No. 19-183(L

Nos. 19-199, 19-201(CON)

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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.

On Appeal from the United States District Court for the Southern District of New York, Nos. 18-cv-8180, 18-cv-9830

BRIEF FOR PLAINTIFFS-APPELLEES ASSOCIATION FOR ACCESSIBLE MEDICINES AND SPECGX LLC

DOUGLAS H. HALLWARD-DRIEMEIER JAY P. LEFKOWITZ

ROPES & GRAY LLP

2099 Pennsylvania Avenue, NW

Washington, DC 20006

(202) 508-4600

douglas.hallward-driemeier@ropesgray.com jay.lefkowitz@kirkland.com

Counsel for SpecGx LLC

KIRKLAND & ELLIS LLP

601 Lexington Avenue New York, NY 10022

(212) 446-4800

Counsel for Association for Accessible

Medicines

(Additional Counsel Listed on Inside Cover)

July 31, 2019

ERIN R. MACGOWAN ROPES & GRAY LLP Prudential Tower 800 Boylston Street Boston, MA 02199

Counsel for SpecGx LLC

MATTHEW D. ROWEN KIRKLAND & ELLIS LLP 1301 Pennsylvania Avenue, NW Washington, DC 20004

Counsel for Association for Accessible Medicines

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1(a), the Association for Accessible Medicines ("AAM") certifies that it is a nonprofit, voluntary organization, and that there are no parent corporations or publicly held companies that own 10% or more of its stock; and SpecGx LLC ("SpecGx") certifies that it is a Delaware limited liability company whose sole member is Mallinckrodt LLC, and that Mallinckrodt plc, a publicly held Irish corporation, owns (indirectly) more than 10% of the stock of SpecGx.

TABLE OF CONTENTS

COR	PORA	TE DISCLOSURE STATEMENT	. i
TABI	LE OF	AUTHORITIES	iv
INTR	RODUC	CTION	1
STAT	EMEN	NT OF JURISDICTION	6
STAT	EMEN	NT OF THE ISSUES	6
STAT	EMEN	NT OF THE CASE AND THE FACTS	7
	A.	New York Enacts the Opioid Stewardship Act	7
	B.	Licensees Subject to the OSA File Suit	0
	C.	The District Court Holds the Anti-Pass-Through Provisions Unconstitutional and Invalidates the Statute	12
	D.	The New York Legislature Amends the OSA, Limits its Application to Already-Completed Sales, and Enacts a New Excise Tax	15
	E.	The State Abandons Its Defense of the Pass-Through Prohibition	16
SUM	MARY	Y OF ARGUMENT1	17
STAN	NDAR	DS OF REVIEW	9
ARG	UMEN	NT 1	9
I.		District Court Correctly Held That Neither The TIA Nor iples Of Comity Bars These Lawsuits	9
II.	This	Court Should Reject The State's Severability Argument	22
	A.	A "Severed" OSA Would Be Fatally Retroactive	23
	B.	Severing the OSA Would Invigorate the Same Unconstitutional Consequences That Led the District Court to Invalidate the Statute	27

CONCLUSION	28
CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION	
CERTIFICATE OF SERVICE	

TABLE OF AUTHORITIES

Cases

Ayotte v. Planned Parenthood of N. New England, 546 U.S. 320 (2006)	5, 25, 28
Buckley v. Valeo, 424 U.S. 1 (1976)	25
City of N.Y. v. Beretta U.S.A. Corp., 524 F.3d 384 (2d Cir. 2008)	19
Concerned Home Care Providers, Inc. v. Cuomo, 783 F.3d 77 (2d Cir. 2015)	25
Dahnke-Walker Milling Co. v. Bondurant, 257 U.S. 282 (1921)	28
De Cisneros v. Younger, 871 F.2d 305 (2d Cir. 1989)	21
E.E.O.C. v. CBS, Inc., 743 F.2d 969 (2d Cir. 1984)	25
Entergy Nuclear Vt. Yankee, LLC v. Shumlin, 737 F.3d 228 (2d Cir. 2013)	2, 21
Gen. Motors Corp. v. Romein, 503 U.S. 181 (1992)	23, 24
<i>In re Pan Am. Corp.</i> , 950 F.2d 839 (2d Cir. 1991)	21
Joseph v. Hyman, 659 F.3d 215 (2d Cir. 2011)	19
Landgraf v. USI Film Prods., 511 U.S. 244 (1994)	5, 23
Luessenhop v. Clinton Cty., 466 F.3d 259 (2d Cir. 2006)	19

20
20
24
2, 21
5, 25
12
25
14
6
6
6
1, 12
3, 15, 16, 20
passim
2, 16, 21
3, 16, 20, 26

Other Authorities

N.Y. State Opioid Annual Assessment Reporting Guidance,	
https://on.ny.gov/2MfST3m (last visited July 30, 2019)	10
Mem. in Support of Defs. Mot. to Dismiss, Ass'n for Accessible Meds.	
v. Underwood, No. 1:18-cv-08180-KPF (S.D.N.Y. Oct. 17, 2018)	12

INTRODUCTION

Three basic questions in these cases were decided by the district court below. Only two of those questions remain on appeal, and developments since the district court issued its opinion have erased any doubt about the soundness of the district court's decision on the remaining questions. The first question below was whether the Tax Injunction Act ("TIA"), 28 U.S.C. § 1341, or some other principle of federal law, precluded the district court from resolving the claims before it. The second was whether the anti-pass-through provisions of the Opioid Stewardship Act ("OSA"), N.Y. Pub. Health Law § 3323(2), (10)(c), violated the Commerce Clause or were otherwise unlawful. The third was whether the anti-pass-through provisions could be severed to save the future application of the OSA. In a decision that has only gotten better with age, the district court resoundingly rejected the State's procedural objections to resolving the plaintiffs' challenges and held that the anti-pass-through provisions do indeed violate the Commerce Clause and cannot be severed.

To start with the threshold issue, the TIA provides that "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. As an initial matter, the OSA conspicuously describes the amount each licensee owes as a "payment," does not once use the term "tax," and is codified in the Public Health Code, *not* the Tax Code. That alone casts

serious doubt on the TIA's application. See Nat'l Fed'n of Indep. Bus. v. Sebelius (NFIB), 567 U.S. 519, 544 (2012) (rejecting argument that courts "should treat [statute's shared-responsibility payment] as [a tax] under the Anti-Injunction Act because it functions like a tax" on the ground that Congress had refused to describe it as a "tax" in the statute). Nor can the OSA "payment" be considered a tax under the usual TIA metrics. The key question for determining whether a state-law monetary exaction is "a tax, as opposed to some other form of state-imposed financial obligation," is whether "the proceeds" of the exaction go "to general state revenues" (in which case the exaction likely is a tax) or whether they go to a "specialpurpose fund[]" reserved "for a[] particular purpose" (in which case it likely is not). Entergy Nuclear Vt. Yankee, LLC v. Shumlin, 737 F.3d 228, 231 (2d Cir. 2013). And here, the "revenues" generated by the ratable share payments "shall be deposited ... into the opioid stewardship fund," not the general treasury, N.Y. Pub. Health Law § 3323(2); "shall be kept separate and shall not be commingled with any other moneys," N.Y. State Fin. Law § 97-AAAAA(2); and may be used only "to support programs ... to provide opioid treatment, recovery and prevention and education services[] and to provide support for the prescription monitoring program registry," N.Y. State Fin. Law § 97-AAAAA(4). That is three strikes against the OSA. The

district court thus had no trouble rejecting the State's TIA argument and the State's related arguments sounding in principles of federal-state comity.¹

Intervening developments have only served to confirm the soundness of that conclusion. In April 2019, the New York Legislature enacted a new statute "[i]n response to the district court's decision." Opening Br. 20. Unlike the original OSA, the proceeds of that new statute flow into the State's general treasury and can be used for any purpose. See 2019 N.Y. Sess. Laws 59, Part XX, § 3. Unlike the original OSA, the new statute specifically designates each licensee's new monetary obligation as a "tax." N.Y. Tax Law § 498. Unlike the original OSA, which measured each licensee's payment based on a set \$100-million-per-year benchmark, the new statute imposes a direct assessment that varies based on the wholesale acquisition cost of the drug at issue in the sale. Compare N.Y. Pub. Health Law § 3323(3), with N.Y. Tax Law § 498(a). And unlike the original OSA, the new statute is codified in the Tax Code. The new statute thus not only shows that the New York Legislature knows how to enact a tax when that is its intention, but also confirms the correctness of the district court's TIA and comity holdings.

The State fares no better on the merits. After fighting tooth and nail to keep these challenges out of federal court, the State "elected not to seek reversal of the

¹ The court likewise had no trouble rejecting the related procedural arguments that the State has chosen not to press on appeal.

district court's invalidation of the pass-through prohibition" on appeal. Opening Br. 2. That decision is sensible, as the anti-pass-through provisions *obviously* violate the Commerce Clause. But that decision comes with consequences. In particular, it is now the law of the case that the anti-pass-through provisions violate the Constitution. The State therefore would be estopped from attempting to enforce them in the future regardless of the resolution of this appeal.

So what is actually left in this appeal? After holding that the OSA's anti-passthrough provisions violate the Commerce Clause, the district court further held that the remainder of the statute could not be severed. In addition to taking issue with the district court's aforementioned TIA and comity holdings, the State challenges that decision on appeal. But when it comes to the severability analysis, the statute that the district court confronted is not the same as the statute that now confronts this Court. The state legislature did not simply replace the OSA with an excise tax; instead, it enacted the excise tax on a forward-looking basis for 2019 and beyond and then amended the OSA so that the requirement to make ratable share payments applies only retroactively to 2017 and 2018 sales. See Opening Br. 21 ("The 2019 Act amends the OSA to provide that the OSA will remain in effect only for sales of opioids that took place before December 31, 2018."). As a result, what the State is asking this Court to do is to invigorate, under the guise of "severability," a payment

mandate that, as written by the legislature and as rewritten by this Court, would apply *only* to sales that have already been completed.

The problems with that request are legion. The Supreme Court has long recognized "the unfairness of imposing new burdens on persons after the fact." Landgraf v. USI Film Prods., 511 U.S. 244, 270 (1994). Yet that is precisely what accepting the State's "severability" argument would accomplish here, given that the legislature has since amended the (currently invalidated) statute to have effect (if at all) only to past conduct, as all sales to which the "severed" OSA would apply are sales that have already been completed. That is particularly problematic in the context of severability, which generally aims to salvage a statute's *future* application, not to rewrite the statute to apply a new rule to past conduct. See People ex rel. Alpha Portland Cement Co. v. Knapp, 129 N.E. 202, 207 (N.Y. 1920) (Cardozo, J.); Ayotte v. Planned Parenthood of N. New England, 546 U.S. 320, 330 (2006). Making matters worse, every sale to which a reinvigorated OSA would apply occurred when the anti-pass-through provisions remained in effect. It should go without saying, however, that a seller cannot rewrite the terms of its settled transactions, and thus cannot go back in time and pass on a portion of the cost of its ratable share payment attributable to those already-completed sales. Accepting the State's argument would thus result in exactly the same constitutional violations that led the district court to invalidate the OSA, which the State does not contest on appeal.

The State's purported severability "solution" is no solution at all. Accepting the State's position would give life to a fatally retroactive regime, fail the basic prerequisites of severability doctrine, and reintroduce the very unconstitutional injuries that the original OSA's anti-pass-through provisions visited on Appellees. Thus, in addition to affirming the district court's TIA and comity conclusions, this Court should reject the State's pseudo-severability argument and hold that the State may not use the language of the severability doctrine to give life to a retroactive regime or to invigorate through the backdoor the very unconstitutional harms that led the district court to invalidate the statute in the first place.

STATEMENT OF JURISDICTION

AAM and SpecGx agree with the State that "[t]he district court had subject matter jurisdiction over th[ese] action[s] under 28 U.S.C. § 1331." Opening Br. 5. "This Court has appellate jurisdiction under 28 U.S.C. § 1291" in HDA's case, Opening Br. 6, and under 28 U.S.C. § 1292(a) in AAM and SpecGx's cases.

STATEMENT OF THE ISSUES

- 1. Whether the district court correctly held that neither the Tax Injunction Act nor principles of comity poses any hurdle to federal resolution of these actions.
- 2. Whether the extant version of the OSA may be "saved" under the guise of a severability analysis.

The balance of this brief has been omitted for this sample.

For a complete version of this brief, please contact our office.

Thank you.