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Court Voids New York's Opioid Surcharge Law

In his Health Law column, Francis J. Serbaroli discusses a recent federal court decision finding New York's statutory surcharges on opioid manufacturers and distributors unconstitutional under the Dormant Commerce Clause of the U.S. Constitution. The court determined that the surcharge was not a tax but a regulatory penalty, and that the law's prohibition on passing-through the surcharges to pharmacies and end users of opioids improperly discriminated against out-of-state opioid customers and favored in-state users.

By Francis J. Serbaroli | January 18, 2019 | New York Law Journal

In a blow to New York's efforts to fund expanded opioid addiction treatment and education, the U.S. District Court for the Southern District of New York has declared the state's new Opioid Stewardship Act unconstitutional. *Healthcare Distribution Alliance v. Zucker et al.*, 16 Civ. 6168 (KPF) U.S. Dist. Ct. SDNY, Dec. 19, 2018. The court did so using the so-called Dormant Commerce Clause (also known as the Negative Commerce Clause), a legal doctrine inferred from the Constitution's Commerce Clause by the Supreme

Court. In essence, the Dormant Commerce Clause prohibits state and local laws from discriminating against interstate commerce, or favoring in-state commerce over out-of-state commerce.

Background

According to the federal Centers for Disease Control, 70,237 drug overdose deaths occurred in the United States in 2017, and New York was one of 23 states with statistically significant increases in drug overdose deaths from 2016-2017. In his 2018 State of the State address, Gov. Andrew Cuomo declared that addressing the opioid addiction crisis would be a priority, and in his proposed budget he included an opioid surcharge to be paid by opioid manufacturers, which would be used to offset the State's costs of treating and preventing opioid abuse. The Opioid Stewardship Act (OSA) was passed by the Legislature, and the Governor signed it into law on April 12, 2018. 2018 N.Y. Session Laws 57, S. 7507-C, codified at NY Public Health Law (PHL) §3323 and NY State Finance Law §97-aaaa.

OSA requires annual "assessments" (hereinafter "surcharges") on pharmaceutical manufacturers of opioid drugs and on wholesale distributors licensed to sell or distribute opioid drugs in New York. The law took effect on July 1, 2018 and was intended to create a $600 million fund with surcharges of $100 million per year for six years. Each year's surcharge would be calculated by the New York State Department of Health (DOH) based upon sales made the previous year, with the surcharge payable the following year, beginning on Jan. 1, 2019. The surcharge excludes opioids manufactured in New York but delivered or sold outside of New York, and excludes opioids sold or distributed to licensed addiction treatment centers in New York. The law requires surcharges to be held in a separate fund and not comingled with the State's general fund.

Significantly, the OSA includes a prohibition on passing the cost of the surcharge to downstream purchasers, including the ultimate users of opioids, under penalty of up to $1 million per incident. It also includes a severability provision intended to keep the remainder of the law in effect if a court were to declare any part of the OSA invalid.

Lawsuits

Three pharmaceutical groups filed separate actions challenging the constitutionality of the OSA. The Healthcare Distribution Alliance (HDA), the national trade association for wholesale distributors of pharmaceuticals, sought both a declaratory judgment that the OSA in its entirety is unconstitutional, and a permanent injunction against its implementation.

HDA cited eight grounds for striking down the OSA, arguing that it:

(i) was an unconstitutional Bill of Attainder;

(ii) was unconstitutionally retroactive;

(iii) violated the Constitution's Takings Clause;

(iv) violated substantive due process;

(v) violated the Dormant Commerce Clause based on its extraterritorial effects;

(vi) violated the Dormant Commerce Clause based on its creation of an undue burden on interstate commerce;

(vii) was unconstitutionally vague as to the calculation of the surcharge; and

(viii) was unconstitutionally vague as to the calculation for the pass-through prohibition.

In separate suits, the Association for Accessible Medicines (AAM), an association representing, among others, manufacturers of generic opioids, and SpecGX, a Delaware-incorporated entity that manufactures and sells generic opioids, both challenged the constitutionality of the law's pass-through prohibition. Among other things, SpecGX claimed that the surcharges it would be obligated to pay under OSA would be greater than its profit margins. SpecGX also asserted that the OSA was pre-empted by the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Amendments (Pub. Law 98-417, 90 Stat. 1585 (1984)). The New York Attorney General filed opposition papers and motions to dismiss each complaint.

Decision

District Judge Katherine Polk Failla issued a decision on Dec. 19, 2018. Her decision first disposed of issues of justiciability such as standing, comity, ripeness, etc. raised by New York in its motions to dismiss. Among other things, New York claimed that the surcharges were taxes and that the three challenges to the OSA were barred by the Tax Injunction Act, 28 U.S.C. §1341. However, Judge Failla found that the surcharges are not a tax serving the State's general revenue-raising purposes, but a regulatory fee or penalty:

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.

After rejecting each of the State's arguments on justiciability, Judge Failla then focused on OSA's pass-through prohibition, finding that it did indeed violate the Dormant Commerce Clause's "… absolute constitutional prohibition on state regulation of commerce occurring beyond the state's borders … ." She quoted from the Supreme Court's holding in *Healy v. Beer Inst.*, 491 U.S. 324, 326 (1989) in addressing the issue of the extra-territorial application of the OSA:

[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.

Judge Failla next noted that the Dormant Commerce Clause also contains an anti-discrimination principle, intended to prohibit states from imposing protective tariffs or customs duty on goods imported from other states while not taxing similar products produced in the taxing state. She pointed out that the Supreme Court has treated state regulatory actions that amount to economic protectionism, i.e., regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors, as almost always invalid per se if the regulation unambiguously discriminates in effect.

She then analyzed OSA's pass-through prohibition under the balancing test set forth by the Supreme Court in *Pike v. Bruce Church*, 397 U.S. 137 (1970), under which a statute that does not discriminate on its face may still be found to violate the Dormant Commerce Clause if it imposes a burden on interstate commerce that is qualitatively or quantitatively different from that imposed on intrastate commerce. Focusing on the OSA's million dollar penalty for manufacturers or suppliers that pass-through surcharges paid on New York opioid transactions, Judge Failla found that if the pass-through prohibition applies only to in-state purchasers:

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 Clause exists, i.e., to prohibit discrimination as to "any part of the stream of commerce—from wholesaler to retailer to consumer." [Citation omitted.]

The State had argued 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 includes the surcharge as a component of the opioid's price; or by spreading the cost of the surcharge among all its drug purchasers—opioid and non-opioid—both within and outside of New York. Judge Failla dismissed these arguments, pointed to the OSA's specific wording prohibiting a pass-through of the surcharge "or any portion thereof" (PHL §3323(10)(c)), and commented:

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.

She continued:

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 would 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.'" [Citation omitted.]

Severability

Having found OSA's pass-through prohibition unconstitutional, Judge Failla turned to whether it could be severed from the rest of the law. AAM and SpecGX had argued that it could be severed while HDA argued against severance. Judge Failla noted that the Governor, the Commissioner of DOH and various state legislators were on record pledging that the costs of the OSA would not flow to end-users of opioids or pharmacies. Despite the OSA's severability clause, Judge Failla wrote:

The legislative history of the OSA evinces a clear surcharge 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 [opioid manufacturers and distributors] …

… [T]he 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 in its entirety.

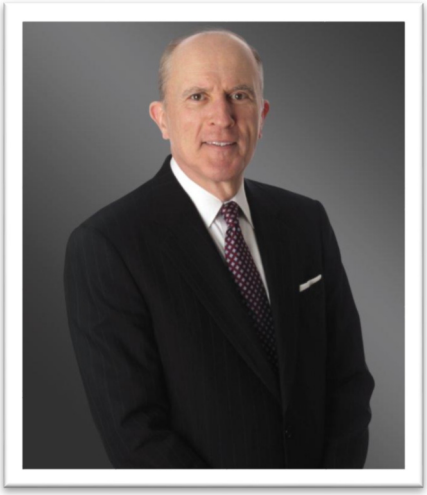
Having declared OSA as unconstitutional under the Dormant Commerce Clause, Judge Failla declined to address HDA's other arguments, *viz.*, that OSA violated substantive due process and the Takings Clause, constituted a Bill of Attainder, was void for vagueness, etc. and declined to address SpecGX's argument that OSA was pre-empted by the Hatch-Waxman Amendments.

Analysis

New York is likely to appeal this decision to the Second Circuit Court of Appeals, and perhaps even to the Supreme Court. These courts may or may not agree that OSA's surcharges are not taxes, that the surcharges are unconstitutional, and even if they affirm the unconstitutionality of the surcharges, they may or may not agree with the severability analysis. The appeals process in this case could be a prolonged one, while the opioid addiction problem in New York continues or even worsens. Perhaps the best option would be for the Governor and the Legislature to identify an alternative approach to raise funds for opioid addiction, prevention, and treatment without the apparent constitutional infirmity of the OSA as drafted. The opioid abuse problem is real, the resources are needed, and time is of the essence.

About the Author:

Francis J. Serbaroli is a shareholder at Greenberg Traurig and the former vice-chair of the New York State Public Health Council.



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