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,

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

BRIEF FOR THE NATIONAL ASSOCIATION OF MANUFACTURERS AS *AMICUS CURIAE* IN SUPPORT OF APPELLANT

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November 26, 2021

CORPORATE DISCLOSURE STATEMENT

Amicus curiae is the National Association of Manufacturers (NAM). Pursuant to Federal Rules of Appellate Procedure 26.1 and 29(a)(4)(A), undersigned counsel certifies that NAM is a nonprofit trade association, and that NAM has no parent corporation and no publicly held corporation owns 10% or more of NAM's stock.

/s/ Sean Marotta
Sean Marotta

Dated: November 26, 2021

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STATEMENT OF COMPLIANCE WITH RULE 29

Amicus curiae submits this brief without an accompanying motion for leave to file because all parties have consented to its filing. *See* Fed. R. App. P. 29(a)(2). No counsel for any party authored this brief in whole or in part and no entity or person, aside from *amicus curiae*, its members, and its counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

IDENTITY AND INTEREST OF *AMICUS CURIAE*

The National Association of Manufacturers (NAM) is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 States. Manufacturing employs more than 12 million men and women, contributes $2.3 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for nearly two-thirds of all private-sector research and development in the Nation. NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

NAM has a strong interest in this case because SB 17 permits California to control wholly out-of-state prices and directly regulate conduct outside its borders. If this Court upholds SB 17, other States will follow suit. *See Union Pac. R.R. Co. v. California Pub. Utils. Comm'n*, 346 F.3d 851, 871 (9th Cir. 2003) (explaining

that if California can regulate extraterritorially, "so can every other state"). Drug manufacturers won't be the only target; state laws modeled on or after SB 17 may very well target California's favored industries. That cycle of retaliation will leave manufacturers stuck in a patchwork regulatory regime, left only with the impossible choice of violating one State's laws or another's.

SUMMARY OF THE ARGUMENT

States violate the Commerce Clause when they legislate extraterritorially, either by controlling out-of-state prices or directly regulating out-of-state conduct. *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 582–583 (1986); *Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608, 615–616 (9th Cir. 2018). SB 17 does both.

SB 17 effectively freezes a prescription drug's wholesale acquisition cost (WAC) nationwide for 60 days before it can be raised. States cannot indirectly influence transaction prices by controlling the benchmark that those transaction prices are anchored to. For that reason, SB 17 would violate the dormant Commerce Clause even if a drug's list price bears little relation to its transaction price. But the violation is even more obvious here, where California's law will directly influence the prices paid by buyers participating in federal healthcare programs and across 44 States.

Moreover, SB 17 "directly regulates" wholly out-of-state conduct—WAC-based drug transactions. By freezing a nationally uniform pricing benchmark, SB 17 interferes with drug sales all over the country. SB 17 "is directed at interstate commerce and only interstate commerce," and should be struck down for that reason as well. *NCAA v. Miller*, 10 F.3d 633, 638 (9th Cir. 1993). And the market participant exemption to the dormant Commerce Clause gives California no out, because California regulates far beyond its borders and downstream of its own purchases.

The District Court nonetheless held that the dormant Commerce Clause permits States to regulate any out-of-state price that "does not necessarily dictate the transaction price." ER-10. That novel ruling is not supported by the Constitution's structure or the policies animating the dormant Commerce Clause. *See Tennessee Wine & Spirits Retailers Ass'n v. Thomas*, 139 S. Ct. 2449, 2460 (2019). It instead erects unnecessary and unsound barriers in the national common market the Framers envisioned.

Enjoining SB 17 also does not infringe California's legitimate sovereign prerogatives. The Supreme Court has long held that "[t]he sovereignty of each State . . . implie[s] a limitation on the sovereignty of all of its sister States." *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 293 (1980). Indeed, "[t]he material success that has come to inhabitants of the states which make up

this federal free trade unit . . . emphasizes the necessity of protecting interstate movement of goods against local burdens and repressions." *H.P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 538 (1949).

Upholding SB 17 threatens the success of the national common market by encouraging every State to find and manipulate pricing benchmarks in hopes of influencing downstream prices. Interested in promoting the coal industry? Target the list price of green technology. Looking to keep cars on the road? Adjust the nationwide pricing structure for subway parts. History teaches that individual States, unchecked by the courts, will tinker with national commerce to further parochial local interests. *See Tennessee Wine & Spirits*, 139 S. Ct. at 2460 (quoting M. Farrand, The Framing of the Constitution of the United States 7 (1913)). The consequences—and the costs—will ultimately be borne by American consumers. *See* Lucia Mutikani, *Supply Chain Bottlenecks Amid Roaring Demand Slow U.S. Manufacturing*, Reuters (May 3, 2021), *available at* https://reut.rs/3nL7qJs (highlighting the effect of slowed manufacturing on consumer access to goods). The Court should stop the downhill slide before it begins and reverse.

ARGUMENT

I. SB 17 VIOLATES EVEN THE CONSTRAINED DORMANT COMMERCE CLAUSE RECOGNIZED BY THIS COURT'S RECENT CASES.

The dormant Commerce Clause provides that Congress, and Congress alone, "shall have Power . . . To regulate Commerce . . . among the several States." U.S. Const. art. I, § 8, cls. 1, 3. Congress's broad authority over interstate commerce means that the States' powers are correspondingly limited. *Gravquick A/S v. Trimble Navigation Int'l Ltd.*, 323 F.3d 1219, 1223–24 (9th Cir. 2003) ("Although the Commerce Clause acts as a grant of power to Congress, it also serves as a limitation on the powers of the states.") (citing *Edgar v. MITE Corp.*, 457 U.S. 624, 640 (1982) (plurality op.)). Having seen the risks of a fragmented trade union under the Articles of Confederation, the Framers used the dormant Commerce Clause to eliminate state trade barriers against a national market. *Tennessee Wine & Spirits*, 139 S. Ct. at 2460.

This Court has recently stated its belief that "[w]hile the dormant Commerce Clause is not yet a dead letter, it is moving in that direction." *National Pork Producers Council v. Ross*, 6 F.4th 1021, 1033 (9th Cir. 2021), *petition for cert. filed*, No. 21-468 (U.S. Sept. 27, 2021). But even then, the Court acknowledged that a state law is unconstitutional if it "directly regulates transactions that are conducted entirely out of state . . . or interferes with a national regime." *Id.* A "price control or price affirmation statute[ ]" is an example of the former; a statute

that "directly regulates conduct that is wholly out of state" is an example of the latter. *Id.* at 1028–29 (citation omitted). SB 17 is unconstitutional because it is an example of both.

A. SB 17 Regulates Out-of-State Drug Pricing Akin To A Price Control Or Price Affirmation Statute.

If the dormant Commerce Clause prohibits anything, it prohibits a State from controlling the prices a seller charges in a different State. As the Supreme Court has explained, the Clause forbids a state law that "regulate[s] the price of any out-of-state transaction, either by its express terms or by its inevitable effect." *Pharmaceutical Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 669 (2003) (citation omitted); *see also National Pork Producers*, 6 F.4th at 1027–28.

SB 17—by its express terms and inevitable effect—impermissibly regulates the price of wholly out-of-state drug transactions. The District Court made three mistakes in holding otherwise. First, the District Court relied on labels over substance, concluding that SB 17 could not be a price-control law because California had labeled it a "notice statute." ER-10. But the dormant Commerce Clause concerns itself with the "practical effect" of a statute, not what a State calls it. *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989); *Brown-Forman*, 476 U.S. at 579; *NCAA*, 10 F.3d at 639.

In practical effect, SB 17 sets a 60-day, nationwide price cap on a manufacturer's WAC. Federal law defines WAC as "the manufacturer's list price

for the drug . . . to wholesalers or direct purchasers in the United States," not including discounts or rebates, "for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data." 42 U.S.C. § 1395w-3a(c)(6)(B). It is, and must be, an objective, uniform, nationwide price. *Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency*, 84 Fed. Reg. 20,732, 20,739 (May 10, 2019) (describing the WAC as "a single, manufacturer-published price that excludes rebates and discounts").

Under SB 17, pharmaceutical manufacturers must provide 60 days' advance notice before increasing a prescription drug's WAC if the drug costs more than $40 "for a course of therapy," and if the new increase, when combined with increases over the previous two calendar years, total 16% or more. Cal. Health & Safety Code § 127677(a)–(b). In effect, then, a manufacturer cannot increase its nationwide WAC—inside or outside California—more than the statutory limit without first waiting 60 days. An example helps illustrates the point. Over the course of two years, a company gradually increases the WAC of a therapy from $100 to $115. Before the company may increase its WAC to $117 in California, it must notify those SB 17 mandates and wait 60 days. But because WAC is a federally defined, nationally uniform measurement, SB 17 freezes the therapy's

price not just in California, but in all other States, too. *See* 42 U.S.C. § 1395w-3a(c)(6)(B). SB 17 may be a "notice statute." But it is not only that.

If the District Court were right that a state "notice" statute that has the practical effect of freezing prices in other States is constitutional, then so is the paradigmatic dormant Commerce Clause violation—a price affirmation statute. A price affirmation statute, at least superficially, only requires a manufacturer to give notice that *at the moment of the affirmation*, the price charged in the State is no higher than those charged elsewhere; following the affirmation, the manufacturer can change prices in other States. *See Healy*, 491 U.S. at 335 (describing Connecticut's price affirmation statute). It is only when the price affirmation interacts with other States' laws that the extraterritorial, price controlling effect becomes clear. *See id.* at 337–340.

So it is here. At least superficially, SB 17 is only about giving notice of price increases in advance of their effectiveness in California. But because SB 17 targets WAC, a national benchmark price, SB 17 has the practical effect of freezing prices nationwide. Like a price affirmation statute, then, SB 17 is unconstitutional.

Second, the District Court ignored that, by regulating WACs, California also regulates transaction prices in other States. As PhRMA explained below, the federal government and several States incorporate manufactuers' WACs into

formulas for determining reimbursement prices. Pl.'s Memo. in Supp. of Mot. for Summ. J. at 2–3, 9–10; *see also, e.g.*, Fla. Admin. Code Ann. r. 59G-4.251(3)(a); 10-144 Me. Code R. ch. 101, ch. II, § 80.09-1(A)(2) (reimbursement at "lowest of" several metrics, including "[t]he Wholesale Acquisition Cost (WAC) plus . . . $11.89"). In fact, California's own expert acknowledged that, for over 15 years, the Medicare Part B program has generally based its reimbursement amount on Average Sales Price plus six percent. The Average Sales Price, in turn, "is computed using [the] manufacturers' . . . WAC[] less all price concessions." ER-33 to ER-34. Because price concessions vary, WACs and reimbursement rates do not *always* move in tandem. But California's expert's charts are telling: For the the top five Medicare Part B reimbursements, the average quarterly reimbursement rate increased every time the average quarterly WAC did. ER-36. Moreover, Medicare Part D expressly authorizes plan sponsors to negotiate for pharmacy reimbursement and price concessions based on benchmark prices such as WAC. 84 Fed. Reg. at 20,739; *see also* ER-38.

WAC's influence does not stop there. Fifteen States' Medicaid programs reimburse pharmacies using a WAC-based formula anytime it represents the least expensive alternative. *See* ER-39. Another 29 States use a WAC-based formula when it yields the lowest price and an Actual Acquisition Cost or National Average Drug Acquisition Cost for a drug is not available. *Id.* And three state Medicaid

programs reimburse pharmacies using a WAC-based formula *anytime* a prescription drug lacks an Actual Acquisition Cost or National Average Drug Acquisition Cost. ER-40. The upshot of these reimbursement regimes is that anytime the WAC-based formula presents the least expensive cost of a drug, and anytime a drug lacks a Actual Acquisition Cost or National Average Drug Acquisition Cost, California law creates a 60-day price cap for pharmacy reimbursements in some non-California States.

The effects of SB 17 differ little from those that the Supreme Court has already condemned. *See Brown-Forman*, 476 U.S. at 579–580 (striking down New York law that established 30-day pricing floor for in-state and out-of-state liquor); *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 519-524 (1935) (holding that neither the health of New York's residents nor the wealth of its farmers could justify the State's attempt to regulate out-of-state milk prices). California created its 60-day pricing cap to supposedly protect its residents from unexpected jumps in the cost of prescription drugs. And California may think its objective is a noble one. *See Healy*, 491 U.S. at 334 (noting that a State "might seek low prices for its residents"). But if New York cannot use its laws to dictate what Vermonters pay for milk, *Baldwin*, 294 U.S. at 521–522, then California cannot use its laws to dictate what all Americans pay for pharmaceuticals.

Third, the District Court incorrectly assumed that the dormant Commerce Clause permits States to regulate out-of-state list prices when they supposedly bear little relation to the transaction price. ER-10. Nothing in the policies animating the dormant Commerce Clause suggests tolerance for States' extraterritorial regulation of *list* prices, but not transaction prices.

The Supreme Court has explained that the dormant Commerce Clause's prohibition against price-control statutes embodies two principles. First, States "may not insist that producers or consumers in other States surrender whatever competitive advantages they may possess." *Brown-Forman*, 476 U.S. at 580. Second, States may not require manufacturers "to forgo the implementation of competitive-pricing schemes in out-of-state markets because those pricing decisions are imported by statute . . . regardless of local competitive conditions." *Healy*, 491 U.S. at 339.

As every manufacturer and retailer knows, an ultimate transaction price is often "anchored" to a list price like the WAC. Andrea J. Caceres-Santamaria, *The Anchoring Effect*, Page One Econ. (Rsch. Div., Fed. Rsrv. Bank of St. Louis, St. Louis, MO), Apr. 2021, https://bit.ly/3HRQqt2 (explaining the use of a manufacturer's suggested retail price as a psychological anchor by consumers). Thus, even if—according to California's expert—"'a constellation of negotiated contracts' yield 'substantial variations in what different purchasers pay for the

same drugs,'" ER-27 (citation omitted), the drug's list price still plays an important role. It is the price by which discounts and rebates are measured; a benchmark by which transaction prices are ultimately judged.

Even California agrees. California stated below that SB 17 was meant to address "[h]igh drug costs," which supposedly "significantly impact states and their taxpayers who pay for drugs for state employees, prisoners, and Medicare and Medicaid recipients." Def.'s Opp. to Mot. for Summ. J. 2. If the WAC were numbers drawn from thin air with no relationship to transaction prices, then requiring drugmakers to report certain WAC increases would have no rational relationship to California's stated goal of combatting drug prices. California regulated WAC prices because it knows that WACs are linked to ultimate transaction prices.

By restraining drugmakers' WACs, California requires drugmakers to give up pricing flexibility in other States during the 60-day SB 17 window. Suppose, for instance, there is a critical shortage of a needed therapy. A drugmaker could address the shortage by surging production at an additional cost and passing the cost along to payors through an increased WAC. SB 17, however, restricts a drugmaker from meeting that demand because it in effect suspends certain WAC increases from going into effect for 60 days, preventing the drugmaker from addressing "competitive conditions." *Healy*, 491 U.S. at 339. And SB 17 will

further prevent drugmakers from using their "competitive advantage[]" in meeting patients' needs when meeting those needs may require a WAC increase. *Brown-Forman*, 476 U.S. at 580. SB 17 is, for that reason, unconstitutional—even if its impact on transaction prices is only indirect.

B. SB 17 Directly Regulates Wholly Out-of-State Conduct.

SB 17 is also unconsitutional because it "directly regulates" inherently national activity: WAC-based drug pricing. The dormant Commerce Clause "precludes the application of a state statute to commerce that takes place wholly outside of the State's borders." *Daniels Sharpsmart, Inc.*, 889 F.3d at 614 (quoting *Healy*, 491 U.S. at 336). As when a State enacts a price-control statute, "[w]hen a state statute directly regulates . . . interstate commerce, . . . [courts] have generally struck down the statute without further inquiry." *Id.* (quoting *Brown-Forman*, 476 U.S. at 579).

To be sure, a "statute is not 'invalid merely because it affects in some way the flow of commerce between the States.'" *Association des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937, 948–949 (9th Cir. 2013) (citation omitted). But at the same time, "[t]he mere fact that some nexus to a state exists will not justify regulation of wholly out-of-state transactions." *Daniels Sharpsmart*, 889 F.3d at 615; *see also Ward v. United Airlines, Inc.*, 986 F.3d 1234, 1240 (9th Cir. 2021) ("The salient question, then, is whether California's ties

to the [regulated conduct] are sufficiently strong to justify its assertion of regulatory authority . . . ."). At bottom, a State may not use its laws to elevate "state automony over local needs" above the "overriding requirement of freedom for the national commerce." *Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1323 (9th Cir. 2015) (en banc) (citation omitted).

A State necessarily brings wholly out-of-state transactions within its regulatory reach when it attempts to regulate inherently national activity. *NCAA*, 10 F.3d at 638. In *NCAA*, this Court struck down a Nevada law that required any national collegiate association to confer additional procedural protections to a Nevada institution, employee, student-athlete, or booster facing disciplinary action and allowed Nevada courts to enjoin any NCAA disciplinary proceeding that failed to provide these additional protections. *Id.* at 637, 640. The Court found it "clear that the Statute [was] directed at interstate commerce and only interstate commerce." *Id.* at 638. The NCAA was an "interstate organization[]" with "member institutions in 40 or more states" that was "engaged in interstate commerce" and "subject to [federal] regulation." *Id.* Moreover, "in order for the NCAA to accomplish its goals, [its] enforcement procedures [had to] be applied even-handedly and uniformly on a national basis." *Id.* (internal quotation marks and citation omtted). This Court found it impractical for the NCAA to both maintain its evenhandedness and comply with the Nevada law. *Id.* at 639. And

once Nevada subjected the NCAA to additional procedural requirements for its citizens, so could every other State. The resulting fractured system would be impossible to sustain. *Id.* at 639–640.

The WAC price measurement is even more inherently national. For drug manufacturers, WAC uniformity is not an organizational objective, as it was for the NCAA, *id.* at 638, but a federal command, 42 U.S.C. § 1395w-3a(c)(6)(B). Entities that do not accurately report their WACs risk civil liability. *See, e.g.*, *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257-PBS, 2007 WL 4287572, at *1 (D. Mass. Dec. 6, 2007). And the WAC plays a critical role in drug-pricing agreements for federal healthcare programs, *e.g.*, 42 U.S.C. §§ 1395w-3a(b)(4), (c)(4); 44 States, *e.g.*, Fla. Admin. Code Ann. r. 59G-4.251(3)(a); and private-party agreements throughout the nation. *See* ER-33 to ER-34, ER-37 to ER-39; *see also* ER-127 to ER-130.

NCAA's logic thus applies here with even more force. Drug manufacturers cannot change their WAC in any State without changing it in California. And with every new law, it becomes harder and harder to comply with States' inconsistent stances on when a WAC increase must be delayed before it takes effect. *See, e.g.*, 2019 Or. Laws 1267 (requiring 60 days' notice in advance of a change in WAC that would result in a total increase exceeding either 10% or $10,000 over the course of one year); 2019 Wash. Sess. Laws 2114, 2118 (requiring 60 days' notice

in advance of a change in WAC that would result in a total increase exceeding either 20% over one year or 50% over three years). So, like in *NCAA*, 10 F.3d at 639–640, it is only a matter of time before compliance goes from hard to impossible.

WAC's nationwide use also means that SB 17's 60-day cap will, at minimum, bear on negotiations with no nexus to California. *See supra* pp. 12–13. But California cannot regulate wholly out-of-state pricing negotiations, just as it cannot dictate out-of-state waste treatment, *Daniels Sharpsmart*, 899 F.3d at 616 (California law was unconstitutional where State officials "sought to punish Daniels for disposing of medical waste in a manner that was perfectly legal in the states in which Daniels had effectuated disposal"), or set the terms of out-of-state art sales, *Sam Francis Found.*, 784 F.3d at 1323–25 (California law was unconstitutional where it sought to regulate the terms of a wholly out-of-state art transaction between private parties). SB 17's direct regulation of non-California conduct renders it impermissibly exterritorial.

C. The Market Participant Exemption Does Not Immunize SB 17.

Below, California argued that the market participant exception to the dormant Commerce Clause saved SB 17. Def.'s Opp. to Mot. for Summ. J. 10-11. Under that exception, a State's *discriminatory* law may be exempt from the dormant Commerce Clause when the State acts as a market participant instead of a

market regulator. *Reeves, Inc. v. Stake*, 447 U.S. 429, 436–437 (1980); *Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794, 806–810 (1976). The dormant Commerce Clause protects the out-of-state business that "enters a State in response to completely private market forces to compete with domestic businesses, only to find itself burdened with discriminatory taxes or regulations." *Hughes*, 426 U.S. at 810 n.20. In other words, when a business enters a State to do business *with* the State, it has no claim to equal treatment with in-state counterparts. *Id.* at 810 & n.20. Nothing in the constitutional structure reflects a "plan to limit the ability of the States themselves to operate freely in the free market," *Reeves*, 447 U.S. at 437 (citing L. Tribe, American Constitutional Law 336 (1978)), and so States may—"when acting as proprietors"—favor their own citizens when buying goods and services. *White v. Massachusetts Council of Constr. Emp'rs, Inc.*, 460 U.S. 204, 207 n.3 (1983) (citation omitted); *see also Engine Mfrs. Ass'n v. South Coast Air Quality Mgmt. Dist.*, 498 F.3d 1031, 1045 (9th Cir. 2007) (explaining that proprietary action "refect[s] the [state] entity's own interest in its efficient procurement of needed goods and services" in view of "the typical behavior of private parties in similar circumstances") (second alteration in original and citation omitted).

The market participant exemption cannot save an impermissibly extraterritorial law, however, because the harm done by a discriminatory law

differs from the harm done when a State directly regulates wholly out-of-state commerce. The former impedes the free flow of goods and services among the States. The latter impedes a co-equal sovereign's ability to regulate its own in-state affairs. California's participation in its own prescription-drug market does nothing to cure the injury SB 17 inflicts upon other States by directly regulating conduct that occurs wholly within their borders. It is no surprise, then, that California to date has not cited a single case that has exempted an extraterritorial state law on the ground that the State was a market participant.

Moreover, as California frames it, the exemption would know no limits. In California's view, it participates in a nationwide market whenever it legislates in furtherance of the "State's interest as a purchaser." Def.'s Opp. to Mot. for Summ. J. 10. But the idea that a State may participate in one market, impose downstream restrictions, and thereby "govern the private, separate economic relationships of its trading partners" has already been rejected. *South-Central Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 99 (1984). "The limit of the market-participant doctrine must be that it allows a State to impose burdens on commerce within the market *in which it is a participant*, but allows it to go no further." *Id.* at 97 (emphasis added). Even assuming the market participant exemption could extend to extraterritorial laws, California does not participate in any of the out-of-state drug

markets with which SB 17 interferes. The market participant exemption therefore cannot immunize SB 17 from constitutional review.

II. ALLOWING STATES TO FREEZE NATIONWIDE PRICING BENCHMARKS THREATENS MANUFACTURERS ACROSS THE COUNTRY.

Upholding SB 17 would harm manufacturers across the country. If California can pass a "notice" statute to control out-of-state prices, so can Texas, and Maine, and Mississippi. If California can regulate a nationwide benchmark to alter wholly out-of-state conduct, so can every other State.

And they will. California is one of at least three States that have sought to control drug prices through WAC-increase notice statutes. 2019 Or. Laws 1267; 2019 Wash. Sess. Laws 2114, 2118. Others are on the way. *See, e.g.*, S.B. 322, 31st Leg. § 1 (Haw. 2021); H.B. 3609, 102d Gen. Assemb. § 16.2(b) (Ill. 2021); S. 4536, 2021–2022 Leg., Reg. Sess. § 1 (N.Y. 2021). But California is wrong to assume that a State's ability to regulate out-of-state drug prices will always promote its preferred policies. States worried about slowing pharmaceutical innovation or losing in-state pharmaceutical jobs might pass extraterritorial drug laws that prop up drug prices. For example, one State may pass a law requiring 1 year's notice before a manufacturer offers more than a 1% discount off its WAC. Another State could then prevent the manufacturer from reducing its WAC, requiring 1 year's notice before decreasing WAC by more than 3%. This would

lock in prices for prescription drugs that are *higher* than the free market would typically facilitate.

Drug pricing alone would be cause for concern, but nothing in the District Court's ruling limits extraterritorial pricing regulations to prescription drugs. Other States will expand to different industries. Those threatened by a push for green energy technology could freeze list prices for wind turbines, solar panels, and utility-scale batteries. Those concerned with marijuana legalization may set extraterritorial minimums on manufacturers' suggested retail prices to dissuade its use. Under the District Court's ruling, there is no principled basis for why these laws would fall while SB 17 remains intact.

And this is the great irony of extraterritorial regulation: It harms those within and without the regulating State. As James Madison observed, allowing States to impose requirements on producers and suppliers beyond their borders "tends to beget retaliating regulations." *See* James Madison, *Vices of the Political System of the United States*, *in* 2 Writings of James Madison 361, 363 (Gaillard Hunt ed., 1901). Alexander Hamilton likewise worried that, if allowed to "multipl[y] and extend[ ]," "[t]he interfering and unneighborly regulations of some States" would become "serious sources of animosity and discord." The Federalist No. 22 (Alexander Hamilton). And other Founders expressed similar concerns. *See* Barry Friedman & Daniel T. Deacon, *A Course Unbroken: The Constitutional*

Legitimacy of the Dormant Commerce Clause, 97 Va. L. Rev. 1877, 1885–86 & n.29 (2011) (collecting other examples of the founders' "references to the nation's commercial woes, including discord among the states"); Letter from James Monroe to James Madison (July 26, 1785)[1] (explaining that allowing the States to pursue separate commercial policies "establish'd deep-rooted jealousies & enmities between them" which, if allowed to persist, "will become instrumental in their hands to impede & defeat those of each other").

Manufacturers will be caught in the middle. Across industries and across state lines, makers that produce the goods Americans need will be subject to a patchwork of obligations that yield one of two scenarios. First, compliance will be possible but impractical. Some manufacturers will be forced to abandon more profitable methods of operation; others will go out of business or pass on costs to consumers. *See, e.g.*, *Eleveurs*, 729 F.3d at 949–950; *National Ass'n of Optometrists & Opticians v. Harris*, 682 F.3d 1144, 1150–51 (9th Cir. 2012). Or, second, compliance will be impossible. Left with irreconcilable obligations, manufacturers will face the unenviable choice of violating one State's laws or another's. *NCAA*, 10 F.3d at 639–640.

This should give California pause. California is home to over 35,000 manufacturing firms. *2021 California Manufacturing Facts*, Nat'l Ass'n of Mfrs.,

[1] *Available at* https://bit.ly/2SWWhGD.

https://bit.ly/30Uwq8g (last visited Nov. 26, 2021). California's manufacturers produce goods ranging from computers and electronics, to fabricated metals and other transportation equipment. *Id.* They account for 10.36% of the total output in the state, and they employ 7.57% of the State's non-farm workforce. *Id.* Extraterritorial laws like SB 17 threaten manufacturing's success in California and across the country.

The rule that one State "has no power to project its legislation into" another State, *Baldwin*, 294 U.S. at 521, is fundamental to our federal system. It embodies "the Constitution's special concern both with the maintenance of a national economic union unfettered by state-imposed limitations on interstate commerce and with the autonomy of the individual States within their respective spheres." *Healy*, 491 U.S. at 335–336 (footnotes omitted). The Court should continue to enforce this fundamental component of our constitutional design.

CONCLUSION

For the foregoing reasons and those in PhRMA's brief, the District Court's order should be reversed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 29(a)(5) because it contains 4,969 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the typestyle requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Office Word for Office 365 in Times New Roman 14-point font.

/s/ Sean Marotta
Sean Marotta

CERTIFICATE OF SERVICE

I certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the CM/ECF system on November 26, 2021.

/s/ Sean Marotta
Sean Marotta