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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA,

Plaintiff,

v.

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

Defendant.

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

MEMORANDUM AND ORDER

Through the present action, Plaintiff Pharmaceutical Research and Manufacturers of America (“PhRMA”) seeks a declaration that Section 4 of a California law, Senate Bill 17 (“SB 17”), is unconstitutional and a permanent injunction preventing its implementation by Defendant Robert P. David, Director of the Office of Statewide Health Planning and Development (“OSHPD” or the “State”).¹ Presently before the Court is PhRMA’s Motion for Summary Judgment. ECF No. 64 (“PhRMA Mot.”). The Court heard oral argument on December 17, 2020. For the reasons set forth below, that Motion is DENIED.

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¹ Marko Mijic has replaced Robert P. David as the Acting Director of OSHPD.

BACKGROUND

A. SB 17

On October 9, 2017, Governor Edmund G. Brown signed SB 17 into law. Section 4 of SB 17 amends the California Health and Safety Code to add Chapter 9, titled “Prescription Drug Pricing for Purchasers,” which imposes various notice, reporting, and justification obligations on the manufacturer of a prescription drug sold to certain purchasers.² More specifically, the manufacturer of a prescription drug subject to SB 17 must notify these purchasers at least 60 days before increasing the drug’s federally-defined wholesale acquisition cost (“WAC”)³ if: (1) a course of therapy has a WAC of more than \$40, and (2) the proposed increase would result in a cumulative increase of 16 percent or more over the two calendar years prior to the current year. Cal. Health & Safety Code § 127677(a)–(b). In addition to the date and amount of the planned increase, each 60-day notice must include a statement as to whether a change or improvement in the drug necessitates the price increase and describing the change, if one occurred. *Id.* § 127677(c). The following legislative intent accompanies these new obligations:

The Legislature finds and declares that the State of California has a substantial public interest in the price and cost of prescription drugs. California is a major purchaser . . . [and] also provides major tax expenditures through the tax exclusion of employer sponsored coverage and tax deductibility . . . of excess health care costs for individuals and families.

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² The statute specifies these purchasers as follows: (1) “[a] state purchaser in California, including, but not limited to, the Public Employees’ Retirement System, the State Department of Health Care Services, the Department of General Services, and the Department of Corrections and Rehabilitation, or an entity acting on behalf of a state purchaser”; (2) “[a] licensed health care service plan”; (3) “[a] health insurer holding a valid outstanding certificate of authority from the Insurance Commissioner”; and (4) a pharmacy benefit manger (“PBM”), as defined in California Business and Professions Code § 4430(j). Cal. Health & Safety Code § 12675(a)(1)–(4).

³ The WAC is defined by federal statute as “with respect to a drug or biological, the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price . . .” 42 U.S.C. § 1395w-3a(c)(6)(B).

1 It is the intent of the Legislature in enacting this chapter to
2 provide notice and disclosure of information relating to the cost
3 and pricing of prescription drugs in order to provide
4 accountability to the state for prescription drug pricing.

5 It is further the intent of the Legislature to permit a
6 manufacturer of a prescription drug to voluntarily make pricing
7 decisions regarding a prescription drug, including any price
8 increases. It is further the intent of the Legislature to permit
9 purchasers, both public and private, as well as pharmacy
10 benefit managers, to negotiate discounts and rebates
11 consistent with existing state and federal law.

12 Id. § 127676.

13 **B. Procedural History**

14 PhRMA commenced this action on December 8, 2017, seeking declaratory and
15 injunctive relief and naming OSHPD and Governor Brown as Defendants. The
16 Complaint alleged that Section 4 of SB 17 violates the Commerce Clause of the United
17 States Constitution by regulating interstate commerce through a de facto 60-day price
18 freeze nationwide on qualifying drugs; violates the First Amendment by compelling
19 pharmaceutical manufacturers to communicate specified information when they would
20 otherwise remain silent; and violates the Fourteenth Amendment's Due Process Clause
21 because it is unconstitutionally vague about the possible retroactive application of
22 certain provisions.

23 On January 26, 2018, OSHPD and Governor Brown collectively filed a Motion to
24 Dismiss the Complaint. ECF No. 19. The Court granted that Motion, finding that
25 (1) Governor Brown must be dismissed as a party because he is immune from suit and
26 (2) the Complaint failed to allege facts sufficient to establish PhRMA's standing. ECF
27 No. 37. PhRMA was granted leave to amend and subsequently filed its First Amended
28 Complaint ("FAC"). ECF No. 38. OSHPD filed a Motion to Dismiss the FAC, arguing
that this suit must again be dismissed for PhRMA's lack of standing and for failure to
state a claim. ECF No. 43. The Court denied OSHPD's motion, finding that the FAC
contained non-conclusory allegations in support of PhRMA's Commerce Clause, First
Amendment, and Fourteenth Amendment claims. ECF No. 55.

1 On November 22, 2019, a Supplemental Pretrial Scheduling Order (“SPTSO”)
2 was issued, which required non-expert discovery to be completed within one year and
3 dispositive motions to be filed within 180 days after the close of discovery. ECF No. 58.
4 PhRMA objected to the SPTSO, seeking to bypass discovery and proceed directly to
5 summary judgment given that its arguments are facial challenges to SB 17’s
6 constitutionality. ECF No. 59. OSHPD, however, wanted to conduct discovery. ECF
7 No. 60. The Court sustained PhRMA’s objections and set a briefing schedule for
8 summary judgment. ECF No. 61. This matter has now been fully briefed. ECF Nos. 64,
9 70, 73, 74.

11 STANDARD

13 The Federal Rules of Civil Procedure provide for summary judgment when “the
14 movant shows that there is no genuine dispute as to any material fact and the movant is
15 entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a); see also Celotex Corp. v.
16 Catrett, 477 U.S. 317, 322 (1986). One of the principal purposes of Rule 56 is to
17 dispose of factually unsupported claims or defenses. Celotex, 477 U.S. at 325.

18 Rule 56 also allows a court to grant summary judgment on part of a claim or
19 defense, known as partial summary judgment. See Fed. R. Civ. P. 56(a) (“A party may
20 move for summary judgment, identifying each claim or defense—or the part of each
21 claim or defense—on which summary judgment is sought.”); see also Allstate Ins. Co. v.
22 Madan, 889 F. Supp. 374, 378–79 (C.D. Cal. 1995). The standard that applies to a
23 motion for partial summary judgment is the same as that which applies to a motion for
24 summary judgment. See Fed. R. Civ. P. 56(a); State of Cal. ex rel. Cal. Dep’t of Toxic
25 Substances Control v. Campbell, 138 F.3d 772, 780 (9th Cir. 1998) (applying summary
26 judgment standard to motion for summary adjudication).

27 In a summary judgment motion, the moving party always bears the initial
28 responsibility of informing the court of the basis for the motion and identifying the

1 portions in the record “which it believes demonstrate the absence of a genuine issue of
2 material fact.” Celotex, 477 U.S. at 323. If the moving party meets its initial
3 responsibility, the burden then shifts to the opposing party to establish that a genuine
4 issue as to any material fact actually does exist. Matsushita Elec. Indus. Co. v. Zenith
5 Radio Corp., 475 U.S. 574, 586–87 (1986); First Nat’l Bank v. Cities Serv. Co., 391 U.S.
6 253, 288–89 (1968).

7 In attempting to establish the existence or non-existence of a genuine factual
8 dispute, the party must support its assertion by “citing to particular parts of materials in
9 the record, including depositions, documents, electronically stored information,
10 affidavits[,] or declarations . . . or other materials; or showing that the materials cited do
11 not establish the absence or presence of a genuine dispute, or that an adverse party
12 cannot produce admissible evidence to support the fact.” Fed. R. Civ. P. 56(c)(1). The
13 opposing party must demonstrate that the fact in contention is material, i.e., a fact that
14 might affect the outcome of the suit under the governing law. Anderson v. Liberty Lobby,
15 Inc., 477 U.S. 242, 248, 251–52 (1986); Owens v. Local No. 169, Assoc. of W. Pulp and
16 Paper Workers, 971 F.2d 347, 355 (9th Cir. 1987). The opposing party must also
17 demonstrate that the dispute about a material fact “is ‘genuine,’ that is, if the evidence is
18 such that a reasonable jury could return a verdict for the nonmoving party.” Anderson,
19 477 U.S. at 248. In other words, the judge needs to answer the preliminary question
20 before the evidence is left to the jury of “not whether there is literally no evidence, but
21 whether there is any upon which a jury could properly proceed to find a verdict for the
22 party producing it, upon whom the onus of proof is imposed.” Anderson, 477 U.S. at 251
23 (quoting Improvement Co. v. Munson, 81 U.S. 442, 448 (1871)) (emphasis in original).
24 As the Supreme Court explained, “[w]hen the moving party has carried its burden under
25 Rule [56(a)], its opponent must do more than simply show that there is some
26 metaphysical doubt as to the material facts.” Matsushita, 475 U.S. at 586. Therefore,
27 “[w]here the record taken as a whole could not lead a rational trier of fact to find for the
28 nonmoving party, there is no ‘genuine issue for trial.’” Id. at 587.

1 In resolving a summary judgment motion, the evidence of the opposing party is to
2 be believed, and all reasonable inferences that may be drawn from the facts placed
3 before the court must be drawn in favor of the opposing party. Anderson, 477 U.S. at
4 255. Nevertheless, inferences are not drawn out of the air, and it is the opposing party's
5 obligation to produce a factual predicate from which the inference may be drawn.
6 Richards v. Nielsen Freight Lines, 602 F. Supp. 1224, 1244–45 (E.D. Cal. 1985), aff'd,
7 810 F.2d 898 (9th Cir. 1987).

9 ANALYSIS

10
11 PhRMA argues that SB 17 is unconstitutional on its face in violation of the
12 dormant Commerce Clause and First Amendment.⁴ A facial challenge is a challenge to
13 an entire legislative enactment or provision. Foti v. City of Menlo Park, 146 F.3d 629,
14 635 (9th Cir. 1998) (explaining that a statute is facially unconstitutional if “it is
15 unconstitutional in every conceivable application, or it seeks to prohibit such a broad
16 range of protected conduct that it is unconstitutionally overbroad”). “A facial challenge to
17 a legislative Act is, of course, the most difficult challenge to mount successfully, since
18 the challenger must establish that no set of circumstances exists under which the Act
19 would be valid.” United States v. Salerno, 481 U.S. 739, 745 (1987). “In determining
20 whether a law is facially invalid, we must be careful not to go beyond the statute’s facial
21 requirements and speculate about ‘hypothetical’ or ‘imaginary’ cases.” Wash. State
22 Grange v. Wash. State Republican Party, 552 U.S. 442, 449–50 (2008). Facial
23 challenges are disfavored because they “often rest on speculation” and as a result, they
24 “raise the risk of premature interpretation of statutes on the basis of factually barebones
25 records.” Id. at 450 (internal citation and quotation marks omitted).

26 This case is also unique in that this Court has rarely encountered a situation
27 where a plaintiff seeks to bypass discovery and proceed directly to summary judgment.

28 ⁴ PhRMA does not raise its Fourteenth Amendment Due Process claim in its present Motion.

1 PhRMA’s position has been that discovery is unnecessary because SB 17 is
2 unconstitutional on its face and thus, no further fact-finding is needed. See ECF No. 59.
3 Given the high standards for both summary judgment and facial challenges, PhRMA
4 must show SB 17 is invalid in all circumstances but as discussed below, the Court finds
5 that there are genuine disputes of material fact which prevent a finding that SB 17 is
6 unconstitutional on its face.

7 **A. Dormant Commerce Clause**

8 The Commerce Clause empowers Congress to “regulate Commerce . . . among
9 the several States.” U.S. Const., art. I, § 83, c. 3. “The modern law of what has come to
10 be called the dormant Commerce Clause is driven by concern about ‘economic
11 protectionism that is, regulatory measures designed to benefit in-state economic
12 interests by burdening out-of-state competitors.’” Dep’t of Revenue of Ky. v. Davis,
13 553 U.S. 328, 337–38 (2008) (citing New Energy Co. of Ind. v. Limbach, 486 U.S. 269,
14 273–74 (1988)).

15 The Supreme Court has adopted a two-tiered approach to analyze whether a
16 state statute violates the Commerce Clause. First, “[w]hen a state statute directly
17 regulates or discriminates against interstate commerce, or when its effect is to favor in-
18 state economic interests over out-of-state interests,” the statute is generally struck down
19 without further inquiry. Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.,
20 476 U.S. 573, 579 (1986) (internal citations omitted). Second, when “a statute has only
21 indirect effects on interstate commerce and regulates evenhandedly,” the court must
22 “examine[] whether the State’s interest is legitimate and whether the burden on interstate
23 commerce clearly exceeds the local benefits.” Id. (citing Pike v. Bruce Church, Inc.,
24 397 U.S. 137, 142 (1970)).

25 Here, PhRMA bases its challenge on the first prong, i.e., whether SB 17 directly
26 regulates interstate commerce. “Direct regulation occurs when a state law directly
27 affects transactions that take place across state lines or entirely outside of the state’s
28 borders.” Valley Bank of Nevada v. Plus Sys., Inc., 914 F.2d 1186, 1189–90 (9th Cir.

1 1990) (internal quotation marks omitted). “The Supreme Court has emphasized that the
2 ‘practical effect’ of a challenged statute is ‘the critical inquiry’ in determining whether that
3 statute constitutes direct regulation.” S.D. Myers, Inc. v. City & Cty. of S.F., 253 F.3d
4 461, 467 (9th Cir. 2001) (quoting Healy v. Beer Inst., 491 U.S. 324, 336 (1989)). The
5 practical effect “must be evaluated not only by considering the consequences of the
6 statute itself, but also by considering how the challenged statute may interact with the
7 legitimate regulatory regimes of other States” Healy, 491 U.S. at 336.

8 As indicated above, SB 17 requires prescription drug manufacturers to provide
9 60-day advance notice of a 16 percent or more increase in the WAC of a prescription
10 drug. Cal. Health & Safety Code § 127677(a)–(b). PhRMA posits that SB 17 directly
11 regulates out-of-state drug prices because the WAC is defined by federal statute and
12 must be uniform in every state. PhRMA Mot. at 8. However, these characteristics are
13 insufficient on their own to support PhRMA’s conclusion. See Nat’l Ass’n of Optometrists
14 & Opticians v. Harris, 682 F.3d 1144, 1148 (9th Cir. 2012) (“[A] state regulation does not
15 become vulnerable to invalidation under the dormant Commerce Clause merely because
16 it affects interstate commerce.”).

17 PhRMA claims SB 17 directly impacts out-of-state drug prices but what that
18 impact may actually be remains unclear. First, the WAC is a list price and not a
19 transaction price. See 42 U.S.C. § 1395w-3a(c)(6)(B). The transaction price of a
20 prescription drug is the result of negotiations between the manufacturer and purchaser
21 and includes discounts and rebates which are explicitly excluded from the federal
22 definition of the WAC. Id.; see Molina Decl., ECF No. 70-2, ¶¶ 15–19 (“Molina Decl.”).
23 Second, SB 17 is a notice statute rather than a price control or price tying statute. In
24 other words, SB 17 does not necessarily dictate the transaction price of prescription
25 drugs in other states. Compare Brown-Forman, 476 U.S. at 576, 583–84 (holding that
26 New York liquor affirmation statute essentially regulated the price of liquor in other states
27 by requiring distillers to affirm that the liquor prices in other states are not lower than
28 those in New York); Ass’n for Accessible Medicines v. Frosh, 887 F.3d 664, 673 (4th Cir.

1 2018) (finding Maryland statute that prohibited drug manufacturers from “price gouging”
2 essentially controlled the price of transactions that occur outside the state).

3 PhRMA also equates the 60-day advance notice period to a nationwide price
4 freeze which means that manufacturers cannot change the WAC outside California and
5 still comply with their legal obligations under SB 17. PhRMA Mot. at 8, 9 (“The fact that
6 SB 17 directly freezes a national price suffices to render it invalid.”). In support of its
7 argument that SB 17 has extraterritorial effects on out-of-state laws, PhRMA provides
8 three examples. First, PhRMA contends that the WAC is a component of reimbursement
9 formulas under several state Medicaid laws and thus SB 17 interferes with those laws.
10 Id. at 9. According to one of the State’s experts, however, none of the states use the
11 WAC solely in their reimbursement formulas:

12 In more than 86 percent of the states (44 of 51 [including
13 D.C.]), Medicaid reimbursement is based on the lowest of
14 several different prices, including WAC. Out of the 44 states
15 that use the lowest of several prices in the reimbursement
16 formula, 29 states use WAC among other prices to determine
17 the lowest price only if Actual Acquisition Cost (“AAC”) or the
18 National Average Drug Acquisition Cost (“NADAC”) is not
19 available.

20 . . .

21 Furthermore, 39 of the 44 states that include WAC among
22 several prices in their “lowest of” formulas also include NADAC
23 NADAC is almost always lower than WAC. Therefore,
24 WAC is not likely to be the basis of reimbursement in these
25 states. This is also true because, in addition to NADAC, the
26 list of several prices to determine the lowest one includes
27 [Affordable Care Act Federal Upper Limit (“FUL”)] and
28 [Maximum Allowed Cost (“MAC”)] in the various states’
reimbursement formulas.

Of the remaining 7 states, 3 have reimbursement formulas
which do not use the “lower of” language, but these
reimbursement formulas specify that AAC or NADAC is the
basis for reimbursement amount. For these states, WAC is
only used if AAC or NADAC is not available.

. . .

The remaining 4 states have reimbursement formulas that do
not include WAC in the list of several prices to determine the
lowest price.

1 Saha Decl., ECF No. 70-1, ¶¶ 37–40 (“Saha Decl.”). Because state Medicaid
2 reimbursement does not rely necessarily on the WAC, it is difficult to see how SB 17
3 interferes with other states’ Medicaid laws.

4 PhRMA next contends that the federal government relies on the WAC in its
5 reimbursement formulas for Medicare Parts B and D. PhRMA Mot. at 9. Regarding
6 Medicare Part B reimbursement, the State’s expert offers the following explanation:

7 Since January 2005, the [Medicare Part B] reimbursement
8 amount (also referred to as the payment limit) has generally
9 been based on Average Sales Price (ASP) plus 6 percent. The
10 ASP is computed using manufacturers’ actual sales, i.e., list
11 price (i.e., WAC) less all price concessions. Thus, the actual
12 prices in Medicare Part B reimbursements is not WAC, but a
transaction price that reflects various negotiated price
concessions. As a result, a change in WAC for a drug does
not necessarily translate in a commensurate change in the
reimbursement amounts (i.e., payment limits).

13 Saha Decl., ¶ 28. As for Medicare Part D, reimbursement is based on negotiations and
14 a competitive bidding process, and while the WAC may serve as a basis for the
15 negotiated prices, “the net prices received by the drug manufacturers for Part D drugs
16 are typically not equal to WAC, and these net prices may change even if WAC does not
17 change.” *Id.* ¶¶ 32, 34–35. Once again, it is unclear what impact, if any, SB 17 has on
18 Medicare reimbursement.

19 Lastly, PhRMA argues that because the WAC is the contractual starting point in
20 private contract negotiations, SB 17 essentially controls market transactions nationwide
21 and forces manufacturers to change their contracting behavior. PhRMA Mot. at 9.
22 However, PhRMA does not provide any explanation or examples as to how these market
23 transactions will be impacted, especially since such contracts involve negotiations on a

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1 wide array of factors, including rebates and discounts.⁵ See Molina Decl., ¶¶ 15–22.
2 PhRMA seeks to infer direct regulation but fails to show how such negotiations will be
3 affected, especially since SB 17 notices are only required when the WAC increases by
4 16 percent or more.

5 In conclusion, PhRMA relies on a general proposition that because the WAC is
6 federally defined and must be uniform nationwide, SB 17 directly regulates out-of-state
7 drug prices. However, this alone does not render SB 17 unconstitutional. There are
8 genuine disputes of material fact as to whether providing advance notice of certain
9 increases in a prescription drug’s WAC results in either direct or extraterritorial
10 regulation. Ultimately, PhRMA has not met its burden in showing that SB 17 violates the
11 dormant Commerce Clause on its face and, accordingly, PhRMA’s Motion is DENIED as
12 to this claim.

13 **B. First Amendment**

14 “As a general rule, laws that by their terms distinguish favored speech from
15 disfavored speech on the basis of the ideas or views expressed are content based.”
16 Turner Broad. Sys. v. F.C.C., 512 U.S. 622, 643 (1994). “A speech restriction is content-
17 neutral if it is ‘justified without reference to the content of the regulated speech.’” S.O.C.,
18 Inc. v. Cty. of Clark, 152 F.3d 1136, 1145 (9th Cir. 1998) (quoting Clark v. Cmty. for
19 Creative Non-Violence, 468 U.S. 288, 293 (1984)). “Content-based regulations are
20 presumptively unconstitutional” and “pass constitutional muster only if they are the least
21 restrictive means to further a compelling interest.” Id.

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24 ⁵ PhRMA relies on Nat’l Collegiate Athletic Ass’n v. Miller, 10 F.3d 633 (9th Cir. 1993), in arguing
25 that SB 17’s regulation of a national list price violates the per se rule against state regulation in areas
26 where national uniformity is required. In that case, the Ninth Circuit invalidated a Nevada statute that
27 imposed standards for how the National Collegiate Athletic Association (“NCAA”), an interstate
28 organization, conducted its enforcement proceedings on grounds that national uniformity is necessary for
the NCAA’s operation and that it could not adopt alternative procedures for its business in other states. Id.
at 638–39. Unlike the NCAA, the pharmaceutical industry is not a nationally uniform business since it is
subject to different regulations in different states, as evidenced by the variance in state Medicaid and
Medicare laws. See Saha Decl., ¶¶ 28, 32, 34–45, 37–40. Furthermore, there are a multitude of factors
besides the WAC that are involved in pharmaceutical drug pricing. See Molina Decl., ¶¶ 15–22.

1 Even a statute that appears neutral on its face as to content and speaker can be
2 rendered unconstitutional if its purpose is to suppress speech and it unjustifiably burdens
3 expression. Sorrell v. IMS Health Inc., 564 U.S. 552, 565–66 (2011). “Commercial
4 speech is no exception.” Id. at 566. A “consumer’s concern for the free flow of
5 commercial speech often may be far keener than his concern for urgent political
6 dialogue.” Bates v. State Bar of Az., 433 U.S. 350, 364 (1977). “Commercial speech is
7 that ‘which does no more than propose a commercial transaction.’” Valle del Sol Inc. v.
8 Whiting, 709 F.3d 808, 818 (9th Cir. 2013) (internal citation omitted). “Such speech is
9 protected by the First Amendment, but to a lesser degree than other types of speech.”
10 Id.

11 Restrictions or prohibitions on commercial speech are traditionally subject to
12 intermediate scrutiny under the test laid out in Cent. Hudson Gas & Elec. Corp. v. Pub.
13 Serv., Comm’n of N.Y., 447 U.S. 557, 566 (1980). However, “[f]ive years after Central
14 Hudson, the [Supreme] Court held that Central Hudson’s intermediate scrutiny test does
15 not apply to compelled, as distinct from restricted or prohibited, commercial speech.”
16 CTIA – The Wireless Ass’n v. City of Berkeley, Cal., 928 F.3d 832, 842 (9th Cir. 2019).
17 Instead, when the government seeks to compel commercial speech, the Supreme
18 Court’s holding in Zauderer v. Office of Disciplinary Counsel of the Supreme Ct. of Ohio,
19 471 U.S. 626 (1985), applies. In such cases, “the government may compel truthful
20 disclosure in commercial speech as long as the compelled disclosure is ‘reasonably
21 related’ to a substantial government interest, and involves ‘purely factual and
22 uncontroversial information’ that relates to the service or product provided.” CTIA,
23 928 F.3d at 842 (quoting Zauderer, 471 U.S. at 651) (internal citations omitted).

24 PhRMA claims the following provision violates the First Amendment: “The notice
25 required by subdivision (a) shall include a statement regarding whether a change or
26 improvement in the drug necessitates the price increase. If so, the manufacturer shall
27 describe the change or improvement.” Cal. Health & Safety Code § 127677(c)(2). First,
28 the parties disagree as to whether SB 17 regulates commercial speech. If commercial

1 speech is involved, then the Zauderer test applies. If not, this Court must then determine
2 whether SB 17 is content-based and survives strict scrutiny or, alternatively, survives
3 rational basis review. In this instance, however, PhRMA ultimately fails to demonstrate
4 that SB 17 would not pass any level of scrutiny or review.

5 The State claims it “has a substantial public interest in the price and cost of
6 prescription drugs” as a major purchaser and further asserts that greater insight and
7 transparency into rising drug prices is necessary to ensure that such prices do not
8 threaten access to life-saving treatments. Def.’s Opp. Mot. Summ. J., ECF No. 70, at 17
9 (“State Opp.”); see Cal. Health & Safety Code § 127676. Requiring advance notice of
10 certain increases in the WAC “allows purchasers proactively to negotiate drug prices
11 before an eventual price increase may go into effect, and to find other alternative
12 therapeutics.” State Opp. at 18 (“Understanding whether a price increase is or is not the
13 result of a change or improvement in a drug also increases drug pricing transparency.”).

14 In response to these stated interests, PhRMA asserts that the State has failed to
15 demonstrate any sufficient interest that SB 17 serves, such as the prevention of
16 consumer deception or the promotion of health and safety, or connect such interests with
17 the scope of the notice and justification requirements. See PhRMA Mot. at 17–18. First,
18 PhRMA contends that if the State is concerned with drug pricing transparency, then all
19 market participants, such as pharmacy benefit managers, pharmacies, and wholesalers,
20 would also be subject to SB 17’s notice requirement. Id. at 18–19. However,
21 manufacturers are the ones who set or increase the WAC, which is already a publicly
22 available benchmark, thus an argument that they are being discriminated against is
23 unpersuasive. See State Opp. at 16; Saha Decl., ¶ 25.

24 PhRMA next argues that the State’s interest in addressing rising drug costs is
25 contradicted by the legislative intent, which states that pricing decisions should be left to
26 the manufacturers. PhRMA Mot. at 17–18; see Cal. Health & Safety Code § 127676. If
27 the State intends to control prices, then advance notice requirements are not the proper
28 means to do so and thus, the “only possible way the compelled statements could curb

1 drug prices would be through public shaming.” PhRMA Mot. at 18. PhRMA relies on
2 Nat’l Assn’ of Mfrs. v. SEC (“NAM”), which involved a requirement that mineral traders
3 must disclose whether their products were “conflict free.” 800 F.3d 518, 530 (D.D.C.
4 2015). The court found that such a disclosure was “hardly factual and non-ideological,”
5 and thus the requirement essentially forced “a company to publicly condemn itself” if its
6 products were not “conflict free.” Id. (internal citation and quotation marks omitted).
7 Unlike the disclosure requirement in NAM, however, explaining whether a 16 percent or
8 more increase in the WAC results from a change or improvement in the drug is hardly
9 inflammatory and does not force manufacturers to promote a state-sponsored message.
10 Such explanations do not on their own reach the level of public condemnation PhRMA
11 suggests and are related to the State’s interest in drug pricing transparency and
12 understanding the rising costs of prescription drugs.

13 Finally, PhRMA argues that the provision which requires manufacturers to include
14 “a statement regarding whether a change or improvement in the drug necessitates the
15 price increase” means that the State recognizes only one rationale for an increase and
16 therefore “convey[s] that certain price increases are morally justifiable and others are
17 not.” PhRMA Mot. at 17. Contrary to PhRMA’s argument, it is not clear from the
18 language of SB 17 that only one rationale will be accepted and that any other
19 explanation is unjustifiable. Manufacturers only have to include a statement as to
20 whether the increase resulted from a change or improvement in the drug. If yes, then
21 the manufacturer describes the change or improvement; if not, the provision does not
22 include any prohibition against manufacturers adding further explanations for the
23 increase. In fact, several manufacturers have added different explanations for WAC
24 increases in their notices.⁶ See, e.g., Ex. A, Goulby Decl., ECF No. 70-3.

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⁶ In arguing that SB 17 is “designed to advance its sponsor’s publicly stated view that ‘BigPharma’
is solely responsible for unjustified ‘price increases,’” PhRMA Mot. at 6, PhRMA relies on statements made
by SB 17’s sponsor taken from his official webpage and Twitter account. See Exs. A and B, PhRMA RJN,
ECF No. 64-3. Such statements, however, are not indicative of legislative intent. See Am. Fuel & Petro.
Manufacturers v. O’Keeffe, 903 F.3d 903, 912 (9th Cir. 2018) (concluding the “district court did not err in
finding that the statements made by Oregon public officials cited in [plaintiff’s] complaint do not
demonstrate that the objectives identified by the legislature were not the true goals of the Program.”).

1 Ultimately, PhRMA has failed to show that the State does not have a sufficient
2 interest or that its interests are unrelated to SB 17's notice and justification requirements.
3 Accordingly, PhRMA's Motion is DENIED as to the First Amendment claim.

4
5 **CONCLUSION**
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7 For the reasons set forth above, PhRMA's Motion for Summary Judgment, ECF
8 No. 64, is DENIED.^{7, 8}

9 IT IS SO ORDERED.

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11 Dated: December 30, 2020

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14 MORRISON C. ENGLAND, JR.
15 SENIOR UNITED STATES DISTRICT JUDGE
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24 _____
25 Because the Court did not consider these exhibits in reaching its decision, PhRMA's Request for Judicial
26 Notice, ECF No. 64-3, is DENIED.

27 ⁷ OSHPD's Conditional Motion to Deny or Defer Ruling on PhRMA's Motion for Summary
28 Judgment, ECF No. 70-8, is DENIED as moot.

29 ⁸ In addition to the previously discussed Request for Judicial Notice by PhRMA (ECF No. 64-3),
30 supra note 6, there are two additional Requests for Judicial Notice filed by PhRMA and OSHPD
31 respectively. ECF Nos. 70-7, 75. Because the Court did not need to consider these exhibits in reaching
32 its decision, both Requests for Judicial Notice are DENIED.