

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 17-2166
(1:17-cv-01860-MJG)

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Plaintiff - Appellant,

v.

BRIAN E. FROSH, in his official capacity as Attorney General for the State of Maryland; DENNIS R. SCHRADER, in his official capacity as Secretary of the Maryland Department of Health,

Defendants - Appellees.

CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA,

Amicus Supporting Appellant.

AARP; AARP FOUNDATION; KNOWLEDGE ECOLOGY INTERNATIONAL;
MARYLAND CITIZENS' HEALTH INITIATIVE EDUCATION FUND,
INCORPORATED; PUBLIC CITIZEN; PUBLIC JUSTICE CENTER;
MARYLAND CITIZENS' HEALTH INITIATIVE EDUCATION FUND,
INCORPORATED; DISABILITY RIGHTS MARYLAND,

Amici Supporting Appellee.

ORDER

The petition for rehearing en banc was circulated to the full court. Judge Wilkinson, Judge Niemeyer, Judge Traxler, Judge King, Judge Duncan, Judge Agee, Judge Diaz, Judge Floyd and Judge Thacker voted to deny rehearing en banc. Chief Judge Gregory, Judge Wynn and Judge Harris voted to grant rehearing en banc. Judge Motz and Judge Keenan did not participate in the poll. The court denies the petition for rehearing en banc.

Entered at the direction of Judge Thacker.

For the Court

/s/ Patricia S. Connor, Clerk

WYNN, Circuit Judge, dissenting from the denial of rehearing en banc:

With respect, I must dissent from my colleagues' refusal to grant en banc rehearing in this case. The right of a State to protect the health, safety, and welfare of its citizens should not be denied by the judicial expansion of a judge-made doctrine with a name that aptly describes what it should be, the dormant Commerce Clause's "extraterritoriality doctrine."

In expanding the extraterritoriality doctrine beyond the contexts in which the Supreme Court and this Court previously have applied it—and in a manner that the panel majority concedes conflicts with the approach taken by other circuits—the majority opinion materially encroaches upon the States' reserved powers to legislate to protect the health, safety, and welfare of their citizens. *See, e.g., L'Hote v. City of New Orleans*, 177 U.S. 587, 596 (1900). By doing so, the majority opinion errantly turns the dormant Commerce Clause into a "weapon" for federal judges to second-guess efforts by state legislatures to protect the health and welfare of their citizens, *Energy & Env'tl. Legal Inst. v. Epel (EELI)*, 793 F.3d 1169, 1175 (10th Cir. 2015) (Gorsuch, J.), even when such efforts do not implicate the two concerns underlying the Supreme Court's "[m]odern" dormant Commerce Clause jurisprudence: state regulations that "discriminate against interstate commerce" or "impose undue burdens on interstate commerce," *South Dakota v. Wayfair*, 138 S. Ct. 2080, 2090–91 (2018). As then-Judge, now-Justice Gorsuch has explained, federal courts should not embark on such an "audacious" and "novel lawmaking project" absent clear instruction from the Supreme Court. *EELI*, 793 F.3d at 1175. At a minimum,

the careful deliberation of this entire Court is warranted before we choose a path that diverges from our sister circuits and raises serious federalism concerns.

At issue is a Maryland law (“HB 631”) that prohibits “unconscionable” price increases for certain generic drugs “made available for sale” to Maryland consumers. Md. Code Ann., Health-Gen. §§ 2-801-803 (2017). After a series of high-profile incidents in which several generic pharmaceutical manufacturers imposed multiple-thousand-fold price increases for single-source generic drugs that treat rare and life-threatening conditions, the Maryland legislature enacted HB 631 to restrain what it viewed as abusive pricing practices specifically designed to prey on the special vulnerabilities of a defenseless group of Maryland citizens.

The majority opinion holds that the statute when applied to any sale of covered drugs consummated outside of Maryland—even when the drugs are later resold to *Maryland consumers*—violates the extraterritoriality doctrine by regulating “commerce occurring wholly outside [Maryland’s] boundaries.” *Ass’n for Accessible Meds. v. Frosh*, 887 F.3d 664, 681 (4th Cir. 2018) (quoting *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989)). That doctrine—which the Supreme Court has not applied in nearly 30 years—has been characterized by our sister circuits as the “the most dormant” of the Supreme Court’s dormant Commerce Clause jurisprudence. *See, e.g., EELI*, 793 F.3d at 1172. More significantly, to date, the extraterritoriality doctrine has been applied “*only* [to] price control or price affirmation statutes that link in-state prices with those charged elsewhere and discriminate against out-of-staters,” *id.* at 1174 (emphasis added), and there *never* has been “a single Supreme Court dormant Commerce Clause holding that relied exclusively

on the extraterritoriality doctrine to invalidate a state law,” *Am. Beverage Ass’n v. Snyder*, 735 F.3d 362, 381 (6th Cir. 2013) (Sutton, J., concurring), as the majority opinion does here.

My dissenting opinion details several ways in which the majority opinion errs in adopting and applying its novel approach to the extraterritoriality doctrine. To begin, the majority opinion ignores basic principles of federalism and judicial restraint to reject the State’s own interpretation of the statute’s extraterritorial reach *before the State had sought to enforce the statute against any generic manufacturer*. *Frosh*, 887 F.3d at 678–80 (Wynn, J., dissenting). Then, relying on its own expansive interpretation of HB 631’s reach, the majority opinion extends the extraterritoriality doctrine beyond the contexts in which the Supreme Court and this Court previously have applied it. *Id.* at 680–87. Notably, the majority opinion concedes that its expansive construction of the extraterritoriality doctrine conflicts with the approach taken by other circuits. *See Frosh*, 887 F.3d at 670 (majority op.); *see also EELI*, 793 F.3d at 1174; *Ass’n des Eleveurs de Canards et d’Oies du Quebec v. Harris*, 729 F.3d 937, 951 (9th Cir. 2013); *IMS Health, Inc. v. Mills*, 616 F.3d 7, 30 (1st Cir. 2010).

The Maryland statute’s constitutionality finds further support in the Supreme Court’s most recent opinion dealing with the dormant Commerce Clause—*South Dakota v. Wayfair*, 138 S. Ct. 2080 (2018)—which the Court issued after the panel decided this case. In *Wayfair*, the Court considered a South Dakota statute that requires out-of-state sellers who deliver, on an annual basis, “more than \$100,000 of goods or services into the State or engage in 200 or more separate transactions for the delivery of goods into the state”

to collect and remit sales tax, *regardless of whether the seller has a physical presence in South Dakota*. *Id.* at 2088–89. South Dakota sought to collect sales taxes from Wayfair, an online retailer who made substantial sales to South Dakota residents but lacked a physical presence in the state. *Id.* at 2089. The South Dakota Supreme Court held that the statute was unconstitutional as-applied to out-of-state sellers who lacked a physical presence in the state, like Wayfair, under the Supreme Court’s decisions in *Quill Corp. v. North Dakota*, 504 U.S. 298 (1992), and *National Bellas Hess, Inc. v. Department of Revenue of Ill.*, 386 U.S. 753 (1967). Those decisions held that a State could not require a seller to collect and remit sales tax unless it had a “physical presence such as ‘retail outlets, solicitors, or property within the State.’” *Wayfair*, 138 S. Ct. at 2091 (quoting *Bellas Hess*, 386 U.S. at 758).

Wayfair overruled the “physical presence” rule set forth in *Quill* and *Bellas Hess*. *Id.* at 2099. The Court reached this conclusion for several reasons relevant to the dormant Commerce Clause challenge to the Maryland price-gouging statute. To begin, the Court reaffirmed both Justice Marshall’s “broad definition of commerce” as “‘the interchange of commodities’ and ‘commercial intercourse’ . . . and the concurrent regulatory power of the States.” *Id.* at 2090 (emphasis added) (quoting *Gibbons v. Ogden*, 9 Wheat. 1, 6 (1824)). As my dissenting opinion more fully explains, the majority opinion fails to adhere to that “broad” definition of commerce by equating “commerce” with a single “transaction” and usurps the States’ concurrent regulatory authority. *Frosh*, 887 F.3d at 683 (Wynn, J., dissenting).

Second, *Wayfair* emphasized the “significant parallels” between the Due Process Clause “minimum contacts” standard for personal jurisdiction and the restrictions on state regulation imposed by the Commerce Clause. *Wayfair*, 138 S. Ct. at 2093. Noting that “physical presence” is not required to satisfy the minimum contacts test, the Court stated that physical presence is likewise a “poor proxy” in the dormant Commerce Clause context. *Id.* The Court further explained that the physical presence rule is particularly inappropriate when considered in light of the “day-to-day functions of marketing and distribution in the modern economy.” *Id.* at 2095. Here, the majority opinion strikes down the Maryland price-gouging statute because it “controls the prices of transactions that occur outside the state,” regardless of whether the drugs conveyed by those out-of-state transactions are later resold in Maryland. *Frosh*, 887 F.3d at 670 (majority op.). The majority’s myopic focus on the *location* of the transaction is precisely the “physical presence” approach *Wayfair* rejected as “artificial in its entirety.” *Wayfair*, 138 S. Ct. at 2095. Likewise, just as e-commerce and nationwide distribution chains rendered the physical presence rule outmoded, so too do the modern nationwide distribution and reimbursement systems for generic pharmaceuticals counsel against the location-focused approach of the majority opinion.

Third, *Wayfair* held that the bright-line physical presence rule ran contrary to the Court’s dormant Commerce Clause jurisprudence, which has “eschewed formalism for a sensitive, case-by-case analysis of purposes and effects.” *Id.* at 2094 (quoting *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 201 (1994)). The majority opinion’s rule—that a State is categorically barred from regulating any transaction consummated outside of the

State’s borders regardless of whether the subject of that transaction is ultimately sold or resold in the State—embraces the same formalism that *Wayfair* rejected, rather than following the case-by-case approach the Court has prescribed. Thus, the majority opinion’s pre-enforcement invalidation of the Maryland statute is antithetical to the Court’s case-by-case approach to dormant Commerce Clause questions.

Fourth, *Wayfair* stated that the physical presence rule amounted to “an extraordinary imposition by the Judiciary on States’ authority to collect taxes and perform critical public functions.” *Id.* at 2095. As explained more fully in my dissent, “the majority opinion’s expansive interpretation of the extraterritoriality doctrine substantially intrudes on the States’ reserved powers to legislate to protect the health, safety, and welfare of their citizens,” calling into question the constitutionality of numerous state antitrust and consumer protection statutes. *Frosh*, 887 F.3d at 687-88 (Wynn, J., dissenting). Accordingly, like the physical presence rule overruled in *Wayfair*, the majority opinion’s expansive interpretation of the extraterritoriality doctrine—an interpretation that the majority opinion concedes is in conflict with that of other circuits—interferes with “States’ authority to . . . perform critical public functions.” *Wayfair*, 138 S. Ct. at 2095.

Finally, *Wayfair* replaced *Bellas Hess* and *Quill*’s physical presence rule with a “substantial nexus” test that has its genesis in Due Process Clause jurisprudence. *Id.* at 2091. Applying that test, the Court held that North Dakota could require Wayfair and the other defendant on-line retailers to collect and remit sales tax because of their “economic and virtual contacts” with the State. *Id.* at 2099. Likewise, under governing Due Process Clause jurisprudence, at a minimum, generic drug manufacturers that “targeted” Maryland

consumers—by, for example, marketing their drugs to Maryland consumers or physicians—lawfully would be subject to the Maryland statute, even if they sold their drugs through out-of-state intermediaries, *see J. McIntyre Machinery, Ltd. v. Nicaastro*, 564 U.S. 873, 882 (2011) (opinion of Kennedy, J.), meaning that the majority’s pre-enforcement invalidation of the Maryland statute was all-the-more improper.

In sum, the majority opinion’s expansive (re)interpretation of the extraterritoriality doctrine expressly diverges from the approach taken by the other circuits and is in significant tension—if not outright conflict—with the Supreme Court’s most recent exposition of the limitations on state action imposed by the dormant Commerce Clause. More significantly, the majority opinion’s expansive interpretation of the extraterritoriality doctrine significantly incurs on the States’ reserved powers to enact legislation to protect the health, safety, and welfare of their citizens. The division between this Court and our sister circuits and the significant federalism concerns posed by the majority opinion’s expansion of the long-dormant extraterritoriality doctrine make this a case ripe for rehearing en banc as a matter of exceptional importance.

With respect, I dissent.