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).

> It is the intent of the Legislature in enacting this chapter to provide notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability to the state for prescription drug pricing.
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> It is further the intent of the Legislature to permit a manufacturer of a prescription drug to voluntarily make pricing decisions regarding a prescription drug, including any price increases. It is further the intent of the Legislature to permit purchasers, both public and private, as well as pharmacy benefit managers, to negotiate discounts and rebates consistent with existing state and federal law.

Id. § 127676.

B. Procedural History

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

On January 26, 2018, OSHPD and Governor Brown collectively filed a Motion to Dismiss the Complaint. ECF No. 19. The Court granted that Motion, finding that (1) Governor Brown must be dismissed as a party because he is immune from suit and (2) the Complaint failed to allege facts sufficient to establish PhRMA's standing. ECF No. 37. PhRMA was granted leave to amend and subsequently filed its First Amended 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.

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

STANDARD

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

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

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

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

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

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

ANALYSIS

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

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

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

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

A. Dormant Commerce Clause

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

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

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

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

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

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

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

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

> In more than 86 percent of the states (44 of 51 [including D.C.]), Medicaid reimbursement is based on the lowest of several different prices, including WAC. Out of the 44 states that use the lowest of several prices in the reimbursement formula, 29 states use WAC among other prices to determine the lowest price only if Actual Acquisition Cost ("AAC") or the National Average Drug Acquisition Cost ("NADAC") is not available.
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> . . .
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> Furthermore, 39 of the 44 states that include WAC among several prices in their "lowest of" formulas also include NADAC . . . . NADAC is almost always lower than WAC. Therefore, WAC is not likely to be the basis of reimbursement in these states. This is also true because, in addition to NADAC, the list of several prices to determine the lowest one includes [Affordable Care Act Federal Upper Limit ("FUL")] and [Maximum Allowed Cost ("MAC")] in the various states' reimbursement formulas.
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> 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.
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> . . .
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> The remaining 4 states have reimbursement formulas that do not include WAC in the list of several prices to determine the lowest price.

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

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

> Since January 2005, the [Medicare Part B] reimbursement amount (also referred to as the payment limit) has generally been based on Average Sales Price (ASP) plus 6 percent. The ASP is computed using manufacturers' actual sales, i.e., list price (i.e., WAC) less all price concessions. Thus, the actual 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).

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

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

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

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

B. First Amendment

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

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[5] PhRMA relies on Nat'l Collegiate Athletic Ass'n v. Miller, 10 F.3d 633 (9th Cir. 1993), in arguing that SB 17's regulation of a national list price violates the per se rule against state regulation in areas where national uniformity is required. In that case, the Ninth Circuit invalidated a Nevada statute that imposed standards for how the National Collegiate Athletic Association ("NCAA"), an interstate 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.

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

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

PhRMA claims the following provision violates the First Amendment: "The notice required by subdivision (a) shall include 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)(2). First, the parties disagree as to whether SB 17 regulates commercial speech. If commercial

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

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

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

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

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

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

[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.").

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

CONCLUSION

For the reasons set forth above, PhRMA's Motion for Summary Judgment, ECF No. 64, is DENIED.[7, 8]

IT IS SO ORDERED.

Dated: December 30, 2020

MORRISON C. ENGLAND, JR
SENIOR UNITED STATES DISTRICT JUDGE

Because the Court did not consider these exhibits in reaching its decision, PhRMA's Request for Judicial Notice, ECF No. 64-3, is DENIED.

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

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