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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

EDMUND GERALD BROWN, Jr., in his official capacity as Governor of the State of California, and

ROBERT P. DAVID, in his official capacity as Director of the California Office of Statewide Health Planning and Development,

Defendants.

Case No.: 2:17-cv-02573-MCE-KJN

PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

The State's summary-judgment-like motion to dismiss cannot overcome three fundamental allegations of the Complaint: *First*, Senate Bill 17 ("SB 17"), in regulating the wholesale acquisition cost ("WAC") of prescription drugs, governs a single *national* price. *Second*, requiring manufacturers to give 60 days' advance notice of a change in that national price necessarily bans the implementation of the change—nationally—before the 60 days expires. *Third*, requiring manufacturers to state publicly whether a change or improvement in the drug justifies a price increase, singling out both manufacturers and this ordained rationale, forces them to endorse by necessary implication California's messages that they are to blame for increases in the cost of the drugs and that the price increases are illegitimate absent a change or improvement in the drug. Ignoring the procedural posture of this case, the State does not accept these allegations in the Complaint as true, as Rule 12(b)(6) requires, but instead challenges them and asks the Court to decide facts as if it were ruling on the merits.

The State, however, *is* obligated to accept these allegations as true. But PhRMA need not rest only on that obligation, for the logic of the allegations is compelling and their legal foundation is unrefuted. Based on these and other, uncontested allegations, PhRMA's Complaint pleads three cognizable constitutional claims.

First, the Complaint states a valid claim under the dormant Commerce Clause. Under SB 17, pharmaceutical manufacturers must provide purchasers registered with the State's Office of Statewide Health Planning and Development ("OSHPD") 60 days' advance notice of an increase in the WAC of a prescription drug with total increases of 16 percent over the prior two calendar years. This provision effectively bans increases in the WAC for 60 days, nationwide. After sending the mandatory notifications, a manufacturer must wait 60 days before raising its price *anywhere in the country*. (Compl. ¶¶ 26, 57, ECF No. 1.) The Supreme Court held in *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573, 582–84 (1986), that tying in-state pricing obligations to out-of-state pricing, as SB 17 does by tying California pricing requirements to the national WAC, violates the dormant Commerce Clause. The State's assertion that manufacturers are "free to set, change, and increase their drug prices as they see fit," (Mot. 2, ECF No. 19-1), is wrong

and contrary to PhRMA's factual allegations. There can be only one nationwide WAC for each drug. Increasing the WAC in Iowa, Maine, or Wyoming within the 60-day window increases it in California, too, in violation of SB 17. This extraterritorial effect was by design. The bill's author proclaimed SB 17 as "a monumental achievement for the *entire nation*" that will "set *national health care policy*, having an impact for consumers and providers *in other states*." (Compl. ¶ 37.)

Even if SB 17 did not directly regulate out-of-state commerce, it would be unconstitutional because its benefits do not outweigh its burdens on interstate commerce. *See Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). SB 17 burdens interstate commerce by distorting the national prescription-drug market. Requiring 60 days' advance notice of a price increase allows some purchasers to hoard products in anticipation of that increase. And while California boasts that SB 17 brings "transparency" to drug pricing, federal antitrust regulators have found such transparency an impediment, not a benefit, to pharmaceutical competition. (Compl. ¶ 63.) On the other side of the balance, SB 17's benefits are inconsequential. The WAC, after all, is publicly available.

Second, PhRMA's Complaint pleads a valid First Amendment claim. In addition to the 60-day advance notice requirement, SB 17 requires manufacturers—and only manufacturers—to justify their pricing decisions. Further, the law isolates one factor manufacturers must address. They must publicly state whether a price increase is attributable to "a change or improvement in the drug." Cal. Health & Safety Code §§ 127677(c)(2); 127679(a)(6). A manufacturer's coerced statement that a price increase is not justified by any change or improvement in the drug elevates that factor above all others and suggests the increase is illegitimate. PhRMA and its members vigorously dispute those propositions and object to the requirement that they implicitly endorse them. Mandating these statements is a regulation of speech. That regulation discriminates based on the identity of the speaker—targeting only pharmaceutical manufacturers—and on the content of the communication, by covering only price *increases* and promoting the State's disputed message about the responsibility for and legitimacy of price increases. It is therefore subject to, and cannot satisfy, the heightened scrutiny applicable to speaker- and content-based impositions on First Amendment rights. In fact, SB 17 cannot survive even the less strict review accorded to commercial speech. Nor can the State invoke the still more lenient standard applicable to compelled commercial speech that

is purely factual and noncontroversial. In short, SB 17 violates the First Amendment right of PhRMA's members to speak or not to speak about price increases if, when, and how they choose, and in particular their right not to convey the self-accusatory messages that SB 17 forces on them.

Third, SB 17 is so vague that it violates due process. Manufacturers cannot discern—and the State has repeatedly refused to clarify—whether price increases in the two calendar years before SB 17's effective date count toward the 16-percent threshold, retroactively. Even in this Court, the State fails to answer the simple question that would resolve this issue. Instead, the State purports to defer to a future regulatory process that the State acknowledges will not be completed until 2019. The State thus leaves PhRMA members in legal limbo, where they either must forgo (nationwide) price increases that they are entitled to take, or suffer impositions on their First Amendment rights under SB 17's disclosure provisions, or treat those provisions as inapplicable and risk that the State will later say the companies violated the Act. Due process requires notice of a law's requirements. *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). SB 17 does not provide it.

Finally, PhRMA's allegations of financial harm to its members due to the State's coercion exceed what is needed to establish PhRMA's associational standing, and thus subject-matter jurisdiction. The Governor, moreover, is a proper party, as he is sued in his official capacity for declaratory and injunctive relief. The Court therefore should deny the State's motion to dismiss.

BACKGROUND

A. Drug Pricing and the Pharmaceutical Supply Chain

As the California Legislature acknowledged in passing SB 17, many entities besides manufacturers are involved in the pricing of pharmaceutical products. (Compl. ¶ 24.) Manufacturers primarily sell their prescription drugs to wholesalers at a price based on the WAC. (*Id.* ¶ 26.) Federal law defines the WAC as the "manufacturer's list price" to "wholesalers or direct purchasers in the United States," not including discounts or rebates. 42 U.S.C. § 1395w-3a(c)(6)(B). Manufacturers set the WAC based on individualized, proprietary, and highly subjective pricing methodologies. (Compl. ¶ 26.) At any time, there is only one WAC for a particular drug, which is published in national compendia and applies uniformly in every state. (*Id.*)

While a drug's wholesale price is based on the WAC, the amounts wholesalers actually pay

depends on other factors, such as discounts calculated as a percentage of the WAC. (Compl. ¶ 27.) Wholesalers also charge manufacturers a fee, usually a percentage of the WAC, for various distribution and logistical services. (*Id.*) Wholesalers then sell the drugs to healthcare providers (*e.g.*, hospitals and doctors) and retailers (*e.g.*, pharmacies) at prices based on the WAC. (*Id.* ¶ 28.)

Most patients who receive drugs directly from a pharmacy or a healthcare provider pay insurance premiums, deductibles, and co-payment amounts. (Compl. ¶ 29.) Third-party payers—private insurers or public healthcare programs, like Medicare and Medicaid—cover the rest of the price charged by the pharmacy or healthcare provider. (*Id.*) Third-party payers across the country typically pay pharmacies and healthcare providers a price based on the single WAC for the drug, which is the same nationwide. (*Id.* ¶ 30.) Pharmacies nationwide usually receive reimbursement in an amount derived from the WAC for drugs dispensed to Medicare or Medicaid beneficiaries. (*Id.* ¶ 29.) For drugs administered by physicians and in hospitals, other reimbursement formulas apply around the country, some of which are based in part on the WAC. (*Id.*) Third-party payers often negotiate rebates from manufacturers, which are calculated as a percentage of the WAC. (*Id.* ¶ 30.) Thus, SB 17's restrictions on WAC pricing affect not only manufacturers' sales to wholesalers, but also the reimbursement rates of other actors throughout the healthcare system nationwide.

For all these reasons, the "WAC neither reflect[s] the actual net revenue paid to manufacturers nor the actual net prices paid by pharmacies . . . or health plans." (Compl. ¶ 33.) In considering SB 17, the Legislature acknowledged that "[t]he WAC price of a drug on the market, as originally announced by the company[,] is also rarely the price paid by a payer." (*Id.*) It is "typically the contractual starting point for business-to-business contracts involving . . . key participants in the pharmaceutical distribution system." (*Id.*) Generally, the actual net prices paid by insurers, pharmacies, healthcare providers, and pharmacy benefit managers ("PBMs") are well below the WAC, though it is often the benchmark for calculating those discounts. (*Id.* ¶ 34.) Although invoice prices for patented drugs jumped 12 percent in 2015 and 9.2 percent in 2016, the average net price increase after rebates and other discounts was only 2.5 and 3.5 percent, respectively. (*Id.*)

B. History and Overview of California Senate Bill 17

The Governor signed SB 17 into law on October 9, 2017. (Compl. ¶ 35.) Proponents touted

SB 17 as a way for California to shame "greedy pharmaceutical companies" into restricting the prices of their innovative drugs "to avoid public scorn." (*Id.* ¶ 36.) While the Act professes an intent "to permit [a] manufacturer of a prescription drug to voluntarily make pricing decisions," Cal. Health & Safety Code § 127676(b)(2), SB 17's notice and reporting requirements in fact were intended to "create[] an incentive for price increases to fall below [the reporting threshold]" and to "dissuade excessive price hikes" by forcing manufacturers to "think twice before raising prices over the threshold that triggers additional reporting." (Compl. ¶ 36.)

The author of SB 17, Senator Ed Hernandez, designed the law to prevent pharmaceutical manufacturers from, in his words, "abus[ing] their market power," and he made clear an intent to affect commerce well beyond California. (Compl. ¶ 37.) He proclaimed, for example, that SB 17 would be "a monumental achievement for the *entire nation*" and would "set *national health care policy*, having an impact for consumers and providers *in other states*." (*Id.* (emphases added).)

Section 4 of SB 17 amends the California Health and Safety Code to add Chapter 9, titled "Prescription Drug Pricing for Purchasers." Chapter 9 imposes notice, reporting, and justification obligations exclusively on the manufacturer of a prescription drug "purchased or reimbursed" by certain purchasers, including state purchasers in California, licensed health service care plans, and PBMs. Cal. Health & Safety Code § 127675(a). The manufacturer of a drug subject to SB 17 must provide at least 60 days' notice to those purchasers before increasing the drug's WAC if: (1) a "course of therapy" has a WAC of more than $40, and (2) the proposed increase would result in a cumulative WAC increase of 16 percent over "the previous two calendar years prior to the current year." *Id.* § 127677 (a)–(e). Additionally, each PBM that receives notice of a WAC increase must "notify its large contracting public and private purchasers," meaning any "purchaser that provides coverage to more than 500 covered lives." *Id.* § 127677(e). To receive the prior notice of a WAC increase, qualifying entities must register with OSHPD, which, in turn, must "make available to manufacturers a list of registered purchasers for the purpose of this notification." *Id.* § 127677(d).

Each 60-day notice must include the date and amount of the WAC increase, plus "a statement regarding whether a change or improvement in the drug necessitates the price increase." If so, "the manufacturer shall describe the change or improvement." Cal. Health & Safety Code

§ 127677(c). SB 17 says nothing about any other potential justifications for a price increase. SB 17 also requires manufacturers to submit quarterly reports to OSHPD describing the factors used in deciding to increase the WAC above the threshold amount, "an explanation of how [those] factors explain the increase in the [WAC]," and, again, whether "a change or improvement" necessitated the increase. *Id.* § 127679(a).

Because the Legislature did not specify an effective date for the 60-day notice provisions, they were, by default, to "go into effect" on January 1, 2018. (Compl. ¶ 42.) On October 13, 2017, PhRMA asked OSHPD whether, in calculating the 16-percent threshold that triggers the Act's notification and reporting requirements, OSHPD intended to include all price increases from January 1, 2016, or only those occurring after January 1, 2018. (*Id.* ¶¶ 48–49.) PhRMA also asked OSHPD whether the State would issue regulations setting forth the purchaser registration and notification processes by November 1, 2017, allowing manufacturers to give 60 days' advance notice prior to the Act's January 1, 2018 effective date. (*See id.* ¶ 49.) Three weeks *after* that November 1 threshold, on November 22, 2017, OSHPD posted on its website a "Cost Transparency Rx Implementation Plan" ("Plan"). (*Id.* ¶ 50 & Ex. C.) The Plan was not responsive to PhRMA's questions about retroactivity. It stated only that as of January 1, 2018, OSHPD would be required to make available a registry of public and private purchasers for purposes of the 60-day advance notice requirement, and that purchasers could register with OSHPD beginning December 1, 2017. (*Id.* ¶ 50.) OSHPD made the list of registered purchasers available on December 29, 2017. (*See* Request for Judicial Notice, Ex. A (OSHPD notification of list availability).) As of the date of this filing, there are 122 registered purchasers with primary addresses in 12 different states.[1]

C. PhRMA's Complaint

On December 8, 2017, PhRMA filed its Complaint challenging SB 17 under the dormant Commerce Clause, the First Amendment, and the Due Process Clause.

The Complaint first alleges that SB 17 violates the dormant Commerce Clause because it prohibits drug manufacturers from raising the WAC of a product *anywhere in the nation* for 60 days

[1] *Cost Transparency Rx*, https://www.oshpd.ca.gov/CTRx.html (last visited Feb. 26, 2018).

after notifying registered purchasers of the increase. (Compl. ¶¶ 52–67.) Because, by statutory definition, the WAC is a national list price, *i.e.*, the WAC for a particular drug is the same in every state, manufacturers cannot avoid the State's burdensome regulations simply by altering their conduct in California. (*Id.* ¶ 59.) An increase in the WAC in California is an increase in the WAC in every other state. Therefore, to avoid triggering SB 17, manufacturers must forgo increases in the list price above the 16-percent threshold in *each and every state*. (*Id.*) If a manufacturer plans to raise its prices above that threshold, it must publicly announce those plans and then wait 60 days before implementing the new price in any state. (*Id.* ¶ 57.) Implementing the price increase on day 45 or 59, or any time before day 60, would violate the Act by giving less than 60 days' notice. SB 17 thus bans price increases outside California and is unconstitutional.

Next, PhRMA alleges that SB 17 violates the First Amendment by forcing manufacturers to make statements implying fault if they increase a drug's WAC above the 16-percent threshold. (Compl. ¶¶ 70–87.) Manufacturers in this position must "explain" their actions, with the inescapable implication—intended by the Legislature but disputed by the companies—that, absent a "change or improvement" in the drug, they misbehaved, overcharged, and acted irresponsibly. (*Id.* ¶ 72.) SB 17 imposes this obligation *solely* on manufacturers, not on others in the distribution channel whose decisions affect drug costs. Moreover, it does so based solely on the content of their communications about prices, requiring statements only about increases in the WAC the State deems objectionable. (*Id.* ¶¶ 74–77.) SB 17 thus compels speech in violation of PhRMA members' free speech rights.

Finally, PhRMA alleges that SB 17 is unconstitutionally vague because it does not specify whether the calculation of the 16-percent threshold includes price increases dating back to January 1, 2016. (Compl. ¶ 84.) Despite repeated requests, OSHPD has refused to clarify this ambiguity, and continues to keep this information secret. (*Id.*) If the Act applies retroactively, it immediately harms PhRMA members with products that have seen list prices increase since January 1, 2016. Any increases before the statute existed would limit the amount members can further increase the WAC of those products without triggering SB 17's unconstitutional impositions. (*Id.* ¶ 85.) The uncertainty about whether the threshold calculation applies retroactively puts PhRMA

members to the untenable choice of either complying with an overbroad interpretation of SB 17 (thus exacerbating its impermissible extraterritorial effects) or risking enforcement action.

ARGUMENT

The State's motion all but ignores the legal standard on a motion to dismiss, which requires the Complaint to plead "only enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Moss v. U.S. Secret Service*, 572 F.3d 962, 969 (9th Cir. 2009) (factual content and reasonable inferences need only be "plausibly suggestive of a claim entitling the plaintiff to relief"). In assessing facial plausibility, "[PhRMA's] allegations *must* be assumed to be true and the complaint *must* be construed in the light most favorable to [PhRMA]." *United States v. City of Redwood City*, 640 F.2d 963, 966 (9th Cir. 1981) (emphases added). Dismissal is appropriate only in the most extraordinary circumstances. *Id.* The same standard applies to the State's Rule 12(b)(1) facial attack on PhRMA's associational standing. *Coal. for a Sustainable Delta v. FEMA*, 711 F. Supp. 2d 1152, 1158 (E.D. Cal. 2010).

I. PHRMA HAS ESTABLISHED ASSOCIATIONAL STANDING

PhRMA has alleged facts satisfying the three elements of associational standing: (1) at least one PhRMA member has standing to sue in its own right; (2) the interests at stake are germane to PhRMA's purpose; and (3) neither the claim asserted nor the relief requested requires participation of individual members in the lawsuit. *See WildEarth Guardians v. U.S. Dep't of Agric.*, 795 F.3d 1148, 1154 (9th Cir. 2015). Pleading injury is a low bar, especially when the defendant does not attack the plaintiff's factual allegations supporting jurisdiction. *See Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004); *Winnemem Wintu Tribe v. U.S. Dep't of Int.*, 725 F. Supp. 2d 1119, 1130 (E.D. Cal. 2010). Accordingly, courts have repeatedly recognized PhRMA's associational standing in similar cases challenging the constitutionality of state laws. *See, e.g.*, *Biotech. Indus. Org. v. Dist. of Columbia*, 496 F.3d 1362, 1371 (Fed. Cir. 2007) (PhRMA had standing to bring preemption challenge to District of Columbia statute); *PhRMA v. Concannon*, 249 F.3d 66, 73–74 (1st Cir. 2001) (PhRMA had standing to bring preemption and Commerce Clause challenges to state law); *PhRMA v. Dist. of Columbia*, 406 F. Supp. 2d 56, 63 (D.D.C. 2005) (same); *PhRMA v. Thompson*, 259 F. Supp. 2d 39, 51 (D.D.C. 2003) (PhRMA had standing to bring

preemption and Commerce Clause challenges to state's Medicaid initiative). This case is no exception.

A. PhRMA Members Have Standing to Sue for Each Claim Asserted

An individual member has standing if it demonstrates injury-in-fact, causation, and redressability. *See Warth v. Seldin*, 422 U.S. 490, 511 (1975). The State does not challenge the Complaint as to causation or redressability, and the allegations of harm to PhRMA's members comfortably satisfy the requirements for pleading standing for each claim asserted.

1. The 60-Day Ban on Price Increases Harms PhRMA Members

The Complaint alleges that PhRMA's members suffer classic economic harm: they are barred from increasing their prices across the country if they fail to comply with California's notice requirements, on pain of statutory penalties. (*See* Compl. ¶¶ 3, 57, 89.) The economic harm resulting from price restrictions is sufficient to confer standing. *See generally Brown-Forman*, 476 U.S. 573; *In re Beer Inst.*, 849 F.2d 753 (2d Cir. 1988). The State does not appear to dispute that a ban on price increases confers standing, and acknowledges PhRMA's allegation that SB 17 imposes a 60-day nationwide ban on price increases. (Mot. 2, 13.)

Instead, the State claims that "choos[ing] not to increase the WAC of products to avoid triggering SB 17's advance notice provisions" does not establish standing. (Mot. 10.) But this argument—a single sentence in the State's brief—is squarely foreclosed by Supreme Court precedent. A plaintiff's "own action (or inaction) in failing to violate the law . . . does not eliminate Article III jurisdiction." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 128–29 (2007). More specifically, a plaintiff's decision to "eliminate[] the imminent threat of harm by simply not doing what he claimed the right to do"—such as increase a drug's WAC—does not preclude subject-matter jurisdiction, "because the threat-eliminating behavior was effectively coerced." *Id.* at 129; *see also Planned Parenthood Fed. of Am., Inc. v. Schweiker*, 559 F. Supp. 658, 663 (D.D.C. 1983) (rejecting argument that minors did not have standing to challenge contraceptive-related rule because they could abstain from intercourse). Moreover, the State's contention ignores that SB 17 bars manufacturers from increasing their prices for 60 days even if they comply with the notice provisions. This is clearly cognizable injury.

2. SB 17's Compelled Speech Provision Harms PhRMA Members

The Complaint alleges that SB 17 causes injury-in-fact to PhRMA members by forcing them to publicly endorse a message that they dispute and that blames them for high drug prices. (Compl. ¶¶ 2, 5, 8–9, 70, 72, 75–76, 93.) PhRMA also alleges that its members could be subject to civil penalties if OSHPD deems their explanations incomplete. (*Id.* ¶ 58.) These allegations more than satisfy standing requirements. *Ariz. Right to Life Political Action Comm. v. Bayless*, 320 F.3d 1002, 1006 (9th Cir. 2003) (finding it "sufficient for standing purposes that the plaintiff intends to engage in 'a course of conduct arguably affected with a constitutional interest' and that there is a credible threat that the challenged provision will be invoked against the plaintiff"); *Bland v. Fessler*, 88 F.3d 729, 737 (9th Cir. 1996) (a plaintiff has standing to bring a First Amendment claim where it runs the risk of civil penalties for violating the challenged statute). PhRMA members have an "actual and well-founded fear that the law will be enforced against them," *Bland*, 88 F.3d at 737 (quoting *Virginia v. Am. Booksellers Ass'n*, 484 U.S. 383, 393 (1988)), either in the form of compelled speech or a fine for refusing to communicate the State's message. Thus SB 17 harms PhRMA members.

3. The Vagueness of SB 17 Harms PhRMA Members

As with the First Amendment claim, PhRMA need only allege that it intends to engage in conduct arguably affected with a constitutional interest, and that there is a credible threat of prosecution if it refuses to comply with SB 17's unconstitutional provisions. *See Carrico v. City and Cty. of San Francisco*, 656 F.3d 1002, 1005–06 (9th Cir. 2011). PhRMA alleges that SB 17's vagueness as to the time periods for calculating the 16-percent cumulative price increase, and its vagueness regarding whether the law would apply retroactively, would exacerbate the law's unconstitutional impact on its member companies' pricing decisions. (Compl. ¶¶ 11, 59, 85, 100.) The State has not indicated that it will refrain from enforcing SB 17 if PhRMA members interpret the statute as applying only prospectively and increase their products' WAC accordingly. For this reason, PhRMA's members suffer cognizable individualized injury from SB 17.

B. PhRMA Satisfies the Remaining Elements of Associational Standing

The allegations supporting the remaining associational standing requirements—germaneness and no need for participation by individual members—are plainly sufficient and the State does not argue otherwise. As for germaneness, an association has standing if it "express[es] the collective views and protect[s] the collective interests" of its members. *Fleck & Assocs., Inc. v. Phoenix, City of, an Ariz. Mun. Corp.*, 471 F.3d 1100, 1106 (9th Cir. 2006) (brackets omitted). PhRMA alleges that it acts as its members' "public policy advocate" and represents their interests before all three branches of government. (*See* Compl. ¶ 13.) And because the Complaint seeks only declaratory and prospective relief and raises pure questions of law not specific to individual members, (*id.* ¶¶ 12, 87, 92, 97), participation by individual members is unnecessary. *Alaska Fish & Wildlife Fed'n & Outdoor Council, Inc. v. Dunkle*, 829 F.2d 933, 938 (9th Cir. 1987); *City of S. Lake Tahoe Retirees Ass'n v. City of S. Lake Tahoe*, 2017 WL 2779013, *2–3 (E.D. Cal. June 27, 2017).

II. SB 17 VIOLATES THE DORMANT COMMERCE CLAUSE

The Constitution assigns Congress—and Congress alone—responsibility to "regulate Commerce . . . among the several States." U.S. Const. art. I, § 8, cl. 3. The Commerce Clause "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). Thus, the Supreme 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." *Id.*

The Supreme Court has adopted a "two-tiered approach to analyzing state economic regulation under the Commerce Clause." *Brown-Forman*, 476 U.S. at 578–79. First, when a state "directly regulates" interstate commerce, the Court has "generally struck down the statute without further inquiry." *Id.* at 579; *see also, e.g.*, *Edgar v. MITE Corp.*, 457 U.S. 624, 640 (1982) (plurality op.) ("The Commerce Clause . . . permits only *incidental* regulation of interstate commerce by the States; direct regulation is prohibited."); *NCAA v. Miller*, 10 F.3d 633, 638 (9th Cir. 1993) (statute

that "directly regulates interstate commerce . . . violates the Commerce Clause per se"). Second, a state law that does not regulate extraterritorially violates the Commerce Clause if "the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits" of the statute. *Pike*, 397 U.S. at 142. SB 17 violates the Commerce Clause under either approach.

A. SB 17 Is Per Se Unconstitutional As a Direct Regulation of Interstate Commerce

Under *Brown-Forman*, SB 17 violates the dormant Commerce Clause because it regulates manufacturers' pricing in every state. *Brown-Forman* invalidated a New York law requiring distillers to submit monthly price schedules and to certify that they would not charge wholesalers in other states less than the scheduled prices in New York. 476 U.S. at 576. The Court held that "[f]orcing a merchant to seek regulatory approval in one State before undertaking a transaction in another directly regulates interstate commerce." *Id.* at 582. New York's "prospective" liquor law violated that precept because, "[o]nce 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." *Id.* New York was thus impermissibly "project[ing]" its legislation into other states. *Id.* at 584.

1. SB 17 Links Prices Paid in California to Prices Paid Out-of-State

The State admits that the Supreme Court has invalidated "price-control or price-affirmation statutes which link prices paid in-state with those that are paid out-of-state." (Mot. 12.) The State asserts, however, that SB 17 does not "tie in-state California prices to out-of-state ones." (*Id.* at 13.) This assertion conflicts with the facts alleged in the Complaint and federal and state pricing laws.

The Complaint alleges, and the applicable law establishes, that SB 17 regulates out-of-state prices almost exactly as the New York statute did in *Brown-Forman*. SB 17 directly ties in-state reporting obligations to the WAC, the benchmark price in contracts between drug manufacturers and wholesalers. (Compl. ¶ 26.) The WAC is a uniform *national* wholesale price. (*Id.*) Under federal law, the price applies to "wholesalers or direct purchasers *in the United States*." 42 U.S.C. § 1395w-3a(c)(6)(B) (emphasis added). That uniform price, published in *national compendia*, is used by federal and state authorities in assessing drug prices for purposes of programs such as Medicaid and Medicare. *See* U.S. Dep't of Health & Human Servs., Office of Inspector General, *Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price* (2005), at 6,

https://oig.hhs.gov/oei/reports/oei-03-05-00200.pdf. Manufacturers may enter rebate agreements with the U.S. Department of Health and Human Services based on the WAC, and must regularly report the WAC to the Secretary. 42 U.S.C. § 1396r-8(b)(3)(A)(iii)(II). It would be neither permissible nor possible for a manufacturer to vary the WAC between jurisdictions. Thus, by burdening and deterring increases in the WAC in California, the State necessarily burdens and deters increases in Illinois, Idaho, Iowa, and all other states, for that matter. Stated differently, a manufacturer that wishes to increase its WAC outside California cannot do so without increasing it in California too, thereby triggering the requirements of SB 17.

The extraterritorial character of SB 17 is even more pronounced than the statute invalidated in *Brown-Forman*. The Court found it "irrelevant" that New York's liquor law "addressed only . . . sales of liquor in New York," because the law's "practical effect" was to control liquor prices in other states. 476 U.S. at 583. By contrast, California's ambitions were overtly national. SB 17 was, in its author's words, "a monumental achievement for the *entire nation*" that would "set *national health care policy*, having an impact for consumers and providers *in other states*." (Compl. ¶¶ 4–5, 37.) A co-sponsor of SB 17 similarly professed that SB 17 was a "big deal bill" that helped patients and purchasers, "*setting national policy* in the process." (*Id.* ¶ 56.)

In arguing that SB 17 does not regulate out-of-state prices, the State misreads *Pharmaceutical Research & Manufacturers of America v. Walsh*, 538 U.S. 644 (2003). The Maine law at issue in *Walsh* permitted the State Medicaid program to require prior authorization for prescriptions of drugs manufactured by companies that did not enter into rebate agreements with the State. The plaintiffs argued that manufacturers' sales to wholesalers occurred outside Maine, and pressuring manufacturers to pay rebates on products resold in Maine reduced the effective price they received in the out-of-state transactions with wholesalers. *See id.* at 656, 669. The Court held that Maine did not insist that "manufacturers sell their drugs to a wholesaler for a certain price," and did not tie "the price of its in-state products to out-of-state prices." *Id.* at 669. The Maine statute simply provided that sales of the manufacturer's products in Maine triggered the rebate or prior authorization requirement. In *Walsh*, manufacturers could increase their out-of-state prices without consequence in or because of Maine. Manufacturers cannot do that here.

The statute at issue in *Association des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937 (9th Cir. 2013), is likewise distinguishable. That case involved California statutes banning the force feeding of birds to enlarge their livers and the sale in the State of foie gras produced from force-fed birds. *Id.* at 942. The law did not require out-of-state producers to change production methods for foie gras sold in other states. *Id.* at 950 (citing *NCAA*, 10 F.3d at 638–39). It merely regulated sales and conduct in California—it barred foie gras sales in the State, by in-state as well as out-of-state producers. Under SB 17, by contrast, pharmaceutical manufacturers must restrict their pricing in other states to avoid violating a California law.

Rocky Mountain Farmers Union v. Corey, 730 F.3d 1070 (9th Cir. 2013), is no more compelling. There, the Ninth Circuit considered a dormant Commerce Clause challenge to California's Low Carbon Fuel Standard, which set the permissible carbon intensity of transportation fuels burned in California. The Standard did not dictate manufacturers' conduct in any other state. Other states could impose whatever standards they wanted, and firms could comply with different standards in different states. Unlike SB 17, the California law did not try to mandate a uniform national standard such that a change in any other state was necessarily a change in California. To be sure, as the Ninth Circuit found, "[f]irms in any location may elect to respond to the incentives provided by the [California regulations] if they wish to gain market share in California, but no firm must meet a particular carbon intensity standard." *Id.* at 1101. Here, by contrast, because of California's choice to penalize increases in the WAC, a national benchmark price, a company cannot change the WAC by the specified amount elsewhere without incurring penalties in this State. *See* Cal. Health & Safety Code § 127675(a) (regulations apply to drugs "purchased or reimbursed" by entities *licensed* in California, regardless of where transaction actually occurs).

The State contends further that the 60-day ban on price increases does not offend the Commerce Clause because its out-of-state effects are mere extraterritorial consequences rather than the direct imposition of extraterritorial regulation, which the Commerce Clause forbids. (*See* Mot. 14–15.) As explained above, SB 17's use of the WAC as a benchmark invariably prohibits increases in the list price in *every state* for 60 days, rendering the statute *per se* unconstitutional. *See supra*

pp. 5–6, 12–13. The cases cited in support of the State's position are inapposite because none involved direct, across-the-board restrictions linked directly to prices in other states.

2. SB 17 Imposes a 60-Day Nationwide Ban on Certain Price Increases

SB 17 requires manufacturers to notify purchasers registered with OSHPD "at least 60 days prior to the planned effective date of the increase" in a drug's WAC. Cal. Health & Safety Code § 127677(b). SB 17, therefore, *bans* manufacturers from increasing the WAC for at least 60 days after they have provided the required notice. (Compl. ¶¶ 56–60.) And, because the WAC is necessarily the same in every state, the ban in California applies nationwide. (*Id.*) The 60-day notice requirement is thus no different than the unconstitutional price-certification in *Brown-Forman*: manufacturers must provide notice "in one State before undertaking a transaction in another," which "directly regulates interstate commerce." 476 U.S. at 582. Even after providing notice in California, a manufacturer "is not free to change its prices elsewhere in the United States during the [next two] month[s]." *Id.* In both cases, adjusting the out-of-state list price less than 60 days after notice would require the same adjustment in California, violating SB 17. *See id.* at 582–83; *see also Healy v. Beer Inst., Inc.*, 491 U.S. 324, 337–38 (1989) ("[T]he interaction of the Connecticut [price] affirmation statute with the Massachusetts beer-pricing statute (which does not link domestic prices with out-of-state prices) has the practical effect of controlling Massachusetts prices.").

The State's argument that there "is no 60-day ban," (Mot. 14), is spurious. In the very next sentence, the State notes that manufacturers may raise prices "within 60 days *after* having provided advance notice," (*id.* (emphasis added))—an acknowledgement of the 60-day ban. It is likewise false that "[d]rug manufacturers remain free . . . to change prices as often as they see fit." (*Id.* at 13.) Manufacturers may not change prices "as they see fit" in other states; they may do so only if they predicted the increase 60 days earlier and disclosed their plan at that time. If, on day 60, they determine that an additional increase is necessary, they will have to wait another 60 days before implementing the additional increase anywhere in the country.

In support of its argument, the State relies on certain legislative findings for SB 17 declaring that it is intended "to permit a manufacturer of a prescription drug to voluntarily make pricing decisions." (Mot. 13). These protestations conflict with statements by SB 17's sponsors promising

that the law will shame "greedy pharmaceutical companies" into forgoing price increases. (Compl. ¶¶ 5, 36.) In any event, the Legislature's self-serving proclamation of its intent "is irrelevant if the 'practical effect' of the law is to control [drug] prices in other States." *Brown-Forman*, 476 U.S. at 583; *accord Rocky Mountain*, 730 F.3d at 1098 ("[W]e will not be bound by the stated purpose when determining the practical effect of a law.").

The State confusingly argues that "[i]f a manufacturer implements another threshold pricing decision within 60-days [sic] of having notified California purchasers of a threshold price increase, all SB 17 requires is that it again notify California purchasers." (Mot. 14.) This claim artfully refers only to "another threshold pricing *decision*," as opposed to a "pricing *increase*." SB 17 is clear: to raise a product's WAC again within 60 days after an initial notice, a manufacturer must provide another notice and wait another 60 days before implementing that increase in any state. This pricing regulation is more direct than in *Brown-Forman*. That the outright ban lasts only 60 days does not save the law any more than the month-long duration salvaged the regulation in *Brown-Forman*.

PhRMA has alleged a more than plausible claim that the challenged provisions of SB 17 directly regulate interstate commerce and thus should be "struck down . . . without further inquiry," just like the law invalidated in *Brown-Forman*. 476 U.S. at 579.

B. SB 17 Imposes Excessive Burdens on Interstate Commerce

SB 17 would violate the dormant Commerce Clause even if its extraterritorial regulation was not direct. Under the *Pike* balancing test, a state law cannot survive constitutional scrutiny if "the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits" of the statute. 397 U.S. at 142. Contrary to the State's claim, *see* (Mot. 16), a *Pike* challenge does not require discrimination. *See, e.g.*, *Edgar*, 457 U.S. at 643–45 (law adding Illinois tender offer requirements to corporations with certain ties to the State was excessive and provided minimal protection to in-state shareholders); *Yamaha Motor Corp., U.S.A. v. Jim's Motorcycle, Inc.*, 401 F.3d 560, 572 (4th Cir. 2005) ("*Pike* balancing is not limited to cases where state statutes interfere with a 'compelling need for national uniformity in regulation.'"). Here, forcing manufacturers to summarize publicly available information and compelling the equivalent of a

public confession that the price increase was illegitimate in the eyes of the State is a meager benefit, compared to the threat SB 17 poses for the national prescription drug market.

1. SB 17 Burdens the Interstate Drug Market

The Complaint alleges that SB 17 distorts the national prescription drug market in two ways. *First*, it incentivizes prescription drug arbitrage. The 60-day notice requirement creates a buying window for registered purchasers (and others that learn of it second-hand) to stockpile drugs before a WAC increase takes effect. (Compl. ¶ 64.) SB 17 picks the winners and losers of this arbitrage by authorizing advance notice to state purchasers, insurers, health plans, and PBMs—including all "large purchasers" who contract with eligible PBMs and presumably all retail and specialty pharmacies owned by or affiliated with these entities. (*See id.* ¶ 65.) The changes disadvantage small, unaffiliated neighborhood pharmacies, and patients. (*Id.*)

Second, while the authors of SB 17 hailed the "transparency" the new law supposedly will achieve, the Federal Trade Commission has questioned "transparency" laws such as SB 17, explaining: "Too much transparency can harm competition in any market, including in health care markets. . . . [W]hen information disclosures allow competitors to figure out what their rivals are charging, [it] dampens each competitor's incentive to offer a low price, or increases the likelihood that they can coordinate on higher prices." (Compl. ¶ 63.)

The State next argues, in a single sentence, that the "allegations regarding potential price stabilization, stockpiling and competitive advantages and disadvantages are generalized, conclusory and speculative." (Mot. 17.) This argument is itself conclusory. Logic and established principles of economics dictate that stockpiling, drug shortages, competitive advantage, and price stabilization—detailed in the Complaint—are the natural consequences of SB 17's restrictions and obligations on the pharmaceutical market. (*See* Compl. ¶¶ 62–66.) These allegations find support in economic literature. (*See id.*). And in any event, Rule 12(b)(6) requires that they be construed as true for purposes of a motion to dismiss. *Redwood City*, 640 F.2d at 966. For the same reasons, the State's contention that the market distortions from SB 17 do not "disrupt the flow of goods" or impose "practical burdens on the drug market," (Mot. 16–17), fail, too.

2. SB 17 Has No Benefits that Outweigh Burdens on Interstate Commerce

While adversely affecting the national drug market, SB 17 achieves little or no benefit for California. With regard to "transparency," the WAC and most other information required to be disclosed are already public, (Compl. ¶ 66); *see* Cal. Health & Safety Code §§ 127679(b); 127681(c), and do not clearly benefit commerce. Further, SB 17 does not make the prices charged by those downstream in the supply chain more transparent, or illuminate the prices that patients or third-party payers actually pay. (*See* Compl. ¶¶ 34, 66.) And, as pharmaceutical supply chains are inherently national and SB 17 is linked to increases in the national list price, California strikes this incoherent bargain not only for itself, but for the entire United States. (*Id.* ¶¶ 66–67.)

Rather than explaining how these measures benefit California consumers, the State directs the Court to legislative findings professing a substantial State interest "in the price and cost of drugs." (Mot. 18.) The *Pike* test requires more than an assertion of an ostensibly legitimate state objective. Ultimately, the State's main argument is that courts need not weigh the benefits of a statute unless they have found it imposes an excessive burden on interstate commerce. (*Id.*) But SB 17 does impose excessive burdens on the interstate prescription-drug market. And, tellingly, none of the cases the State cites dismissed a complaint on this basis. *See CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 75–78, (1987) (appeal of preliminary injunction); *Nat'l Ass'n of Optometrists & Opticians*, 682 F.3d 1144, 1147 (9th Cir. 2012) (summary judgment); *Alaska Airlines, Inc. v. City of Long Beach*, 951 F.2d 977, 980 (9th Cir. 1991) (permanent injunction). Thus, PhRMA has stated a claim that SB 17 violates the Commerce Clause.

III. SB 17 VIOLATES THE FIRST AMENDMENT

The First Amendment protects both the right to speak and the right not to speak. *Wooley v. Maynard*, 430 U.S. 705, 714 (1977); *accord Knox v. Empls. Int'l Union, Local 1000*, 567 U.S. 298, 309 (2012) ("The government may not prohibit the dissemination of ideas it disfavors, nor compel the endorsement of ideas that it approves."). Put simply, "freedom of speech prohibits the government from telling people what they must say." *Rumsfeld v. Forum for Academic and Inst. Rights*, 547 U.S. 47, 61 (2006). SB 17 violates these rights of PhRMA members. It discriminates based on who is speaking, targeting only pharmaceutical companies. And it discriminates based on

what is said, compelling companies to communicate about price increases, but not price decreases, and forcing them to provide subjective explanations that echo the State's faulty premises about pricing decisions. (Compl. ¶ 72.) Therefore, under *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011), SB 17 triggers heightened scrutiny. (Compl. ¶ 74.) Under that standard—in fact, under *any* standard—the Complaint states a claim that SB 17 violates the First Amendment. (*Id.* ¶¶ 78–82.)

A. SB 17 Regulates Communications Protected by the First Amendment

SB 17 regulates communication about pricing, which the Supreme Court has repeatedly held warrants First Amendment scrutiny. *Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144, 1151 (2017); *cf. Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976) (the First Amendment protects the free "flow of prescription drug price information"). In other words, communications about pricing are speech, and thus laws regulating those communications—unlike laws that merely regulate pricing—must satisfy the First Amendment. *See Expressions Hair Design*, 137 S. Ct. at 1150–51; *see also Italian Colors Rest. v. Becerra*, 878 F.3d 1165, 1175–76 (9th Cir. 2018) (same).

The Supreme Court has left no room for argument on this point. In *Expressions Hair Design*, the Court explained that a "typical price regulation," such as one "requiring all New York delis to charge $10 for their sandwiches," would regulate only the sandwich seller's conduct by standardizing the amount a sandwich vendor could collect. 137 S. Ct. at 1150. But, as the Court explained, a law that regulated not only how the transaction was *conducted* (i.e. how much the vendor charged), but also how it was *described*, was different, and implicated the First Amendment. *Id.* at 1151. Under this framework, the Court considered a New York law which prohibited merchants from imposing a surcharge when consumers used a credit card to purchase merchandise, but allowed merchants to charge a higher price for merchandise and then provide a discount for paying cash. *Id.* The Court found that in "regulating the communication of prices rather than prices themselves," the law "regulate[d] speech" and was, therefore, subject to First Amendment scrutiny. *Id.* And similarly, in *Virginia State Board of Pharmacy*, the Court struck down part of a Virginia statute providing that a pharmacist would be guilty of unprofessional conduct if he or she advertised prices of prescription drugs. The Court found that pharmacists had a First Amendment interest in

conveying, and that patients had a First Amendment interest in receiving, information regarding the prices at which pharmacists proposed to sell prescription drugs. *See* 425 U.S. at 761, 765, 770. Thus, conveying those prices constituted speech protected by the First Amendment.

Yet the State argues otherwise, apparently contending that SB 17 regulates pricing, as opposed to communications *about* pricing. As such, according to the State, the Act regulates only conduct, and therefore does not implicate the First Amendment rights of PhRMA members. (Mot. 19–20.) Insofar as the State is arguing that SB 17 regulates pricing, *i.e.*, conduct rather than speech, the text of SB 17 provides a conclusive rebuttal. Under the Act, manufacturers must give registered purchasers 60 days' advance notice of an increase in a drug's WAC. The law mandates not just factual disclosures, but also "a statement regarding whether a change or improvement in the drug necessitates the price increase." Cal. Health & Safety Code § 127677(c)(2). Manufacturers also must submit a quarterly report to OSHPD for publication on the OSHPD website that includes:

> (1) "A description of the specific financial and nonfinancial factors used to make the decision to increase the [WAC] of the drug . . . including, but not limited to, an explanation of how these factors explain the increase in the [WAC] of the drug"; and
>
> (2) "A description of the change or improvement in the drug, if any, that necessitates the price increase."

Id. § 127679(a)(1) & (6). The law thus requires manufacturers not merely to communicate prices, but also to convey a subjective narrative about the supposed illegitimacy of the prices at issue. (*See* Compl. ¶ 72.) By no stretch of law or language can the State plausibly assert that these provisions regulate only conduct outside the First Amendment's protection, or that notification and reporting requirements are merely "incidental to the price increase." (Mot. 19–20.) SB 17's compelled speech is not incidental to a distinct statutory purpose; it *is* the statutory purpose. *See* Cal. Health & Safety Code § 127676(b)(1) (purpose of SB 17 is to "provide notice and disclosure of information relating to the cost and pricing of prescription drugs").

Tellingly, the State fails to account for any of the Court's recent cases addressing the critical difference between the regulation of pricing and the regulation of *communications about* pricing. Contending that "price regulations and other forms of economic regulation do not implicate speech

so long as they do not preclude [the] retailer from providing truthful, nonmisleading information about the regulated product," the State ignores the development of First Amendment jurisprudence over the last two decades and is wrong as a matter of law. (Mot. 19.) Even the cases cited by the State do not support its position. In *44 Liquormart*, the Court addressed a law that prohibited advertisements which provided the public with accurate information about the retail prices of alcoholic beverages. 517 U.S. at 489. All nine Justices recognized that the First Amendment protection applies to a retailer providing truthful, nonmisleading information regarding a product. *See id.* at 504, 518, 528. The Court did *not* hold that no other speech about pricing is entitled to First Amendment protection. And in *National Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. 2013), the First Circuit made clear that while "[p]ricing information concerning lawful transactions has been held to be protected speech by the Supreme Court," the ordinance at issue, which prohibited vendors from accepting coupons as payment for tobacco products, was not speech because it only regulated the method of sale rather than the "communicat[ion of] pricing information concerning the lawful sale price of cigarettes." *Id.* at 76–77.

In sum, because SB 17 regulates, and indeed compels, communication about the pricing of drugs, rather than merely regulating the price of drugs, it regulates speech and must withstand First Amendment scrutiny. As demonstrated below, and as alleged in PhRMA's Complaint, SB 17 fails under any standard this Court may apply.

B. SB 17 Is Discriminatory and Thus Subject to Heightened Scrutiny

Speech regulations that discriminate based on the content of the communication or that disfavor a particular speaker are subject to heightened judicial scrutiny. *See Reed v. Town of Gilbert,* 135 S. Ct. 2218, 2227 (2015); *Sorrell*, 564 U.S. at 564–66. Because SB 17 discriminates on both bases, heightened scrutiny applies.

It is well-established that laws compelling a speaker to "utter or distribute speech bearing a particular message" are content-based, and subject to heightened scrutiny. *Turner Broadcasting Sys. Inc., v. FCC*, 512 U.S. 622, 642 (1994). Laws that mandate "speech that a speaker would not otherwise make" are also content-based, because forcing a speaker to convey a message

"necessarily alters the content of the speech." *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 795 (1988).[2] SB 17 fits squarely in this realm, as it forces pharmaceutical manufacturers to speak at a particular time, to a particular audience, to convey a particular message: that they are planning a price increase of a type that State officials have disparaged repeatedly in the strongest terms, that the State presumptively disfavors this increase, and that the only justification the State acknowledges is a change or improvement in the drug. (*See* Compl. ¶¶ 8–10, 72–73.) And the requirement that the manufacturer state whether a "change or improvement in the drug" necessitated the price increase, Cal. Health & Safety Code §§ 127677(c)(2), 127679(a)(6)—without requiring that the manufacturer list all the other factors that did or did not dictate the change—subordinates any alternative explanation the manufacturer might offer. (Compl. ¶ 72.) Indeed, the disclosure that SB 17 would compel, that no "change or improvement in the drug" necessitated the price increase, plainly impugns both the company and its pricing, which is precisely what it was designed to do. A law that "requires the utterance of a particular message favored by the Government" indisputably violates the First Amendment. *Turner Broad.*, 512 U.S. at 641. "Laws of this sort pose the inherent risk that the Government seeks not to advance a legitimate regulatory goal, but to . . . manipulate the public debate through coercion rather than persuasion." *Id.*

The State contends, despite the array of communications SB 17 requires, that the law does not compel speech and is, therefore, not content-based because it neither "restricts [n]or restrains manufacturers from communicating or contextualizing pricing information about the sale of drugs to anyone." (Mot. 19.) The State's suggestion that such impositions are acceptable so long as the manufacturer can say more, commences a slide down a slippery slope to intolerable infringements on individual freedom. Fortunately, the law does not support the State's narrow reading of the First Amendment. The Ninth Circuit has made clear that First Amendment protection does not turn on

[2] SB 17 also discriminates on the basis of viewpoint by imposing burdens based on "the specific motivating ideology [and] the opinion or perspective of the speaker." *Reed*, 135 S. Ct. 2230 (internal quotation marks omitted); *see also Frudden v. Pilling*, 742 F.3d 1199, 1206–07 (9th Cir. 2014). Because viewpoint- and content-based discrimination are related and, under the circumstances here, effectively indistinguishable, PhRMA encompasses both in discussing content-based violations.

whether a speaker has "alternative means to disclaim" the government's chosen message. *Frudden v. Pilling*, 742 F.3d 1199, 1205–06 (9th Cir. 2014). In other words, compelled speech is no less offensive to the First Amendment merely because the speaker can voice disagreement with the message it was forced to communicate.

Nor does it matter whether the State's message is implicitly or explicitly attributed to the speaker. SB 17 forces manufacturers to disclose only certain information regarding price increases, and in doing so, makes it appear that the manufacturers agree with the State's chosen message: that there is only one legitimate reason for such an increase. Because SB 17 compels manufacturers to utter a particular message favored by the government, and makes it appear as though the manufacturers agree with that message, SB 17 discriminates based on content and is subject to heightened scrutiny. *Cf. Pac. Gas & Elec. Co. v. Public Utilities Commission of Cal.*, 475 U.S. 1, 5–7, 15 (1986) (plurality) (invalidating requirement that PG&E place third-party's newsletter in its billing envelopes because doing so required it to "associate with speech with which [it] may disagree," forcing PG&E "to appear to agree with [the newsletter] or to respond").

SB 17 is subject to heightened scrutiny for a second reason: it discriminates based on who is speaking. Although it is well-established that "government regulation may not favor one speaker over another," *Rosenberger v. Rector,* 515 U.S. 819, 828 (1995), SB 17 "on its face burdens . . . disfavored speakers," *Sorrell*, 564 U.S. at 556. SB 17 is even more suspect because it reflects the State's aversion to what the disfavored speakers have to say. *See Turner Broad.*, 512 U.S. at 658. By singling out pharmaceutical manufacturers, SB 17 communicates that those companies are primarily or even exclusively at fault for the alleged high drug prices in California and the financial burdens borne by consumers. (Compl. ¶ 75.) The bill's author could not have been clearer that this was the intended message. (*See id.* ¶ 5 (the statute singles out "greedy pharmaceutical companies), ¶ 10 (the problem of high drug prices can "no longer be blamed on a few bad actors").)

The State's response misses the point. It contends that SB 17 is neutral because it "applies evenhandedly to all *drug manufacturers*," (Mot. 23 (emphasis added)), but the concern is not discrimination between manufacturers. Rather, the concern is that SB 17 discriminates between manufacturers and other market participants, such as PBMs, wholesalers, and pharmacies. In

Sorrell, the Supreme Court found that a statute prohibiting only pharmaceutical manufacturers from using prescriber-identifiable data to market brand-name drugs impermissibly discriminated based on who was speaking. 564 U.S. at 563–64. Here, as in *Sorrell*, manufacturers are uniquely targeted, rendering SB 17 a far cry from neutral. (Compl. ¶ 75.) Perhaps aware of this argument's shortcomings, the State also contends that different "transparency-focused policies" cover others in the healthcare industry. (Mot. 3 (alteration omitted) (citing, for example, requirements that hospitals disclose prices for common surgeries).) But none of these so-called "transparency-focused" regulations require an entity to notify downstream purchasers in advance of increases to a list price that they do not actually pay, or mandate a public justification of the price increase, or imply that prices reflecting market forces are somehow improper. These various "transparency-focused policies" therefore do nothing to alleviate the discriminatory nature of SB 17.

In sum, because SB 17 imposes speaker-based and content-based burdens on speech, it is subject to heightened scrutiny. *Turner Broad.*, 512 U.S. at 642, 658. To satisfy this standard, the State must demonstrate that the law is "narrowly tailored to serve [a] compelling state interest[]." *Reed*, 135 S. Ct. at 2226. The allegations contained in the Complaint, taken as true, clearly establish that the State cannot satisfy this standard. (Compl. ¶¶ 79–82.) Critically, the State cannot regulate speech as a backdoor means to achieve its regulatory objectives, particularly ones that it cannot pursue directly. *Cf. Clairmont v. Sound Mental Health*, 632 F.3d 1091, 1100 (9th Cir. 2011) ("Where the government may not prohibit certain speech, it also many not threaten to exert economic pressure on a private employer in order to produce a result which it could not command directly" (alterations and quotations omitted)); (Compl. ¶ 80). California cannot dictate the prices of pharmaceutical products directly, and it cannot try to do so indirectly by dictating what manufacturers say about drug price increases.

Even if SB 17 advances legitimate State interests, it still cannot be said that SB 17 is "narrowly tailored" to serve those interests.[3] Indeed, whatever interests California has in

[3] In any event, the State bears the burden to demonstrate that compelling manufacturers to explain pricing decisions will benefit consumers. *Ibanez v. Fl. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 142–43 (1994); *see also Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989). It is therefore particularly inappropriate to decide this issue on a motion to dismiss.

accountability and consumer protection, (Mot. 24), SB 17 does not advance them at all. For one thing, the factual information that SB 17 requires pharmaceutical manufacturers to report to OSHPD is already publicly available. Cal. Health & Safety Code §§ 127679(b), 127681(c). And there is no basis to predict that SB 17 will reduce prescription drug prices. Even the staff of the California Senate Committee on Appropriations advised that "it is not likely that the [statute's] requirement to provide [information on drug pricing] will provide a sufficient incentive for drug companies to actually reduce prices. Therefore, it is unlikely that the bill will result in reduced health care spending on prescription drugs." (Defs.' Request for Judicial Notice Ex.1 at 19–20.) And the Complaint alleges that it is equally or more plausible that SB 17 will distort the market for pharmaceutical products and undermine consumer welfare. *See supra*, pp. 17–18. Accordingly, taking the allegations in the Complaint as true, SB 17 fails to clear the hurdles of *Sorrell*'s heightened scrutiny standard.

C. SB 17 Is Not Permissible as Compelled Commercial Speech

The State's next line of defense is the conclusory assertion that "if the disclosures required by SB 17 implicate any kind of speech, it is commercial speech." (Mot. 22.) And because SB 17 compels, rather than restricts, commercial speech, "a level of scrutiny resembling rational basis review" applies under *Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio*, 471 U.S. 626 (1985). (Mot. 22.) According to the State, SB 17 satisfies this standard. For several reasons, these arguments miss the mark.

Although the disclosures that SB 17 requires pertain to price, they are not commercial speech. Commercial speech "relate[s] solely to the economic interests of the speaker and its audience," *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 561–62 (1980), and "does no more than propose a commercial transaction," *Va. State Bd. of Pharmacy*, 425 U.S. at 762 (quotations omitted). Commercial speech is generally defined as "an advertisement [that] . . . refers to a particular product" where "the speaker has an economic motivation." *Hunt v. City of Los Angeles*, 638 F.3d 703, 715 (9th Cir. 2011). The disclosures mandated by SB 17 do not satisfy these elements. Through the SB 17-mandated disclosures, manufacturers are not proposing a commercial transaction or advertising a product. Moreover, their economic interest is in *not*

speaking, as speaking requires them to deliver a message they strongly oppose. The non-commercial nature of this message, and thus of the disclosures, is illuminated by the Legislature's intent in compelling them: to "shame" pharmaceutical companies and assign them blame for the rising cost of medical care. (*See* Compl. ¶¶ 5, 10, 36–37.) Far from mandating commercial speech, the statute realizes the "risk" that concerned the Court in *Turner Broadcasting*. It seeks not to achieve a "legitimate regulatory goal," but rather "to manipulate the public debate through coercion rather than persuasion." 512 U.S. at 641. Thus, even if characterized as broadly related to commerce, the disclosures convey a message that is far from solely commercial.

In *National Ass'n of Manufacturers. v. SEC*, 800 F.3d 518, 530 (D.C. Cir. 2015), the D.C. Circuit faced a situation analogous to this case, where Congress sought to discourage companies from trading in conflict minerals by requiring that they disclose such trade, inviting public condemnation. In the Court's view, "requiring a company to publicly condemn itself is undoubtedly a more 'effective' way for the government to stigmatize and shape behavior than for the government to have to convey its views itself." *Id.* (alterations and quotations omitted). But this so-called "effectiveness," the Court found, "[made] the requirement more constitutionally offensive, not less so." *Id.* (quotations omitted). The Court thus recognized that these disclosures were not like the compelled commercial speech allowed in *Zauderer,* but rather served the Government's own illegitimate objective of regulation through public shaming.

Even if SB 17 compelled commercial speech and did so for a legitimate purpose, SB 17 still would not pass muster under *Zauderer*. The Ninth Circuit recently clarified that "[u]nder *Zauderer*, compelled disclosure of commercial speech complies with the First Amendment if the information in the disclosure is reasonably related to a substantial governmental interest and is purely factual." *CTIA-The Wireless Ass'n v. City of Berkeley*, 854 F.3d 1105, 1118 (9th Cir. 2017), *petition for cert. filed*, No. 17-976 (Jan. 9, 2018). SB 17 does not meet either of these requirements.

The disclosure mandated by SB 17, far from being factual, is subjective, discriminatory, and implicitly disapproving. And, as the Ninth Circuit has recognized, "a statement may be literally true but nonetheless misleading and, in that sense, untrue." *CTIA Wireless*, 854 F.3d. at 1119. The disclosures required by SB 17 suffer from precisely this problem. While they may be literally true,

they suggest that only the manufacturer is responsible for changes in the price of a drug, and that a drug's price was either raised (1) because of a "change or improvement in the drug," or (2) for no reason at all. Cal. Health & Safety Code §§ 127677(c)(2); 127679(a)(6). There are any number of reasons that the price of a drug may increase. The Act's requirement that only one of these reasons be disclosed—thereby suggesting that there are no other reasons (or at least, legitimate reasons) for a price increase—is misleading, and thus, untrue. 854 F.3d at 1119.

The State cites cases involving commercial disclosures that it argues are akin to this case. But none of the regulations in those cases required regulated parties to notify downstream purchasers in advance of a price adjustment or to explain their decisions. For instance, the law in *New York State Restaurants Ass'n v. New York City Board of Health*, 556 F.3d 114, 120–22 (2d Cir. 2009), requiring certain restaurants to post calorie content on their menus, did not compel restaurants to justify their 840-calorie taco salad or 160 calories' worth of mayonnaise on their premium hamburgers. Nor did the Secretary of Agriculture require the meat industry, in adding "country-of-origin" labels, to explain how or why they decided to purchase meat products in foreign countries. *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 20–21 (D.C. Cir. 2014). The disclosures in those cases were undisputedly factual and implicated the regulated parties' exclusively economic interests. That is not remotely the case here.

Nor is SB 17 related to a "substantial" State interest. For the same reasons that SB 17 is not "narrowly tailored to serve [a] compelling state interest," *supra* pp. 24–25, SB 17 is not reasonably related to a "substantial" state interest as *Zauderer* requires. *CTIA Wireless*, 854 F.3d at 1118. The government's interest in compelling condemnatory public disclosures to shame companies into forgoing conduct is not valid, and thus cannot be an interest that suffices to justify a compelled disclosure under the First Amendment, even of commercial speech.

Thus, under any First Amendment standard, PhRMA has set forth a cognizable claim.

IV. SB 17 IS UNCONSTITUTIONALLY VAGUE

A statute violates due process if it "fails to provide a person of ordinary intelligence fair notice of what is prohibited." *Fox Television Stations*, 567 U.S. at 253. The Court has addressed two due process concerns: "first, that regulated parties should know what is required of them so they

may act accordingly; second, precision and guidance are necessary so that those enforcing the law do not act in an arbitrary or discriminatory way." *Id.* "When speech is involved, rigorous adherence to those requirements is necessary to ensure that ambiguity does not chill protected speech," *id.* at 253–54, or, as in this case, compel speech or chill manufacturers from legitimate conduct in order to preserve their First Amendment right to remain silent, *see Wooley*, 430 U.S. at 714.

SB 17 violates manufacturers' right to due process because they cannot discern from the plain text whether WAC increases from January 1, 2016, through December 31, 2017, are retroactively included in calculating the threshold 16-percent increase over "the previous two calendar years prior to the current year." Cal. Health & Safety Code § 127677(a). It is inappropriate to implement a de facto nationwide ban on WAC increases and to compel self-accusatory statements by manufacturers based on price increases before SB 17 was even enacted. It is even more problematic for the State to exploit the vague text of the statute by marshaling the threat of such retroactive enforcement. OSHPD's failure to respond to PhRMA's multiple requests to dispel the vagueness concerning SB 17's possible retroactive effect, (Compl. ¶¶ 48–51), forces manufacturers seeking to avoid regulatory missteps to refrain from price increases they are entitled to make, to observe the 60-day ban on price hikes they are entitled to implement, and to issue self-accusatory statements they vigorously dispute. California cannot *sub silentio* increase the reach of SB 17's coercive effect by refusing to clarify its scope.

The State nowhere disputes that SB 17 is vague regarding the retroactivity of the 16-percent threshold. Instead, the State attacks PhRMA's due process claim as unripe because OSHPD has yet to demand either a 60-day notice or an implicitly self-disparaging justification based on WAC increases made before 2018. (*See* Mot. 26.)[4] In addition, the State cites authority "rejecting the argument that 'self-censorship suffices for injury-in-fact.'" (*Id.* (quoting *Humanitarian Law Project v. U.S. Treasury Dep't*, 578 F.3d 1133, 1143 (9th Cir. 2009))). But that same authority goes on to

[4] The State also argues that "OSHPD plans to the enact regulations by January 2019," and that California law prohibits OSHPD from issuing guidance regarding SB 17's possible retroactive application in the meantime. (Mot. 25.) However, the cited authority does not prevent OSHPD from proposing regulations that address the retroactivity issue.

state that courts reject self-censorship as a cognizable injury only "when the statute on its face does not regulate expressive activity." *Humanitarian Law Project*, 578 F.3d at 1143. The State's authority is thus inapposite because, on its face, SB 17 involves speech. *See supra* pp. 19–21.

PhRMA members whose products have already increased by 16 percent since January 2016 have a well-founded fear of enforcement. (*See* Compl. ¶¶ 11, 85, 100.) For these products, *any* price increase "arguably falls within the statute's reach," making SB 17 ripe for a vagueness challenge. *Cal. Pro-Life Council, Inc. v. Getman*, 328 F.3d 1088, 1095 (9th Cir. 2003). Each day, the affected members must refrain from legitimate price increases in order to preserve their constitutionally protected silence. The corrosive effects of uncertainty on manufacturers' First Amendment rights undercut the State's proposition that the companies should construe the law for themselves. (*See* Mot. 28.) And denying the motion to dismiss would not subject "virtually every new law . . . to a vagueness challenge." (*Id.* at 26.) Only laws with vague language that impairs First Amendment or other constitutional rights would be exposed to such a challenge.

Furthermore, the liberty interests protected by the Constitution are not so narrow that PhRMA must show "the disclosures required by SB 17 . . . concern a personal choice that is central to human dignity and autonomy." (Mot. 27.) The Supreme Court has repeatedly recognized the centrality of First Amendment rights to ordered liberty, and has recognized as well that the right to speak includes the right not to speak. *See, e.g.*, *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos.*, 515 U.S. 557, 573 (1995) ("[O]ne important manifestation of the principle of free speech is that one who chooses to speak may also decide 'what not to say.'"); *Pac. Gas & Elec.*, 475 U.S. at 16 ("The danger that appellant will be required to alter its own message as a consequence of the government's coercive action is a proper object of First Amendment solicitude.").

Finally, the State cites *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 494–95 (1982), in asserting that a facial vagueness challenge is appropriate only where a law is impermissibly vague in all of its applications or "specifies no standard of conduct." (Mot. 28.) But *Hoffman Estates* concerned the second due process principle, *i.e.*, arbitrary or discriminatory enforcement. *Fox*, 567 U.S. at 253. PhRMA is concerned less with discriminatory enforcement than with OSHPD using the implicit threat of retroactive enforcement to force

manufacturers into the Catch 22 of either complying with an overbroad reading of the statute or facing the risks of penalties and forced speech. *See id.* ("[R]egulated parties should know what is required of them so they may act accordingly."). PhRMA has stated a cognizable due process claim.

VI. THE GOVERNOR IS NOT IMMUNE FROM SUIT

A state official sued in his official capacity is not immune from suit if he has "some connection with the enforcement of the [allegedly unconstitutional] act." *Ex Parte Young*, 209 U.S. 123, 157 (1908). The Governor's connection with the enforcement of SB 17 precludes Eleventh Amendment immunity. (Compl. ¶ 14.) The State has "vest[ed] in the Governor the civil administration of the laws of the State," Cal. Gov't Code § 11150, specifically including the duty to appoint the Director of OSHPD, who "hold[s] office at the pleasure of the Governor." Cal. Health & Safety Code § 127005. The Governor is thus the ultimate arbiter of OSHPD's interpretation and enforcement of SB 17. In this case, his authority is not limited to only "general oversight of the executive branch," (Mot. 9), or a "general duty to enforce California law," as in the one case the State cites, *Eleveurs de Canards et d'Oies*, 729 F.3d at 943.

CONCLUSION

PhRMA has alleged cognizable constitutional challenges to SB 17 under the Commerce Clause, First Amendment, and Fourteenth Amendment Due Process Clause. The Complaint pleads that the statute's 60-day advance notice requirement results in a nationwide 60-day ban on price increases for medicines. SB 17 enforces this extraterritorial effect through a compelled speech requirement that violates the First Amendment, and it does so in a manner that is unconstitutionally vague. For the foregoing reasons, the State's motion to dismiss should be denied.

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