No. 21-16312

IN THE

United States Court of Appeals for the Ninth Circuit

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Plaintiff-Appellant,

v.

ELIZABETH LANDSBERG, in her official capacity as Director of the California Office of Statewide Health Planning and Development,
Defendant-Appellee.

On Appeal from the United States District Court
for the Eastern District of California, No. 2:17-cv-02573-MCE
Hon. Morrison C. England, Jr., U.S. District Judge

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* SUPPORTING PETITIONER

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RULE 26.1 CORPORATE DISCLOSURE STATEMENT

The Chamber of Commerce of the United States of America is a nonprofit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10 percent or greater ownership in the Chamber.

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INTEREST OF *AMICUS CURIAE*

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation.[1] It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. The Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

The Chamber's members routinely transact business in interstate commerce. For that reason, they have a strong interest in the enforcement of constitutional principles that protect the conduct of economic transactions over state lines, prevent one state from imposing mandates on businesses operating in other states, and protect

[1] No counsel for any party authored this brief in whole or in part, and no entity or person, aside from *amicus curiae*, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to the filing of this brief.

businesses' right to control their own speech about their products. This case presents those important constitutional issues.

In what the bill's author called "a monumental achievement for the entire nation," ER-133, California Senate Bill 17 imposes California's policy preferences related to prescription-drug pricing on manufacturers' operations in every state in the nation. And it does so by controlling what those manufacturers can say about their drugs and business decisions. The district court's decision approving SB 17 is thus of obvious interest to the Chamber's pharmaceutical-company members. Beyond that, the district court's reasoning would permit states to regulate a broad array of commercial activity and speech outside of their borders, exceeding federal limits on state power, subjecting businesses to a burdensome patchwork of inconsistent regulations of their operations, and obstructing the interstate commerce and free speech protected by the U.S. Constitution. The Chamber's members have a strong interest in preventing that result.

INTRODUCTION AND SUMMARY OF ARGUMENT

Drug pricing is a hotly disputed policy question throughout the United States. It is the subject of op-eds, politicians' stump speeches, and

ongoing negotiations in both Houses of Congress. Yet California has preempted this national debate and, through SB 17, sought to legislate its policy preferences in such a way as to govern the rest of the nation.

In an acknowledged attempt to "set national health care policy" for "consumers and providers in other states," ER-133, California's SB 17 requires pharmaceutical manufacturers to give 60 days' advance notice to the state before increasing a drug's list price, known as its wholesale acquisition cost ("WAC"). Because federal law requires a national WAC, California's law imposes a 60-day freeze on price increases in *every* state. More than that, the law orders manufacturers to make statements explaining whether their pricing decisions comply with California's controversial views on appropriate drug pricing—statements that manufacturers disagree with and would never make unless compelled. On both accounts, SB 17 is unconstitutional. As the Pharmaceutical Research and Manufacturers of America ("PhRMA") demonstrates in its brief, SB 17 violates the dormant Commerce Clause and the First Amendment by directly regulating extraterritorial commerce and compelling speech on a controversial policy question.

In defending this drastic overreach, California speaks out of both sides of its mouth. California defends SB 17 under the dormant Commerce Clause by arguing that the WAC does not affect transaction prices in other states. At the same time, California defends SB 17 under the First Amendment by arguing that SB 17 provides consumers important information about drug pricing, which presumes that the WAC *does* affect transaction prices. These arguments cannot both be right. If the WAC does not affect transaction prices, then California has no substantial interest in compelling manufacturers' speech. That would violate the First Amendment. But if the WAC does affect transaction prices, then SB 17 directly regulates transactions beyond California's borders. That would violate the Commerce Clause.

The district court endorsed California's Commerce Clause argument, finding that SB 17 likely is constitutional because it does not "necessarily dictate the transaction price of prescription drugs in other states." ER-10. But the Commerce Clause prohibits all state laws that regulate extraterritorial commerce, not only those that dictate final transaction prices. If the district court were correct, then California could fix list prices nationwide for any number of goods. And it could require

businesses in other states to obey California's many laws regulating wages, workplace safety, environmental protection, and on and on. Any interpretation of the Commerce Clause that would permit California to rule over its sister states cannot be right.

For these reasons, this Court should reverse the district court and hold that SB 17 is unconstitutional.

ARGUMENT

I. California's mutually inconsistent defenses of SB 17 confirm that it is unconstitutional.

The Chamber agrees with PhRMA's arguments that SB 17 violates both the Commerce Clause and the First Amendment because it regulates commerce beyond California and compels pharmaceutical manufacturers to express controversial views with which they disagree. But even if California could defend SB 17 under either the Commerce Clause *or* the First Amendment, it cannot defend SB 17 under *both*. The arguments California offers under the Commerce Clause are inconsistent with the arguments it offers under the First Amendment—and vice-versa. So if California were correct that SB 17 satisfies the Commerce Clause, then it would violate the First Amendment. And if California

were correct that SB 17 satisfies the First Amendment, then it would violate the Commerce Clause.

Start with the Commerce Clause. California argues, and the district court agreed, that SB 17 would not violate the Commerce Clause if it "does not necessarily dictate the transaction price of prescription drugs in other states." ER-10. As PhRMA explains, that is wrong. PhRMA Br. 37-43. But even if California's argument were correct, it turns on the premise that a pharmaceutical manufacturer's WAC is irrelevant to final transaction prices. Everyone agrees that California may not regulate transaction prices in other states. *See* ER-10-11; *e.g.*, *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986); *Assoc. for Accessible Medicines v. Frosh*, 887 F.3d 664, 671-73 (4th Cir. 2018).

At the same time, California's First Amendment argument depends on the premise that WAC *does* affect final transaction prices. As PhRMA explains, SB 17's content- and speaker-based speech regulation must satisfy strict scrutiny. PhRMA Br. 51-63. But even if, as California argues, the more relaxed *Zauderer* standard applies, California must still prove that SB 17 is "'reasonably related' to a substantial governmental

interest." *CTIA v. City of Berkeley*, 928 F.3d 832, 842 (9th Cir. 2019) (quoting *Zauderer v. Office of Disciplinary Counsel of Supreme Ct. of Ohio*, 471 U.S. 626, 651 (1985)). And California's claimed interests are to cause "a beneficial impact on pricing," D. Ct. Dkt. 70 at 18, to provide "greater insight and transparency into rising drug prices," and to "allow[] purchasers proactively to negotiate drug prices before an eventual price increase may go into effect," ER-15 (cleaned up). All of those claimed interests depend on the assumption that the WAC influences transaction prices. If WAC has no such effect, then freezing WAC could have no impact, beneficial or otherwise, on pricing; could provide no insight or transparency into actual drug prices; and could not aid any consumer in negotiating purchases.

California cannot have it both ways. If WAC affects final transaction prices, as required by California's First Amendment argument, then SB 17 unconstitutionally regulates transactions in states other than California. And if WAC does *not* affect final transaction prices, as required by California's Commerce Clause argument, then SB 17 unconstitutionally regulates pharmaceutical manufacturers' speech without serving any substantial state interest. Either way, SB 17 must fall.

II. The district court's erroneous rationale would improperly permit states to regulate a vast amount of extraterritorial commerce.

PhRMA's brief explains why the district court was wrong to hold that SB 17 would violate the dormant Commerce Clause only if it "necessarily dictate[s] the transaction price of prescription drugs in other states." ER-10; *see* PhRMA Br. 28-45. This Court has held that "the extraterritoriality principle" is not limited "to only price-control and price-affirmation cases, and [it] has recognized a broader understanding of the extraterritoriality principle may apply outside this context." *Nat'l Pork Producers Council v. Ross*, 6 F.4th 1021, 1028 (9th Cir. 2021) (cleaned up). That is, the Commerce Clause forbids *any* "statute that directly controls commerce occurring wholly outside the boundaries of a State." *Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608, 614 (9th Cir. 2018) (quoting *Healy*, 491 U.S. at 336); *Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1323 (9th Cir. 2015) (en banc); *NCAA v. Miller*, 10 F.3d 633, 639 (9th Cir. 1993).

Because states can "control[] commerce occurring wholly outside [their] boundaries," *id.*, without "dictat[ing]" final transaction prices, ER-10, the district court's rationale would grant states a breathtakingly

broad power to regulate commerce in other states. For one thing, the district court's reasoning would bless laws this Court has already invalidated.

In *Sam Francis*, for instance, this Court struck down part of a California law requiring an art seller to pay a royalty to the artist if the seller lived in California, even if the sale occurred in another state. 784 F.3d at 1323-25. The statute did not dictate the final price of any art sale, but it still unconstitutionally "regulate[d] a commercial transaction that takes place wholly outside of the State's borders." *Id.* at 1323. Similarly, this Court in *Miller* invalidated a Nevada law requiring the NCAA to follow certain procedural requirements "in enforcement proceedings in every state in the union." 10 F.3d at 639. That law did not regulate any commercial transaction, let alone dictate transaction prices, but this Court still had no trouble holding that it violated the Commerce Clause by "directly regulat[ing] a product in interstate commerce beyond Nevada's state boundaries." *Id.* at 640; *see also Daniels Sharpsmart*, 889 F.3d at 613-16 (invalidating California law regulating disposal of biological waste outside of California).

It is not difficult to conceive of other ways in which states could impose their policy preferences on purely extraterritorial commerce without violating the district court's narrow prohibition on dictating final transaction prices. If California can freeze pharmaceuticals' list prices nationwide, then what is to stop it from freezing list prices for cars or any other product? Retailers, after all, are not required to charge consumers a manufacturer's suggested retail price. So a California statute prohibiting all manufacturers whose goods end up in California from increasing their MSRPs in other states without advance notice would not "dictate" transaction prices under the district court's reasoning. But such a law would allow a single state to regulate a significant portion of the entire U.S. economy, "exceed[ing] the inherent limits of the enacting State's authority." *Healy*, 491 U.S. at 336.

The implications of the district court's rationale extend beyond pricing laws. California has never been shy about reaching outside its borders—even sending its officials into other states—to enforce state policies. *See, e.g.*, *Franchise Tax Bd. v. Hyatt*, 139 S. Ct. 1485, 1490-91 (2019) (describing how California sent its tax agents into Nevada in an effort to enforce California tax laws). So there is every reason to think

that it will aggressively seize on the district court's decision here to regulate national businesses' operations in other states. For example, if the Commerce Clause prohibits only extraterritorial controls on final transaction prices, then California could require a national retailer to pay its Kansas employees a $14/hour minimum wage,[2] a national manufacturer to follow California's workplace safety laws at its Ohio factories,[3] or cars sold nationwide to satisfy California's emission standards in every state.[4] *See* PhRMA Br. 38-39 (listing other examples). And if California can do it, so can other states. Texas could prohibit a national restaurant chain from requiring its California employees to be vaccinated against COVID-19.[5] Or Iowa could limit the topics that a

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[2] *See* Cal. Dep't of Indus. Relations, Minimum Wage, https://bit.ly/30nTZGs (listing California minimum wage)

[3] *See* Cal. Dep't of Indus. Relations, Cal/OSHA, https://www.dir.ca.gov/dosh (arguing "California Leads the Nation on Worker Safety").

[4] *See Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1078-80, 1103-04 (9th Cir. 2013) (discussing California's history of regulating car emissions, while holding that California could not "impose its own regulatory standards on another jurisdiction").

[5] *See* Tex. Exec. Order No. GA-40 (Oct. 11, 2021), *available at* https://bit.ly/3HfrBXV (prohibiting all "entit[ies] in Texas" from "compel[ling] receipt of a COVID-19 vaccine by any individual, including an employee or a consumer, who objects to such vaccination for any

national corporation is allowed to discuss when providing diversity training at its San Francisco headquarters.[6]

None of these laws would "dictate the transaction price" of any product, ER-10, but they would all be inconsistent with the Founders' vision. The Founders designed the Commerce Clause to repair the "economic Balkanization that had plagued relations among the Colonies." *Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979). If states could exceed their "jurisdictional bounds," *C&A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 393 (1994), by imposing their policy preferences on the entire nation, it would "create just the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude," *Healy*, 491 U.S. at 337.

The Commerce Clause thus "protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State." *Id.* at 336. But the district court's

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reason of personal conscience, based on a religious belief, or for medical reasons").

[6] *See* Colleen Flaherty, *No More 'Divisve Concepts' in Iowa?*, Inside Higher Ed (Mar. 18, 2021), https://bit.ly/3qw1KFd (discussing proposed Iowa law prohibiting "race and sex 'stereotyping' and 'divisive concepts' in diversity training").

refusal to meaningfully police extraterritorial regulation would, in principle, allow every state to enact different laws regulating countless aspects of national commerce. A business could thus be subject to dozens of contradictory laws regulating product design, warning labels, warranties, hiring, wages, labor relations, workplace safety, environmental protection, anti-discrimination policies, and much more besides, subject only to the toothless requirement that the laws not dictate final transaction prices. Such "inconsistent obligations" would freeze interstate commerce in its tracks, disrupting the national economy that the Constitution was created to protect. *Brown-Forman*, 476 U.S. at 583.

CONCLUSION

For the reasons set forth above, this Court should reverse.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that:

This brief complies with the length limitations of Fed. R. App. P. 29(a)(5) and Ninth Circuit Rule 32-1 because this brief contains 2,424 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared using Microsoft Word in 14-point Century Schoolbook font.

Date: November 23, 2021

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