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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

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

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

Defendants.

Case No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA"), on behalf of itself and its members, for its Complaint against Edmund Gerald Brown, Jr., in his official capacity as Governor of the State of California (the "State"), and Robert P. David, in his official capacity as Director of the California Office of Statewide Health Planning and Development (together, "Defendants"), alleges as follows:

INTRODUCTION

1. In this action, PhRMA seeks to block an unprecedented and unconstitutional California law, Senate Bill No. 17 ("SB 17" or the "Act," attached as Exhibit A). The new law imposes nationwide restrictions on the list price of pharmaceutical manufacturers' products. It penalizes manufacturers for conduct that occurs exclusively outside California. And it intentionally exports California's policy choices regarding prescription drug pricing on the entire nation.

2. In addition to this interference with interstate commerce, the Act imposes improper—and unconstitutional—burdens on pharmaceutical manufacturers. It requires them to publicly convey and implicitly endorse the State's position that the manufacturers are to blame for the allegedly inflated prices of prescription drugs. And it incorrectly and unfairly singles them out for public condemnation.

3. SB 17 provides that, if a manufacturer has increased a qualifying product's wholesale acquisition cost ("WAC"), a federally defined list price, by 16 percent or more cumulatively over the prior two to three calendar years, including the proposed increase, then that company may not increase its WAC list price unless it first provides registered purchasers and State purchasers with 60 days' advance notice. That means the manufacturer cannot increase its WAC list price for qualifying drugs *anywhere* during the 60-day advance notice period. It is thus an unconditional nationwide ban. In *Brown-Forman Distillers Corp. v. N.Y. State Liquor Authority*, 476 U.S. 573 (1986), the Supreme Court struck down an analogous ban on price changes. The New York law there required distillers to file a monthly price list and to affirm that the listed prices were no higher than those charged in other states. The law thus imposed a one-

month nationwide ban on decreasing prices below New York's. The Court held that New York could not ban price changes outside the state. California cannot do so either.

4. SB 17 in fact is more intrusive and problematic than the statute invalidated in *Brown-Forman.* Not only does SB 17 *effectively* ban out-of-state pricing, it *overtly* prescribes policy on drug pricing for the entire United States. The author of SB 17 proclaimed that it would "*set national health care policy*, having an impact for consumers and providers *in other states*."[1] Because SB 17 seeks to regulate a national list price, these other states are saddled with California's policy, even if they disagree with it. At least some states likely disagree, as SB 17 conflicts with key tenets of a free market economy, in particular, that market participants should not have to justify their pricing to the government or be compelled to make controversial public statements about their pricing. The extraterritorial dictates of the Act are even more pronounced and widespread because contract prices with wholesalers, hospitals, pharmacies, pharmacy benefit managers, payers, and others across the nation are typically based on a product's WAC list price.

5. The Act further requires manufacturers to state in their announcement of the price increase whether it is justified on one ground—a change or improvement in the drug. While the asserted purpose of this provision is to "provide accountability" for price increases, the Act reflects openly acknowledged animus towards an industry that has developed—and continues to produce—life-saving and life-enhancing medicines. The author of the Act cited "[p]ublic anger at rising drug prices,"[2] and charged, among other things, that the pharmaceutical industry has earned "obscene profits at the expense of the entire healthcare system."[3] The Act singles out, in

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[1] Sen. Ed Hernandez, *Statement: Senator Hernandez Calls on Congress to Tackle Drug Prices* (Sept. 13, 2017), http://sd22.senate.ca.gov/news/2017-09-13-statement-senator-hernandez-calls-congress-tackle-drug-prices-nationally (emphases added); *see also* Sen. Ed Hernandez (@SenatorDrEd22), Twitter (Sept. 12, 2017, 2:48 PM), https://twitter.com/SenatorDrEd22/status/907679770468540416 ("CA is setting national policy. What we do in CA with bringing transparency to drug prices will have positive impacts in other states.").

[2] Press Release, *Drug Pricing Transparency Bill Approved by the Assembly*, Sen. Ed Hernandez, (Sept. 11, 2017), http://sd22.senate.ca.gov/news/2017-09-11-release-drug-pricing-transparency-bill-approved-assembly.

[3] Sen. Ed Hernandez, Press Conference at 7:30 (Mar. 15, 2017), http://sd22.senate.ca.gov/video; *see also* Editorial Bd., *Passing Bill Would Curb Prescription Drug Price Abuses*, East Bay Times

the author's own words, the "greedy pharmaceutical companies,"[4] forcing manufacturers to invite public condemnation for any price increases above California's ordained threshold, even though myriad other participants in the supply chain significantly affect the cost of healthcare generally and prescription drugs specifically. Against this backdrop, it is clear that "accountability" means the political assignment of blame, regardless of the facts, for prices the Legislature deems too high.

6. Aside from being poorly conceived, SB 17 is also counterproductive. By banning price increases for qualifying drugs for 60 days and burdening manufacturers with an inculpatory "justification" requirement, the Act may actually encourage informal price coordination that diminishes competition between manufacturers. It could, in short, distort the prescription drug market in ways that harm consumers.

7. These infirmities render SB 17 unconstitutional, on multiple grounds. *First*, SB 17 violates the Commerce Clause by directly restricting the list price used nationwide—including outside California. The author of the Act, in his own words, announced unconstitutional, extraterritorial objectives to "set national health care policy" and "impact [] consumers and providers in other states."[5] The Act implements these objectives by banning increases in the WAC—a federally defined list price covering the entire nation—for drugs with a list price greater than $40 for a course of therapy for a period of 60 days after a manufacturer notifies registered purchasers and State purchasers of the intent to increase the WAC for the product. The notice required by SB 17, however, will signal to the statutorily specified purchasers nationwide that they should attempt to buy in that window, creating a potential spike in purchasing—*i.e.*, stockpiling—that could produce drug shortages harmful to many patients. Further, the Act permanently restricts national prices by penalizing any manufacturer that raises the WAC for qualifying drugs by more than California deems proper, regardless of whether that increase affects the price that customers in California ultimately pay. The Commerce Clause prohibits

(Apr. 25, 2017) (quoting Sen. Ed Hernandez).

[4] Issues, Dr. Ed Hernandez for Lt. Governor 2018 (last visited Nov. 14, 2017), https://www.edhernandez4ca.com/issues/healthcare.

[5] Hernandez, *supra* note 1.

California from foisting its policies onto other states in this manner, and for good reason. California's intrusion into the commerce among other states will disrupt the drug market. The Commerce Clause also prohibits California from imposing obligations that will result in stockpiling, opportunities for price coordination, and other burdens on interstate commerce in return for making already public information more "transparent."

8. *Second*, SB 17 violates the First Amendment. The Act compels speech, requiring manufacturers to communicate to potentially thousands of registered purchasers that the pharmaceutical companies plan to increase the WAC of their prescription drugs in 60 days, even if they otherwise would provide less notice or no notice at all. Worse, SB 17 endorses only one potential justification for a price increase—a "change or improvement" in the drug—and compels manufacturers to publicly explain whether that justification applies, even when the manufacturers disagree as to the need for any justification, let alone the appropriateness of this one. Further, the Act treats as irrelevant other common, long-established reasons for price increases, such as raising capital for research, recognizing the value of a drug in generating cost savings for the health care system, and compensating investors for assuming the enormous risks entailed in developing an innovative drug. SB 17's misapprehension of drug pricing is unsurprising, however, given that the author of the bill opined that pharmaceutical companies "[don't] tie price increases to value, effectiveness, research costs or changes in manufacturing costs."[6]

9. In compelling this speech, the Act discriminates based on speaker, content, and viewpoint. It discriminates based on the speaker by singling out pharmaceutical manufacturers and forcing them to disseminate California's message that they alone are responsible for increases in the prices of prescription drugs—a message that is simply not correct. SB 17 also dictates content by forcing manufacturers to speak about drug pricing where they otherwise would not. And the Act discriminates based on both content and viewpoint by forcing manufacturers to endorse and disseminate the message the required statements unavoidably convey—that prescription drug prices are too high and that only chemical changes or improvements to a drug

[6] Sen. Ed Hernandez (@SenatorDrEd22), Twitter (Sept. 6, 2017, 12:23 PM), https://twitter.com/SenatorDrEd22/status/905511884241211393.

can justify a 16-percent increase in the WAC over a period of two to three years. SB 17 further reflects this discrimination by imposing speech requirements, including the mandated self-condemnatory justifications, only when a manufacturer *increases* prices, but not when the manufacturer lowers them.

10. The author of the bill left no doubt as to the import of the justification requirement, repeatedly denouncing the pharmaceutical industry, asserting that the "problem" can "no longer be blamed on a few bad actors,"[7] and declaring that, "[f]or the first time, companies will have to explain to the public why their drugs cost so much."[8] As the D.C. Circuit held in striking down a requirement that companies disclose use of conflict minerals, "[r]equiring a company to publicly condemn itself is undoubtedly a more 'effective' way for the government to stigmatize and shape behavior than for the government to have to convey its views itself, but that makes the requirement more constitutionally offensive, not less so." *Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 530 (D.C. Cir. 2015) (internal citations omitted).

11. *Third*, SB 17 is unconstitutionally vague. The statutory text offers no specifics on whether past WAC increases, as far back as January 2016, contribute toward the Act's *de facto* price freeze—whether, for example, a 7-percent increase in June 2016 and a 6-percent increase in May 2017 would mean that a manufacturer could not raise the price of a prescription drug more than 3 percent of the initial price before June 2018 without triggering the public disclosures. Equally concerning, the Act does not state whether the 60-day notice requirement triggers prior to the presumed effective date of January 1, 2018. For example, if a manufacturer wants to increase the price of a drug above the threshold on January 2, 2018, could it do so if it did not provide notice on November 3, 2017—even though, as of the November 3 date, the statute was not

[7] Sen. Ed Hernandez (@SenatorDrEd22), Twitter (Sept. 6, 2017, 3:21 PM), https://twitter.com/SenatorDrEd22/status/905511381495054337.

[8] Sen. Ed Hernandez, *The Difference Between Life and Death for Diabetics*, Sacramento Bee (June 9, 2017), http://www.sacbee.com/opinion/op-ed/soapbox/article155343174.html; *see also* Alexei Koseff, *Your Drug Costs Might Drop If Lawmakers Can Agree on Why They're So High*, Sacramento Bee (May 29, 2017), http://www.sacbee.com/news/politics-government/capitol-alert/article152922344.html ("[A] pharmaceutical drug company should be allowed to make a profit, but not so much so that they gouge the consumer or the taxpayer . . . . None of them are going into bankruptcy.") (quoting Sen. Hernandez).

effective and California's Office of Statewide Health Planning and Development ("OSHPD") had not even set up a process for providing such notices or a registration process for entities to receive such notices? Even though PhRMA asked OSHPD, the agency tasked with enforcing and thus interpreting SB 17, to clarify these ambiguities, OSHPD to date has not provided such guidance. Not knowing whether the State will adopt these improper interpretations, many manufacturers likely will either refrain from price increases they are entitled to make or risk the State alleging violations of the statute and potentially undertaking enforcement. The vagueness of the statute thus exacerbates the burdens SB 17 imposes on interstate commerce and on speech.

12. PhRMA therefore seeks a declaration that Section 4 of SB 17 violates the Commerce Clause, the First Amendment, and the Fourteenth Amendment's Due Process Clause, as well as an injunction prohibiting Defendants from implementing or enforcing Section 4 of SB 17.

PARTIES

13. PhRMA is a non-profit corporation organized under Delaware law, with its headquarters in Washington, D.C. PhRMA serves as the pharmaceutical industry's principal public policy advocate, representing the interests of its members before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. Among other objectives, PhRMA seeks to advance public policies that foster continued medical innovation and to educate the public about the process for discovering and developing new drugs. PhRMA members are the leading research-based pharmaceutical and biotechnology companies in America, devoted to discovering and developing new medications that allow people to live longer, healthier, and more productive lives.[9]

14. Defendant Edmund Gerald Brown, Jr. is the Governor of the State of California and is sued in his official capacity only. As Governor, Defendant Brown is responsible for the execution of SB 17.

15. Defendant Robert P. David is the Director of OSHPD and is sued in his official

[9] A list of PhRMA members is available at http://www.phrma.org/about/members.

capacity only. As Director of OSHPD, Defendant David is responsible for the implementation and execution of SB 17, including the promulgation of rules and the assessment of administrative penalties authorized by the Act. *See* Chapter 603, Statutes of 2017, § 4 (Cal. 2017) (adding Cal. Health & Safety Code § 127679).

JURISDICTION AND VENUE

16. PhRMA's causes of action arise under 42 U.S.C. § 1983 and the United States Constitution. The Court has jurisdiction under 28 U.S.C. § 1331.

17. Venue is proper in this district under 28 U.S.C. § 1391(b) because PhRMA's claims arise in this judicial district and because Defendants reside and perform their official duties in this district.

18. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201, and this Court has the authority under 28 U.S.C. §§ 2201–02 to grant PhRMA declaratory and injunctive relief from Section 4 of SB 17.

FACTUAL ALLEGATIONS

PhRMA Members Spend Enormous Sums on Research and Development

19. PhRMA members develop life-saving and life-enhancing medicines that are promoted, prescribed, and sold throughout the nation, including in California. Pharmaceutical manufacturers, including PhRMA's members, invest huge sums in the research and development of new medicines. "Since 2000, more than 475 new prescription medicines . . . have been approved for use by the U.S. Food and Drug Administration" ("FDA").[10] PhRMA members are responsible for much of this innovation, including more than a third of the 34 novel drugs—those containing "new molecular entities"—approved by FDA this year.[11] FDA has recognized that such drugs "frequently provide important new therapies for patients."[12]

[10] Genia Long, *The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development*, Analysis Group (July 2017), at Executive Summary, http://www.analysisgroup.com/uploadedfiles/content/insights/publishing/the_biopharmaceutical_pipeline_report_2017.pdf.

[11] *See* U.S. Food & Drug Admin., *Novel Drug Approvals for 2017*, https://www.fda.gov/drugs/developmentapprovalprocess/druginnovation/ucm537040.htm.

[12] *Id.*

20. The cost of developing innovative medicines is staggering and presents enormous financial risks. On average, a manufacturer spends between 10 and 15 years—and as much as $2.6 billion—developing a single new medicine.[13] PhRMA members invest billions each year on research and development.[14] And the time and expense required to research and develop a new drug is continually rising.[15] These increases result from many factors, including that clinical drug development takes more time because the required research is increasingly technically complex, that attrition rates for drugs during the research phase are high, and that demands by regulatory authorities and payers are escalating.[16]

21. The low likelihood of securing FDA approval magnifies the risk and multiplies the cost of developing new drugs. Between 1988 and 2014, only 12 percent of drug candidates that entered clinical testing were approved for use by FDA. Between 2002 and 2014, the failure rate for Alzheimer drugs was 99.6 percent; only one out of 244 compounds received FDA approval.[17] Of 103 drugs tested for Melanoma between 1999 and 2015, only seven came to market.[18] According to an estimate focusing on the most prolific developers of new drugs, "95% of the

[13] Joseph A. DiMasi, et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 23 (2016), http://csdd.tufts.edu/news/complete_story/cost_study_press_event_webcast

[14] *See, e.g.*, *2017 Biopharmaceutical Research Industry Profile*, PhRMA (2017), https://www.phrma.org/industryprofile/; Alexander Schuhmacher et al., *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 J. Transl. Med. 105 (Apr. 27, 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4847363/# (some pharmaceutical companies have invested over $10 billion per novel drug); Kim Thomas, *The Price of Health: The Cost of Developing New Medicines*, Guardian (Mar. 30, 2016, 6:00 AM), https://www.theguardian.com/healthcare-network/2016/mar/30/new-drugs-development-costs-pharma (noting that "[d]rugs typically take 12 years from the initial discovery stage to reach the market").

[15] Schuhmacher et al., *supra* note 14 (the average time for clinical development increased from 6.4 years between 2005-2009 to 9.1 years between 2008-2012; research and development costs have increased 8.6% over the past sixty years); Rick Mullin, *Tufts Study Finds Big Rise in Cost of Drug Development*, Chem. & Eng'g News (Nov. 20, 2014), http://cen.acs.org/articles/92/web/2014/11/Tufts-Study-Finds-Big-Rise.html (study found that "developing a prescription drug that gains market approval [costs] $2.6 billion, a 145-percent increase" from 2003).

[16] *Id.*

[17] Jeffrey L. Cummings, et al., *Alzheimer's Disease Drug-Development Pipeline: Few Candidates, Frequent Failures*, 6 Alzheimer's Research & Therapy 37 (Jul. 3, 2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4095696/pdf/alzrt269.pdf.

[18] L. Endrenyi, et al. BioSimilar Drug Product Development 418 (CRC Press 2017).

experimental medicines that are studied in humans fail to be both effective and safe."[19] Even when a product reaches the market, the manufacturer may not earn back the cost of research and development.

22. Recouping the investment in research and development is increasingly difficult (and the cost of failure greater) because of the increased focus on novel medicines for small patient populations. Drug treatments are becoming increasingly personalized, taking into consideration a patient's "genetic, anatomical, and physiological characteristics."[20] More than 20 percent of new drugs approved by FDA in 2014 were personalized medicines with labels that refer to specific biological markers to help guide prescribers' decisions.[21] Pharmaceutical researchers are now developing gene therapies that work by "administ[ering] genetic material to modify or manipulate the expression of a gene product or to alter the biological properties of living cells for therapeutic use."[22] These targeted drugs are often critical in treating rare illnesses. But they cost more to develop and in some cases are effective only in treating relatively small numbers of patients.

23. As pharmaceutical companies build on new technologies and advances in scientific knowledge, they continue to develop groundbreaking therapies to combat devastating diseases. Pharmaceutical researchers are currently honing in on "disease-modifying treatments that may stop or slow down disease progression [of Alzheimer's]," developing almost 250 different medicines and vaccines that use the immune system to combat cancer, and are "working on cutting-edge medicines needed to bring new treatments to patients with mental illness."[23] As

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[19] Matthew Herper, *The Cost of Creating a New Drug Now $5 Billion, Pushing Big Pharma to Change*, Forbes (Aug. 11, 2013, 11:10 AM), http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine.

[20] *Paving the Way for Personalized Medicine*, FDA 4 (Oct. 2013), https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PersonalizedMedicine/UCM372421.pdf.

[21] *More Than 20 Percent of the Novel New Drugs Approved by FDA's Center for Drug Evaluation and Research in 2014 Are Personalized Medicines*, Personalized Med. Coalition, http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/2014-fda-approvals-personalized-medicine2.pdf.

[22] *What is Gene Therapy?* FDA, https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm573960.htm.

[23] *Medicines in Development 2017 Update: Alzheimer's Disease*, America's Biopharmaceutical

of July, pharmaceutical companies were pursuing more than 700 projects using gene therapy, more than 170 projects using DNA or RNA therapies, and more than 180 projects using antibodies that join to chemotherapy drugs and other agents to ensure those agents target specific cells (such as tumors).[24]

Drug Pricing and the Pharmaceutical Supply Chain

24. SB 17 regulates the price of pharmaceutical products, both during the 60-day ban on price increases and by dictating manufacturers' communications about pricing. Understanding the pharmaceutical supply chain and how prices are set at different levels is critical to assessing the impact of SB 17. As the California Legislature acknowledged in passing the Act, many entities besides manufacturers are involved in setting prices of pharmaceutical products.[25]

25. Manufacturers primarily sell their prescription drugs to wholesalers. Three companies hold the vast majority of the wholesale market: AmerisourceBergen, Cardinal Health, and McKesson Corporation, the last of which is headquartered in California. Approximately 90 percent of all pharmaceuticals distributed in the United States move through one of these wholesalers.

26. Manufacturers sell to wholesalers at a price derived from the WAC. Federal law defines the WAC as "the manufacturer's list price" to wholesalers or direct purchasers, "not including prompt pay or other discounts, rebates or reductions in price." 42 U.S.C. § 1395w-3a(c)(6)(B). Manufacturers set the WAC for their drugs based on individualized, proprietary, and highly subjective pricing methodologies. A drug's WAC is uniform across the United States and is already publicly available.

27. While a drug's wholesale price is based on the WAC, what the wholesalers actually pay depends on the items the statute excludes from the definition, such as discounts

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Companies, http://phrma-docs.phrma.org/files/dmfile/MID-Alz-Update_FINAL.pdf; *Medicines in Development: Immuno-oncology*, America's Biopharmaceutical Companies, http://phrma-docs.phrma.org/files/dmfile/GoBoldlyImmuno_OncologyReport_2017.pdf; *Medicines in Development 2017: Mental Illness*, America's Biopharmaceutical Companies, http://phrma-docs.phrma.org/files/dmfile/MentalIllness_MIDReport_2017.pdf.

[24] Long, *supra* note 10, at 13.

[25] State of Cal. Assemb. Comm. on Appropriations, *Comm. Analysis of SB 17 (Hernandez)* at 3 (Aug. 23, 2017), attached as Exhibit E.

calculated as a percentage of the WAC.[26] Wholesalers also charge manufacturers a negotiated fee, usually calculated, again, as a percentage of the WAC, for a variety of distribution and logistics services.

28. Wholesalers sell drugs to healthcare providers (such as hospitals and doctors) and retailers (such as pharmacies) at prices that are based on the product's WAC. The prices wholesalers charge healthcare providers and pharmacies are not public.

29. Most patients who receive drugs directly from a pharmacy or a healthcare provider pay insurance premiums, deductibles, and co-payment amounts. Third-party payers—private insurers or public healthcare programs, like Medicare and Medicaid—cover the rest of the price charged by the pharmacy or healthcare provider. For drugs dispensed to Medicare or Medicaid beneficiaries, pharmacies usually receive reimbursement at an amount based on the WAC.[27] For drugs administered by physicians and in hospitals, other reimbursement formulas apply, some of which are based in part on the WAC.[28] Thus, SB 17's restrictions on WAC affect not only manufacturers' sales, but also the reimbursement rates of other actors throughout the healthcare system.

30. Third-party payers typically pay pharmacies and healthcare providers a price derived from the WAC. They also typically negotiate rebates from manufacturers, which are calculated as a percentage of the WAC. In exchange for the rebates, the payers provide access to, or preferred placement on, the list of prescription drugs that the payer will reimburse, which is known as the payer's formulary.

31. Many third-party payers also contract with Pharmacy Benefit Managers ("PBMs"),

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[26] Adam J. Fein, *McKesson's Profit Shortfall: How Wholesalers Benefit from Rising Drug List Prices*, Drug Channels (Jan. 26, 2017), http://www.drugchannels.net/2017/01/mckessons-profit-shortfall-how.html.

[27] *See, e.g.*, Centers for Medicare & Medicaid Services, *Medicaid Covered Outpatient Prescription Reimbursement Information by State*, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxreimbursement-chart-current-qtr.pdf.

[28] *See* Letter from James Cosgrove, Director of Health Care, Gov't Accountability Office, to Rep. Sander M. Levin, Ranking Member, House Comm. on Ways and Means 4 (Aug. 1, 2016), http://www.gao.gov/assets/680/678784.pdf (noting that two private payers surveyed indicated ASP "may be used as a benchmark for negotiation").

which often negotiate larger rebates from manufacturers.[29] Three PBMs—CVS Caremark, Express Scripts, and OptumRx—manage claims for well over half of the domestic healthcare market.[30]

32. Additionally, for many end-customers, federal law mandates discounted prices. For example, disproportionate share hospitals, cancer hospitals, and children's hospitals, among others, can purchase prescription drugs at steep discounts under the federal "340B Program."[31] Likewise, the Veteran's Healthcare Act requires steeply discounted prices for sales to the Department of Veterans Affairs, the Department of Defense, the Coast Guard, and the Public Health Service.[32] And, under the Medicaid program, manufacturers must pay substantial rebates to the States, including California, to help offset a percentage of prescription drug costs for Medicaid utilization.[33]

33. For these reasons, the "WAC neither reflect[s] the actual net revenue paid to manufacturers nor the actual net prices paid by pharmacies . . . or health plans."[34] In considering SB 17, the California Legislature acknowledged that "[t]he WAC price of a drug on the market, as originally announced by the company[,] is also rarely the price paid by a payer."[35] It is "typically the contractual starting point for business-to-business contracts involving . . . key participants in the pharmaceutical distribution system."[36]

34. Generally, the prices actually paid by insurers, pharmacies, healthcare providers,

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[29] Jessica Wapner, *Understanding the Hidden Villain of Big Pharma: Pharmacy Benefit Managers*, Newsweek (Mar. 17, 2017, 3:25 PM), http://www.newsweek.com/big-pharma-villain-pbm-569980 (80 to 85%); Matan C. Dabora, et al., *Financing and Distribution of Pharmaceuticals in the United States, Journal of the American Medical Association* (July 4, 2017), https://jamanetwork.com/journals/jama/fullarticle/2627994?amp;utm_source=JAMAPublishAheadofPrint&utm_campaign=15-05-2017 (73%).

[30] *Id.*

[31] 42 U.S.C. § 256b.

[32] 38 U.S.C. § 8126.

[33] 42 U.S.C. § 1396r-8.

[34] Steven M. Lieberman and Paul B. Ginsburg, *Would Price Transparency for Generic Drugs Lower Costs for Payers and Patients?*, Brookings Institution 8, 11 (June 2017), https://www.brookings.edu/wp-content/uploads/2017/06/es_20170613_genericdrugpricing.pdf

[35] State of Cal. Sen. Comm. on Health, *Comm. Analysis of SB 17 (Hernandez)* at 6 (Apr. 19, 2017), attached as Exhibit F.

[36] *Id.*

and PBMs are significantly lower than the WAC, though the WAC is typically used in calculating those negotiated discounts. Although invoice prices for patented drugs jumped 12 percent in 2015 and 9.2 percent in 2016, the average net price increase after rebates and other discounts was only 2.5 and 3.5 percent, respectively.[37] The price ultimately paid to the manufacturer is the "net effective price" for the drug. Unlike the WAC, the net effective price is not transparent to the public and is competitively sensitive.

Overview of California Senate Bill 17

35. On May 30, 2017, the California State Senate passed SB 17. On September 11, 2017, the California State Assembly passed an amended version, which the Senate approved two days later. On October 9, 2017, Defendant Governor Brown signed SB 17 into law.

36. Although the California Legislature states that it intended "to permit manufacturers of a prescription drug to voluntarily make pricing decisions," SB 17 § 4 (adding HSC § 127675(b)(2)), proponents acknowledged that the Act's true function was to name and shame "greedy pharmaceutical companies"[38] into restricting the price of their innovative drugs "to avoid public scorn."[39] At the Act's signing, one co-sponsor remarked that SB 17 "is not just transparency for transparency's sake, it is transparency with teeth" because it forces manufacturers to "think twice before raising prices over the threshold that triggers additional reporting."[40] Another co-sponsor touted SB 17's notice requirement because it "creates an incentive for price increases to fall below 10% [the reporting threshold in a previous version],"[41] and others argued that "[r]eporting requirements will dissuade excessive price hikes."[42] While

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[37] IMS Institute for Healthcare Informatics, National Sales Perspectives (Mar. 2016).
[38] Issues, *supra* note 4.
[39] *Hearing on SB 17 (Hernandez) Before the Assemb. Comm. on Health*, 2017–18 Sess., at 26:10 (Cal. June 27, 2017) (statement of Sen. Hernandez), http://www.calchannel.com/video-on-demand/.
[40] Anthony Wright (for Health Access California), Press Conference at 2:10 (Oct. 9, 2017), http://sd22.senate.ca.gov/video.
[41] Letter from A. Wright (Health Access Cal.) to Assemb. Gonzalez Fletcher (July 17, 2017), attached as Exhibit G; *see also* Sen. Hernandez Author's Bill File, *SB 17 (Hernandez) - Drug Pricing Transparency* (April 17, 2017) ("Why Transparency? Transparency Works. When we've required transparency in pricing on other sections of the industry, prices have stabilized or have decreased."), attached as Exhibit H.
[42] America's Health Insurance Plans, *Assemb. Floor Alert re: S.B. 17 (Hernandez) - Support* (Sept. 7, 2017), attached as Exhibit I.

Legislators acknowledged that such innovative therapies were "protected by market exclusivity provisions granted by the U.S. Patent and Trademark Office and the FDA," this exclusivity was seen as a justification *for* imposing state price controls to counteract this federal right.[43] For instance, Assembly member David Chiu, a co-author of the law, claimed that SB 17 was warranted in part because pharmaceutical manufacturers are "protect[ed] as monopolists because of the patents that they receive."[44]

37. The bill's author, Senator Ed Hernandez, was even more pointed, arguing that pharmaceutical manufacturers "have no right to abuse their market power"[45] and making clear that SB 17 was intended to affect commerce outside California. He proclaimed, for example, that SB 17 would be "a monumental achievement for the *entire nation*" and would "set *national health care policy*, having an impact for consumers and providers *in other states*."[46]

38. Section 4 of SB 17 amends the California Health and Safety Code to add Chapter 9, titled "Prescription Drug Pricing for Purchasers." Chapter 9 imposes various notice, reporting, and justification obligations on the manufacturer of a prescription drug "purchased or reimbursed" by any of the following (collectively, "Purchasers"):

- "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";
- "A licensed health care service plan";
- "A health insurer holding a valid outstanding certificate of authority from the Insurance Commissioner";

[43] State of Cal. Assemb. Comm. on Health, *Comm. Analysis of SB 17 (Hernandez)* at 6 (June 27, 2017), attached as Exhibit J; *see also* Ed Hernandez & Tom Steyer, *Require Drugmakers to Report When They Raise Prices*, S.F. Chronicle (Apr. 18, 2017), http://www.sfchronicle.com/opinion/openforum/article/Require-drugmakers-to-report-when-they-raise-11081982.php ("Thanks to government-authorized monopoly protections, we have no choice but to pay whatever price Big Pharma charges, no matter how high.").

[44] Assemb. David Chiu Statement on Governor Brown Signing Drug Pricing Transparency Bill SB 17, 1:25–1:38 (Oct. 9, 2017), https://a17.asmdc.org/press-releases/assemblymember-david-chiu-statement-governor-brown-signing-drug-pricing-transparency.

[45] Ed Hernandez & Tom Steyer, *Require Drugmakers to Report When They Raise Prices*, S.F. Chron. (April 18, 2017), http://www.sfchronicle.com/opinion/openforum/article/Require-drugmakers-to-report-when-they-raise-11081982.php.

[46] Hernandez, *supra* note 1 (emphases added).

- "A pharmacy benefit manager as defined in subdivision (j) of Section 4430 of the Business and Professions Code."

Id. § 4 (adding HSC § 127675(a)). Although commercial purchasers, such as retail pharmacies, are not eligible to register for advance notice of price increases, certain pharmacies, such as CVS, are owned by PBMs that are eligible for registration. Pharmacies that are owned or controlled by a PBM or a health plan thus have a competitive advantage to the extent they can access information on price increases up to 60 days before those pharmacies or other purchasers not owned or controlled by a PBM or health plan.

39. The manufacturer of a prescription drug subject to SB 17 must notify "each purchaser described in Section 127675" at least 60 days before increasing the drug's WAC if: (1) a "course of therapy" has a WAC of more than $40, and (2) the proposed increase would result in a cumulative WAC increase of 16 percent over "the previous two calendar years prior to the current year." *Id.* § 4 (adding HSC § 127677 (a)–(e)). The Act defines a "course of therapy" as "the recommended daily dosage units of a prescription drug pursuant to its [FDA-approved] prescribing label," either "for 30 days" or "for a normal course of treatment that is less than 30 days." *Id.* § 4 (adding HSC § 12677(a)).

40. Given California's size and robust healthcare industry, huge numbers of entities are potentially eligible to receive a 60-day notice every time a drug's WAC increases beyond the 16-percent threshold. Additionally, the Act requires each PBM that receives notice of a WAC increase to "notify its large contracting public and private purchasers," which the Act defines as any "purchaser that provides coverage to more than 500 covered lives." *Id.* § 4 (adding HSC § 12677(e)).

41. Qualifying entities wishing to receive 60 days' prior notice of a WAC increase must register with OSHPD, which, in turn, will "make available to manufacturers a list of registered purchasers for the purpose of this notification." *Id.* § 4 (adding HSC § 127677(d)). In addition to the date and amount of the planned WAC increase, each 60-day notice must include "a statement regarding whether a change or improvement in the drug necessitates the price

increase," and, "[i]f so, the manufacturer shall describe the change or improvement." *Id.* § 4 (adding HSC § 127677(c)).

42. Because the Legislature did not expressly include an effective date for the 60-day notice provisions, they are scheduled to "go into effect" on January 1, 2018. Cal. Const. art. IV, § 8 (newly enacted statute "shall go into effect on January 1 next following the enactment date of the statute"). However, it is unclear what this "effect" will be. The State could maintain that it is entitled to look backward from the effective date and retroactively include WAC increases that occurred as early as January 1, 2016 (*i.e.*, over "the two previous calendar years" before the Act's effective date), in calculating whether a drug's list price has increased by more than the 16-percent threshold. This interpretation would mean that for many drugs, *any price increase* subsequent to January 1, 2018, would trigger SB 17, because pharmaceutical manufacturers already increased the drug's WAC by 16 percent or more since January 1, 2016. Alternatively, the State could give SB 17 prospective effect only by counting each WAC increase beginning January 1, 2018, toward the 60-day notice requirement's 16-percent threshold.

43. Likewise, the State could interpret SB 17 to require that price increases in January 2018 trigger the notice requirements, even though a 60-day advance notice of such a price increase would not be possible unless the law required notice prior to its effective date, and prior to the establishment of any process for providing such notice. Because there is no process for providing advance notice of a January 2018 price increase, such an interpretation would effectively ban price increases on a national basis before March 1, 2018. Alternatively, the State could determine that the 60-day notice requirement becomes effective January 1, 2018, such that price increases prior to March 1, 2018, are not subject to a notice requirement.

44. Beginning on January 1, 2019, SB 17 requires manufacturers to report the following information to OSHPD quarterly for each prescription drug subject to the Act's 60-day notice provisions—*i.e.*, any drug with a WAC of more than $40 per course of treatment and subject to an increase in WAC of more than 16 percent over the previous two calendar years:

- "A description of the specific financial and nonfinancial factors used to make the decision to increase the [WAC] of the drug and the amount of the increase, including,

but not limited to, an explanation of how these factors explain the increase in [WAC]";

- "A schedule of [WAC] increases for the drug for the previous five years if the drug was manufactured by the company";
- "If the drug was acquired by the manufacturer within the previous five years, all of the following information: (A) The [WAC] of the drug at the time of acquisition and in the calendar year prior to acquisition[;] (B) The name of the company from which the drug was acquired, the date acquired, and the purchase price[; and] (C) The year the drug was introduced to market and the [WAC] of the drug at the time of introduction";
- "The patent expiration date of the drug if it is under patent";
- "If the drug is a multiple source drug, an innovator multiple source drug, a non-innovator multiple source drug, or a single source drug, as defined in [42 U.S.C.] § 1396r-8(k)(7)(A)";
- "A description of the change or improvement in the drug, if any, that necessitates the price increase"; and
- "Volume of sales of the manufacturer's drug in the United States for the previous year."

SB 17 § 4 (adding HSC § 127679(a)). A "manufacturer may limit the information reported [quarterly to the State] to that which is otherwise in the public domain or publicly available." *Id.* § 4 (adding HSC §§ 127679(b); 127681(c)).

45. SB 17 also requires a manufacturer to notify OSHPD of any newly introduced prescription drug for which the WAC exceeds the threshold set for a specialty drug under Medicare Part D, which was $670 per month in 2017. The notification must occur either within three days of that drug coming to market or pending FDA approval "if commercial availability is expected within three days of approval." *Id.* § 4 (adding HSC § 127681(a)). Within 30 days, the manufacturer also must report the following information:

- "A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally";
- "The estimated volume of patients that may be prescribed the drug";
- "If the drug was granted breakthrough therapy designation or priority review by [FDA] prior to final approval"; and
- "The date and price of acquisition if the drug was not developed by the manufacturer."

Id. § 4 (adding HSC § 127681(b)).

46. Reporting is compulsory. If a manufacturer fails to report any of the required information, OSHPD may impose "a civil penalty of one thousand dollars ($1,000) per day for every day after the notification period." *Id.* § 4 (adding HSC §§ 127679(d)–(f); 127681(e)–(g)).

47. OSHPD must publish all the information reported by manufacturers—with respect to both new and existing drugs—on its website "in a manner that identifies the information that is disclosed on a per-drug basis," and the information "shall not be aggregated in a manner that would not allow identification of the drug." *Id.* § 4 (adding HSC §§ 127679(c); 127681(d)).

OSHPD Fails to Clarify Whether SB 17 Applies Retroactively

48. On October 13, 2017, PhRMA Senior Director of State Policy, Asher Lisec, sent a letter to OSHPD and Defendant David (attached as Exhibit B).

49. Among other things, "PhRMA request[ed] clarification regarding calculation of the threshold that triggers reporting requirements." Ex. B at 2; that is, whether OSHPD intended to include all price increases from January 1, 2016, in calculating whether a drug's WAC had increased by more than 16 percent over "the two previous calendar years," or would count only price increases occurring after January 1, 2018. PhRMA noted that, "given the presumption against retroactivity, any price changes that occurred prior to the effective date of the bill should not be included in the calculation of the 16% threshold for reporting," and asked whether OSHPD would "please confirm that price increases taken prior to the effective date of the bill will not be used in the calculation of the threshold described in Section 127677(a)?" *Id.* Similarly, PhRMA inquired whether "the State will issue regulations for the purchaser registration and notification processes" on or before November 1, 2017. *Id.*

50. Neither OSHPD nor Defendant David provided the clarifications PhRMA requested. Instead, on November 22, 2017, OSHPD issued a "Cost Transparency Rx Implementation Plan" ("Plan," attached as Exhibit C) on its website, which did not respond to PhRMA's specific inquiries. The Plan does not address whether manufacturers will be responsible for sending 60-day notices based on WAC increases that occurred between January 1, 2016, and January 1, 2018. The Plan states only that, "[b]eginning January 1, 2018, SB 17 requires OSHPD to make available a registry of public and private purchasers for purposes of the

60-day advance notice requirement for specified increases in the wholesale acquisition cost of a prescription drug. Public and private purchasers may register with OSHPD beginning December 1, 2017." *Id.* OSHPD also offered the vague representation that it would "[b]egin outreach to stakeholders" between "January - March 2018." *Id.* Nor does the Plan address whether notices are required prior to the January 1, 2018 presumed effective date, or how drug manufacturers should address price increases taken in January or February of 2018.

51. PhRMA continues to seek clarification that, consistent with the presumption against retroactivity, SB 17 does not apply retroactively to include increases in the WAC list price made before January 1, 2018. On November 30, 2017, PhRMA sent another letter to OSHPD and Defendant David (attached as Exhibit D) asking, "Would you please confirm that price increases taken prior to the effective date of the bill will not be used in the calculation of the threshold described in Section 127677(a)?" Ex. D at 1. Additionally, PhRMA's November 30, 2017 letter provided: "[s]ince the registry of purchasers will not be available until January 1, 2018 and given the presumption the law does not have retroactive effect, PhRMA interprets this to mean that 60-day advanced notification is not required until after that date. Would you please confirm this is the correct interpretation?" PhRMA has yet to receive a response to its letter or otherwise to receive any guidance from OSHPD regarding implementation of SB 17's advance notice requirements.

SB 17'S CONSTITUTIONAL DEFECTS

SB 17 Sets National Drug Pricing Policy in Violation of the Dormant Commerce Clause

52. The Constitution grants Congress the power "[t]o regulate Commerce . . . among the several States." U.S. Const. art. I, § 8, cl. 3. The Commerce Clause "reflect[s] a central concern of the Framers that[,] . . . in order to succeed, the new Union would have to avoid the tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation." *Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979).

53. The Supreme Court has "long interpreted the Commerce Clause as an implicit restraint on state authority, even in the absence of a conflicting federal statute." *United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338 (2007). This is the "so-called 'dormant' aspect of the Commerce Clause." *Id.*

54. When a state "directly regulates" interstate commerce, the Supreme Court has "generally struck down the statute without further inquiry." *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986); *see also Edgar v. MITE Corp.*, 457 U.S. 624, 640 (1982) (plurality op.) ("The Commerce Clause, however, permits only *incidental* regulation of interstate commerce by the States; direct regulation is prohibited."); *NCAA v. Miller*, 10 F.3d 633, 638 (9th Cir. 1993) (statute that "directly regulates interstate commerce . . . violates the Commerce Clause per se"); *Alliant Energy Corp. v. Bie*, 336 F.3d 545, 547 (7th Cir. 2003) ("[D]irect regulation of interstate commerce is virtually per se unconstitutional.").

55. In the seminal case of *Brown-Forman*, the Supreme Court invalidated a state law that required distillers to submit monthly price schedules to New York and to certify that they would not charge wholesalers in other states less than the scheduled prices. 476 U.S. at 576. The Court held that this requirement violated the dormant Commerce Clause because, "[o]nce a distiller has posted prices in New York, it is not free to change its prices elsewhere in the United States during the relevant month." *Id.* at 582. The Court found that New York was impermissibly "project[ing]" its legislation into other states. *Id.* at 584.

56. SB 17 directly regulates out-of-state prices, just like the New York statute invalidated in *Brown-Forman*. Indeed, SB 17 intrudes more significantly than the offending New York law. The nationwide ban on price changes in *Brown- Forman* lasted one month. SB 17 imposes a 60-day nationwide ban on price increases. Further, in defending the law in *Brown-Forman*, New York argued that it "addressed only . . . sales of liquor in New York." *Id.* at 583. By contrast, SB 17 was, in its author's words, "a monumental achievement for the *entire nation*" and would "set *national health care policy*, having an impact for consumers and providers *in*

other states."[47] Anthony Wright, the Executive Director of Health Access California, a co-sponsor of SB 17, similarly professed that SB 17 was a "big deal bill" that helped patients and purchasers, "*setting national policy* in the process."[48]

57. To that end, California has tied the Act's 60-day notice and reporting obligations to increases in the WAC, defined by federal law as the *national* list price for pharmaceuticals. As a practical matter, SB 17 bans manufacturers from raising prices anywhere in the United States during the 60-day notice period because the WAC is the list price in *every* state, and an increase anywhere in the country during the 60-day notice period would violate California law. As a result, in New Hampshire, Pennsylvania, Arkansas, and elsewhere, a manufacturer cannot increase the list price that governs in that state until California's 60-day ban expires. The requirement of 60 days' notice is functionally equivalent to the requirement of price-certification in *Brown-Forman*. While New York in *Brown-Forman* at least purported to regulate only New York prices, in both cases, adjusting an out-of-state list price violates an in-state requirement. Under SB 17, increasing the WAC will trigger the Act's impositions, even if developments in other states or throughout the supply chain spurred the adjustment.

58. The Act's quarterly reporting requirements requiring an explanation for price increases constitute an additional burden. Violation of that requirement could subject a manufacturer to fines of $1,000 per drug, per day if the State deems a manufacturer's "explanation" incomplete. By forcing manufacturers to justify price increases, SB 17 imposes burdens on pricing nationwide. A manufacturer of a qualifying drug that wishes to increase the WAC, which is a nationwide list price, above the 16-percent threshold, must provide advance notices, must comply with California's reporting and justification requirements, and must engage in compelled and self-disparaging speech (as discussed in detail below). And any failure to provide OSHPD with an adequate justification for increases in the national list price subjects the manufacturer to fines in California. The purpose and effect of these requirements is to control prices in other states—again, as the author of SB 17 proclaimed, to create a "national policy."

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[47] Hernandez, *supra* note 1 (emphases added).
[48] Anthony Wright (for Health Access California), *supra* note 40, at 1:44-2:02 (emphasis added).

59. Tying SB 17's burdensome requirements and the threat of civil penalties to the WAC list price necessarily regulates out-of-state conduct. The Act's 60-day notice provision and the uncertain (but potentially significant) economic risk surrounding its reporting requirements were designed specifically to discourage manufacturers from increasing national prices to those deemed excessive by California. Because the WAC is, by law, a national list price, manufacturers cannot avoid the State's intrusive regulations simply by altering their conduct in California. Notice and the accompanying "explanation" are mandatory even where a registered Purchaser has negotiated rebates that increase in proportion to the WAC. Manufacturers must refrain from increasing the list price used in *every* state if they wish to avoid triggering SB 17, thereby giving the Act an inescapable, impermissible, and intended extraterritorial effect. *See, e.g.*, *Edgar*, 457 U.S. at 642–43 (plurality op.) ("The Commerce Clause also precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State."); *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1103 (9th Cir. 2013) ("States may not mandate compliance with their preferred policies in wholly out-of-state transactions."); *NCAA*, 10 F.3d at 639 (invalidating statute that required NCAA "to apply Nevada's procedures to enforcement proceedings throughout the country"). Moreover, the vague language of SB 17 and OSHPD's failure to clarify it compound the extraterritorial impact and impose an additional burden on interstate commerce. Uncertain whether OSHPD will count price increases from as far back as January 2016 in enforcing the Act or will apply the 60-day notice requirement for a price increase taken within the first 60 days of 2018, manufacturers may refrain, nationwide, from implementing even small increases in order to forestall potential exposure.

60. Manufacturers cannot avoid triggering SB 17 even by refusing to sell drugs in-state. *See Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1323 (9th Cir. 2015) (invalidating state law that applied to art transactions involving California residents, even if the resident conducted the transaction entirely out of state and never brought the artwork to California), *cert. denied*, 136 S. Ct. 795 (2016). SB 17 applies not just to drugs purchased *in* California, but also to drugs that are "purchased or reimbursed" by entities *licensed* in California,

regardless of where the transaction actually occurs. SB 17 § 4 (adding § 127675(a)). In fact, the law appears to require manufacturers to give notice to health care plans and PBMs that merely solicit business in California, even if they are licensed elsewhere. *See id.* § 4 (adding HSC § 127675(a)); HSC § 1345; Cal. Bus. & Prof. Code § 4430. SB 17 also directs each PBM that receives notice to relay the information to every one of its contracting purchasers "that provide[] coverage to more than 500 covered lives," without regard to whether those covered lives reside in or are otherwise connected to California. SB 17 § 4 (adding HSC § 127677(e)). This kind of attempt to "extend [a state's] police power beyond its jurisdictional bounds" violates the Commerce Clause. *C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 393 (1994). And, nothing in SB 17 prohibits those PBMs from sharing the advance notice with its affiliates, which in some cases include major national retail or specialty pharmacy chains. The parties receiving the information can disseminate it however they want. This further exacerbates the extraterritorial effects of the law.

61. SB 17 would violate the Commerce Clause even if—contrary to the Act's plain language and avowed purpose—it is held not to regulate extraterritorially. A non-extraterritorial regulation will not survive scrutiny if "the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits" of the statute. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

62. SB 17 will generate substantial harmful economic effects that extend unavoidably beyond California, because pharmaceutical list prices and supply chains have an inherently national character. *See Nat'l Ass'n of Optometrists & Opticians v. Harris*, 682 F.3d 1144, 1148 (9th Cir. 2012) ("[S]ignificant burdens on interstate commerce generally result from inconsistent regulation of activities that are inherently national or require a uniform system of regulation.").

63. The 60-day notice also burdens interstate commerce by promoting price stabilization and potentially reducing competition.[49] The Federal Trade Commission, for example, has questioned "transparency" laws such as SB 17, explaining: "Too much

[49] Ian Spatz, *California Takes on Drug Pricing: Real Progress or Illusion*, Health Affairs (Oct. 2, 2017), http://www.healthaffairs.org/do/10.1377/hblog20171002.062240/full.

transparency can harm competition in any market, including in health care markets. . . . [W]hen information disclosures allow competitors to figure out what their rivals are charging, [it] dampens each competitor's incentive to offer a low price, or increases the likelihood that they can coordinate on higher prices."[50] In markets without such transparency, the FTC has recognized that "manufacturers have powerful incentives to bid aggressively for formulary position, because preferential formulary treatment may yield increased sales."[51]

64. The advance notice requirement also will distort the market by incentivizing prescription-drug arbitrage. SB 17 effectively creates a "buying window" for the selected entities to stockpile products before price increases go into effect, which in turn could create substantial market distortions.[52] Entities that receive advanced notice under SB 17 and that have the necessary financial resources may buy up the product at the current price to try to make an additional profit margin on resale at the future higher price. The 60-day notice requirement gives those entities with substantial inventory capacity the opportunity and incentive to purchase mass quantities of the drug at the lower price and stockpile it, knowing that they will be able to resell the drug at a higher profit margin if they wait until the WAC is implemented. And, the PBMs can earn higher margins based on the higher WAC. Meanwhile, those unfortunate entities without the means or access to the advance notice will face potential product shortages and a substantial competitive disadvantage. SB 17 thus will disrupt the availability of medicines and free-market competition not only in California, but also nationwide.

65. Worse, SB 17 picks the winners and losers of this prescription-drug arbitrage. The Act authorizes state purchasers, insurers, health plans, and PBMs—including presumably all

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[50] Tara Isa Koslov & Elizabeth Jex, *Price Transparency or TMI?*, Fed. Trade Comm'n (July 2, 2015, 2:31 PM), https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi.

[51] Letter from James Cooper, Pauline M. Ippolito, & David P. Wales of the Fed. Trade Comm'n to Hon. James L. Seward (Mar. 31, 2009), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf; *see also* Cong. Budget Office, *Increasing Transparency in the Pricing of Health Care Services and Pharmaceuticals* 6 (June 5, 2008), https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/06-05-pricetransparency.pdf.

[52] Spatz, *supra* note 49.

retail and specialty pharmacies owned by or affiliated with these entities, as well as "large purchasers" who contract with eligible PBMs—to receive advance notice of an increase in the WAC list price directly from the manufacturer. *See* SB 17 § 4 (adding §§ 127675(a), 127677(a) & (e)). Even if a small, unaffiliated local pharmacy were capable of purchasing excess inventory during the 60 days before a price increase takes effect, SB 17 gives its PBM-affiliated competitors a head start. SB 17 creates the temporal equivalent of a volume buying discount; those entities favored by the Act have up to 60 additional days to take advantage of the lower list price. SB 17 thus discriminates between market participants on the same level, specifically favoring certain select purchasers to the detriment of others who do not have access to advance notices.

66. SB 17 achieves little or nothing to offset the harmful effects of drug stockpiling and reduced competition. The law irrationally seeks to achieve transparency for a national list price that is already transparent. *See id.* 17 § 4 (adding HSC §§ 127679(b); 127681(c)). At the same time, it does nothing to make the prices charged by downstream participants in the supply chain more transparent, or to illuminate the prices that patients or third-party payers actually pay. And because the requirements of SB 17 are triggered by increases in the national list price, California strikes this incoherent bargain not only for itself, but for the entire United States. The author of SB 17 has confirmed that this result was deliberate.[53]

67. In sum, SB 17 has inevitable and impermissible extraterritorial effects on pharmaceutical pricing and imposes burdens on interstate commerce that clearly exceed any legitimate local benefit. The Constitution entrusts national economic policy to Congress precisely to avoid such outcomes.

SB 17 Singles Out Manufacturers and Forces Them to Communicate California's Message on Drug Pricing Against Their Will in Violation of the First Amendment

68. In addition to violating the Commerce Clause, SB 17 violates the First Amendment by requiring manufacturers, and only manufacturers, to announce increases to WAC

[53] *See supra*, ¶¶ 4–7, 36–37.

list prices for qualifying drugs 60 days in advance and to explain whether the increase is attributable to factors that California approves.

69. "The First Amendment mandates that we presume that speakers, not the government, know best both what they want to say and how to say it." *Riley v. Nat'l Fed. of the Blind of N.C., Inc.*, 487 U.S. 781, 790–91 (1988). The government thus may not "substitute its judgment as to how best to speak for that of speakers and listeners." *Id.* at 791.

70. SB 17 violates the First Amendment by compelling pharmaceutical manufacturers to communicate the information included in the 60-day notice and the OSHPD report; information that manufacturers would not provide unless the Act compelled them to do so. "[T]he right of freedom of thought protected by the First Amendment against state action includes both the right to speak freely and the right to refrain from speaking at all." *Wooley v. Maynard*, 430 U.S. 705, 714 (1977). "'Since *all* speech inherently involves choices of what to say and what to leave unsaid,' one important manifestation of the principle of free speech is that one who chooses to speak may also decide 'what not to say.'" *Hurley v. Irish-Am. Gay, Lesbian, & Bisexual Grp. of Boston*, 515 U.S. 557, 573 (1995) (quoting *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U. S. 1, 11, 16 (1986) (plurality op.)). "Outside [the] context" of "commercial advertising," the State "may not compel affirmance of a belief with which the speaker disagrees." *Id.* Put simply, "freedom of speech prohibits the government from telling people what they must say." *Rumsfeld v. Forum for Academic & Inst. Rights*, 547 U.S. 47, 61 (2006).

71. The Supreme Court has repeatedly held that laws regulating "how sellers may communicate their prices" are subject to First Amendment scrutiny. *Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144, 1151 (2017). In particular, the First Amendment protects the free "flow of prescription drug price information." *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976). Decisions about when to announce a price increase, and whether and how to explain that price increase, are inherently communicative. *See id.* at 761, 770 (pharmacist's communication "I will sell you the X prescription drug at the Y price" was protected by First Amendment). As SB 17 "regulat[es] the communication of prices

rather than prices themselves," the law on its face implicates the First Amendment. *Expressions Hair Design*, 137 S. Ct. at 1151.

72. SB 17 further harms PhRMA's members by requiring them implicitly to endorse a message that manufacturers' WAC list price increases are primarily or even solely responsible for patients and payers' increased prescription drug costs. Requiring an explanation implies that price increases over the designated amount are inherently suspicious because lesser increases and lower prices require no "explanation."[54] And equating an adequate justification for increasing the WAC list price with "a change or improvement in the drug," necessarily subordinates alternative justifications. Although participants at multiple levels of the supply chain play a role in setting the cost of prescription drugs that patients pay out of pocket, only a manufacturer must "explain" its actions, with the subtext that it has misbehaved, overcharged the public, or acted irresponsibly absent a "change or improvement" in the drug. SB 17 thus burdens manufacturers' First Amendment rights by "forcing [them] to tailor [their] speech to [the State's] agenda." *Am. Beverage Ass'n v. City & Cty. of S.F.*, 871 F.3d 884, 897 (9th Cir. 2017); *see also Pac. Gas & Elec. Co.*, 475 U.S. at 15 (plurality op.).

73. The Act's proponents ensured that these messages permeated the public discussion of health care. They repeatedly denounced "drug companies" that "don't tie price increases to effectiveness."[55] One proponent described the pharmaceutical industry as "a broken marketplace, where patents are extended" and manufacturers "continue to raise prices on existing drugs once, twice or even three times per year—and yet that new, higher price brings no additional value or clinical benefit."[56]

74. Where a speech regulation discriminates based on the content of the communication, favors a particular viewpoint, or favors or disfavors a particular speaker, courts apply heightened judicial scrutiny. *See Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2227 (2015);

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[54] Sen. Ed Hernandez, Press Conference, *supra* note 3, at 9:16 (noting SB 17 is triggered "when drug companies increase prices in a way that would be shocking in any other industry, any other segment of the healthcare industry.").
[55] Sen. Ed Hernandez, Press Conference, *supra* note 3, at 8:35.
[56] Letter from T. Stark (Kaiser Permanente) to Assemb. Gonzalez Fletcher (July 10, 2017), attached as Exhibit K.

Sorrell v. IMS Health Inc., 564 U.S. 552, 564-66 (2011). Heightened scrutiny applies to this case because SB 17 discriminates on all three bases: content, viewpoint, *and* speaker.

75. **Speaker-Based Discrimination.** "[G]overnment regulation may not favor one speaker over another." *Rosenberger v. Rector*, 515 U.S. 819, 828 (1995). But SB 17 "on its face burdens . . . disfavored speakers." *Sorrell*, 564 U.S. at 556 (overturning Vermont law that "disfavor[ed] certain speakers, namely pharmaceutical manufacturers," by prohibiting them alone from using prescriber-identifying information to communicate with physicians). SB 17 requires pharmaceutical manufacturers alone—and not wholesalers, PBMs, group purchasing organizations, pharmacies, hospitals, or clinics—to comply with a burdensome, implicitly disparaging notification, reporting, and justification scheme. By singling out pharmaceutical manufacturers, the Act communicates that manufacturers are primarily or even exclusively at fault for the State's alleged drug pricing problems and the financial burdens borne by consumers. Worse, the Act forces manufacturers to publicly carry that message.

76. **Content Based Discrimination.** Laws that "[m]andat[e] speech that a speaker would not otherwise make" are content based, because forcing a speaker to convey a message "necessarily alters the content of the speech." *Riley*, 487 U.S. at 795. SB 17 dictates both when pharmaceutical manufacturers must speak about their pricing decisions and what they must say. It forces them to speak at a particular time (at least 60 days in advance of a price increase), to a particular audience (at a minimum, drug purchasers, third-party payers, and the state of California), with a particular message (that they are planning a price increase of a type that State officials have disparaged repeatedly in the strongest terms, that the State presumptively disfavors, and that, according to the State, can be justified only by a change or improvement in the drug). SB 17 compels manufacturers to "assist in disseminating" the messages the state entrenched in the public consciousness: that drug prices are too high, that manufacturers are responsible, and that only changes or improvement can justify an increase. Further, SB 17 requires manufacturers publicly to "associate with speech with which [they] disagree." *Pac. Gas & Elec. Co.*, 475 U.S. at 15 (plurality op.).

77. **Viewpoint-Based Discrimination.** For similar reasons, SB 17 also discriminates on the basis of viewpoint, because it imposes burdens based on "the specific motivating ideology [and] the opinion or perspective of the speaker." *Reed*, 135 S. Ct. 2230 (internal quotation marks omitted). A manufacturer may freely express its opinions—or remain silent—regarding reductions in drug prices, or even increases in drug prices below the level the State deems excessive. The law thus uses speech regulation to advance the State's view that drug prices should be lower and that price increases exceeding 16 percent when added to the previous two calendar years, or any price above the specialty drug threshold, are improper. Once that threshold is reached, manufacturers are subject to notification, reporting, and justification requirements.

78. Even if SB 17 did not discriminate on its face, it would still violate the First Amendment under the test set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980). Courts apply that test to scrutinize the regulation of all non-discriminatory commercial speech other than the most basic, "purely factual and uncontroversial information" that is "orthodox in commercial advertising." *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985). Under *Central Hudson*, the State must demonstrate that the regulation of speech "directly advances a substantial governmental interest" and "is not more extensive than is necessary to serve that interest." 447 U.S. at 566; *see also Sorrell*, 564 U.S. at 572 (*Central Hudson* requires a "fit between the legislature's ends and the means chosen to accomplish those ends.").

79. SB 17 does not advance a legitimate, much less substantial, state interest. California's desire to "set national health care policy"[57] and reduce prescription drug prices nationwide is not only illegitimate, it is also independently unconstitutional under the Commerce Clause.

80. Even if regulating pharmaceutical prices nationwide were a legitimate state interest, the State does not and cannot advance that interest by mandating speech about prices and then regulating that speech as a backdoor means to achieve its regulatory objectives. *Lanphere &*

[57] Sen. Ed Hernandez, *supra* note 1.

Urbaniak v. State of Colo., 21 F.3d 1508, 1519 (10th Cir. 1994). Indeed, this is precisely what the U.S. Government sought to do with regard to conflict minerals—resources extracted from a conflict zone and sold to finance continued fighting. Rather than regulating use of possible conflict minerals directly, the Dodd-Frank Act required disclosure about that use. The D.C. Circuit struck down the law. As the Court observed, "Requiring a company to publicly condemn itself is undoubtedly a more 'effective' way for the government to stigmatize and shape behavior than for the government to have to convey its views itself, but that makes the requirement more constitutionally offensive, not less so." *Nat'l Ass'n of Mfrs. v. SEC*, 800 F. 3d 518, 530 (D.C. Cir. 2015). Compelling speech about pricing is not a legitimate alternative to regulating pricing directly. The Supreme Court has made clear: "If the First Amendment means anything, it means that regulating speech must be a last—not first—resort." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002).

81. Nor does the Act directly accomplish the State's interest in lowering healthcare costs. Instead, it attempts to make prescription drug pricing more "transparent." Even assuming that transparency would lead to lower prices—a proposition the FTC has called into question—SB 17 cannot fulfill its stated mission, as the Act does not require "transparency" by other participants in the pharmaceutical supply chain.

82. Even if SB 17 did directly advance a substantial state interest, the law still would not survive because the "fit between the legislature's ends and the means chosen to accomplish those ends" is incongruous. *Sorrell*, 564 U.S. at 572 (internal quotation marks omitted). The Act imposes burdens on a single actor in a complex distribution system, ties its speech restrictions to a federally required list price, and not only is unlikely to have the intended effect of lowering the cost of prescription drugs, but may in fact spawn a host of market distortions, such as drug stockpiling and reduced competition.[58]

83. Furthermore, SB 17 is unconstitutionally vague because it "fails to provide a person of ordinary intelligence fair notice of what is prohibited" and "is so standardless that it

[58] *See supra*, ¶¶ 63–66.

authorizes or encourages seriously discriminatory enforcement." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). Statutes that regulate speech are subject to particularly searching review for vagueness. While vagueness is an outgrowth of due process rather than the First Amendment itself, *United States v. Williams*, 553 U.S. 285 (2008), it is well recognized that "where a vague statute abuts upon sensitive areas of basic First Amendment freedoms, it operates to inhibit the exercise of those freedoms." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). Thus, "[w]hen speech is involved, rigorous adherence to [due process] requirements is necessary to ensure that ambiguity does not chill protected speech." *Fox*, 567 U.S. at 253.

84. SB 17's 60-day notice provision offends due process because the Act is silent on which WAC increases determine whether a manufacturer has breached the statutory threshold of increases over 16 percent during "the previous two calendar years prior to the current year." SB 17 § 4 (adding HSC § 127677 (a)–(e)). Although SB 17 "go[es] into effect" on January 1, 2018, Cal. Const. art. IV, § 8, manufacturers cannot determine from the face of the Act whether that "effect" is retroactive, such that OSHPD will include all price increases since January 1, 2016, in its calculation, or prospective, such that OSHPD will count only WAC increases after January 1, 2018. And OSHPD—the agency charged with enforcing and interpreting SB 17—has not responded to PhRMA's multiple direct requests to clarify this ambiguity.

85. If the Act applies retroactively, SB 17 will cause immediate harm to several PhRMA members whose products' list prices have increased since January 1, 2016—even though those prior price adjustments occurred without warning from California that the adjustments could subject the manufacturer to burdensome notice requirements and compelled speech in 2018. Many of these manufacturers will not increase the WAC of products at the same time and in the same manner that they otherwise would without the risk of past increases triggering SB 17's 60-day notice provision. The impact of this ambiguity on due process deserves intense scrutiny because it "abuts upon sensitive areas of basic First Amendment freedoms" in two ways: not only does SB 17's vagueness chill manufacturers' protected price communications, *Schneiderman*, 137 S. Ct. at 1151, but it does so with the threat of compelled speech, *see Fox*, 567 U.S. at 253.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – SB 17 Has Impermissible Extraterritorial Reach and Imposes an Excessive Burden on Interstate Commerce in Violation of the Commerce Clause of the U.S. Constitution)

86. Plaintiff re-alleges and incorporates by reference all prior and subsequent paragraphs.

87. An actual controversy has arisen and now exists between the parties within the meaning of 28 U.S.C. § 2201, in regards to whether Section 4 of SB 17 violates the Commerce Clause.

88. The Constitution grants Congress the power "[t]o regulate Commerce . . . among the several States." U.S. Const. art. I, § 8, cl. 3. The Commerce Clause places an implicit restraint on state laws that are inimical to national commerce.

89. SB 17 violates the Commerce Clause because, in purpose and effect, it regulates drug pricing beyond California's jurisdiction. Because WAC is a national list price, SB 17 will affect the entire country. The Act will prohibit manufacturers from lawfully increasing the list price of their qualifying products in other states regardless of whether those products are ever sold to or used to treat patients in California. It will also curtail lawful pricing activities conducted entirely outside California by burdening that conduct with notice and reporting requirements and the threat of substantial fines in California.

90. In addition to these substantial, extraterritorial, and impermissible effects on interstate commerce, the Act creates a significant risk of drug stockpiling, price stabilization, and distortion of the national pharmaceuticals market. These burdens to interstate commerce clearly exceed any putative local benefit to residents of California. The Constitution entrusts national economic policy to Congress precisely to avoid such outcomes. U.S. Const. art. I, § 8, cl. 3.

SECOND CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – SB 17 Compels Speech in Violation of the First Amendment to the U.S. Constitution)

91. Plaintiff re-alleges and incorporates by reference all prior and subsequent paragraphs.

92. An actual controversy has arisen and now exists between the parties within the meaning of 28 U.S.C. § 2201, in regards to whether Section 4 of SB 17 violates the First Amendment.

93. SB 17 violates the First Amendment because it compels pharmaceutical manufacturers alone to communicate publicly the State's designated message about their drug pricing decisions even when they prefer to remain silent. The messages SB 17 forces manufacturers to disseminate are that manufacturers charge inflated prices for drugs, that only changes or improvements in the drug can justify an increase, and that manufacturers bear primary responsibility for increases in drug prices. PhRMA's members disagree with and do not want to endorse those messages, implicitly or explicitly.

94. SB 17 discriminates on the basis of content, viewpoint, and speaker. It is an impermissible effort by California to mandate speech to regulate drug prices that the State cannot regulate directly.

95. SB 17 fails heightened judicial scrutiny because it is not narrowly tailored to advance any compelling state interest and it fails the *Central Hudson* test because it does not directly advance a substantial government interest and lacks a sufficient fit.

THIRD CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – SB 17 is Unduly Vague in Violation of the Due Process Clause of the Fourteenth Amendment to the U.S. Constitution)

96. Plaintiff re-alleges and incorporates by reference all prior and subsequent paragraphs.

97. An actual controversy has arisen and now exists between the parties within the meaning of 28 U.S.C. § 2201, in regards to whether Section 4 of SB 17 violates the Fourteenth

Amendment's Due Process Clause.

98. A statute is unconstitutionally vague in violation of due process when it "fails to provide a person of ordinary intelligence fair notice of what is prohibited" and "is so standardless that it authorizes or encourages seriously discriminatory enforcement." *Fox*, 567 U.S. at 253; *see also* U.S. Const., Amend. XIV, § 1.

99. SB 17 violates the Due Process Clause of the Fourteenth Amendment because it is impossible for manufacturers to discern from the Act's plain text whether increases in the WAC list price from January 1, 2016, through December 31, 2017, are retroactively included in determining whether the list price for those drugs has increased by 16 percent or more over "the previous two calendar years prior to the current year," SB 17 § 4 (adding HSC § 127677 (a)), thereby triggering SB 17's 60-day notice requirement. It is also unclear whether price increases taken in the first 60 days of 2018 are subject to the 60-day notice requirement. OSHPD, the agency charged with interpreting and enforcing SB 17, has to date declined to provide necessary clarity in response to PhRMA's requests for guidance on whether SB 17 applies retroactively.

100. It would be inappropriate to implement a *de facto* nationwide ban on price increases for qualifying drug products and to compel self-accusatory statements by manufacturers based on price increases before SB 17 was enacted, and even more problematic to refuse to reveal whether the statute will be enforced in that manner. OSHPD's failure to respond to PhRMA's multiple requests that OSHPD resolve the vagueness regarding the Act's possible retroactive effect violates due process because it forces manufacturers seeking to avoid regulatory missteps to refrain from price increases they are entitled to make, to observe the 60-day ban on price hikes when they should not have to do so, and to issue objectionable statements that they should not have to issue. The vagueness of the statute, and OSHPD's failure to date to provide clarification, thus needlessly and unfairly exacerbate the burdens SB 17 imposes on interstate commerce and on speech.

PRAYER FOR RELIEF

NOW, THEREFORE, Plaintiff requests a judgment in its favor against Defendants as follows:

1. A declaration that Section 4 of SB 17 is unconstitutional and void;

2. A permanent injunction preventing Defendants from implementing or enforcing Section 4 of SB 17;

3. That Plaintiff be awarded attorneys' fees and costs, plus interest accruing thereon, in their favor at the maximum rate allowed by law; and

4. That the Court award such other and further relief as it may deem appropriate.

DATED: December 8, 2017

DOWNEY BRAND LLP

By: */s/ Annie S. Amaral*
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