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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
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.

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

MEMORANDUM AND ORDER

Plaintiff Pharmaceutical Research and Manufacturers of America (“PhRMA”) seeks in this action a declaration that Section 4 of a California law, Senate Bill 17 (“SB 17”), is unconstitutional and a permanent injunction preventing Defendants Edmund Gerald Brown, Governor of California (the “Governor”), and Robert P. David, Director of the Office of Statewide Health Planning and Development (the “Director,” together, “California”), from implementing Section 4. Presently before the Court are the parties’ Motions for Judicial Notice, ECF Nos. 19-2 and 22, and California’s Motion to Dismiss, ECF No. 19-1, in which it argues, among other things, that the Governor must be dismissed as a party to the suit because he is immune thereto, and that the suit must be

1 dismissed in its entirety because the Complaint fails to allege facts sufficient to establish
2 standing.¹ For the reasons that follow, California’s Motion to Dismiss is GRANTED as to
3 these issues only, and PhRMA is given leave to amend. The Court does not reach the
4 motion’s non-jurisdictional arguments or the parties’ Motions for Judicial Notice since it is
5 acting on facial jurisdictional grounds.

6
7 **BACKGROUND²**
8

9 According to the Complaint, the Governor signed SB 17 into law on October 9,
10 2017. Section 4 of SB 17 amends the California Health and Safety Code to add
11 Chapter 9, titled “Prescription Drug Pricing for Purchasers.” Chapter 9 imposes various
12 notice, reporting, and justification obligations on the manufacturer of a prescription drug
13 sold to certain purchasers.

14 More specifically, the manufacturer of a prescription drug subject to SB 17 must
15 notify these purchasers at least 60 days before increasing the drug’s federally-defined
16 wholesale acquisition cost—the manufacturer’s list price for wholesalers, not including
17 certain discounts—if: (1) a course of therapy has a wholesale acquisition cost of more
18 than \$40, and (2) the proposed increase would result in a cumulative increase of
19 16 percent or more over the two calendar years prior to the current year.

20 In addition to the date and amount of the planned increase, each 60-day’ notice
21 must include a statement whether a change or improvement in the drug necessitates the
22 price increase and describing the change, if one occurred. Beginning on January 1,
23 2019, SB 17 also requires manufacturers to report certain information to California’s
24 Office of Statewide Health Planning and Development (“OSHPD”) quarterly for each
25 ///

26 _____
27 ¹ Because oral argument would not have been of material assistance, the Court ordered this
matter submitted on the briefs. See ECF No. 20; E.D. Cal. Local Rule 230.

28 ² The following facts are derived, at times verbatim, from PhRMA’s Complaint. See ECF No. 1.

1 prescription drug subject to SB 17's 60-day' notice provisions, including the statement,
2 as above, whether a change or improvement in the drug necessitates the price increase.

3 SB 17 additionally requires a manufacturer to notify OSHPD of any newly
4 introduced prescription drug for which the wholesale acquisition cost exceeds the
5 threshold set for a specialty drug under Medicare Part D, which was \$670 per month in
6 2017. The notice must include a description of the marketing and pricing plans used in
7 the launch, among other things.

8 OSHPD must publish all the information reported by manufacturers on its website,
9 and reporting under SB 17 is compulsory. If a manufacturer fails to report any of the
10 required information, OSHPD may impose a civil penalty of \$1,000 per day for every day
11 after the notification period.

12 PhRMA filed its Complaint for declaratory and injunctive relief on December 8,
13 2017. It alleges Section 4 of SB 17 violates the Commerce Clause of the United States
14 Constitution by regulating interstate commerce through a de facto 60-day' price freeze
15 nationwide on qualifying drugs, violates the First Amendment by compelling
16 pharmaceutical manufacturers to communicate specified information when they would
17 otherwise remain silent, and violates the Fourteenth Amendment's Due Process Clause
18 because it is unconstitutionally vague about the possible retroactive application of
19 certain provisions.

20 California filed its Motion to Dismiss the Complaint on January 26, 2018.

21
22 **STANDARD**

23
24 California moves to dismiss the Complaint pursuant to Federal Rules of Civil
25 Procedure 12(b)(1), for lack of subject-matter jurisdiction, and 12(b)(6), for failure to state
26 a claim upon which relief may be granted. Notice of Mot. 1, ECF No. 19. The Court
27 reaches only the issue of jurisdiction under Rule 12(b)(1), which also includes the

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1 Eleventh Amendment inquiry. See, e.g., Taylor v. Westly, 402 F.3d 924, 925 (9th Cir.
2 2005); Broudy v. United States, 661 F.2d 125, 128 n. 5 (9th Cir. 1981).

3 Federal courts are courts of limited jurisdiction, and are presumptively without
4 jurisdiction over civil actions. Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375,
5 377 (1994). The burden of establishing the contrary rests upon the party asserting
6 jurisdiction. Id. “A Rule 12(b)(1) jurisdictional attack may be facial or factual.” Safe Air
7 for Everyone v. Meyer, 373 F.3d 1035, 1039 (9th Cir. 2004) (citing White v. Lee,
8 227 F.3d 1214, 1242 (9th Cir. 2000)). “In a facial attack, the challenger asserts that the
9 allegations contained in a complaint are insufficient on their face to invoke federal
10 jurisdiction,” and “in a factual attack, the challenger disputes the truth of the allegations
11 that, by themselves, would otherwise invoke federal jurisdiction.” Id. California argues
12 that “[t]he complaint *fails to allege* any direct connection between the Governor and
13 SB 17,” Mot. to Dismiss 9:23–24 (emphasis added), and that “[t]he complaint *fails to*
14 *allege* facts sufficient to establish standing for plaintiff,” id. at 10:3 (emphasis added); the
15 Court treats these as facial attacks.

16 When a party makes a facial attack on a complaint, the attack is unaccompanied
17 by supporting evidence, and it challenges jurisdiction based solely on the pleadings.
18 Safe Air for Everyone v. Meyer, 373 F.3d 1035, 1039 (9th Cir. 2004). If the motion to
19 dismiss constitutes a facial attack, the Court must consider the factual allegations of the
20 complaint to be true, and determine whether they establish subject matter jurisdiction.
21 Savage v. Glendale High Union Sch. Dist. No. 205, 343 F.3d 1036, 1039 n.1 (9th Cir.
22 2003). In the case of a facial attack, the motion to dismiss is granted only if the
23 nonmoving party fails to allege an element necessary for subject matter jurisdiction. Id.

24 A court granting a motion to dismiss a complaint must then decide whether to
25 grant leave to amend. Leave to amend should be “freely given” where there is no
26 “undue delay, bad faith or dilatory motive on the part of the movant, . . . undue prejudice
27 to the opposing party by virtue of allowance of the amendment, [or] futility of the
28 amendment” Foman v. Davis, 371 U.S. 178, 182 (1962); Eminence Capital, LLC v.

1 Aspeon, Inc., 316 F.3d 1048, 1052 (9th Cir. 2003) (listing the Foman factors as those to
2 be considered when deciding whether to grant leave to amend). Not all of these factors
3 merit equal weight. Rather, “the consideration of prejudice to the opposing party . . .
4 carries the greatest weight.” Id. (citing DCD Programs, Ltd. v. Leighton, 833 F.2d 183,
5 185 (9th Cir. 1987)). Dismissal without leave to amend is proper only if it is clear that
6 “the complaint could not be saved by any amendment.” Intri-Plex Techs. v. Crest Group,
7 Inc., 499 F.3d 1048, 1056 (9th Cir. 2007) (citing In re Daou Sys., Inc., 411 F.3d 1006,
8 1013 (9th Cir. 2005)); Ascon Props., Inc. v. Mobil Oil Co., 866 F.2d 1149, 1160 (9th Cir.
9 1989) (“Leave need not be granted where the amendment of the complaint . . .
10 constitutes an exercise in futility . . .”).

11 12 ANALYSIS

13
14 Before the Court can address the merits of any case, it must ascertain its
15 jurisdiction. See Steel Co. v. Citizens for a Better Env’t, 523 U.S. 83, 94 (1998). The
16 Complaint does not allege facts sufficient to initiate suit against the Governor and, more
17 generally, does not allege facts sufficient to establish PhRMA’s standing to bring suit
18 over Section 4 of SB 17. California’s Motion to Dismiss is therefore GRANTED on those
19 grounds. Because these defects might be cured, however, the Court grants PhRMA
20 leave to amend the Complaint.

21 A. The Governor Must Be Dismissed As A Party Because He Is Immune 22 From Suit And The Complaint Fails To Allege Facts Sufficient To Apply An Exception

23 The Eleventh Amendment to the United States Constitution protects states from
24 suit brought by citizens in federal court. Coll. Sav. Bank v. Fla. Prepaid Postsecondary
25 Educ. Expense Bd., 527 U.S. 666, 669 (1999). This “principle of sovereign immunity is a
26 constitutional limitation on the federal judicial power established in Art. III.” Pennhurst
27 State Sch. & Hosp. v. Halderman, 465 U.S. 89, 98 (1984). An exception exists under
28 Ex Parte Young, 209 U.S. 123 (1908), allowing citizens to sue state officers in their

1 official capacities for prospective declaratory or injunctive relief for alleged violations of
2 federal law. See, e.g., Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris,
3 729 F.3d 937, 943 (9th Cir. 2013). To fall within this exception, the state official “must
4 have some connection with the enforcement of the act.” Ex Parte Young, 209 U.S. at
5 157. But the “general duty to enforce [state] law” is not a sufficiently close connection to
6 except a state governor from the Eleventh Amendment’s protection, Ass'n des Eleveurs
7 de Canards et d'Oies, 729 F.3d at 943, and California argues that, for this reason, the
8 Governor must be dismissed as a party to this suit, Mot. to Dismiss, ECF No. 19, at 9.

9 PhRMA’s complaint, naming the Governor as a defendant, states only that he
10 “signed SB 17 into law,” Compl. ¶ 35, ECF No. 1, and “is responsible for the execution of
11 SB 17,” id. ¶ 14. In opposing California’s Motion to Dismiss, PhRMA argues:

12 The State has “vest[ed] in the Governor the civil administration
13 of the laws of the State,” Cal. Gov’t Code § 11150, specifically
14 including the duty to appoint the Director of OSHPD, who
15 “hold[s] office at the pleasure of the Governor.” Cal. Health &
16 Safety Code § 127005. The Governor is thus the ultimate
17 arbiter of OSHPD’s interpretation and enforcement of SB 17.
18 In this case, his authority is not limited to only “general
19 oversight of the executive branch,” (Mot. 9), or a “general duty
20 to enforce California law,” as in the one case the State cites,
21 Eleveurs de Canards et d'Oies, 729 F.3d at 943.

22 Opp’n, ECF No. 21, at 30:5-14.

23 PhRMA’s rationale does not amount to more than the general oversight of the
24 executive branch. Just because the Governor might appoint the head of an agency
25 directly involved does not mean the Governor has more than general oversight. See,
26 e.g., Nat'l Audubon Soc'y, Inc. v. Davis, 307 F.3d 835, 847 (9th Cir.), opinion amended
27 on denial of reh’g, 312 F.3d 416 (9th Cir. 2002) (allowing a suit to continue against the
28 Director of the California Department of Fish and Game but not against the Governor or
the Secretary of Resources); Cal. Gov’t Code § 12805 (establishing that the Department
of Fish and Game is within the Natural Resources Agency); Cal. Gov’t Code § 12801
(establishing that the secretaries of the departments hold their positions at the

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1 Governor's pleasure); Cal. Fish & Game Code § 701 (establishing the Director of
2 Department of Fish and Game is appointed by the Governor).

3 Because PhRMA has not plead the requisite connection, the Governor is
4 dismissed as a party. PhRMA is granted leave to amend the Complaint not later than
5 thirty (30) days following the date this Memorandum and Order is electronically filed, as it
6 may be able to plead additional facts supporting the Governor's direct connection to
7 SB 17.

8 **B. The Suit Must Be Dismissed In Its Entirety Because The Complaint**
9 **Fails To Allege Facts Sufficient To Establish PhRMA's Standing**

10 "[T]he core component of standing is an essential and unchanging part of the
11 case-or-controversy requirement of Article III [of the United States Constitution]."
12 Lujan v. Defs. of Wildlife, 504 U.S. 555, 560 (1992) (citing Allen v. Wright, 468 U.S. 737,
13 751 (1984)). "In essence the question of standing is whether the litigant is entitled to
14 have the court decide the merits of the dispute or of particular issues." Warth v. Seldin,
15 422 U.S. 490, 498 (1975).

16 "To establish standing, a plaintiff must show that (1) he or she has suffered an
17 injury in fact that is concrete and particularized, and actual or imminent; (2) the injury is
18 fairly traceable to the challenged conduct; and (3) the injury is likely to be redressed by a
19 favorable court decision." WildEarth Guardians v. U.S. Dep't of Agric., 795 F.3d 1148,
20 1154 (9th Cir. 2015) (internal citations and quotation marks omitted). In assessing
21 whether the injury is imminent, "we consider whether the plaintiffs face 'a realistic danger
22 of sustaining a direct injury as a result of the statute's operation or enforcement,' or
23 whether the alleged injury is too 'imaginary' or 'speculative' to support jurisdiction."
24 Thomas v. Anchorage Equal Rights Comm'n, 220 F.3d 1134, 1139 (9th Cir. 2000)
25 (en banc) (quoting Babbitt v. United Farm Workers Nat'l Union, 442 U.S. 289, 298
26 (1979)).

27 Where a party brings suit not to vindicate its own rights, but on behalf of its
28 members, that party has standing only if: (1) "its members would otherwise have

1 standing to sue in their own right,” (2) “the interests at stake are germane to the
2 organization’s purpose,” and (3) “neither the claim asserted nor the relief requested
3 requires the participation of individual members in the lawsuit.” WildEarth Guardians,
4 795 F.3d at 1154 (quoting Friends of the Earth, Inc. v. Laidlaw Env’tl. Servs. (TOC), Inc.,
5 528 U.S. 167, 181 (2000)).

6 The parties here dispute whether the Complaint contains sufficient facts to
7 establish that any PhRMA member has been injured or faces an imminent injury and,
8 thus, whether any PhRMA member would have standing to sue in their own right. See
9 Mot. to Dismiss 10:3–27; Opp’n 9:8–10:27; Reply 2:25–5:16, ECF No. 24.

10 California cites Thomas v. Anchorage Equal Rights Comm’n, 220 F.3d 1134
11 (9th Cir. 2000) (en banc), to argue that the injuries PhRMA alleges are hypothetical and
12 conjectural rather than concrete. Reply 2:25–5:16. The challenged law in Thomas
13 made it illegal to refrain from selling, leasing, or renting real property to a person
14 because of their marital status, and the plaintiffs showed only that they planned to
15 disobey the law at some point in the future. Id. Under those circumstances, the Ninth
16 Circuit held the plaintiffs did not have standing to challenge the law. Id. at 1140. The
17 same was true in San Diego Cty. Gun Rights Comm. v. Reno, where “[t]he complaint
18 [did] not specify any particular time or date on which plaintiffs intend[ed] to violate the
19 Act” by acquiring certain banned devices and guns. 98 F.3d 1121, 1127 (9th Cir. 1996).
20 It has long been held that “[s]uch ‘some day’ intentions—without any description of
21 concrete plans, or indeed even any specification of when the some day will be—do not
22 support a finding of the ‘actual or imminent’ injury that [the case law] require[s].” Id.
23 (quoting Lujan, 504 U.S. at 564).

24 In its opposition, PhRMA argues: “The Complaint alleges that PhRMA’s members
25 suffer classic economic harm: they are barred from increasing their prices across the
26 country if they fail to comply with California’s notice requirements, on pain of statutory
27 penalties.” Opp’n 9:9–11. This is not quite so. Rather, the Complaint alleges that
28 PhRMA’s members might be harmed at some point. In the Complaint, PhRMA

1 describes the operation of the statute in painstaking detail and highlights the harm that a
2 manufacturer subject to the reporting and 60-day' notice requirements will face but,
3 importantly, does not state that one of its members actually plans to make a pricing
4 change that will force it to give 60-days' notice and trigger reporting or that one of its
5 members will affirmatively refrain from increasing a drug price in order to avoid triggering
6 the requirements.

7 Specifically, PhRMA pleads speculatively about what its members "may" do. See
8 Compl. ¶ 59 ("Uncertain whether OSHPD will count price increases from as far back as
9 January 2016 in enforcing the Act or will apply the 60-day notice requirement for a price
10 increase taken within the first 60 days of 2018, manufacturers may refrain, nationwide,
11 from implementing even small increases in order to forestall potential exposure."
12 (emphasis added)). PhRMA also recounts in detail how the law would injure its
13 members if they were to trigger the law's notice and reporting provisions or explains
14 what would occur to a member who wished to take certain actions. See, e.g., id. ¶ 3
15 ("SB 17 provides that, if a manufacturer has increased a qualifying product's wholesale
16 acquisition cost . . . , a federally defined list price, by 16 percent or more cumulatively
17 over the prior two to three calendar years, including the proposed increase, then that
18 company may not increase its [wholesale acquisition cost] list price unless it first
19 provides registered purchasers and State purchasers with 60 days' advance notice. That
20 means the manufacturer cannot increase its [wholesale acquisition cost] list price for
21 qualifying drugs *anywhere* during the 60-day advance notice period."); id. ¶ 58 ("A
22 manufacturer of a qualifying drug that wishes to increase the [wholesale acquisition
23 cost], which is a nationwide list price, above the 16-percent threshold, must provide
24 advance notices, must comply with California's reporting and justification requirements,
25 and must engage in compelled and self-disparaging speech . . .").

26 PhRMA also pleads what will happen only if certain predicates are in place. See
27 id. ¶ 85 ("If the Act applies retroactively, SB 17 will cause immediate harm to several
28 PhRMA members whose products' list prices have increased since January 1, 2016—

1 even though those prior price adjustments occurred without warning from California that
2 the adjustments could subject the manufacturer to burdensome notice requirements and
3 compelled speech in 2018. Many of these manufacturers will not increase the
4 [wholesale acquisition cost] of products at the same time and in the same manner that
5 they otherwise would without the risk of past increases triggering SB 17's 60-day notice
6 provision." (emphasis added)). This is not sufficient to take the possibility of future harm
7 outside the realm of conjecture.

8 Dismissing PhRMA's Complaint for lack of standing may seem overly technical,
9 since "PhRMA members are the leading research-based pharmaceutical and
10 biotechnology companies in America," Compl. ¶ 13, and SB 17 is directed squarely at
11 the pharmaceutical industry. PhRMA pleads that "invoice prices for patented drugs
12 jumped 12 percent in 2015 and 9.2 percent in 2016." Compl. ¶ 34. The Court is not
13 given numbers for 2017, or for any part of 2018, but one might imagine that PhRMA's
14 members will either be affected by SB 17's requirements or will refrain from increases to
15 avoid them. However:

16 It is a long-settled principle that standing cannot be inferred
17 argumentatively from averments in the pleadings, but rather
18 must affirmatively appear in the record. . . . Thus, petitioners
19 in this case must allege facts essential to show jurisdiction. If
they fail to make the necessary allegations, they have no
standing.

20 FW/PBS, Inc. v. City of Dallas, 493 U.S. 215, 231 (1990) (internal quotation marks and
21 citations omitted). For this reason, PhRMA's Complaint is dismissed.

22 Dismissal for lack of jurisdiction is without prejudice, Fleck & Assocs., Inc. v.
23 Phoenix, City of, an Arizona Mun. Corp., 471 F.3d 1100, 1106 (9th Cir. 2006), and a
24 court may grant leave to amend where a plaintiff might be able to cure the fatal defects,
25 see Carrico v. City & Cty. of San Francisco, 656 F.3d 1002, 1008 (9th Cir. 2011).

26 Consequently, PhRMA may amend the Complaint not later than thirty (30) days following
27 the date this Memorandum and Order is electronically filed.

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CONCLUSION

For the reasons set forth above, California’s Motion to Dismiss, ECF No. 19-1, is GRANTED as follows:

1. The Governor is DISMISSED as a party to this action but PhRMA is granted leave to amend the Complaint not later than thirty (30) days following the date this Memorandum and Order is electronically filed.
2. The Complaint is DISMISSED in its entirety, but PhRMA is granted leave to amend the Complaint not later than thirty (30) days following the date this Memorandum and Order is electronically filed.
3. The Court takes no action on any other aspect of California’s Motion to Dismiss.

The Court takes no action on the parties’ Motions for Judicial Notice, ECF Nos. 19-2, 22.

IT IS SO ORDERED.

Dated: August 28, 2018


MORRISON C. ENGLAND, JR.
UNITED STATES DISTRICT JUDGE