 2018. Subsequent annual reports shall be submitted on April first of each year based on the actual opioid sales and distributions of the prior calendar year.

- (b) For the purpose of such annual reporting, MMEs shall be determined pursuant to a formulation to be issued by the department and updated as the department deems appropriate.

5. Determination of ratable share.

Each manufacturer and distributor licensed under this article that sells or distributes opioids in the state of New York shall pay a portion of the total opioid stewardship payment amount. The ratable share shall be calculated as follows:

- (a) The total amount of MMEs sold or distributed in the state of New York by the licensee for the preceding calendar year, as reported by the licensee pursuant to subdivision four of this section, shall be divided by the total amount of MME sold in the state of New York by all licensees pursuant to this article to determine the licensee payment percentage. The licensee payment percentage shall be multiplied by the total opioid stewardship payment. The product of such calculation shall be the licensee's ratable share. The department shall have the authority to adjust the total number of a licensee's MMEs to account for the nature and use of the product, as well as the type of entity purchasing the product from the licensee, when making such determination and adjust the ratable share accordingly.
- (b) The licensee's total amount of MME sold or distributed, as well as the total amount of MME sold or distributed by all licensees under this article, used in the calculation of the ratable share shall not include the MME of those opioids which are:

- (i) manufactured in New York state, but whose final point of delivery or sale is outside of New York state;
 - (ii) sold or distributed to entities certified to operate pursuant to article thirty-two of the mental hygiene law, or article forty of the public health law; or
 - (iii) the MMEs attributable to buprenorphine, methadone or morphine.
- (c) The department shall provide to the licensee, in writing, on or before October fifteenth, two thousand eighteen, the licensee's ratable share for the two thousand seventeen calendar year. Thereafter, the department shall notify the licensee in writing annually on or before October fifteenth of each year based on the opioids sold or distributed for the prior calendar year.

6. Payment of ratable share.

The licensee shall make payments quarterly to the department with the first payment of the ratable share, provided that the amount due on January first, two thousand nineteen shall be for the full amount of the first annual payment, with additional payments to be due and owing on the first day of every quarter thereafter.

7. Rebate of ratable share.

In any year for which the commissioner determines that a licensee failed to report required information as required by this section, those licensees complying with this section shall receive a reduced assessment of their ratable share in the following year equal to the amount in excess of any overpayment in the prior payment period.

8. Licensee opportunity to appeal.

A licensee shall be afforded an opportunity to submit information to the department to justify why the ratable share provided to the licensee, pursuant to paragraph (c) of subdivision five of this section, or amounts paid thereunder are in error or otherwise not warranted. If the department determines thereafter that all or a portion of such ratable share, as determined by the commissioner pursuant to subdivision five of this section, is not warranted, the department may:

- (a) adjust the ratable share;
- (b) adjust the assessment of the ratable share in the following year equal to the amount in excess of any overpayment in the prior payment period; or
- (c) refund amounts paid in error.

9. Department annual review.

The department shall annually review the amount of state operating funds spent in the office of alcoholism and substance abuse services (OASAS) budget for opioid prevention, treatment and recovery. The commissioner of OASAS shall certify to the department the amount of annual spending for such services, utilizing available information on patient demographics and the actual cost of services delivered by the state and by state-funded providers. The certification of such spending shall begin in state fiscal year two thousand eighteen-nineteen, and continue annually thereafter. The total amount of such spending shall be provided to the department by the commissioner of OASAS no later than June thirtieth of each year. There shall be no stewardship fund payments beginning on July first in the event state operating funds spent in the OASAS budget for opioid prevention, treatment and recovery in the most recently reported year is equal to or less than

state operating funds spent for such purposes in state fiscal year two thousand nine-ten.

10. Penalties.

(a) The department may assess a civil penalty in an amount not to exceed one thousand dollars per day against any licensee that fails to comply with subdivisions four and four-a of this section.

(b) In addition to any other civil or criminal penalty provided by law, where a licensee has failed to pay its ratable share in accordance with subdivision six of this section, the department may also assess a penalty of no less than ten percent and no greater than three hundred percent of the ratable share due from such licensee.

(c) Where the ratable share, or any portion thereof, has been passed on to a purchaser by a licensee, the commissioner may impose a penalty not to exceed one million dollars per incident.

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**State Finance Law § 97-aaaaa
Opioid stewardship fund.**

1. There is hereby established in the joint custody of the state comptroller and the commissioner of taxation and finance an account of the miscellaneous special revenue account to be known as the "opioid stewardship fund".

2. Moneys in opioid stewardship fund shall be kept separate and shall not be commingled with any other moneys in the custody of the state comptroller and the commissioner of taxation and finance.

3. The opioid stewardship fund shall consist of moneys appropriated for the purpose of such account, moneys transferred to such account pursuant to law, contributions consisting of promises or grants of any money or property of any kind or value, or any other thing of value, including grants or other financial assistance from any agency of government and moneys required by the provisions of this section or any other law to be paid into or credited to this account.

4. Moneys of the opioid stewardship fund, when allocated, shall be available, subject to the approval of the director of the budget, to support programs operated by the New York state office of alcoholism and substance abuse services or agencies certified, authorized, approved or otherwise funded by the New York state office of alcoholism and substance abuse services to provide opioid treatment, recovery and prevention and education services; and to provide support for the prescription monitoring program registry as established pursuant to section thirty-three hundred forty-three-a of the public health law.

5. At the request of the budget director, the state comptroller shall transfer moneys to support the costs of opioid treatment, recovery, prevention, education services, and other related programs, from the opioid stewardship fund to any other fund of the state to support this purpose.

6. (i) Notwithstanding the provisions of any general or special law, no moneys shall be available from the opioid stewardship fund until a certificate of allocation and a schedule of amounts to be available therefor shall have been issued by the director of the budget, upon the recommendation of the commissioner of the office of alcoholism and

substance abuse services, and a copy of such certificate filed with the comptroller, the chairman of the senate finance committee and the chairman of the assembly ways and means committee.

(ii) Such certificate may be amended from time to time by the director of the budget, upon the recommendation of the commissioner of the office of alcoholism and substance abuse services, and a copy of such amendment shall be filed with the comptroller, the chairman of the senate finance committee and the chairman of the assembly ways and means committee.

7. The moneys, when allocated, shall be paid out of the opioid stewardship fund, pursuant to subdivision four of this section, and subject to the approval of the director of the budget, on the audit and warrant of the comptroller on vouchers certified or approved by (i) the commissioner of the office of alcoholism and substance abuse services or his or her designee; or (ii) the commissioner of the department of health or his or her designee.