XAVIER BECERRA, State Bar No. 118517
Attorney General of California
ANTHONY R. HAKL, State Bar No. 197335
Supervising Deputy Attorney General
S. MICHELE INAN, State Bar No. 119205
Deputy Attorney General
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (415) 703-5474
Fax: (415) 703-5480
E-mail: Michele.Inan@doj.ca.gov
Attorneys for Defendants Edmund G. Brown, Jr., Governor of the State of California, and Robert P. David, Director of the California Office of Statewide Health Planning and Development

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

SACRAMENTO DIVISION

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.

2:17-cv-02573-MCE-KJN

DEFENDANTS' MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO DISMISS COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF PURSUANT TO FED. R. CIV. P. 12(b)(1) and 12(b)(6)

Date: April 19, 2018
Time: 2:00 p.m.
Courtroom: 7, 14th Floor
Judge: Honorable Morrison C. England, Jr.
Trial Date: Not Set
Action Filed: December 8, 2017

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

STATUTES

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

CONSTITUTIONAL PROVISIONS

COURT RULES

OTHER AUTHORITIES

INTRODUCTION

Senate Bill 17, California's Drug Price Transparency Law, requires that pharmaceutical manufacturers, health care service plans, and health insurers meet certain notification and reporting requirements for significant increases in their prescription drug prices. The California Legislature passed Senate Bill 17 ("SB 17") last Fall with overwhelming bipartisan support following years of increases in the cost of prescription drugs. 2017 Cal. Stat., ch. 603, §§ 1-9. To frame the current lawsuit challenging SB 17 – and why this lawsuit should be dismissed – it is important to distinguish between what SB 17 actually does, and what it does not do.

SB 17 has six main notification and reporting requirements to increase drug picing transparency. It requires drug manufacturers selling prescription drugs to statutorily-specified California purchasers to provide them with 60-days advance written notice of the implementation of an increase in the Wholesale Acquisition Cost of a drug that has increased by more than 16 percent within the last two calendar years. Following implementation of a threshold price increase, effective January 2019, drug manufacturers must report factual information about the circumstances and factors of the price increase to the California Office of Statewide Health Planning and Development ("OSHPD"), who, in turn, must publish the information on its Internet site. California's health care service plans and health insurers must also report, to the California Department of Managed Care, frequently-prescribed drug, cost, and premium information for all covered prescription drugs starting in 2018. Manufacturers must notify OSHPD if a new prescription drug is being introduced to the market at a Wholesale Acquisition Cost that exceeds a certain threshold, and must provide this notice in writing within three days after the release of the drug in the commercial market. And, no later than 30 days after providing OSHPD with the new drug notice, manufacturers must report other factual information regarding that new drug to OSHPD, who, in turn, must publish the information on its internet site. All of this information must be compiled into a public report.

By initiating these reporting and notification provisions, SB 17 is designed to, as the Senate Floor Analysis explained, "bring prescription drugs in line with the rest of the health care sector by *shining a light on drugs that are having the greatest impact on our health care dollar*."

Senate Floor Analysis, dated September 12, 2017 (italics added). The Senate Floor Analysis, citing to the bill's Author's Statement, further explained that:

> This change is absolutely necessary in an environment where consumer spending on prescription drugs increased by a staggering $65 billion from 2012 to 2015, according to the Kaiser Family Foundation. These are drugs that treat diseases that impact millions of Americans, including hundreds of thousands of patients in public programs like Medi-Cal, and *we have the right to know why they cost so much*.

Id. (italics added).[1] Thus, SB 17, as a right-to-know law, sheds light on what has been up to this point for policymakers and purchasers, a rather opaque process as to why particular drug prices increase from one year to the next. And as a right-to-know law, SB 17 enables purchasers of drugs to make their purchasing decisions with greater transparency. SB 17 is about drug pricing notification and reporting of information.

Then there is that which SB 17 does not do:

First, SB 17 does not, as the complaint alleges, control, or in any way mandate, "ban," or "overtly prescribe[]," Compl. ¶ 4, the price of any drug. Instead, as SB 17 makes drug pricing information more readily available to California drug purchasers, one may expect that such purchasing decisions will become more rationalized and more easily communicated to those affected by such price increases.

Second, SB 17 does not, as the complaint alleges, "impose[] nationwide restrictions on the list price of pharmaceutical manufacturers' products." Compl. ¶ 1. To the contrary, after the enactment of SB 17, drug manufacturers remain free to set, change, and increase their drug prices as they see fit. All that SB 17 requires is that manufacturers notify and report about when, how much, and why they are setting the drug price at a particular level or why they are increasing the price of a drug already on the market.

Third, SB 17 does not, as the complaint alleges, compel protected speech by requiring drug manufacturers to "speak about drug pricing where they otherwise would not" in a manner that forces them to "publicly convey and implicitly endorse the State's position that the manufacturers

[1] Defendants have requested judicial notice of SB 17's legislative history. The referenced history is found at Request for Judicial Notice ("RJN") Exh. 1 at 0036.

are to blame for the allegedly inflated prices of prescription drugs." Compl. ¶¶ 2, 9. SB 17 requires disclosure of price increase information only, and in no way holds the pen of any drug manufacturer and does not limit or constrain in any way how the manufacturers may explain or contextualize their price setting or price increases.

Fourth, SB 17 does not, as the complaint alleges, "single out" drug manufacturers. Compl. ¶ 5. Again, to the contrary, SB 17's legislative history is unmistakably clear that this new law "will bring prescription drugs *in line with the rest of the health care sector . . .*" RJN Exh. 1 at 0036 (italics added). The Senate Floor Analysis, again quoting the Author's Statement, notes that "[t]ransparency-focused policies in this state have led to rules requiring hospitals in California to provide information on pricing for common surgeries, health plans to submit detailed data regarding premium changes, and doctors to report more information to the federal government. But somehow, drug makers have been granted an exception to this forward-thinking trend." *Id.*

Upon clarification of what SB 17 does (and does not) do, all of plaintiff's legal claims fail, particularly because they must meet the high standards of a facial constitutional challenge and show that the law can never be implemented in a constitutional manner. As threshold matters, the Governor is immune from suit, and cannot be named in this lawsuit under the *Ex parte Young* doctrine. The complaint also fails to plead facts to establish standing for this plaintiff, a non-profit advocacy organization, either on behalf of itself, or on behalf of its members.

On the merits, SB 17 does not violate the dormant Commerce Clause either by directly regulating interstate commerce or excessively burdening interstate commerce. The law only requires notification of large threshold price increases and the reporting of basic factual information about the price increase.

SB 17 also does not regulate speech protected by the First Amendment. SB 17 regulates conduct subject to rational basis review that is easily satisfied in light of the consumer protection and public welfare interests at stake. And even if SB 17 is considered a speech regulation, it survives First Amendment scrutiny as a valid commercial speech law that is subject to rational basis review. The law would also survive heightened review, as SB 17's disclosure requirements are narrowly tailored to advance the significant interest of protecting patient care.

The Court should also dismiss the claim that SB 17 is unconstitutionally vague in violation of the Fourteenth Amendment's Due Process Clause. That claim is not ripe. The complaint fails to allege a protected liberty or property interest protected by the Due Process Clause. And plaintiff's mere assertions about possible retroactive applications of the law do not render the law unconstitutional.

Because the complaint's flaws cannot be cured by amendment, the Court should grant the motion to dismiss without leave to amend.

STATEMENT OF FACTS

I. SENATE BILL 17

A. Drug Manufacturer Requirements

SB 17 requires manufacturers of a "prescription drug" with a Wholesale Acquisition Cost ("WAC"), of more than $40 for a course of therapy (as defined in the law), that is purchased or reimbursed by specified California "purchasers" of the drug, to notify these purchasers of an increase in the WAC, if the price increase for a course of therapy "is more than 16 percent, including the proposed increase and the cumulative increases that occurred within the previous two calendar years prior to the current year." 2017 Cal. Stat., ch. 603, § 4 (enacting Cal. Health & Safety Code § 127677(a)).[2] Purchasers entitled to receive notice are state purchasers in California, California-licensed health care service plans, health insurers holding a valid outstanding California certificates of authority from the California Insurance Commissioner, and pharmacy benefit managers ("PBMs"), as defined in California Business and Professions Code section 4430, subdivision (j). § 127675(a).[3]

SB 17 requires that manufacturers provide the notice "at least 60 days prior to the planned effective date of the increase," and include in the notice the date of the increase, the current WAC

[2] SB 17 enacted new statutes in section 4 of the bill that are in the California Health and Safety Code, and amended existing statutes in the California Health and Safey Code and Insurance Code in the bill's other sections. Subsequent statutory references are to the California Health and Safety Code, unless otherwise noted.

[3] A PBM manages the prescription drug coverage provided by insurers, health care service plans, or other third-party payers under contract. Cal. Bus. & Prof. § 4430(j).

of the drug, the dollar amount of the future increase, and "a statement regarding whether a change or improvement in the drug necessitates the price increase . . . [and i]f so, a description of the change or improvement." § 127677(b)-(c).[4] SB 17 also requires a manufacturer of a "*new* prescription drug" to notify OSHPD, if it is introducing a new drug at a WAC that exceeds the threshold set for a specialty drug under the Medicare Part D program at least three days after release of the drug. § 127681(a) (italics added).

Commencing January 1, 2019, SB 17 also requires a manufacturer to provide more detailed factual information to OSHPD (specified in the law), about each prescription drug for which a threshold price increase is covered by section 127677. § 127679(a). That information must include a "description of the change or improvement in the drug, if any, that necessitates the price increase." § 127679(a)(6). Detailed factual information must also be reported about each *new* prescription drug for which notification of a threshold price increase is made, no later than 30 days after the notification of the price increase. § 127681(b)(1)-(4). SB 17 then requires OSHPD to publish the information, on a quarterly basis, on a per-drug basis, within 60 days of receipt of the information. §§ 127679(c), 127681(d). SB 17 allows a manufacturer to limit the scope of required information to information "which is otherwise in the public domain or publicly available." §§ 127679(b), 127681(c). If a manufacturer does not report to OSHPD, it may face a civil penalty of $1,000 per day for every day the information is not reported. §§ 127679(e)-(f), 127681(f)-(g).

B. Health Care Service Plan and Health Insurer Requirements

Beginning in October 2018, SB 17 also imposes new prescription drug disclosure requirements on health care service plans and health insurers that already report premium rate information to the California Departments of Managed Health Care and Insurance. Health care service plans and health insurers are required to report for all "covered prescription drugs:" the 25 most frequently prescribed drugs, the 25 costliest drugs, and the 25 drugs with the highest year-

[4] Purchasers who desire to receive the advance notice must register with OSHPD, and OSHPD must make available a list of registered purchasers for the purpose of this notification. § 127677(d). If a PBM elects to receive notice, SB 17 requires the PBM to notify its large contracting public and private purchasers of the price increase. § 127677(e).

over-year increase in total annual spending. § 1367.243; Cal. Ins. Code § 10123.205. These state departments are then required to compile and publish the data into a report that evaluates the overall impact of drug costs on health care premiums. § 1367.243(b), (d); Cal. Ins. Code § 10123.205(b), (d). Except for the published report, the information provided to these state departments must be kept confidential. § 1367.243(f); Cal. Ins. Code § 10123.205(f). Health care service plans and health insurers must also annually report drug coverage information. This includes, for example, the percentage of the premium attributable to drug costs, as part of the large group rate review process, for all covered prescription drugs, excluding specialty drugs. § 1385.045(c)(4)(A)-(C); Cal. Ins. Code § 10181.45(c)(4)(A)-(C). Some but not all of the information reported as part of this process must be maintained confidentially. § 1385.045(d); Cal. Ins. Code § 10181.45(d).

C. Legislative Finding and Intention

SB 17 is based on a legislative finding "that California has a substantial public interest in the price and cost of prescription drugs" as a "major purchaser" and because it provides "major tax expenditures" to support health care. § 127676(a). In enacting the law, SB 17 states that the Legislature intends "to provide accountability to the state for prescription drug pricing," while permitting "a manufacturer of a prescription drug to voluntarily make pricing decisions regarding a prescription drug, including any price increases," and allowing "purchasers, both public and private, as well as pharmacy benefit managers, to negotiate discounts and rebates consistent with existing state and federal law." § 127676(b)(1)-(2).

California is not the first state to enact a drug pricing transparency law requiring disclosure of drug pricing information. Vermont, Maryland and Nevada have already enacted different versions of such laws. RJN Exh. 1 at 0066. And manufacturers currently report drug pricing information to the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services, as a condition of their participation in the federal Medicare Part B and Medicaid programs. 42 U.S.C. § 1927(b)(3); 42 C.F.R. § 414.804(a)(5).

II. THE COMPLAINT'S ALLEGATIONS

A. Relevant Factual Allegations

The complaint's relevant factual allegations are few and relate mainly to drug pricing as drugs move through the distribution chain. The complaint alleges that manufacturers sell their drugs primarily to wholesalers at a benchmark price known as the WAC. That term is defined in 42 U.S.C. § 1395w-3a(c)(6)(B), as "the manufacturer's list price" to wholesalers or direct purchasers that excludes prompt pay or other discounts, rebates, or reductions in price that a manufacturer offers to wholesalers and direct purchasers. Compl. ¶¶ 25-27.[5] According to the complaint, a drug's WAC is a uniform price benchmark that is "already publicly available." *Id.* ¶ 26. The complaint alleges that the manufacturers calculate their discounts, rebates, or reductions that are offered to wholesalers or direct purchasers as a percentage of the WAC, and that wholesalers charge manufacturers a fee for their distribution and logistics services that are also calculated as a percentage of the WAC. *Id.* ¶ 27. A drug's actual price is a "net effective price" after application of manufacturer discounts, etc., and wholesaler fees. *Id.* ¶ 34. This net price is competitively sensitive information that is not publicly available. *Id.*

The complaint further alleges that wholesalers sell the drugs purchased from manufacturers to healthcare providers and pharmacies at prices that, while based on the WAC, are significantly lower. Compl. ¶ 28. These prices are also not publicly available. *Id.* ¶ 28. However, the complaint alleges that most patients who receive a drug from a healthcare provider or pharmacy pay an insurance premium, deductible and co-payment amount, and third-party payers, such as private health insurers or publicly funded health programs, like Medicare and Medicaid, cover the rest of the price charged by wholesaler. *Id.* ¶ 29.

The complaint alleges that, for drugs dispensed by pharmacies to Medicare and Medicaid beneficiaries, pharmacies receive reimbursement at amounts based on the WAC; for drugs dispensed by hospitals and physicians to these beneficiaries, other reimbursement protocols

[5] The statute is a part of the federal Social Security Act, as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (or Medicare Part B).

apply, some of which are based in part on the WAC. Compl. ¶ 29. Third-party payers also typically pay pharmacies or providers a price derived from the WAC. *Id.* ¶ 30.

Finally, the complaint alleges that third-party payers, like wholesalers, also typically pay amounts to drug manufacturers that are calculated as a percentage of the WAC, after negotiating discounts or rebates from manufacturers calculated as a percentage of the WAC. Compl. ¶ 30, *see* ¶ 27. For these discounts or rebates, third-party payers provide manufacturers access to, or preferred placement on, a list of drugs that the payer will reimburse, known as the payer's formulary. *Id.* According to the complaint, many third-party payers also contract with PBMs who often negotiate larger rebates from manufacturers. *Id.* ¶ 31. Many "end-customers," such as hospitals that participate in the federal 340B Program, as well as U.S. departments serving veterans, military, coast guard, public health service and Medicaid recipients negotiate even larger discounts and rebates from manufacturers. *Id.* ¶ 32.[6]

B. Claims for Relief

The complaint sets forth three claims brought under 42 U.S.C. § 1983. The first claim alleges that SB 17 directly regulates out-of-state drug prices, and imposes an excessive burden on interstate commerce, in violation of the dormant Commerce Clause. Compl. ¶¶ 86-90. The second claim alleges that SB 17 compels advance notice of price increases and reporting of related information in violation of the First Amendment. *Id.* ¶¶ 91-95. The third claim alleges that retroactive applications of SB 17 would render the law impermissibly vague in violation of the Due Process Clause of the Fourteenth Amendment. *Id.* ¶¶ 96-100. The complaint is brought

[6] To be clear, while the complaint alleges that drug prices with respect to these sales relationships are related to but lower than the WAC due to discounts or rebates, the complaint does not allege that the specified "end-customer" *public* third-party payers identified in paragraph 32, or any of the California *state* purchasers specified in section 127675(a)(1), reimburse health care providers, or receive manufacturer rebates, for drugs covered under these programs based on the WAC. With some exceptions, the two giant public third-party payers of the Medicare Part B and Medicaid programs do *not* reimburse health care providers, or receive manufacturer rebates, based on the WAC. These programs typically pay for drugs based on other price benchmarks known as reported average sales price (or ASP), and average manufacturer price (or AMP), respectively. 42 U.S.C. § 1927. These price benchmarks are defined in 42 U.S.C. § 1847A(c)(3). And California's Medicaid program covering more than 13 million beneficiaries generally reimburses health care providers based on another price benchmark, the average wholesale price (AWP), and is transitioning to yet another price benchmark, the National Average Drug Acquisition Cost (or NADAC). Cal. Welf. & Inst. Code § 14105.45.

against the Governor of California and the Director of OSHPD in their official capacities, and prays for a judicial declaration that SB 17 is unconstitutional and void and an injunction preventing defendants from implementing or enforcing the law. *Id.* ¶¶ 14, prayer.

STANDARD OF REVIEW

The legal standards applicable to motions under Rule 12(b)(1) of the Federal Rules of Civil Procedure, *see, e.g., Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994), and Rule 12(b)(6) of the Federal Rules of Civil Procedure, *see, e.g., N. Star Int'l v. Ariz. Corp. Comm'n*, 720 F.2d 578, 581 (9th Cir. 1983), are well known, and in the interest in brevity defendants do not repeat them here. However, it is worth specifying at the outset that courts disfavor facial challenges to new statutes, which is the situation here. *Wash. State Grange v Wash. State Republican Party*, 552 U.S. 442, 450-451 (2008). Consequently, plaintiff can only succeed in its facial challenge by establishing that no set of circumstances exists under which the statute would be valid, i.e., the law is unconstitutional in all of its applications. *Id.* at 449.

ARGUMENT

I. THE GOVERNOR IS IMMUNE FROM SUIT UNDER THE ELEVENTH AMENDMENT

The Governor is named as a defendant simply because "he is responsible for the execution of SB 17." Compl. ¶ 14. This is insufficient to subject the Governor to suit. States are protected by the Eleventh Amendment from suits brought by citizens in federal court. An exception exists under *Ex parte Young*, 209 U.S. 123 (1908), that allows suits against state officers in their official capacities for prospective declaratory or injunctive relief for alleged violations of federal law, but only if they have some direct connection with enforcement of the challenged act. *Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937, 943 (9th Cir. 2013) (citing *Ex parte Young*, 209 U.S. at 157). The complaint fails to allege any direct connection between the Governor and SB 17 and his general oversight of the executive branch does not suffice under *Ex parte Young*. Consequently, the Governor is immune and must be dismissed. *Ass'n des Eleveurs de Canards* at 943 (dismissing Governor on this ground).

II. THE COMPLAINT FAILS TO ALLEGE FACTS SUFFICIENT TO ESTABLISH STANDING FOR PLAINTIFF

An association has standing to bring a complaint directly on behalf of itself, or on behalf of its members. The complaint fails to allege facts sufficient to establish standing for plaintiff.

An association has standing on its own behalf if "it [shows] a drain on its resources from both a diversion of its resources and frustration of its mission." *Fair Hous. Council v. Roommate.com, LLC*, 666 F.3d 1216, 1219 (quoting *Fair Hous. of Marin v. Combs*, 285 F.3d 899, 905 (9th Cir. 2002)). However, "standing must be established independent of the lawsuit filed by the plaintiff." *Walker v. City of Lakewood*, 272 F.3d 1114, 1124 n.3 (9th Cir. 2001); *see also Combs*, 285 F.3d at 903 ("[A]n organization cannot, of course, manufacture the injury necessary to maintain a suit from its expenditure of resources on that very suit") (internal quotation marks omitted). Alternatively, an association has standing on behalf of members when its members would otherwise have standing to sue in their own right, the interests at stake are germane to the association's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members. *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000).

Plaintiff brings the complaint on behalf of itself and its members, *see* Compl. at 1, but no facts are plead to establish standing. Plaintiff has not alleged "a diversion of its resources" resulting from enactment of SB 17. Instead, all that the complaint alleges is that plaintiff serves as the pharmaceutical industry's principal public policy advocate representing members before executive agencies, legislatures and courts to foster medical innovation and educate the public. Compl. ¶ 13. These allegations are informative, but they do not establish plaintiff's standing to sue on its own behalf. Nor does the complaint allege any facts that meet the first element for associational standing, namely, that plaintiff's members are injured in their own right. Plaintiff's members who allegedly choose not to increase the WAC of products to avoid triggering SB 17's advance notice provisions do not have standing to sue in their own right. *See post* at 26.

The complaint fails to demonstrate direct or associational standing.

III. SENATE BILL 17 DOES NOT VIOLATE THE COMMERCE CLAUSE

To determine whether a state statute violates the dormant Commerce Clause, courts take a two-tiered approach. *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 579 (1986); *Pharma Research & Mfrs. of Am. v. County of Alameda*, 768 F.3d 1037, 1039 (9th Cir. 2014). 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*, 476 U.S. at 579. Second, when a statute does not discriminate against interstate commerce but "regulates even-handedly" and only incidentally affects interstate commerce, the court conducts the balancing test articulated in *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970). Under this balancing test, courts look to "whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits." *Brown-Forman*, 476 U.S. at 579. The dormant Commerce Clause is concerned about state economic protectionism designed to benefit in-state economic interests by burdening out-of-state competitors. *Pharma Research & Mfrs. of Am.*, 768 F.3d at 1041 (citing *Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 337-338 (2008)).

Plaintiff claims that SB 17 does not survive under the first tier of the test because the law directly regulates out-of-state commerce, and excessively burdens interstate commerce under the second tier of the test. However, the dormant Commerce Clause is not violated under either theory of liability here. In the absence of adequate allegations, it is appropriate to dismiss both claims on the pleadings. *See, e.g.*, *Chinatown Neighborhood Ass'n v. Harris*, 794 F.3d 1136, 1147 (9th Cir. 2015); *Sam Francis Foundation v. Christie's Inc.*, 784 F.3d 1320, 1322-1323 (9th Cir. 2015)

A. Senate Bill 17 Does Not Directly Regulate Interstate Commerce

1. Authorities Addressing Direct Regulation of Interstate Commerce

Three United States Supreme Court decisions illustrate dormant Commerce Clause doctrine based on direct regulation of interstate commerce: *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935), *Brown-Forman*, 476 U.S. 573 (1986), and *Healy v. Beer Inst., Inc.*, 491 U.S. 324 (1989).

In *Baldwin*, the United States Supreme Court struck down a New York law that prohibited out-of-state companies from selling milk in the state unless they purchased their milk from dairy farmers at the same price paid to New York dairy farmers. The Court explained that the law impermissibly established "a wage scale or a scale of prices for use in other states" and would "bar the sale of the products . . . unless the scale has been observed." 294 U.S. at 528.

In *Brown-Forman*, the Court struck down a provision of the New York Alcoholic Beverage Control Law that required liquor distillers or producers selling to wholesalers within the state to affirm that their prices for products sold to in-state wholesalers were no higher than the lowest price at which the same product was sold in any other state during the current month. *Brown-Forman*, 476 U.S. at 575. The Court found that, although the statute was addressed only to the sale of liquor in New York, it had the impermissible "practical effect" of controlling liquor prices in other states because the distiller was not free to change its prices elsewhere in the United States during the relevant month. *Id.* at 582-583.

Similarly, in *Healy*, the Court struck down the Connecticut Liquor Control Act, which required out-of-state beer shippers to affirm that the prices of their products sold to Connecticut wholesalers were no higher than the prices of those same products sold in bordering states. The Court reasoned that the statute tied pricing decisions to the regulatory schemes of these bordering states, thus preventing brewers from undertaking competitive pricing in other states. *Healy*, 491 U.S. at 338-39. The Court stated that a state law may not "directly control[] commerce occurring wholly outside the boundaries of a State," either by its terms or in "practical effect." *Id*. at 336.

The United States Supreme Court has limited the extraterritoriality principle enunciated in *Baldwin*, *Brown-Foreman*, and *Healy* to price-control or price-affirmation statutes which link prices paid in-state with those that are paid out-of-state. In *Pharm. Research & Mfrs. of Am. v. Walsh*, nonresident drug manufacturers challenged a Maine statute that required certain manufacturers selling drugs in Maine to enter into a rebate agreement with the Maine State Commissioner, or else meet a set of prior authorization requirements to dispense drugs in the state, that reduced a company's sales and market share in Maine. 538 U.S. 644, 653-654, 655-656 (2003). The *Walsh* plaintiff argued that "with the exception of sales to two resident

distributors, all of their prescription drug sales occur outside of Maine," so the act must be an impermissible extraterritorial regulation. *Id.* at 656. The United States Supreme Court disagreed, explaining that the rule articulated in *Baldwin and Healy* "is not applicable to this case" because the Maine Act is not a price-control or price-affirmation statute either by its express terms or by its inevitable effect, does not regulate prices of any out-of-state transaction, and does not tie in-state prices to out-of-state ones. *Id*. at 669. *See Ass'n des Eleveurs de Canards*, 729 F.3d at 951 ("*Healy* and *Baldwin* involved 'price control or price affirmation statutes'" and are inapplicable to a statute "that does not dictate the price of a product and does not 't[ie] the price of its in-state products to out-of-state prices'"); *Energy & Env't Legal Inst. v. Epel*, 793 F.3d 1169, 1175 (10th Cir. 2015) (extending *Baldwin* doctrine to become a "weapon far more powerful than" established dormant Commerce Clause jurisprudence would be "novel lawmaking project").

2. Application to Senate Bill 17

Plaintiff's dormant Commerce Clause claim alleges that SB 17's requirement that manufacturers provide advance notice of implementation of a threshold price increase directly regulates out-of-state drug prices. Compl. ¶¶ 54-57. However, SB 17 on its face does not set or regulate drug prices of any in-state or out-of-state drug transactions, and does not tie in-state California prices to out-of-state prices. Drug manufacturers remain as free after the enactment of SB 17 as before, to set their prices at whatever level they choose, and to change prices as often as they see fit. SB 17 only requires 60-days advance notice of implementation of a price increase of a drug that is purchased or reimbursed by California purchasers. § 127677(a). Even if this were not clear from the bill's text, SB 17 states explicitly the Legislature's intent "to permit a manufacturer of a prescription drug to voluntarily make pricing decisions regarding a prescription drug, including any price increases," and "to permit purchasers, both public and private, as well as [PBMs], to negotiate discounts and rebates consistent with existing state and federal law." § 127676(b)(1)-(2).

Nor does SB 17 inevitably or practically impose a "60-day nationwide ban on price increases" following advance notice of a threshold price increase to California purchasers "because the WAC is the list price in every state" as is alleged in the Complaint. Compl. ¶¶ 56-

57. There is no 60-day ban. A manufacturer is free to continue to voluntarily implement pricing decisions in all states within 60 days after having provided advance notice to California purchasers. If a manufacturer implements another threshold pricing decision within 60-days of having notified California purchasers of a threshold price increase, all SB 17 requires is that it again notify California purchasers. *See Ass'n des Eleveurs de Canards*, 729 F.3d at 950-951 (at preliminary injunction stage, plaintiffs failed to show that statute's effect was a complete import and sales ban on foie gras).

Further, a state statute is not extraterritorial in effect because it may affect business decisions made out-of-state or have out-of-state consequences. Compl. ¶¶ 58-59 (alleging law's requirement that manufacturers explain a price increase burdens nationwide pricing and discourages them from increasing national price), ¶ 60 (alleging that law's extraterritorial reach is exacerbated by requirement that PBMs share advance notice with large contracting purchasers while failing to prohibit PBMs from sharing advance notice with their own retail pharmacies). In *Rocky Mt. Farmers Union v. Corey*, 730 F.3d 1070 (9th Cir. 2012), the court rejected an extraterritoriality challenge to California's Low Carbon Fuel Standard, which limited the average carbon-intensity of fuel sold for use within the state. *Id*. at 1101-1106. The court recognized that California's standard might lead some fuel producers, including some out-of-state producers, to make different business decisions in order to obtain price premiums or increase their competitiveness in California's market. *Id*. at 1101. The court found these indirect effects permissible because California's standard, unlike the law in *Healy*, controlled only its own market. *Id*. at 1102-1103.

Similarly, in *Walsh*, the plaintiff submitted affidavits on actual and potential out-of-state impacts of a new state law requiring manufacturers selling drugs in Maine to enter into a rebate agreement, including the law's effect on pricing decisions. 538 U.S. at 656-657. *Walsh* held that the Maine law did not impermissibly dictate the terms of any out-of-state transaction either directly or by "its inevitable effect." *Id*. at 669; *accord Ass'n for Accessible Meds. v. Frosh*, 2017 U.S. Dist. LEXIS 161168, at *14 (D. Md. September 29, 2017), *appeal docketed* No. 17-2166 (Maryland law prohibiting drug manufacturers and others from engaging in price-gouging in the

sale of drugs in Maryland did not tie the price charged on the sales of in-state drugs with the price charged on the sales of out-of-state drugs).

Another challenge based on purported extraterritorial effects was rejected in *Ass'n des Eleveurs de Canards*, challenging California's prohibition on in-state sale of products made by force-feeding birds, on grounds that it banned sales nationwide. 729 F.3d at 949-951. The court recognized that the statute did not have the practical effects held unlawful in *Healy* because the statute did not set prices or tie prices to those charged elsewhere, and did not require out-of-state producers to change production methods for products sold in other states. *Id.*

Additionally, a law is not impermissibly extraterritorial because a person covered by a California purchaser may purchase or receive a drug out-of-state by virtue of their health care plan or program that provides, arranges, pays for, or reimburses for the cost of prescribed drugs. Comp. ¶ 60 (alleging the law requires advance notice to be given to each California purchaser "regardless of where the transaction actually occurs"). If this were the case, every California statute regulating a California managed, licensed or certified health care program, plan or insurer, (potentially providing healthcare to tens of millions of residents) would be impermissibly extraterritorial because a covered person sought health care while out-of-state. SB 17 only applies to manufacturers of a prescription drug purchased or reimbursed by specified California purchasers, § 127675(a), and attaches no restrictions that wholly control out-of-state commerce. *Healy* at 336. Where a patient happens to fill a drug prescription is not relevant.

For these reasons, SB 17 does not directly regulate interstate commerce.

B. Senate Bill 17 Does Not Excessively Burden Interstate Commerce

1. The *Pike* Balancing Test

When a statute "regulates even-handedly" and only incidentally affects interstate commerce, the analysis enunciated in *Pike*, 397 U.S. 137 (1970) applies. Under *Pike*, a statute will be upheld unless the burden imposed on interstate commerce "is clearly excessive" in relation to the putative local benefits. 397 U.S. at 142. If a legitimate local purpose is found, the question becomes the degree of any burden and the existence of ready alternatives. *Id.* A substantial burden on commerce will be tolerated depending on the nature of the local interest

involved, and on whether it could be promoted with a lesser impact on interstate activities. *Id.* A plaintiff must show a substantial burden before the court will determine whether local benefits of a law are illusory. *Pharma Research & Mfrs. of Am.*, 768 F.3d at at 1044. The analysis "turn[s] on the interstate flow of goods." *Id.* at 1044-1045.

In *General Motors Corp. v. Tracy*, the United States Supreme Court recognized that a number of its cases purporting to apply the *Pike* balancing test turned on the discriminatory character of the challenged regulations. 519 U.S. 278, 298 n.12 (1997). Only a small number of cases invalidating laws under the dormant Commerce Clause involved laws that were "genuinely nondiscriminatory, in the sense that they did not impose disparate treatment on similarly situated in-state and out-of-state interests." *Id.*

2. Application to Senate Bill 17

The complaint does not allege that SB 17 is discriminatory. Most statutes that impose substantial burden do so because they are discriminatory. *Ass'n des Eleveurs de Canards*, 729 F.3d at 952. Instead, the complaint alleges SB 17 burdens interstate commerce because: (1) "drug list prices and supply chains" have an "inherently national character," Compl. ¶ 62; (2) the 60-day advance notice "promot[es] price stabilization and *potentially* reduces competition," *id.* ¶ 63 (italics added); and (3) the 60-day advance notice distorts the drug market "by incentivizing prescription-drug arbitrage," or stockpiling, causing "*potential* product shortages" and competitive disadvantage to those entities without advance notice of a price increase, *id.* ¶¶ 64-66 (italics added). *Cf. id.* ¶ 39 (alleging SB 17 allows "competitive advantage" to PBMs' large purchasers and their retail pharmacies to whom advance notice of a price increase must be distributed). None of these theories support a cognizable claim that SB 17 excessively burdens interstate commerce.

First, the claimed inherently national character of "drug list prices and supply chains" is an insufficient allegation of excessive burden. The complaint fails to allege any practical burdens on the drug market. Further, statutes that typically impose burdens due to their market's "inherently national character" due so "as a consequence of 'inconsistent regulation of activities that are inherently national or require a uniform system of regulation,'" and fall into cross-border

categories such as transportation or professional sports leagues. *Ass'n des Eleveurs de Canards*, 729 F.3d at 952. The complaint also fails to allege that inconsistent legislation that impedes the flow of interstate goods is already in place, or there is actual or imminent threat of such legislation. *Rocky Mt. Farmers Union*, 730 F.3d t 1104-1105; *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 128 (1978) (declining to accept Exxons "novel suggestion" "that because the economic market for petroleum products is nationwide, no State has the power to regulate the retail marketing of gas").

Next, plaintiff's allegations regarding potential price stabilization, stockpiling and competitive advantages and disadvantages are generalized, conclusory and speculative. Moreover, the complaint acknowledges that these behaviors are already happening in the drug market. The complaint generally describes a market wherein manufacturers currently set prices and then control the flow of drugs through a distribution system with discounts and rebates that allow purchasers to purchase and stockpile discounted or rebated drugs and stabilize their prices, with large purchasers enjoying a competitive advantage compared to others. *See* Compl ¶¶ 25-34. According to the complaint, a drug's WAC is solely set by a manufacturer and becomes publicly available to all competitors at the time of manufacturer implementation. *Id.* ¶ 26. The drug market allows purchasers to negotiate discounts or rebates from manufacturers, and allows PBMs to negotiate larger discounts or rebates. *Id.* ¶¶ 30-31. And the market allows other "end-customers," including government purchasers such as a state participating in the Medicaid program, to negotiate even larger discounts or rebates from manufacturers. *Id.* ¶ 32.

SB 17 does not the disrupt the flow of goods in this system. SB 17 only makes the public price available to purchasers 60 days prior to price implementation to allow purchasers to *proactively* evaluate the actions they may (or may not) take in response to such a price increase, actions that may or may not be the same action they would have taken without that knowledge. If this results in drug purchases at the pre-implementation price during the 60-day period, either because purchasers choose to buy large quantities of a drug whose price will soon increase, or because they switch to other products from that manufacturer or a competitor's comparable product to offset price increases, this market response is no different than the market behaviors

alleged to exist in the market currently. Simply put, SB's 17 implementation of advance notice to purchasers has no extraterritorial reach; manufacturers continue to be able to sell drugs in California at whatever price they choose. The only difference is that purchasers are allowed to make a proactive business decision instead of a reactive one. The dormant Commerce Clause allows this. *Nat' Ass'n of Optometrists & Opticians v. Harris*, 682 F.3d 1144, 1149-1151 (9th Cir. 2012) (state law adjusting structure or method of operation in retail market not protected by Commerce Clause).

Finally, SB 17's local benefits clearly exceed any purported burden. Where a challenged law is not discriminatory on its face and does not impose a significant burden on interstate commerce, a court does not assess the benefits of the laws or the state's wisdom in adopting them. *Nat'l As''n of Optometrists & Opticians*, 682 F.3d at 1156; *see CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 92 (1987) (noting that the United States Supreme Court is not inclined to second-guess empirical judgments of lawmakers concerning the utility of legislation); *Alaska Airlines, Inc. v. City of Long Beach*, 951 F.2d 977, 983, 984 (9th Cir. 1991) (holding that it was inappropriate for district court to make quasi-legislative judgment by weighing community concerns about noise against the need for safe and efficient national transportation system). Nevertheless, the legislative history for SB 17 articulates a substantial interest for California purchasers in the price and cost of drugs and because California provides tax incentives that support health care for its residents. § 127676(a). States have a legitimate interest in the protection of consumers in retail markets within their borders. *See Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 144, 146 (1963). SB 17 advances that interest by requiring drug manufacturers to disclose drug pricing information and allowing California purchasers a 60-day window to consider impending price increases.

IV. SENATE BILL 17 DOES NOT VIOLATE THE FIRST AMENDMENT

The complaint fails to sufficiently allege a free speech violation under the First Amendment. The claimed violation is framed as one of compelled speech. According to the complaint, SB 17: (1) singles out manufacturers and compels them, but not others in the supply chain, to disclose prices, Compl. ¶¶ 68, 70, 75; (2) forces manufacturers to speak about drug

prices at a particular time (60-days before a price increase), to a particular audience (California purchasers), with a specified disparaging message (that a drug price increase is planned that may not be justified by a change or improvement in the drug), *id.* ¶¶ 71, 76; *see also* ¶ 24; and (3) compels manufacturers to endorse California's message that drug prices should be lower and increases in drug prices that are not tied to a change or improvement in the drug are the cause of higher prescription drug costs. *Id.* ¶¶ 72-73, 75, 77.

None of these allegations amount to a cognizable constitutional claim. First, the complaint fails to allege any infringement on speech. SB 17 regulates conduct, not speech, and is therefore subject to rational basis review, which is easily satisfied. Second, even if SB 17 regulates speech, it easily survives First Amendment scrutiny as a permissible regulation of commercial speech because it has a rational basis. However, even under heightened scrutiny, which does not apply, the law survives because the governmental interests advanced by the law are significant and the required disclosures are no more than necessary to convey the required factual information.

A. SB 17 Regulates Conduct, Not Speech, and is Therefore Subject to Rational Basis Review

SB 17 regulates conduct. Nothing in SB 17 restricts or restrains manufacturers from communicating or contextualizing pricing information about the sale of drugs to anyone. *44 Liquormart v. R.I.*, 517 U.S. 484, 507, 530 (1996) (plurality opinion) (in striking down ban on liquor price advertising, majority of Justices indicated that price regulations and other forms of economic regulation do not implicate speech so long as they do not preclude retailer from providing truthful, nonmisleading information about the regulated product to consumers); *National Ass'n of Tobacco Outlets, Inc. v. City of Providence, Rhode Island*, 731 F.3d 71, 77 (1st Cir. 2013) (ordinance preventing tobacco retailers from selling products at discount regulates pricing, not speech, because it does not restrict dissemination of pricing information); *Meese v. Keene*, 481 U.S. 465, 480-481(1987) (requirement that films be labeled "political propaganda" that does not restrict, restrain, or edit films does not implicate speech).

Rather, SB 17's objectives are more limited, requiring manufacturers to provide advance notice of a price increase and to also report factual information about the increase. While the

notice must be in writing, and the related reporting may also involve writing, these requirements are only incidental to the price increase, and do not give rise to heightened protection under the First Amendment. "It has never been an abridgment of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *Rumsfeld v. Forum for Academic and Institutional Rights, Inc.*, 547 U.S. 47, 62 (2006) (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949) (federal law requiring law schools to assist military recruiters in holding on-campus events regulated conduct, not speech).

As a conduct regulation, SB 17 must be upheld if it bears a rational relationship to some legitimate state interest. *See, e.g., Heller v. Doe by Doe*, 509 U.S. 312, 320 (1993); *Classic Dairies v. Milk Control Bureau*, 847 F.2d 593, 596 (9th Cir. 1988) (state milk pricing laws regulating milk industry satisfy rational basis test); *FPC v. Hope Natural Gas Co.*, 320 U.S. 591, 610-612 (1944) (primary aim of Natural Gas Act to protect consumers against exploitation at hands of natural gas companies); *Pennell v. San Jose*, 485 U.S. 1, 13 (1988) (primary aim of rent control is protection of tenants). Plaintiff faces an insurmountable burden in attempting to show a lack of a valid ground for this legislation. "We do not require that the government's action actually advance its stated purposes, but merely look to see whether the government could have had a legitimate reason for acting as it did." *Dittman v. California*, 191 F.3d 1020, 1031 (9th Cir. 1999) (quoting *Halverson v. Skagit County*, 42 F.3d 1257, 1262 (9th Cir.1995) (substantive due process challenge)).

SB 17 more than meets that test, considering its demonstrable relationship to consumer protection and public welfare by way of enabling better awareness of drug pricing information. Its legislative history indicates that specialty drugs experienced steep price increases, but drugs that had been on the market for many years also saw inexplicable increases. RJN Exh. 1 at 0005-0006. Drug costs increased by 12.4 percent in 2014, and nine percent in 2015 to $324.6 billion, and outpaced all other health services in 2015, and drug spending was projected to grow an

average of 6.7% per year for 2016 through 2025. *Id.* at 0005.[7] SB 17 provides accountability for drug prices to purchasers and consumers. SB 17 thus "gives purchasers, both public and private, time to adjust formularies, to negotiate price concessions, and to seek other alternatives, including alternative formulations of drugs for which there are therapeutic equivalents." *Id.* at 0008.

B. Even if Senate Bill 17's Requirements Are Considered Speech, the Law Passes Constitutional Muster Because it is a Valid Commercial Speech Regulation

Although SB 17 requires notification of only conduct and does not regulate speech, the complaint goes much further, alleging that the law regulates speech by discriminating against manufacturers as disfavored speakers, by compelling them to disclose price information that they do not want to disclose, and by forcing disclosures that, as plaintiff alleges, amount to an endorsement of California's view on drug prices. Compl. ¶¶ 70, 72, 74-77. However, even if SB 17 regulates speech, it withstands the review applicable to commercial regulations.

The First Amendment "includes both the right to speak freely and the right to refrain from speaking at all." *Wooley v. Maynard*, 430 US 705, 714 (1977). In some instances, a law compelling speech that a speaker would not otherwise make may be subject to strict scrutiny. *Riley v. Nat'l Fed'n of Blind*, 487 U.S. 781, 798 (1988). However, when a state regulates commercial messages simply to require disclosure of beneficial consumer information, the

[7] Further indicated in the legislative history are references to conclusions of recent federal investigations of rising drug prices. Congress had investigated a number of notable drug price increases -- from Sovaldi to Epipens and insulin -- detailing how many price increases had little relation to improvements in the effectiveness of the drug or the cost of research and development. RJN Exh. 1 at 0008. SB 17 followed on the heels of a bipartisan Congessional Special Report, S. Report 114-429, filed December 2016, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model That Harms Patients, Taxpayers, and the U.S. Health System*, documenting sudden price increases taken by four manufacturers with respect to drugs for which there was only one manufacturer, *id.* Exh. 2 at 4-6, and recommending "improve[d] transparency" in drug prices. *Id.* at 10, 123-124. A government report issued by the Government Accountability Office in August 2016, *Generic Drugs Under Medicare*, also studied 1,441 established generic drugs and found that, during the period from 2010 to 2015, manufacturers imposed at least one extraordinary price increase of more than 100 percent within a one-year period for 315 of those drugs. *Id.* Exh. 3 at 12, 45. Moreover, out of the 315 extraordinary price increases, 48 were 500 percent or higher and 15 were 1,000 percent or higher. *Id.* at 14.

purpose of its regulation is consistent with the reasons for according constitutional protection to commercial speech and therefore justifies less than strict review. *44 Liquormart*, 517 U.S. at 501-502.

Commercial speech is an "expression related solely to the economic interests of the speaker and its audience," or alternatively, speech "proposing a commercial transaction." *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N. Y.*, 447 U.S. 557, 560 (1980). Although the United State Supreme Court has recognized that this definition is not precise, and it is often difficult to distinguish between commercial and noncommercial speech, if the disclosures required by SB 17 implicate any kind of speech, it is commercial speech. *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 419 (1993). And because the disclosures concern commercial speech, if they concern speech at all, a lower level of constitutional review applies. Compelled commercial speech of "purely factual and uncontroversial information" is subject to a level of scrutiny resembling rational basis review *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 650-651 (1985); *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229 (2010) (noting that "required disclosures [regarding debt relief assistance] are intended to combat the problem of inherently misleading commercial advertisements").

"Laws requiring a commercial speaker to make purely factual disclosures relating to its business affairs, whether to prevent deception or simply to promote informational transparency, have a purpose consistent with the reasons for according constitutional protection to commercial speech." *Beeman v. Anthem Prescription Management, LLC*, 58 Cal.4th 329, 356 (2013). One circuit court has explained that the "[m]andated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests. Such disclosure furthers, rather than hinders, the First Amendment goal of the discovery of truth and contributes to the efficiency of the 'marketplace of ideas.'" *Nat'l Elec. Manufacturers Assn. v. Sorrell*, 272 F.3d 104, 113-114 (2d Cir. 2011). Indeed, that court took note of "the potentially wide-ranging implications" of a First Amendment claim like the one here, as "[i]nnumerable federal and state regulatory programs require the disclosure of product and other commercial information," ranging from securities

disclosures and disclosures in prescription drug advertisements to tobacco and nutritional labeling and California's Proposition 65." *Nat'l Elec*. at 116. Here, the disclosures required by SB 17 are purely factual and incontrovertible commercial information.

Further, SB 17 on its face does not regulate any expressive activity as in *Riley*, 487 U.S. at 795. SB 17 applies evenhandedly to all drug manufacturers and does not prefer or exclude some manufacturers. *Cf. Sorrell v. IMS Health Inc.*, 564 U.S. 552, 563-564 (2011) (state law prohibiting drug manufacturers and distributors from acquiring prescription-identifying information while allowing others to acquire the information implicated protected speech). The law's requirement that manufacturers disclose whether a change or improvement in a drug necessitates the price increase allows manufacturers to answer, apply to their responses whatever contextualization they feel necessary, and does not express a preference for a particular response. § 127677(c)(2). And if a price increase is not necessitated by any change or improvement in a drug, a manufacturer may offer any explanation it chooses when it reports to OSHPD. § 127679(a)(1). The Legislature's statement of purpose evidences this neutrality. § 127676(b)(1)-(2)).

The disclosures are also akin to other commercial disclosures of fact upheld by the courts. These include, for example, calorie-content information posted on menus, *see New York State Rest. Ass'n v. New York City Bd. of Health*, 556 F.3d 114, 131-136 (2d Cir. 2009); disclosures related to products containing mercury, *see Nat'l Elec.*, 272 F.3d at 104, 113-114; financial disclosure requirements designed to protect against questionable business practices, *see Pharmaceutical Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 316 (1st Cir.2005); the disclosure of country-of-origin information about meat products, *see Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 20 (D.C. Cir. 2014); government-compelled disclosures by a Website operator regarding potential criminal liability if patrons use the site to evade taxes, *see United States v. Schiff*, 379 F.3d 621, 630–631 (9th Cir. 2004); and disclosure on attorney advertisements of contingency-fee-based representation, *see Zauderer*, 471 U.S. at 626.

For these reasons, even if SB 17's requirements are considered compelled speech, the relevant disclosures are a valid regulation of commercial speech.

C. Senate Bill 17 Survives Review Under Any Level of Scrutiny

If they are considered speech, the advance notice and reporting disclosures required by SB 17 are subjected to rational basis review because they are a valid regulation of commercial speech, but they would survive review under any level of scrutiny. As indicated, the disclosures reasonably relate to California's interests in accountability and protecting consumers. *Zauderer*, 471 U.S. at 651; § 127676(b)(1)-(2). These are important interests, and courts have recognized as much. *Ante* at 20-21; *see also Commc'ns Telesystems Int' v. California Pub. Util. Comm'n*, 196 F.3d 1011, 1017 (9th Cir. 1999) (state has important interest in "the protection of consumers from unfair business practices, the compensation of those consumers for harm, and the need to ensure fair competition"); *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 460 (1978) (states have a particularly strong "interest in protecting consumers and regulating commercial transactions").

The disclosures would also survive review under any level of scrutiny as they are narrowly tailored to serve a significant governmental interest. *Ward v. Rock Against Racism*, 491 U.S. 781, 796 (1989). Narrow tailoring in the commercial speech context is satisfied so long as the regulation promotes a substantial government interest that would be achieved less effectively absent the regulation. *Id.* at 799. California's interests are even more compelling when viewed in light of the legislative history's account of the dramatic rise in drug prices in recent years and the impact attributed to those prices on patient care. As the legislative history documents, many consumers, particularly low-income consumers, are having a hard time affording their co-pays and other drug costs, and as a result many people are forced to skip prescriptions, cut pills in half, or go without necessary care as a result of higher and higher drug costs. RJN Exh. 1 at 0009. A study cited in the legislative history, published in August 2016 in the Journal of American Medical Association, also reports that almost a quarter of 648 respondents to a 2015 poll report that they or another family member did not fill a prescription in the last year because of cost, *id.* at 0064, and the Congressional Special Report discussed *ante* identifies significant harms to patients and their families due to sudden drug price increases. *Id.* Exh. 2 at 1, 7-8, 98.

SB 17 is narrowly tailored. As the Legislature and SB 17's author recognized, drug pricing transparency is a critical step to informing and allowing purchasers to develop responses to price increases.

V. SENATE BILL 17 IS NOT VAGUE

The complaint bases its entire claim that SB 17 is vague on a failure to include "an effective date" for the 60-day notice provision, which (1) potentially allows price increases before January 1, 2018, to trigger the 60-day notice provision in effect on that date, and (2) potentially requires 60-day notice for a price increase in January 2018, even though 60-day notice would not be possible before the law's effective date. Compl. ¶¶ 11, 42-43, 84. The complaint alleges that OSHPD failed to respond to plaintiff's letters requesting clarification on these points. *Id.* ¶¶ 11, 48-51, 84, 100. And the complaint alleges that uncertainty as to these retroactive applications will cause harm to many of plaintiff's members whose prices have increased since January 1, 2016, and who will not increase the WAC to avoid the risk of past increases triggering notice, and potentially triggering enforcement. *Id.* ¶¶ 11, 85, 100. No other provision of SB 17 outside of the 60-day provision is challenged on vagueness.

The vagueness claim is not ripe and plaintiff lacks standing to advance a claim that is neither concrete nor particularized. It also fails for lack of a protected liberty or property interest. And speculation about retroactive applications does not render the law unconstitutionally vague. A challenge on vagueness is upheld only if the enactment is impermissibly vague in all of its applications, or specifies "no standard of conduct . . . at all." *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 494-495, 489 n. 7 (1982); *Boutilier v. Immigration and Naturalization Service*, 387 U.S. 118, 121 (1967) (statute must be "so vague and indefinite as really to be no rule or standard at all").

Moreover, OSPHD, who is tasked with promulgating regulations to implement the law, cannot meet plaintiff's demands for pre-regulatory clarification of the law's reach. California law prohibits an administrative agency from providing any pre-regulatory guidance regarding the application of the law in advance of enactment of regulations. Cal. Gov't Code § 11340.5(a). OSPHD plans to enact regulations by January 2019, but it has not done so yet. RJN Exh. 4. And

even if OSHPD could provide pre-regulatory guidance, while that guidance is entitled to deference by a court, the guidance would not be conclusive of a new law's applications. Final responsibility for interpretation of a state law always rests with courts. *Diablo Valley Coll. Faculty Senate v. Contra Costa Cmty. College Dist.*, 148 Cal. App. 4th 1023, 1037 (2007).

A. The Complaint Fails to Plead a Ripe Claim

Article III of the United States Constitution requires that an actual controversy exist at all phases of the litigation. *Protectmarriage.com-Yes on 8 v. Brown*, 752 F.3d 827, 834 (9th Cir. 2014). Federal courts confine themselves to actual cases and controversies. *See* U.S. Const. art III, § 2, cl. 1; *Gator.com Corp. v. L.L. Bean, Inc.*, 398 F.3d 1125, 1128 (9th Cir. 2005). Where an injury allegation is conjectural or hypothetical, concepts of standing and ripeness overlap and both provide grounds for dismissing a complaint. *Wolfson v. Brammer*, 616 F.3d 1045, 1058 (9th Cir. 2010); *Texas v. United States*, 523 U.S. 296, 300 (1998).

Here, the complaint fails to allege facts demonstrating a ripe vagueness claim. The mere allegation of potential for retroactive applications is too speculative, and it is contingent on a number of events that have yet to pass, namely enforcement of the law retroactively. If such allegations were sufficient, virtually every new law could be subject to a vagueness challenge. Similarly, the bare allegation that many manufacturers will not increase prices after January 1, 2018, to avoid having to comply with the law, *see* Compl. ¶¶ 11, 85, 100, is insufficient to establish standing to pursue a ripe claim. *See Humanitarian Law Project v. U.S. Treasury Dep't*, 578 F.3d 1133, 1143 (9th Cir. 2009) (rejecting argument that "self-censorship suffices for injury-in-fact"); *United States v. Stephens*, 206 F.3d 914, 917 (9th Cir.2000) (defendant who voluntarily abandons property has no standing to contest its search and seizure).

B. The Complaint Fails to Plead Deprivation of a Liberty or Property Interest Protected by Due Process

The vagueness claim also fails because it does allege deprivation of a protected liberty or property interest. A threshold requirement of a vagueness challenge under the Due Process Clause is the showing of a protected liberty or property interest protected by the Fourteenth Amendment. *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 569 (1972); *Wedges/Ledges*,

Inc. v. City of Phoenix, Ariz., 24 F.3d 56, 62 (9th Cir. 1994). A vagueness claim that lacks such an interest fails. *Stone v. Univ. of Md. Med Sys. Corp.*, 855 F.2d 167, 172 (4th Cir. 1988) (citing *Roth*, 408 U.S. at 577); *Int'l Church of the Foursquare Gospel v. City of San Leandro*, 632 F. Supp. 2d 925, 955 (N.D. Cal. 2001).

Liberty interests protected by due process "include most of the rights enumerated in the Bill of Rights . . . [and] extend to certain personal choices central to individual dignity and autonomy, including intimate choices that define personal identity and beliefs." *Obergefell v. Hodges*, __ U.S. __, 135 S.Ct. 2584, 2598 (2015). "Only those aspects of liberty that we as a society traditionally have protected as fundamental are included within the substantive protection of the Due Process Clause." *Mullins v. State of Or.*, 57 F.3d 789, 793 (9th Cir. 1995). To have a property interest protected by due process, a person must have a legitimate claim of entitlement to a particular government benefit. *Gerhart v. Lake County*, 637 F.3d 1013, 1019 (9th Cir. 2011) (citing *Roth*, 408 U.S. at 577). Such property rights are not created by the federal Constitution, but must arise from an independent source, "such as state law -- or understandings that secure certain benefits and support entitlements to those benefits." *Id.; Roth*, 408 U.S. at 577. A legitimate claim of entitlement is determined when a statute's language couches an entitlement in mandatory terms. *Johnson v. Rancho Santiago Cmty Coll. Dist.*, 623 F.3d 1011,1030 (9th Cir. 2010).

Here, the disclosures required by SB 17 do not concern a personal choice that is central to human dignity and autonomy. Nor does the law support generalized business interests creating a property interest entitled to constitutional protection. Business interests are not legally protected property interests unless they have "the law back of [it]." *Kaiser Eetna v. United States*, 444 U.S. 164, 178 (1979). In *College Savings Bank v. Florida Prepaid*, 527 U.S. 666 (1999), plaintiff claimed a right to be free from a business competitor's false advertising and a generalized right to be secure in one's business interests. The United States Supreme Court held that neither business interest qualified as a property interest protected by due process. *Id*. at 672. Relying on *Kaiser Eetna v. United States*, the Court held that the hallmark of a protected property interest is the right to exclude others from using property. *Id*. at 673. The provisions of federal false-advertising law

bore no relationship to any right upon which plaintiff had exclusive domain. *Id*. Similarly, here, any business preference or advantage of a manufacturer is not a cognizable property interest.

C. Retroactive Applications of Law Are Governed by Rules of Statutory Interpretation

Finally, as explained *ante*, retroactive applications of SB 17 cannot render the law unconstitutionally vague unless it is impermissibly vague in all of its applications, or it specifies no standard of conduct. *Village of Hoffman Estates*, 455 U.S. at 494-495, 498 n.7; *Boutilier*, 387 U.S. at 121. SB 17 does not reach constitutionally protected conduct, and the conduct it does reach is adequately specified. Whether SB 17 has retroactive applications is governed by well-established rules of statutory interpretation. These rules consider whether a statute operates to increase a party's liability for past conduct and then whether the Legislature intended that the statute govern past conduct determined by the statute's language and legislative intent. *Myers v. Philip Morris Companies, Inc.*, 28 Cal. 4th 828, 839-841 (2002) (citing *Landgraf v. USI Film Products*, 511 U.S. 244, 265, 269 (1994); *Evangelatos v. Superior Court*, 44 Cal. 3d 1188, 1206 (1988). If a statute is ambiguous with respect to retroactive applications, it is construed to be unambiguously prospective. *Id.* at 841 (citing *I.N.S. v. Sy. Cyr*, 533 U.S. 289, 320 (2001)). Drug manufacturers are able to assess these legal rules and adjust their behavior.

CONCLUSION

For all of the foregoing reasons, defendants respectfully request that the Court grant their motion to dismiss without leave to amend.

Dated: January 26, 2018

Respectfully Submitted,

XAVIER BECERRA
Attorney General of California
ANTHONY R. HAKL
Supervising Deputy Attorney General

/s/ S. Michele Inan
S. MICHELE INAN
Deputy Attorney General
Attorneys for Defendants

SA2017109671