No. 21-468

In the Supreme Court of the United States

NATIONAL PORK PRODUCERS COUNCIL, ET AL.,
PETITIONERS,

v.

KAREN ROSS, IN HER OFFICIAL CAPACITY AS SECRETARY OF THE CALIFORNIA DEPARTMENT OF FOOD & AGRICULTURE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

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STATEMENT OF INTEREST

Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, non-profit association representing the nation's leading biopharmaceutical and biotechnology companies.[1] PhRMA's members are dedicated to innovating medicines that help patients lead longer, healthier, and more productive lives. Since 2000, PhRMA's members have invested over $1 trillion into discovering and developing new treatments and cures, including over $91 billion in 2020 alone. See PhRMA, *Research & Development Policy Framework*.[2] Among

[1] Pursuant to Supreme Court Rule 37.6, PhRMA affirms that no counsel for a party authored this brief in whole or in part, that no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief, and that no person other than PhRMA or its counsel made such a monetary contribution. Counsel for all parties have consented to the filing of this brief.

[2] https://onphr.ma/3lHKSHP.

numerous other efforts, they have led the way in developing new vaccines and treatments for the coronavirus—with 40% of COVID-19 clinical trials studying products developed by PhRMA's members. PhRMA, *COVID-19 Treatment Progress* (June 14, 2022).[3]

PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates as an *amicus curiae* in cases before this Court.[4] The issues in this case—including the interpretation of the Commerce Clause, and in particular the rule against extraterritorial state legislation—is of significant concern to PhRMA and its members. With increasing frequency, legislatures around the nation have enacted laws attempting to regulate the interstate commercial practices of pharmaceutical manufacturers, often in ways that impose inconsistent or conflicting obligations.

PhRMA is currently involved in litigation challenging two such laws, enacted by California and Oregon, that require manufacturers to provide advance notice before increasing the nationwide list price of their products beyond certain percentage thresholds.[5] Because a drug's list price must be uniform under federal law, see 42 U.S.C. § 1395w-3a(c)(6)(B), the direct and inevitable legal effect of these state laws is to freeze prices in all 50 states during the statutory notice period. And still other states have enacted or introduced legislation imposing similar—

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[3] https://phrma.org/Coronavirus/Activity-Tracker.

[4] See, *e.g.*, *Minerva Surgical, Inc.* v. *Hologic, Inc.*, No. 20-440; *AMG Capital Mgmt., LLC* v. *FTC*, Nos. 19-508, 19-825; *Ford Motor Co.* v. *Mont. Eighth Jud. Dist. Ct.*, Nos. 19-368, 19-369.

[5] *PhRMA* v. *Landsberg*, No. 21-16312 (9th Cir.); *PhRMA* v. *Stolfi*, No. 6:19-cv-1996 (D. Or.).

though sometimes inconsistent—obligations that are triggered by changes to this same nationwide price.[6]

Under well-established Commerce Clause principles, these direct regulations of out-of-state commerce are invalid per se. PhRMA thus has a strong interest in ensuring a proper understanding and application of the anti-extraterritoriality rule.

SUMMARY OF THE ARGUMENT

This case presents the question whether California's Proposition 12 violates the dormant Commerce Clause because it imposes "severe indirect effects upon the massive and critical nationwide pork market . . . , which will land almost entirely on residents outside of California." Pet. 25. Under this Court's precedents, the answer to that question is yes.

But no matter what this Court concludes about the constitutionality of laws, like Proposition 12, that impose "indirect" effects outside the enacting state, this case does not implicate the dormant Commerce Clause's prohibition on *direct* extraterritorial regulation—*i.e.*, the prohibition against state regulations that impose out-of-state effects by automatic operation of law. State regulations with extraterritorial *legal* effect are always categorically invalid—as the parties and the court below acknowledged. This Court should not disturb that consensus.

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[6] See, *e.g.*, S.B. 322, 31st Leg. § 1 (Haw. 2021) (considering a bill requiring 60 days' notice prior to changes in the WAC exceeding 16% over two-year period); H.B. 3609, 102d Gen. Assembly § 16.2(b) (Ill. 2021) (60 days' notice for WAC changes exceeding 10% over two-year period); S. 1615, 220th Leg. § 2 (N.J. 2022) (60 days' notice for WAC changes exceeding 10% over one-year period); S. 4536, 2021-2022 Leg., Reg. Sess. § 1 (N.Y. 2021) (30 days' notice for WAC changes exceeding 100% over one-year period); Wash. Rev. Code §§ 43.71C.010, .070 (60 days' notice for WAC changes of at least 20% over one-year period or 50% over three-year period).

I. PhRMA agrees with petitioners that Proposition 12 violates the rule against extraterritorial state legislation. Although Proposition 12 on its face purports to regulate only what in-state sellers may do, the law by its practical effect regulates farming and production practices nationwide. This Court's precedents make clear that a law can violate the ban on extraterritorial state legislation even if it is ostensibly addressed only to in-state activity.

The Court should also reject the suggestion from the decision below that the rule against extraterritorial state legislation is limited to so-called "price affirmation" statutes. That suggestion, which has no basis in constitutional text or history, would be catastrophic for interstate commerce: It would allow large states, like California, to leverage their domestic markets as a means of exerting regulatory influence beyond their own borders. For example, California could require fast-food chains, as a condition of doing business within the State, to follow California's health and safety code—at all of their locations nationwide. The Commerce Clause was adopted to prevent states from projecting those sorts of policy preferences beyond their own borders.

II. Petitioners' challenge to Proposition 12 is based on the *indirect* effects that the law imposes on out-of-state pork producers as a *practical* matter: They allege that, given the fully integrated supply chain serving the national market, there is no way for pork producers to comply with the law without completely restructuring their out-of-state operations.

This case accordingly does not present the distinct question whether a state may regulate out-of-state commerce *directly*—*i.e.*, whether a state may control out-of-state conduct not merely by virtue of how participants in a particular market have chosen to structure their affairs, but rather by automatic operation of law. A law has that kind of extraterritorial *legal* effect if a regulated party may become noncompliant with the enacting state's law based solely on its out-of-state behavior. In such circumstances, the law's extraterritorial consequences are automatic and unavoidable: A regulated party has no option to avoid them by restructuring its operations.

Decisions of this Court and other courts have consistently distinguished laws that impose "direct" and "legal" restraints on interstate commerce from those that have only "indirect" and "practical" effects outside the state. Laws that impose legal effects based on out-of-state conduct have invariably been struck down. By contrast, laws that merely give regulated parties an economic incentive to change their out-of-state conduct—but do not render such conduct unlawful in itself—require a different analysis.

In between those two ends of the spectrum, there is an intermediate category: state attempts to regulate a feature of commerce that *inherently* requires national uniformity. An example is *Southern Pacific Co.* v. *Arizona ex rel. Sullivan*, 325 U.S. 761 (1945), where this Court invalidated Arizona's attempt to regulate the length of train cars traveling within the State. Even though rail carriers could theoretically change their business practices to avoid the law's out-of-state effects—by reconstituting their trains as they entered and exited the State—the law functionally (if not legally) required rail carriers to apply Arizona's policy preferences to other states. Here, petitioners similarly allege that the pork industry is inherently national in character, effectively requiring farmers outside California to comply with Proposition 12 even if they do not intend for their product to be sold in California.

But wherever the Court decides to draw the line between permissible and impermissible out-of-state effects as a *practical* matter, the Court should not disturb the per se ban on state laws with direct extraterritorial *legal* effect. That categorical prohibition is vital to interstate businesses, like PhRMA's members, that produce and sell products nationwide. With increasing frequency, states have sought to regulate features of the pharmaceutical market that *by law* must be uniform nationwide—including the national list price of pharmaceutical products. Manufacturers subject to these direct restrictions cannot avoid their out-of-state effects merely by electing to vary their business practices between states. And because their extraterritorial consequences are automatic and unavoidable, such laws are particularly likely to generate intractable conflicts between a manufacturer's obligations in different states.

ARGUMENT

I. PROPOSITION 12 VIOLATES THE COMMERCE CLAUSE BECAUSE IT CONTROLS OUT-OF-STATE COMMERCE BY PRACTICAL EFFECT

A. The Constitution gives Congress exclusive authority to "regulate Commerce … among the several States." U.S. Const. art. I, § 8, cl. 3. The Commerce Clause thus "reflect[s] a central concern of the Framers" that, "in order to succeed, the new Union would have to avoid the tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation." *Hughes* v. *Oklahoma*, 441 U.S. 322, 325 (1979); see *Tenn. Wine & Spirits Retailers Ass'n* v. *Thomas*, 139 S. Ct. 2449, 2460 (2019) ("[R]emoving state trade barriers was a principal reason for the adoption of the Constitution. Under the Articles of Confederation, States notoriously obstructed the interstate shipment of goods.").

In light of its history and purpose, this Court has "long interpreted the Commerce Clause as an implicit restraint on state authority, even in the absence of a conflicting federal statute." *United Haulers Ass'n* v. *Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S.

330, 338 (2007). This is the "so-called 'dormant' aspect of the Commerce Clause." *Ibid.*

Among the most flagrant violations of the dormant Commerce Clause is a state law that regulates conduct "occurring wholly outside [its] boundaries," which "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." *Healy* v. *Beer Inst.*, 491 U.S. 324, 336 (1989). When one state attempts to regulate commercial activity occurring in another state, therefore, courts have "generally struck down the statute without further inquiry." *Brown-Forman Distillers Corp.* v. *N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986); see, *e.g.*, *Baldwin* v. *G.A.F. Seelig*, 294 U.S. 511, 521 (1935) ("New York has no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there").

B. PhRMA agrees with petitioners that the Ninth Circuit in the decision below misapplied the rule against extraterritoriality. Proposition 12, by its express goal and inevitable practical effect, extends California's animal-confinement regulations to farmers and producers nationwide. The law does so by prohibiting the sale of meat from an animal—regardless of its state of origin—that the seller knows was confined in violation of California's requirements. Given the interconnected nature of hog farming, the "practical effect" of this restriction is to control farming and production practices "beyond the boundaries of the State." *Healy*, 491 U.S. at 336. That exceeds California's regulatory power under the Commerce Clause.

The Ninth Circuit nonetheless upheld Proposition 12 on the ground that the law "is aimed at the in-state sales of pork, regardless whether it is produced by in-state or out-of-state farmers." Pet. App. 14a. But that feature is common among extraterritorial laws; legislatures typically know better than to explicitly target out-of-state businesses. To automatically exempt state law from constitutional scrutiny, merely because the law facially applies to domestic sales, would allow states to project their legislation beyond their own borders "by indirection." *Baldwin*, 294 U.S. at 524.

Unsurprisingly, this Court has never embraced such a rule. Several decisions, for instance, featured laws that by their terms were addressed only to conduct within the state. See, *e.g.*, *Brown-Forman*, 476 U.S. at 575 (New York law controlled price of liquor sold "to wholesalers within the State"); *Baldwin*, 294 U.S. at 519 (New York law prohibited dealers from selling milk within the state, if purchased from outside the state at prices lower than those governing in-state sales). These laws were nonetheless held invalid because of *how* they operated—*i.e.*, based on the "practical effect of the statute," which "must be evaluated not only by considering the consequences of the statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory regimes of other States." *Healy*, 491 U.S. at 336; see *Brown-Forman*, 476 U.S. at 580 ("mere fact that the effects" of a law "are triggered only by [in-state] sales . . . does not validate the law if it regulates . . . out-of-state transactions").

C. The Ninth Circuit also suggested that the prohibition on extraterritorial state legislation should be limited to "price control or price affirmation statutes," such as those struck down in *Healy*, *Brown-Forman*, and *Baldwin*. Pet. App. 8a (citation omitted). But that limitation also cannot be squared with constitutional text, history, or precedent. The Commerce Clause, as its name suggests, forbids states from regulating interstate *commerce*—a term that "comprehend[s] every species of commercial intercourse." *Gibbons* v. *Ogden*, 22 U.S. 1, 193

(1824). "[A]ll interstate commerce is not sales of goods," but includes "every negotiation, contract, trade, and dealing" that occurs across state borders. *Furst* v. *Brewster*, 282 U.S. 493, 497-498 (1931).

Consider Justice Cardozo's opinion in *Baldwin*, a foundational decision under the dormant Commerce Clause. Justice Cardozo hypothesized, as a paradigmatic example of impermissible extraterritorial legislation, a state law that "condition[ed] importation" into the legislating state of any goods manufactured in another state "upon proof of a satisfactory wage scale in a factory or shop, or even upon proof of the profits of the business." 294 U.S. at 524. Though not a price affirmation statute, such a law would "obstruct[] . . . the normal flow of commerce in its movement between states." *Ibid.* It would accordingly violate the ban on extraterritorial regulation, because "[o]ne state may not put pressure of that sort upon others to reform their economic standards." *Ibid.*

Limiting the anti-extraterritoriality rule to price affirmation statutes would also produce deeply troubling consequences. If states could regulate any feature of interstate commerce other than price, then they could leverage their domestic markets as a means of exerting regulatory influence beyond their own borders. As a condition of doing business in the Nation's largest state market, California could thus require an interstate corporation to follow the State's employment and labor laws—at *all* of its locations nationwide.

Potential examples are not hard to imagine. For instance, California bans employers from asking job applicants to disclose their arrest record, Cal. Lab. Code § 432.7, and guarantees employees 40 hours per year to attend a child's school-related activities, *id.* § 230.8. Any corporation that wished to do business within the State would have to abide by these California laws—even for the business's operations in Maine. And a nationwide food chain like McDonald's could be forced to abide, at all of its locations, by California's retail food code, see Cal. Health & Safety Code § 113700 *et seq.*

Worse still, other states would be free to pile on with their own regulations, inviting "just the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude." *Healy*, 491 U.S. at 337. Indeed, states could impose inconsistent or even contradictory requirements: Another state might disagree with California's policy on job applicants' arrest records, and instead might *require* the disclosure of such records. To avoid these sorts of intractable conflicts, and to respect the axiom that "[n]o State can legislate except with reference to its own jurisdiction," *Bonaparte* v. *Tax Court*, 104 U.S. 592, 594 (1881), the Commerce Clause forbids a state from attempting to impose its policy preferences—whether regarding price or other facets of commerce—beyond its own borders.

II. THE COURT SHOULD NOT ADDRESS THE CONSTITUTIONALITY OF STATE LAWS WHOSE EXTRATERRITORIAL EFFECT IS LEGAL RATHER THAN PRACTICAL

The question in this case is whether California may enact a law that imposes "dramatic economic effects largely outside the state and requires pervasive changes to an integrated nationwide industry." Pet. i. Petitioners argue that, given the structure of the nationwide pork market, "Proposition 12 in *practical effect* regulates wholly out-of-state commerce." Pet. 2 (emphasis added). To comply with its requirements, pork producers would need to restructure their farming practices in other states, and these "severe *indirect effects* upon the massive and critical nationwide pork market . . . will land almost entirely on residents outside of California." Pet. 25 (emphasis added).

Because Proposition 12's out-of-state effects are "practical" and "indirect," this case does not ask whether the Commerce Clause prohibits a different category of state laws—those that *directly* control out-of-state conduct by virtue of their *legal* effect. Laws of that nature pose a very different question. And the answer to that question should be uncontroversial: As the decision below and all parties agree, states may not "directly regulate[ ] conduct that is wholly out of state." Pet. App. 10a.

However this Court rules on the permissibility of Proposition 12, therefore, the Court should reserve any issue regarding state laws that have extraterritorial legal effect. See *PDK Labs. Inc.* v. *U.S. Drug Enforcement Agency*, 362 F.3d 786 (D.C. Cir. 2004) (Roberts, J., concurring in part and in the judgment) ("[T]he cardinal principle of judicial restraint—if it is not necessary to decide more, it is necessary not to decide more—counsels us to go no further.").

A. The key distinction—between (1) laws that regulate out-of-state commerce *directly* by virtue of their extraterritorial *legal* effect; and (2) laws that *indirectly* produce economic effects outside the state purely as a *practical* matter—is well illustrated by *Brown-Forman*. There, New York law required alcohol distillers within the state to submit monthly price schedules and to affirm that they would not charge wholesalers in other states less than the scheduled New York prices. 476 U.S. at 575-76. In evaluating the law's permissibility under the dormant Commerce Clause, this Court articulated the general rule against extraterritorial state legislation as follows:

> When a state statute *directly regulates* or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, we have generally struck down the statute without further inquiry. When, however, a statute has only *indirect effects* on interstate commerce and regulates evenhandedly, we have

> examined whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits.

Id. at 579 (citing *Pike* v. *Bruce Church, Inc.*, 397 U.S. 137 (1970)) (emphasis added; citations omitted).

It is thus imperative to distinguish laws constituting "direct regulation" of interstate commerce from those that have only "indirect effects" outside the state. *Brown-Forman* articulated two key insights into that distinction.

First, the Court explained that a law can regulate interstate commerce "directly" even if the law facially operates on in-state activity: Although the alcohol law challenged in *Brown-Forman* was "addressed only to sales of liquor in New York," the Court explained, it would nonetheless be per se invalid "if the 'practical effect' of the law is to control liquor prices in other States." *Id.* at 583-84 (citation omitted).

Second, a law's *legal* consequences are qualitatively different than other types of consequences. What made the New York alcohol law particularly problematic, the Court explained, was its compulsory effect on out-of-state activity: "Once a distiller ha[d] posted prices in New York, it [was] not free to change its prices elsewhere in the United States during the relevant month," lest it violate New York's law. *Id.* at 582. The law thus "[f]orc[ed] a merchant to seek regulatory approval in one State before undertaking a transaction in another." *Ibid.*

In combination, these two insights shed light on the type of "practical effect" that renders a law clearly impermissible under the dormant Commerce Clause. A law that facially targets in-state sales, but does so in a manner that *legally prohibits* regulated parties from engaging in disfavored activity outside the state, always exceeds the enacting state's authority under the dormant Commerce Clause. Other types of out-of-state effects, such as those of an economic nature, require a different analysis.

B. Decisions from this Court and others under the dormant Commerce Clause reflect these principles. Where a regulated party may become noncompliant with the enacting state's law based solely on its out-of-state behavior, then the law is properly understood as having extraterritorial *legal* effect; courts have inevitably struck such laws down. See, *e.g.*, *Healy*, 491 U.S. at 338 (invalidating Connecticut law that "prospectively preclude[d] the alteration of out-of-state prices") (quotation marks omitted); *Edgar* v. *MITE Corp.*, 457 U.S. 624, 641-43 (1982) (plurality op.) (invaliding Illinois law requiring registration of takeover offers, including from out-of-state acquirers to out-of-state shareholders). By contrast, laws that merely give regulated parties an economic incentive to change their out-of-state conduct—but do not render such conduct unlawful in itself—are better understood as imposing only practical, indirect effects on interstate commerce.

Consider *Online Merchants Guild* v. *Cameron*, 995 F.3d 540 (6th Cir. 2021), which involved a Kentucky price-gouging law that capped prices charged by "Kentucky-based sellers in connection with sales to Kentucky consumers." *Id.* at 544. By its "express terms," the law imposed no consequence on sellers based solely on their out-of-state behavior. *Id.* at 558. The plaintiff there nevertheless claimed a national pricing effect because the online merchant Amazon had chosen, as a matter of commercial practice, not to allow state-specific prices; those selling via Amazon would accordingly need "to propose a lower price, which would apply to all sales—including out-of-state sales." *Id.* at 553.

But that extraterritorial effect, the Sixth Circuit explained, was not "the *direct* or *inevitable* result" of Kentucky's law *Id.* at 554. Rather, it depended on

Amazon's "decision to structure its online marketplace to allow only a single, national price while preventing third-party sellers from limiting the states in which their goods are sold." *Id.* at 556. Thus, although sellers might end up losing revenue from out-of-state sales as a consequence of the Kentucky law, any such effect would be based "entirely upon decisions made by Amazon," rather than resulting from a legal "prohibit[ion]" applying to "wholly out-of-state commerce." *Id.* at 555.

Other decisions have similarly rejected claims under the dormant Commerce Clause where the challenged state law had only economic, rather than legal, out-of-state consequences. See, *e.g.*, *PhRMA* v. *Walsh*, 538 U.S. 644, 669 (2003) (Maine statute requiring drug manufacturers to make rebate payments to Maine citizens left them free to change prices outside the State without legal consequence); *Association des Eleveurs de Canards et d'Oies du Quebec* v. *Harris*, 729 F.3d 937, 949 (9th Cir. 2013) ("California's standards" for the production of foie gras left producers legally free to "force feed birds to produce foie gras for non-California markets"). Courts have thus regularly upheld state laws regulating the "quality" or "labeling" of goods imported into and sold within the state. *Energy & Env't Legal Inst.* v. *Epel*, 793 F.3d 1169, 1173 (10th Cir. 2015) (Gorsuch, J.).

To be sure, such laws often require interstate businesses to alter their out-of-state conduct if they want to sell their goods in the regulating state. These laws may be costly or burdensome, causing "ripple effects, including price effects, both in-state and elsewhere." *Ibid.* But because these laws do not *demand* that businesses change their out-of-state practices—or render businesses noncompliant based on those practices—any extra-territorial effect results from commercial reality, not direct legal control. See *ibid.*

C. In between these two ends of the spectrum—state laws that have extraterritorial legal effect, and those that merely have practical effect—there is an intermediate category: state attempts to regulate a feature of commerce that *inherently* requires national uniformity. In such cases, altering out-of-state behavior to comply with state law is not merely inconvenient or costly; it is functionally impossible. State regulations of this type are impermissible even if regulated parties might theoretically be able to restructure their practices to avoid the law's extraterritorial effects.

An example is *Southern Pacific Co.* v. *Arizona ex rel. Sullivan*, 325 U.S. 761 (1945), which involved Arizona's attempt to regulate the length of train cars traveling within the State. This Court acknowledged that rail carriers could hypothetically change their business practices to avoid the law's out-of-state effects—namely, by "br[eaking] up and reconsitut[ing]" their trains as they entered and exited the State. *Id.* at 773. But the Court nonetheless invalidated the law, recognizing that railroad travel is one of those "phases of the national commerce which, because of the need of national uniformity, demand that their regulation, if any, be prescribed by a single authority." *Id.* at 767. "[I]f the length of trains is to be regulated at all," the Court explained, "national uniformity in the regulation adopted, such as only Congress can prescribe, is practically indispensable to the operation of an efficient and economical national railway system." *Id.* at 771.

A similar principle was applied in *NCAA* v. *Miller*, 10 F.3d 633 (9th Cir. 1993). There, the Ninth Circuit struck down a Nevada law requiring "any national collegiate athletic association" to provide Nevada-based institutions, employees, and student-athletes "with certain procedural due process protections during an enforcement proceeding." *Id.* at 637. Though the NCAA could theoretically adopt different enforcement procedures in different states, doing so would conflict with the organization's "fundamental goals" of promoting fair competition. *Id.* at 639. Because those procedures "must be applied even-handedly and uniformly on a national basis," therefore, Nevada's law functionally (if not legally) required the NCAA to "apply Nevada's procedures to enforcement proceedings throughout the country." *Id.* at 639-40.

Here, petitioners similarly allege that the pork industry is inherently national in character: The segmented nature of hog farming, and the way in which cuts are disbursed to different buyers from a single animal, "mean there is virtually no such thing as a processed hog whose cuts are all sold in California." Pet. 12. Farmers outside California will accordingly be forced—in all but legal effect—to comply with Proposition 12, even if they do not intend for their product to be sold in California.

D. Wherever the Court decides to draw the line between permissible and impermissible out-of-state effects as a *practical* matter, however, the Court should not disturb the per se ban on state laws with extraterritorial *legal* effect. The prohibition on such direct regulation does not implicate the division of authority that warranted review in this case: The court below, like others, properly recognized that state laws "directly regulat[ing] transactions conducted entirely out of state" always violate the dormant Commerce Clause. Pet App. 13a.

Honoring the categorical prohibition on state regulation with extraterritorial legal effect is crucial for maintaining an integrated national market—and for PhRMA's members in particular. In recent years, several states have adopted laws and regulations that not only impose significant out-of-state practical consequences, but that control out-of-state activity directly, by automatic operation of law.

A prominent example is a category of state laws seeking to regulate the nationwide list prices of pharmaceutical products. At least three states have enacted laws requiring manufacturers to provide 60 days' advance notice before increasing a prescription drug's wholesale acquisition cost (WAC)—that is, the drug's *national* list price—beyond certain percentage thresholds. See Cal. Health & Safety Code § 127677(a), (b); Or. Rev. Stat. § 646A.683(2), (3); Wash. Rev. Code §§ 43.71C.010, .070. Once such an advance-notice requirement has been triggered, a manufacturer is barred from changing the drug's WAC for 60 days; by law, it remains frozen during the notice period.

The extraterritorial effect of such laws is legally imposed, not merely practically created. The WAC is defined under federal law as "the manufacturer's list price," exclusive of discounts or rebates, to "wholesalers or direct purchasers *in the United States*." 42 U.S.C. § 1395w-3a(c)(6)(B) (emphasis added). As such, it is required to be uniform nationwide. See *id.* § 1396r-8(b)(3)(A)(iii)(II) (manufacturers must report the WAC to the Department of Health and Human Services). Once a state's advance-notice requirement has been triggered, therefore, the manufacturer is barred from changing the drug's list price anywhere in the nation for the entire notice period. That extraterritorial effect is direct and automatic: A manufacturer would immediately be subject to sanction in California if it changed its list price in (for example) Missouri.

The extraterritorial effect is also unavoidable. Given the uniformity in pharmaceutical list prices required under federal law, a manufacturer cannot adopt a state-specific WAC. Unlike the online sellers at issue in *Online Merchants Guild*, the manufacturer cannot avoid liability by setting different list prices in California than in other states; it simply "lacks the power to structure [the] marketplace" in such a fashion. 995 F.3d at 555.

For similar reasons, state laws that have extraterritorial legal effect are particularly likely to result in "inconsistent obligations in different States." *Brown-Forman*, 476 U.S. at 583. As noted, drug manufacturers have no way to restructure their affairs to avoid applying California's advance-notice requirement nationwide. Yet if California can validly *require* manufacturers to disclose in advance any changes to a product's WAC, then Florida could enact a law *forbidding* such advance disclosures (say, to foster competitive pricing). Manufacturers would have to choose which law to comply with—"just the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude." *Healy*, 491 U.S. at 337.

* * *

In sum, state laws that impose extraterritorial legal obligations are qualitatively different than laws that, as a practical matter, provide economic incentives for changing behavior. Whatever the Court concludes about the (massive) indirect economic effects of Proposition 12 on out-of-state pork producers, it should not disturb the categorical prohibition on laws, like California's advance-notice law, that leave regulated parties with no legal choice but to alter their out-of-state conduct.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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