### IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA HUNTINGTON DIVISION

GENBIOPRO, INC.,

Plaintiff,

v.

Civil Action No. 3:23-cv-00058

MARK A. SORSAIA, in his official capacity, AND PATRICK MORRISEY, in his official capacity,

Hon. Robert C. Chambers

Defendants.

DEFENDANTS' SUPPLEMENTAL BRIEFING IN LIGHT OF NATIONAL PORK  $\frac{PRODUCERS\ COUNCIL\ V.\ ROSS,}{\text{NO.}\ 21\text{-}468, -- S.\ CT. -- (2023)}$ 

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#### INTRODUCTION

GenBioPro's Commerce Clause claim¹ boils down to this: the challenged laws negatively affect its bottom line because it cannot market its products within West Virginia. The Supreme Court's decision in *National Pork Producers Council v. Ross*, \_\_ S. Ct. \_\_, No. 21-468, 2023 WL 3356528 (U.S. May 11, 2023), clarifies that allegation does *not* present a Commerce Clause problem.

In National Pork Producers, the Court addressed a California statute that banned "the in-state sale of certain pork products derived from breeding pigs confined in stalls so small they cannot lie down, stand up, or turn around." Id. at \*4. The Pork Producers challenged that law, "arguing that the law unconstitutionally interferes with their preferred way of doing business in violation of th[e] Court's dormant Commerce Clause precedents." Id. "Both the district court and court of appeals dismissed the producers' complaint for failing to state a claim." Id. The Supreme Court affirmed, explaining that "[c]ompanies that choose to sell products in various States must normally comply with the laws of those various States." Id. at \*5. For the same reason, GenBioPro must comply with the laws of West Virginia if it wishes to market its product there, and its dormant Commerce Claim should be dismissed.

#### ARGUMENT

GenBioPro argued in its opposition to Defendant Morrisey's motion to dismiss that the challenged laws "violate the [Commerce] Clause by imposing an undue

<sup>&</sup>lt;sup>1</sup> GenBioPro also asserts a preemption claim under the Supremacy Clause. *National Pork Producers* does not address preemption and therefore, has no impact on that claim, which was fully addressed in Defendant Morrisey's opening brief and reply in support of his motion to dismiss.

burden on interstate commerce, by regulating extraterritorially, and by functionally banning an article of commerce." Pl.'s Opp'n 23, ECF No. 35. Each of these arguments fails under *National Pork Producers*.

# I. The Commerce Clause does not prohibit extraterritorial regulation by a State absent purposeful discrimination against out-of-state economic interests.

GenBioPro argues that the challenged laws violate the Commerce Clause because they "have the 'practical effect' of regulating extraterritorially." Pl.'s Opp'n 26. In National Pork Producers, the Supreme Court unanimously disavowed an "almost per se' rule against laws with extraterritorial effects." Nat'l Pork Producers Council v. Ross, No. 21-468, 2023 WL 3356528, at \*15 n.4 (U.S. May 11, 2023). If extraterritoriality has any relevance to the Commerce Clause at all, it is a non-dispositive factor that may be considered as part of the balancing test of Pike v. Bruce Church, Inc., 397 U.S. 137 (1970). Compare Nat'l Pork Producers, 2023 WL 3356528, at \*12–13 (plurality) (holding that a plaintiff cannot allege a claim under Pike absent evidence of discrimination, regardless of extraterritorial effects), with id. at 21 (Roberts, C.J., concurring in part and dissenting in part) (arguing that extraterritorial effects are relevant but not dispositive under Pike). Therefore, GenBioPro's independent extraterritoriality claim must fail as a matter of law.

## II. The Commerce Clause does not prohibit a State from banning an article of commerce.

Relying on a single case from 1898, GenBioPro argues that the challenged laws violate the Commerce Clause because they ban an article of commerce. Pl.'s Opp'n 27 (citing *Schollenberger v. Pennsylvania*, 171 U.S. 1, 12 (1898)). But the plurality opinion in *National Pork Producers* criticizes the dissent's proposed rule because it

could "require any consumer good available for sale in one State to be made available in every State." *Nat'l Pork Producers*, 2023 WL 3356528, at \*15 (plurality). The plurality does not even mention *Schollenberger* and cites State laws banning ordinary consumer goods "ranging from fireworks . . . to single-use plastic grocery bags." *Id.* Critically, the dissent responds not by citing some *per se* rule against banning particular articles of commerce, but by explaining that the dissent's proposed rule applies only where a challenged law requires "compliance even by producers who do not wish to sell in the regulated market." *Id.* at \*21 (Roberts, C.J., concurring in part and dissenting in part). None of the other Justices so much as mention a rule against States banning articles of commerce within their own borders.

Regardless, the challenged laws do *not* ban mifepristone within West Virginia's borders, but instead allow for the use of mifepristone for exceptional circumstances when an abortion can be performed legally, such as "within the first 8 weeks of pregnancy if the pregnancy is the result of sexual assault," W. Va. Code § 16-2R-3(b), so long as the doctor does not prescribe mifepristone by telemedicine, *id.* § 30-3-13a(g)(5). Thus, GenBioPro's argument that the challenged laws violate the Commerce Clause by banning an article of commerce fails as a matter of law.

### III. The challenged laws do not violate the Pike balancing test.

Finally, GenBioPro argues that the challenged laws unduly burden interstate commerce under *Pike*. Pl.'s Opp'n 23. The Justices in *National Pork Producers* appear to disagree about whether *Pike* remains good law and, if it does, how it should be applied. A majority of the Court "agree[d] that heartland *Pike* cases seek to smoke out purposeful discrimination in state laws (as illuminated by those laws' practical

effects) or seek to protect the instrumentalities of interstate transportation." Nat'l Pork Producers, 2023 WL 3356528, at \*15 n.4. And a majority of the Court held that Pike does not cover laws like the California statute at issue in National Pork Producers. Id.

A three-Justice plurality of the Court rejected the idea that *Pike* "authoriz[es] judges to strike down duly enacted state laws regulating the in-state sale of ordinary consumer goods (like pork) based on nothing more than their own assessment of the relevant law's 'costs' and 'benefits." *Id.* at \*12 (plurality).

A different four-Justice plurality posited that *Pike* requires a plaintiff to plead "facts leading, 'either logically or as a practical matter, to [the] conclusion that the State [was] discriminating against interstate commerce." *Id.* at \*13 (plurality) (quoting *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 125 (1978)). Because the National Pork Producers failed to "plead facts 'plausibly' suggesting a substantial harm to interstate commerce," *Pike* balancing did not apply. *Id.* at \*14; *accord id.* at \*17 (Sotomayor, J., concurring in part).

The four partially dissenting Justices opined that "Pike extends beyond laws either concerning discrimination or governing interstate transportation." Id. at \*19 (Roberts, C.J., concurring in part and dissenting in part). Two partially concurring Justices agreed but adopted a higher standard for alleging a substantial harm to interstate commerce. Id. at \*17 (Sotomayor, J., concurring in part). And one Justice stated that while she agrees with two other Justices that balancing the benefits and burdens of a law is not a judicial endeavor, she "would permit petitioners to proceed

with their *Pike* claim"—like the partially dissenting Justices—if "the burdens and benefits were capable of judicial balancing." *Id.* at \*18 (Barrett, J., concurring).

Justice Gorsuch claimed that "[a] majority [of the Court] rejects any effort to expand *Pike*'s domain" outside its "heartland" of "smok[ing] out purposeful discrimination" and "protect[ing] the instrumentalities of interstate transportation." *Id.* at \*15 n.4 (plurality). Yet the Chief Justice asserted that "a majority of the Court agrees" that "*Pike* extends beyond laws either concerning discrimination or governing interstate transportation." *Id.* at \*19 (Roberts, C.J., dissenting in part and concurring in part). And Justice Kavanaugh seems to think that Justice Gorsuch's opinion controls "for purposes of the Court's judgment as to the plaintiffs' *Pike* claim," *id.* at \*22 (Kavanaugh, J., concurring in part and dissenting in part), but that the Chief Justice's opinion "reflects the majority view" on "whether to retain the *Pike* balancing test," *id.* at \*24 n.3.

Fortunately, this Court need not discern which opinion controls to resolve this case because GenBioPro's Commerce Clause claims fail under all three formulations of *Pike*.

## A. GenBioPro impermissibly asks this Court to engage in "freewheeling" balancing of the challenged laws' "costs" and "benefits."

GenBioPro asks this Court to balance the State's interest in "protecting unborn lives" against "the burden on West Virginians' right to access lifesaving, safe, and necessary healthcare." Pl.'s Opp'n 25. This is precisely the sort of balancing that a majority of the Court rejected in *Dobbs* and that a three-Justice plurality of the Court rejects in *National Pork Producers*. In *Dobbs*, the Court held that courts must not

engage in "freewheeling judicial policymaking" under the Fourteenth Amendment (or the Constitution generally) to "weigh th[e] [important policy] arguments" concerning "how abortion may be regulated to the States," and that the issue of abortion should be left to "the people and their elected representatives." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2242, 2248, 2259 (2022).

In *National Pork Producers*, the three-Justice plurality reaffirmed that courts also may not exercise "freewheeling power" to "strike down duly enacted state laws... based on nothing more than their own assessment of the relevant law's 'costs' and 'benefits'" under the Commerce Clause. 2023 WL 3356528, at \*12 (plurality). As in *Dobbs*, the *National Pork Producers* plurality explains that "[i]n a functioning democracy, policy choices like these usually belong to the people and their elected representatives" who are "entitled to weigh the relevant 'political and economic' costs and benefits for themselves . . . and 'try novel social and economic experiments' if they wish." *Id.* at \*13 (internal citations omitted).

Regardless, "noneconomic interests," such as the "putative harms" to West Virginia women seeking abortions, are not "freestanding harms cognizable under the dormant Commerce Clause." *Id.* at \*15. As explained below, *see infra* Parts III.B and III.C, the only economic harm that GenBioPro alleges is damage to its own bottom line. But that is precisely the sort of weighing of "economic costs (to some) against noneconomic benefits (to others)" that the plurality says is "insusceptible to resolution by reference to any juridical principle." *Id.* at \*12. Consequently,

GenBioPro has failed to plead a claim under the three-Justice plurality's formulation of *Pike*.

B. Even if *Pike* applied, the challenged laws pass muster under the version of the *Pike* balancing test articulated in Part IV.C of Justice Gorsuch's opinion.

Pike balancing does not apply here because GenBioPro does not allege a burden in interstate commerce, let alone a substantial one. A four-Justice plurality in National Pork Producers held that "Pike requires a plaintiff to plead facts plausibly showing that a challenged law imposes 'substantial burdens' on interstate commerce before a court may assess the law's competing benefits or weigh the two sides against each other." Id. at \*13. If, as the plurality held, the National Pork Producers' complaint "fail[ed] to clear even that bar," id., then GenBioPro's complaint is plainly insufficient to state a Commerce Clause claim because it alleges no burden on interstate commerce at all.

The plurality further held that *Pike* requires a plaintiff "to plead facts leading, 'either logically or as a practical matter, to [the] conclusion that the State [was] discriminating against interstate commerce." *Id.* at \*13 (plurality) (quoting *Exxon Corp.*, 437 U.S. at 125). Relying on *Exxon Corp.*, the plurality explained that a "change [in] the market structure" resulting from the law is insufficient absent discrimination.

Even if the *Pike* balancing test applied, GenBioPro has failed to meet it. Nothing in GenBioPro's complaint alleges discrimination against interstate commerce. West Virginia seeks to prevent all abortions except in very limited circumstances, W. Va. Code § 16-2R-3(a), regardless of where the abortion-inducing

drug is produced or whether an abortion-inducing drug (as opposed to a surgical procedure) is used at all. And for those abortions that fall under the statute's exceptions, West Virginia's telemedicine requirements have no relation to whether the abortion-inducing drug was produced out-of-state. See id. §30-3-13a(g)(5).<sup>2</sup>

Instead, GenBioPro alleges that the challenged laws "prevent. GenBioPro from developing a market for its product, mifepristone, in West Virginia" and "force. West Virginia] patients to fulfill waiting period and counseling requirements before accessing mifepristone." Compl. ¶¶ 107, 108, ECF No. 1. In other words, GenBioPro merely alleges a burden on its own sales within West Virginia and on consumers within West Virginia. But the plurality is clear that "no one thinks that costs ultimately borne by in-state consumers thanks to a law they adopted counts as a cognizable harm under [the Court's] dormant Commerce Clause precedents." Nat'l Pork Producers, 2023 WL 3356528, at \*14. Therefore, GenBioPro has failed to state a claim under the four-Justice plurality's formulation of Pike.

# C. The challenged laws also pass muster under the version of the *Pike* balancing test articulated in Chief Justice Roberts's dissent.

The four partially dissenting Justices opined that *Pike* concerns *economic* harms to the *interstate* market. *Id.* at \*19 (Roberts, C.J., concurring in part and dissenting in part). The alleged harms must be broad, "market-wide *consequences*;" mere "compliance costs" are insufficient for a Commerce Clause violation. *Id.* (emphasis by the Court). Critically, these harms must be *economic*; noneconomic

<sup>&</sup>lt;sup>2</sup> This also holds true for the informed consent provisions challenged by GenBioPro, which are currently ineffective. *See* W. Va. Code § 16-2I-2.

harms are not relevant to the Commerce Clause. *Id.* at \*20. "[S]weeping extraterritorial effects" are relevant, but not dispositive, under *Pike*. *Id.* at \*21.

GenBioPro fails to allege facts sufficient to meet even the dissent's lower bar. GenBioPro has alleged *no* harms, economic or otherwise, outside of West Virginia. The *National Pork Producers* dissent relied on "compliance even by producers who do not wish to sell in the regulated market," "industry-wide harms," and "pervasive changes to the pork production industry nationwide" to argue that the California law violated the Commerce Clause. *Id.* at \*21–22.

In contrast, GenBioPro clearly wishes to market its product in West Virginia, Compl. ¶ 107, and it alleges no harms to the abortion industry (or abortion patients) outside West Virginia. Nor does GenBioPro allege any changes to its own business model as a result of the challenged laws. In its opposition to Defendant Morrisey's motion to dismiss, GenBioPro argues that "manufacturers will face increased regulatory costs and unresolvable complexity with deleterious effects throughout the national healthcare delivery system and the pharmaceutical market." Pl.'s Opp'n 25. In support of this argument, GenBioPro cites paragraph 17 of its complaint. *Id.* But paragraph 17 merely restates GenBioPro's preemption argument that the Challenged Laws conflict with FDA regulations. Compl. ¶ 17. Nowhere in the complaint does GenBioPro allege the type of "industry-wide harm" that the *National Pork Producers* dissent would require.

The challenged laws do not require GenBioPro to change its chemical formula, its production methods, or even the conditions of its workers. In fact, the challenged

laws do not regulate GenBioPro or its competitors at all; the laws regulate abortion providers, not manufacturers of products that may be used to perform an abortion. See W. Va. Code §§ 16-2R-3(a) ("An abortion may not be performed or induced . . . unless in the reasonable medical judgment of a licensed medical professional . . . . " (emphasis added); 16-2R-3(g) ("An abortion performed or induced . . . shall be performed by a licensed medical professional who has West Virginia hospital privileges." (emphasis added)); 16-2I-2(a) (requiring that informed consent information be given to the abortion patient "by the physician or the licensed medical professional to whom the responsibility has been delegated by the physician who is to perform the abortion" (emphasis added)); 30-3-13a(g)(5) (providing that "[a] physician or health care provider may not prescribe any drug with the intent of causing an abortion" over telemedicine (emphasis added)). Nor do the challenged laws regulate manufacturers indirectly by requiring providers to only prescribe drugs from manufacturers who follow certain constraints. Therefore, GenBioPro has failed to state a claim under the dissent's formulation of *Pike*.

\* \* \*

A majority of the Supreme Court held in *National Pork Producers* that "extreme caution' is warranted before a court deploys [its] implied authority" under the dormant Commerce Clause. *Nat'l Pork Producers*, 2023 WL 3356528, at \*16 (quoting *General Motors Corp. v. Tracy*, 519 U.S. 278, 310 (1997)). The Court further explained that "[p]reventing state officials from enforcing a democratically adopted state law in the name of the dormant Commerce Clause is a matter of 'extreme

delicacy,' something courts should do only 'where the infraction is clear." *Id.* (quoting *Conway v. Taylor's Executor*, 1 Black 603, 634 (1862)). Here, GenBioPro has alleged nothing more than harm to its own bottom line because it claims it can no longer market its product in West Virginia. That allegation does not present a dormant Commerce Clause problem under *any* understanding of the Court's decision.

#### CONCLUSION

For the foregoing reasons, this Court should grant Defendant Morrisey's motion to dismiss for failure to state a claim under the Commerce Clause.

Respectfully submitted,

PATRICK MORRISEY
West Virginia Attorney General

/s/ Curtis R. A. Capehart

Douglas P. Buffington, II (WV Bar No. 8157)

Chief Deputy Attorney General

Curtis R. A. Capehart (WV Bar No. 9876)

Deputy Attorney General

OFFICE OF THE ATTORNEY GENERAL

State Capitol Complex

1900 Kanawha Boulevard E,

Building 1, Room E-26

Charleston, WV 25305-0220

Tel.: (304) 558-2021

Fax: (304) 558-0140

curtis.r.a.capehart@wvago.gov

Denise M. Harle\*
ALLIANCE DEFENDING FREEDOM
1000 Hurricane Shoals Rd. NE, Ste. D-1100
Lawrenceville, GA 30043
Tel.: (770) 339-0774
Fax: (770) 339-6744
dharle@adflegal.org

Erin M. Hawley\*
ALLIANCE DEFENDING FREEDOM
440 First Street NW, Ste. 600
Washington, DC 20001
Tel.: (202) 393-8690
Fax: (202) 347-3622
ehawley@adflegal.org

Counsel for Defendant Patrick Morrisey, in his official capacity as Attorney General of the State of West Virginia

<sup>\*</sup>visiting attorney

# MARK A. SORSAIA Prosecuting Attorney

/s/ Jennifer Scragg Karr (by permission)
Jennifer Scragg Karr (WV Bar No. 8051)
Assistant Prosecuting Attorney
Putnam County Judicial Building
12093 Winfield Road
Winfield, WV 25213
Tel.: (304) 586-0205

Fax: (304) 586-0269 jkarr@putnamwv.org

Counsel for Defendant Mark A. Sorsaia, in his official capacity as Prosecuting Attorney of Putnam County

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Defendants.

#### CERTIFICATE OF SERVICE

I hereby certify that, on this 19<sup>th</sup> day of May, 2023, I electronically filed the foregoing Supplemental Brief with the Clerk of Court and all parties using the CM/ECF System.

/s/ Curtis R. A. Capehart Curtis R. A. Capehart Deputy Attorney General