DORMANT COMMERCE CLAUSE — EXTRATERRITORIALITY DOCTRINE — FOURTH CIRCUIT INVALIDATES MARYLAND STATUTE REGULATING PRICE GOUGING IN THE SALE OF GENERIC DRUGS. — *Association for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018).

Price gouging of generic drugs has incited public anger and new legislation. While federal bills remain mired in congressional committees,[1] some state legislatures have considered bills targeting pharmaceutical price gouging.[2] However, the Supreme Court has long recognized that Congress's power to regulate interstate commerce implies a corollary limitation on state authority.[3] Certain state regulations are preempted even in the face of congressional silence. This is commonly known as the dormant commerce clause.[4] One element of the doctrine is that states may not regulate commerce that takes place entirely outside their territories.[5] This extraterritoriality principle is rooted in the idea that the authority of a state applies only within its own borders.[6] The simplicity of this idea belies the difficulty of its application, and courts have struggled to define the extraterritoriality principle's precise scope.[7] Recently, the Fourth Circuit in *Association for Accessible Medicines v. Frosh*[8] used the extraterritoriality principle to strike down Maryland's regulation of pharmaceutical price gouging. Its decision was ultimately correct, but its application of the extraterritoriality principle missed an opportunity to clarify the doctrine's scope.

In late 2015, Turing Pharmaceuticals acquired the rights to the life-saving drug Daraprim and subsequently raised its price from $13.50 to $750 per pill.[9] This ignited a public outcry, inflamed by a pattern of similar price hikes on generic drugs.[10] In response, the Maryland legislature passed House Bill 631, "An [Act] concerning Public Health —

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[1] *See, e.g.*, S. 3754, 115th Cong. (2018).

[2] PRESCRIPTION DRUG RES. CTR., NAT'L CONFERENCE OF STATE LEGISLATURES, STATE ACTIONS TO HALT PRICE GOUGING FOR GENERIC DRUGS (2018), http://www.ncsl.org/Portals/1/Documents/Health/Generic_drug_antiprice_gouging_Maryland_31894.pdf [https://perma.cc/5H75-UNFK].

[3] *See* Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 10 (1824).

[4] *E.g.*, Jack L. Goldsmith & Alan O. Sykes, Essay, *The Internet and the Dormant Commerce Clause*, 110 YALE L.J. 785, 804–05 (2001).

[5] *See* Healy v. Beer Inst., 491 U.S. 324, 336 (1989).

[6] *See, e.g.*, Bonaparte v. Tax Court, 104 U.S. 592, 594 (1881) ("No State can legislate except with reference to its own jurisdiction.").

[7] *See, e.g.*, Energy & Env't Legal Inst. v. Epel, 793 F.3d 1169, 1172 (10th Cir. 2015) ("[The] extraterritoriality principle may be the least understood of the Court's three strands of dormant commerce clause jurisprudence.").

[8] 887 F.3d 664 (4th Cir. 2018).

[9] *See* Andrew Pollack, *Drug Goes from $13.50 a Tablet to $750, Overnight*, N.Y. TIMES (Sept. 20, 2015), https://nyti.ms/1V3cJvC [https://perma.cc/AT76-ZKG7].

[10] *See id.*

Essential Off-Patent or Generic Drugs — Price Gouging — Prohibition" (the Act).[11] The legislature targeted the source of price gouging, which occurs primarily in sales on the manufacturer-wholesaler level.[12] Thus, the Act prohibited manufacturers and wholesale distributors from "engag[ing] in price gouging in the sale of an essential off-patent or generic drug."[13] Price gouging was defined as "an unconscionable increase in the price of a prescription drug."[14] To qualify as an essential off-patent or generic drug under the Act, a drug must be "made available for sale in the State [of Maryland]."[15]

The Association for Accessible Medicines (AAM), a group of pharmaceutics manufacturers and wholesalers, brought suit challenging the constitutionality of the Act.[16] Echoing concerns raised previously by Governor Larry Hogan,[17] AAM sought injunctive relief on two grounds: first, that the Act regulated manufacturer-wholesaler transactions that occur outside Maryland, violating the extraterritoriality principle of the dormant commerce clause;[18] and second, that the definition of price gouging was impermissibly vague under the Due Process Clause.[19] The district court was unpersuaded by the first claim. It found that the plaintiff's claim "appear[ed] to rest in part on a practical problem" — pharmaceutics sellers "do not know which of their drugs end up in Maryland" — rather than on a constitutional violation.[20] However, the district court found plausible AAM's constitutional vagueness claim, allowing it to proceed but declining to grant an injunction.[21] AAM appealed the dismissal of the dormant commerce clause claim.

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[11] H.D. 631, 2017 Leg., 437th Sess. (Md. 2017).

[12] *See, e.g.*, Daniel Moritz-Rabson, *Drug Price Hikes 2019: Drugmakers Raise Prices on Hundreds of Medications at New Year*, NEWSWEEK (Jan. 3, 2019, 11:46 AM) https://www.newsweek.com/drugmakers-raise-prices-hundreds-medications-1277433 [https://perma.cc/ZY6L-CJSD] (discussing price hikes by manufacturers).

[13] Md. H.D. 631 § 1 (adding MD. CODE. ANN., HEALTH–GEN. § 2-802(A) (West 2019)).

[14] *Id.* (adding MD. CODE. ANN., HEALTH–GEN. § 2-801(C)).

[15] *Id.* (adding MD. CODE. ANN., HEALTH–GEN. § 2-801(B)(IV)).

[16] Ass'n for Accessible Meds. v. Frosh, No. 17-cv-01860, 2017 WL 4347818, at *1 (D. Md. Sept. 29, 2017).

[17] Governor Larry Hogan did not sign the Act, citing concerns over the constitutionality of the regulation. *See* Letter from Governor Lawrence J. Hogan, Jr. to Michael E. Busch, Speaker of the Md. House of Delegates (May 26, 2017), https://content.govdelivery.com/attachments/MDGOV/2017/05/26/file_attachments/822635/HB631Letter.pdf [https://perma.cc/6ABX-6GVH]. However, he did not veto the Act either, permitting it to pass into law. *See id.*

[18] *Ass'n for Accessible Meds.*, 2017 WL 4347818, at *5–6. AAM challenged the regulation *as applied* to manufacturer-wholesaler transactions taking place outside Maryland. *Id.* at *1. However, almost all manufacturers and wholesalers reside outside Maryland, so the vast majority of manufacturer-wholesaler transactions occur beyond Maryland's borders. Complaint for Declaratory & Injunctive Relief at 13–14, *Ass'n for Accessible Medicines*, 2017 WL 4347818 (No. 17-cv-01860). Thus, a successful as-applied challenge would neutralize the Act.

[19] *Ass'n for Accessible Meds.*, 2017 WL 4347818, at *9.

[20] *Id.* at *7.

[21] *Id.* at *11, *15.

A divided panel of the Fourth Circuit reversed. Writing for the court, Judge Thacker[22] established at the outset that "the extraterritoriality principle is violated if the state law at issue 'regulate[s] the price of any out-of-state transaction, either by its express terms or by its inevitable effect.'"[23] Under this standard, the court proceeded to analyze the Act. First, the court rejected the idea that the statute's "made available for sale" provision limited the statute's reach to only transactions relating to drugs actually sold in Maryland.[24] Rather, the court found that the plain language of the statute had no limiting constraint: it could assign liability against parties to a transaction outside Maryland "that did not result in a single pill being shipped to Maryland."[25] But even if the Act did require a nexus linking the out-of-state conduct to a sale in Maryland, it excluded retailers (which reside in Maryland) and instead targeted the upstream manufacturers and wholesalers, nearly all of which transact outside Maryland.[26] The statute "effectively seeks to compel manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland."[27]

Further, relying on Supreme Court precedent, the court found that the statute effectively and impermissibly served as a price control on out-of-state transactions.[28] In *Brown-Forman Distillers Corp. v. New York State Liquor Authority*,[29] the Court struck down a New York statute that required distillers to set liquor prices no higher than the lowest price in any other state.[30] The statute fixed the price of out-of-state liquor to the price schedule used for in-state liquor sales, with the practical effect of controlling the price of liquor sold outside New York.[31] Subsequently, the Court applied the same extraterritoriality principle in *Healy v. Beer Institute*,[32] which invalidated a Connecticut price-affirmation statute tying the price of in-state beer to out-of-state beer.[33] Here, the Fourth Circuit found that Maryland's price-gouging prohibition had the practical effect of "specify[ing] the price at which goods may be sold beyond Maryland's borders," so *Brown-Forman* and *Healy* were controlling.[34]

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[22] Judge Agee joined in the opinion.

[23] *Ass'n for Accessible Meds.*, 887 F.3d at 670 (alteration in original) (quoting Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 669 (2003)).

[24] *Id.* at 670–71.

[25] *Id.* at 671.

[26] *Id.* at 671–72.

[27] *Id.* at 672.

[28] *Id.*

[29] 476 U.S. 573 (1986).

[30] *Id.* at 575–76, 585.

[31] *Id.* at 583.

[32] 491 U.S. 324 (1989).

[33] *Id.* at 326, 337.

[34] *Ass'n for Accessible Meds.*, 887 F.3d at 673.

Judge Wynn's dissenting opinion fought the court's decision every step of the way. It rejected the court's expansive interpretation of the statute's reach, arguing that the correct interpretation of the statute would limit its scope to only those streams of commerce that end in Maryland.[35] The dissent then defined commerce to encompass the entire stream of commerce; thus regulation of a single transaction in that chain is not a regulation of commerce.[36] Rather, the state is permitted to regulate the preceding upstream transactions that occurred out of state because they form part of the in-state commerce.[37] In any case, the dissent argued, the extraterritoriality principle applies "*only* [to] price control or price affirmation statutes that link in-state prices with those charged elsewhere and discriminate against out-of-staters."[38] The Act did not satisfy these criteria and thus the court erred in holding otherwise.[39] The Fourth Circuit declined to rehear the case en banc.[40]

The court's conflict over the extraterritoriality principle in *Association for Accessible Medicines* does little to clarify the scope of the doctrine. The majority opinion adopted a test that is implausibly broad, while the dissent's understanding of the doctrine bears little relation to the purposes of the extraterritoriality principle. The court could have better defined the extraterritoriality principle by drawing inspiration from jurisdictional due process jurisprudence, with which the dormant commerce clause shares several similarities. Doing so would present a starting point for the doctrine to develop around, while remaining faithful to the purposes of the principle.

The extraterritoriality principle is about the limitations of state authority. It reflects both vertical and horizontal constraints imposed on the states. Vertically, state authority is subordinate to the enumerated powers of the federal government.[41] Horizontally, states are limited by the equal authority of the other states.[42] The extraterritoriality principle ensures equal state sovereignty because the balance of power among the states in the area of interstate commerce is properly left to the federal government.[43] Congress may adopt one state's law as the

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[35] *Id.* at 679–80 (Wynn, J., dissenting).

[36] *Id.* at 681–83.

[37] *Id.* at 683.

[38] *Id.* at 686 (alteration in original) (quoting Energy & Env't Legal Inst. v. Epel, 793 F.3d 1169, 1174 (10th Cir. 2015) (emphasis added)). Judge Wynn's dissent leaned on the district court's opinion that the real underlying problem is a practical one — requiring manufacturers to distinguish distribution channels. *Id.* at 690. One possible solution to this practical problem would be to contractually negotiate the liability between manufacturers and wholesalers. *Id.* at 690–91.

[39] *Id.* at 690–91.

[40] Ass'n for Accessible Meds. v. Frosh, 742 F. App'x 720, 720–21 (4th Cir. 2018) (mem.).

[41] *See* Allan Erbsen, *Horizontal Federalism*, 93 MINN. L. REV. 493, 494 & n.1 (2008).

[42] *See id.* at 498–510.

[43] *See* LAURENCE H. TRIBE, 1 AMERICAN CONSTITUTIONAL LAW §§ 6-2, 6-8, at 1042, 1080 (3d ed. 2000). Professor Donald Regan rightly disputes the idea that the extraterritoriality principle is

national regime, but a state may not force its own law upon another state. Any such unilateral assertion of state authority outside its territory "would offend sister States and exceed the inherent limits of the State's power."[44] The difficulty is determining at what point one state has infringed upon the sovereignty of another state — a problem that neither the majority nor the dissent resolved satisfactorily.

The majority's expansive understanding of the extraterritoriality principle proves too much. Its opinion turned largely on the Act's effect. Its definition of the principle set the tone: "A state law violates the extraterritoriality principle if it either expressly applies to out-of-state commerce *or has that 'practical effect.'*"[45] And the majority focused on the latter condition when it examined the Act's relationship with the interstate market for pharmaceuticals. The Act does not expressly regulate the market but exerts influence in its effect: it targets the participants (manufacturers and wholesalers), has the "practical effect" of a price control, and supersedes market forces to dictate market prices.[46] These concerns led the majority to conclude that "the Act effectively seeks to compel manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland."[47] "This it cannot do."[48] The problem, of course, is that many valid regulations have effects almost entirely directed at and experienced in other states.[49] If the test is whether there exists an out-of-state effect,[50] the extraterritoriality principle threatens broad swaths of product liability law, internet regulations, and environmental protections.[51] Defining the extraterritoriality principle by extraterritorial effect is untenable, for this is no limit at all.

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located solely within the Commerce Clause. *See* Donald H. Regan, Essay, *Siamese Essays: (I)* CTS Corp. v. Dynamics Corp. of America *and Dormant Commerce Clause Doctrine; (II) Extraterritorial State Legislation*, 85 MICH. L. REV. 1865, 1887–89 (1987). Instead, Regan argues that multiple constitutional provisions together create a structural inference sufficient to justify the principle. *Id.* at 1894–95. However, he acknowledges that the principle will inevitably be applied formalistically through individual constitutional provisions, one of which is the more specific Commerce Clause formulation described here. *Id.* For a more detailed description of this argument, see *id.* at 1887–95.

44 Edgar v. MITE Corp., 457 U.S. 624, 643 (1982) (opinion of White, J.) (quoting Shaffer v. Heitner, 433 U.S. 186, 197 (1977)).

45 *Ass'n for Accessible Meds.*, 887 F.3d at 668 (emphasis added) (citation omitted) (quoting Star Sci. Inc. v. Beales, 278 F.3d 339, 355 (4th Cir. 2002)); *see also id.* at 670.

46 *Id.* at 671–73.

47 *Id.* at 672.

48 *Id.* (citing Healy v. Beer Inst., 491 U.S. 324, 336 (1989)).

49 *See* Regan, *supra* note 43, at 1878.

50 The majority did not explore whether there is a threshold level of out-of-state effects before the extraterritoriality principle applies. Nor would such an exercise in line drawing necessarily be possible given the varying nature of regulatory effects. For some commentators, this indicates that the application of the extraterritoriality principle involves an implicit balancing of regulatory burdens and benefits. *See* Goldsmith & Sykes, *supra* note 4, at 804–05.

51 *See id.* at 795; *see also Ass'n for Accessible Meds.*, 887 F.3d at 688 (Wynn, J., dissenting) (critiquing the effects of the majority's reading on state antitrust and consumer protection laws).

On the other hand, the dissent's proposal to limit the extraterritoriality principle to price controls, as adopted by the Ninth and Tenth Circuits,[52] makes little sense. It is true that the iconic extraterritoriality decisions — *Baldwin v. G.A.F. Seelig, Inc.*,[53] *Brown-Forman*, and *Healy* — all involved price controls of some sort. *Baldwin* considered a New York law that prohibited out-of-state wholesalers from selling milk in New York unless they purchased their milk from dairy farmers at the price paid to New York dairy farmers.[54] *Brown-Forman* and *Healy* both concerned price-affirmation regulations.[55] But price is a poor limiting principle. As the majority opinion showed, many regulations designed to influence markets can be described in terms of price depending on perspective.[56] Further, the dissent's opinion provided a descriptive account of the doctrine, not a normative one. It isolated price controls as the only class of regulations to which the extraterritoriality principle applies, but it provided no compelling justification for why price regulations deserve more dormant commerce clause scrutiny than other regulations.[57] There appears nothing special about price regulations that causes particular offense to state sovereignty.

Rather, the Fourth Circuit might have looked to the Supreme Court's jurisdictional due process doctrine for guidance in setting boundaries to the extraterritoriality principle. As a plurality of the Court noted in *Edgar v. MITE Corp.*,[58] "[t]he limits on a State's power to enact substantive legislation are similar to the limits on the jurisdiction of state

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[52] *See* Association des Eleveurs de Canards et d'Oies du Que. v. Harris, 729 F.3d 937, 951 (9th Cir. 2013); Energy & Env't Legal Inst. v. Epel, 793 F.3d 1169, 1174 (10th Cir. 2015). However, the Ninth Circuit later distinguished its precedent in striking down an extraterritorial tax on sales of fine art. *See* Sam Francis Found. v. Christies, Inc., 784 F.3d 1320, 1324 (9th Cir. 2015) (en banc).

[53] 294 U.S. 511 (1935).

[54] *Id.* at 519.

[55] Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 582 (1986); Healy v. Beer Inst., 491 U.S. 324, 326 (1989).

[56] *Ass'n for Accessible Meds.*, 887 F.3d at 672–73.

[57] *See id.* at 685–86 (Wynn, J., dissenting). The dissent borrowed heavily from then-Judge Gorsuch's opinion in *Energy & Environment Legal Institute v. Epel*, 793 F.3d 1169, which described the extraterritoriality principle as a "shortcut" for resolving issues that would otherwise be decided by the dormant commerce clause's undue burdens inquiry, *id.* at 1174. Under this reasoning, price controls are a class of particularly obvious and inimical regulations, making it appropriate to apply extraterritoriality's per se rule of invalidity against them. Quality or health regulations are not so clearly burdensome and warrant a more nuanced case-by-case inquiry, so the extraterritoriality principle does not apply to them. While this theory explains the differential dormant commerce clause treatment for price controls, it leaves the extraterritoriality principle as little more than a crutch for judicial efficiency — a far cry from its federalism roots.

[58] 457 U.S. 624 (1982). The decisional split in this case was unusual. Only five Justices reached the Commerce Clause analysis. *Id.* at 625. All five agreed that the regulation was unduly burdensome, violating a different branch of the dormant commerce clause doctrine. *Id.* at 643. Justice Powell, however, did not sign onto the extraterritoriality analysis, leaving it a four-Justice opinion. *Id.* at 642–43 (opinion of White, J.); *id.* at 646–67 (Powell, J., concurring in part).

courts."[59] Those jurisdictional limits are delineated by the Fourteenth Amendment's Due Process Clause. Due process permits a state court to exercise personal jurisdiction over an out-of-state defendant only if there exist "minimum contacts" between the defendant and the state.[60] This requirement is more than just a guarantee of fundamental fairness in state action against an individual — it is a "consequence of territorial limitations on the power of the respective States."[61] Thus, due process doctrine is in part designed to "ensure that the States . . . do not reach out beyond the limits imposed on them by their status as coequal sovereigns in a federal system."[62]

Given the similar purposes underlying extraterritoriality and due process, it is not surprising that the two areas of law share some history.[63] In *BMW of North America, Inc. v. Gore*,[64] the Court invalidated an Alabama court's award of punitive damages because of concerns over extraterritoriality — the liability arose under state law, but the punitive damages were calculated against the defendant's nationwide conduct.[65] The Court used the Due Process Clause to strike down the award,[66] but the Court's opinion also painted a dormant commerce clause picture: "[W]hile . . . Congress has ample authority to enact such a policy [of liability] for the entire Nation, it is clear that no single State could do so, or even impose its own policy choice on neighboring States."[67] And just recently, the Court in *South Dakota v. Wayfair, Inc.*[68] — a case concerning the power of a state to tax nonresident online retailers transacting with the state's residents — reaffirmed that there are "significant parallels" between the Due Process Clause and the dormant commerce clause.[69] In fact, the test for if a state tax violates the dormant commerce clause is remarkably similar to the due process

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[59] *Id.* at 643 (opinion of White, J.).

[60] Int'l Shoe Co. v. Washington, 326 U.S. 310, 316 (1945).

[61] World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 294 (1980) (quoting Hanson v. Denckla, 357 U.S. 235, 251 (1958)).

[62] *Id.* at 292. In one of the most recent cases concerning personal jurisdiction, the Court reemphasized the importance of this goal, noting that "at times, this federalism interest may be decisive" in resolving the jurisdictional question. Bristol-Myers Squibb Co. v. Superior Court, 137 S. Ct. 1773, 1780 (2017).

[63] For a detailed account of the origins of the extraterritoriality principle and its early interactions with the Due Process Clause, see Brannon P. Denning, *Extraterritoriality and the Dormant Commerce Clause: A Doctrinal Post-Mortem*, 73 LA. L. REV. 979, 980–84 (2013).

[64] 517 U.S. 559 (1996).

[65] *Id.* at 573–74.

[66] *Id.* at 574, 585–86.

[67] *See id.* at 571 (footnote omitted). Indeed, several commentators have sorted this case within the dormant commerce clause's extraterritoriality cases. *See* TRIBE, *supra* note 43, § 6-8, at 1078 n.21.

[68] 138 S. Ct. 2080 (2018).

[69] *Id.* at 2093.

minimum contacts requirement.[70] The dormant commerce clause should not shy away from its similarities to the Due Process Clause, especially here.

The extraterritoriality principle might be clarified if it adopted a version of the minimum contacts test — one that looks at the strength of connections between the regulated out-of-state actor and the regulating state. Of course, this test need not be identical to or coterminous with the due process minimum contacts test.[71] But at a minimum, the extraterritoriality test should demand enough contacts between the state and the regulated actor to satisfy due process if the state sought to judicially enforce its regulation. The jurisdictional analysis becomes informative as a floor, and in the case of Maryland's regulation, that floor is sufficient to determine the constitutionality of the regulation. Consider the jurisdictional query: Can manufacturers that sell to distributors be subject to Maryland courts if the distributors later sell their products in Maryland?[72] On these facts alone, the answer is likely no. Under the Act, manufacturers are penalized for participating in a stream of commerce leading to Maryland, without regard to whether they possess any contacts with Maryland or make any effort to purposefully avail themselves of Maryland law. But, under the Court's stream of commerce analysis in *J. McIntyre Machinery, Ltd. v. Nicastro*,[73] merely entering the stream of commerce is insufficient to find personal jurisdiction.[74] The due process analysis here suggests a lack of minimum contacts — that Maryland is exceeding its authority and infringing upon the sovereignty of its sister states. That provides ample justification for applying the extraterritoriality principle to Maryland's law.

*Association for Accessible Medicines* was a win for Big Pharma but could have been an even bigger success for constitutional law. As it stands, the court's opinion merely adds another data point to the increasingly confusing extraterritoriality precedent. The doctrine needs to be straightened out. Other areas of law have engaged similar problems of state overreach before. Their successes have the potential to pave the way for a coherent extraterritoriality principle.

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[70] *See* Nat'l Bellas Hess, Inc. v. Dep't of Revenue, 386 U.S. 753, 756 (1967), *overruled on other grounds by Wayfair*, 138 S. Ct. 2080. Indeed, Justice White was convinced that the dormant commerce clause analysis "is really a due process fairness inquiry" (although he disagreed on whether such a due process test should be used in dormant commerce clause inquiries). Quill Corp. v. North Dakota *ex rel.* Heitkamp, 504 U.S. 298, 326 (1992) (White, J., concurring in part and dissenting in part); *see id.* at 327. And by eliminating the "physical presence" requirement of the dormant commerce clause analysis, which the due process analysis had ceased using long ago, the Court in *Wayfair* actually pushed the two analyses closer together. *See* 138 S. Ct. at 2093.

[71] Due process delineates the absolute limits of state authority — Congress itself could not authorize a violation of due process. *Cf.* Prudential Ins. Co. v. Benjamin, 328 U.S. 408, 422–23 (1946) (holding that Congress may authorize state regulation that would otherwise violate the dormant commerce clause). The dormant commerce clause, on the other hand, can go further in limiting state extraterritorial regulation and might reasonably possess a more stringent minimum contacts requirement.

[72] This question ignores for the moment the possibility of general in personam jurisdiction.

[73] 564 U.S. 873 (2011).

[74] *See id.* at 882 (plurality opinion); *see also id.* at 888–89 (Breyer, J., concurring in the judgment).