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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*
ANNIE S. AMARAL
Attorney for Plaintiff
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Exhibit A

Senate Bill No. 17

CHAPTER 603

An act to amend Sections 1385.045 and 127280 of, to add Section 1367.243 to, to add Chapter 9 (commencing with Section 127675) to Part 2 of Division 107 of, and to repeal Section 127686 of, the Health and Safety Code, and to amend Section 10181.45 of, and to add Section 10123.205 to, the Insurance Code, relating to health care.

[Approved by Governor October 9, 2017. Filed with Secretary of State October 9, 2017.]

LEGISLATIVE COUNSEL'S DIGEST

SB 17, Hernandez. Health care: prescription drug costs.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care (DMHC) and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance (DOI). Existing law requires health care service plans and health insurers to file specified rate information with DMHC or DOI, as applicable, for health care service plan contracts or health insurance policies in the individual or small group markets and for health care service plan contracts and health insurance policies in the large group market. Existing law requires health care service plans and health insurers to also disclose specified supporting information for the rate information described above. Existing law requires the DMHC and DOI, as applicable, to conduct an annual public meeting regarding large group rates within 3 months of posting that information.

This bill would require health care service plans or health insurers that file the above-described rate information to report to DMHC or DOI, on a date no later than the reporting of the rate information, specified cost information regarding covered prescription drugs, including generic drugs, brand name drugs, and specialty drugs, dispensed as provided. DMHC and DOI would be required to compile the reported information into a report for the public and legislators that demonstrates the overall impact of drug costs on health care premiums and publish the reports on their Internet Web sites by January 1 of each year. Except for the report, DMHC and DOI would be required to keep confidential all information provided pursuant to these provisions. The bill would also require health care service plans or health insurers that file the above-described rate information to disclose to DMHC and DOI with the rate information specified information regarding the relation of prescription drug costs to plan or insurer spending and premium charges. The bill would instead require DMHC and DOI to conduct an annual public meeting within 4 months of posting the rate information

described above. Because a willful violation of these provisions by a health care service plan would be a crime, the bill would impose a state-mandated local program.

The bill would require a manufacturer of a prescription drug with a wholesale acquisition cost of more than $40 that is purchased or reimbursed by specified purchasers, including state agencies, health care service plans, health insurers, and pharmacy benefit managers, to notify the purchaser of an increase in the wholesale acquisition cost of a prescription drug if the increase in the wholesale acquisition cost for a course of therapy, as defined, exceeds a specified threshold. The bill would require that notice to be given at least 60 days prior to the planned effective date of the increase. Commencing no earlier than January 1, 2019, the bill would require the manufacturer to notify the Office of Statewide Health Planning and Development (OSHPD) of specified information relating to that increase in wholesale acquisition cost on a quarterly basis at a time and in a format prescribed by the office. The bill would require the manufacturer to notify OSHPD of specified information relating to the wholesale acquisition cost, marketing, and usage of a new prescription drug if the cost exceeds a specified threshold, and would require OSHPD to publish that information on its Internet Web site, as specified. The bill would require OSHPD to enforce the provisions requiring manufacturer reporting to OSHPD and would subject a manufacturer to liability for a civil penalty if the information described above is not reported. The bill would authorize OSHPD to adopt regulations or issue guidance for the implementation of these provisions. The bill would require the California Research Bureau to report to the Legislature on the implementation of these provisions, and would subject these provisions to review by the appropriate policy committees of the Legislature, as specified.

Existing law establishes the California Health Data and Planning Fund within the office for the purpose of receiving and expending certain fee revenues. Existing law establishes the Managed Care Fund for the purpose of supporting the administration of DMHC. Existing law establishes the Insurance Fund for, among other things, the support of DOI as authorized in the annual Budget Act.

This bill would prohibit the use of any moneys in the fund from being used for the implementation of these provisions. The bill would provide that funding for the office to conduct the activities described above shall be provided, subject to appropriation by the Legislature, from transfers of moneys from the Managed Care Fund and the Insurance Fund, as specified.

This bill would provide that the above-described provisions are severable.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 1367.243 is added to the Health and Safety Code, to read:

1367.243. (a) (1) A health care service plan that reports rate information pursuant to Section 1385.03 or 1385.045 shall report the information described in paragraph (2) to the department no later than October 1 of each year, beginning October 1, 2018.

(2) For all covered prescription drugs, including generic drugs, brand name drugs, and specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use, all of the following shall be reported:

(A) The 25 most frequently prescribed drugs.

(B) The 25 most costly drugs by total annual plan spending.

(C) The 25 drugs with the highest year-over-year increase in total annual plan spending.

(b) The department shall compile the information reported pursuant to subdivision (a) into a report for the public and legislators that demonstrates the overall impact of drug costs on health care premiums. The data in the report shall be aggregated and shall not reveal information specific to individual health care service plans.

(c) For the purposes of this section, a "specialty drug" is one that exceeds the threshold for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)).

(d) By January 1 of each year, beginning January 1, 2019, the department shall publish on its Internet Web site the report required pursuant to subdivision (b).

(e) After the report required in subdivision (b) is released, the department shall include the report as part of the public meeting required pursuant to subdivision (b) of Section 1385.045.

(f) Except for the report required pursuant to subdivision (b), the department shall keep confidential all of the information provided to the department pursuant to this section, and the information shall be protected from public disclosure.

SEC. 2. Section 1385.045 of the Health and Safety Code is amended to read:

1385.045. (a) For large group health care service plan contracts, each health plan shall file with the department the weighted average rate increase for all large group benefit designs during the 12-month period ending January

1 of the following calendar year. The average shall be weighted by the number of enrollees in each large group benefit design in the plan's large group market and adjusted to the most commonly sold large group benefit design by enrollment during the 12-month period. For the purposes of this section, the large group benefit design includes, but is not limited to, benefits such as basic health care services and prescription drugs. The large group benefit design shall not include cost sharing, including, but not limited to, deductibles, copays, and coinsurance.

(b) (1) A plan shall also submit any other information required pursuant to any regulation adopted by the department to comply with this article.

(2) The department shall conduct an annual public meeting regarding large group rates within four months of posting the aggregate information described in this section in order to permit a public discussion of the reasons for the changes in the rates, benefits, and cost sharing in the large group market. The meeting shall be held in either the Los Angeles area or the San Francisco Bay area.

(c) A health care service plan subject to subdivision (a) shall also disclose the following for the aggregate rate information for the large group market submitted under this section:

(1) For rates effective during the 12-month period ending January 1 of the following year, number and percentage of rate changes reviewed by the following:

(A) Plan year.

(B) Segment type, including whether the rate is community rated, in whole or in part.

(C) Product type.

(D) Number of enrollees.

(E) The number of products sold that have materially different benefits, cost sharing, or other elements of benefit design.

(2) For rates effective during the 12-month period ending January 1 of the following year, any factors affecting the base rate, and the actuarial basis for those factors, including all of the following:

(A) Geographic region.

(B) Age, including age rating factors.

(C) Occupation.

(D) Industry.

(E) Health status factors, including, but not limited to, experience and utilization.

(F) Employee, and employee and dependents, including a description of the family composition used.

(G) Enrollees' share of premiums.

(H) Enrollees' cost sharing, including cost sharing for prescription drugs.

(I) Covered benefits in addition to basic health care services, as defined in Section 1345, and other benefits mandated under this article.

(J) Which market segment, if any, is fully experience rated and which market segment, if any, is in part experience rated and in part community rated.

(K) Any other factor that affects the rate that is not otherwise specified.

(3) (A) The plan's overall annual medical trend factor assumptions for all benefits and by aggregate benefit category, including hospital inpatient, hospital outpatient, physician services, prescription drugs and other ancillary services, laboratory, and radiology for the applicable 12-month period ending January 1 of the following year. A health plan that exclusively contracts with no more than two medical groups in the state to provide or arrange for professional medical services for the enrollees of the plan shall instead disclose the amount of its actual trend experience for the prior contract year by aggregate benefit category, using benefit categories, to the maximum extent possible, that are the same as, or similar to, those used by other plans.

(B) The amount of the projected trend separately attributable to the use of services, price inflation, and fees and risk for annual plan contract trends by aggregate benefit category, including hospital inpatient, hospital outpatient, physician services, prescription drugs and other ancillary services, laboratory, and radiology. A health plan that exclusively contracts with no more than two medical groups in the state to provide or arrange for professional medical services for the enrollees of the plan shall instead disclose the amount of its actual trend experience for the prior contract year by aggregate benefit category, using benefit categories that are, to the maximum extent possible, the same or similar to those used by other plans.

(C) A comparison of the aggregate per enrollee per month costs and rate of changes over the last five years for each of the following:

(i) Premiums.

(ii) Claims costs, if any.

(iii) Administrative expenses.

(iv) Taxes and fees.

(D) Any changes in enrollee cost sharing over the prior year associated with the submitted rate information, including both of the following:

(i) Actual copays, coinsurance, deductibles, annual out of pocket maximums, and any other cost sharing by the benefit categories determined by the department.

(ii) Any aggregate changes in enrollee cost sharing over the prior years as measured by the weighted average actuarial value, weighted by the number of enrollees.

(E) Any changes in enrollee benefits over the prior year, including a description of benefits added or eliminated, as well as any aggregate changes, as measured as a percentage of the aggregate claims costs, listed by the categories determined by the department.

(F) Any cost containment and quality improvement efforts since the plan's prior year's information pursuant to this section for the same category of health benefit plan. To the extent possible, the plan shall describe any significant new health care cost containment and quality improvement efforts and provide an estimate of potential savings together with an estimated cost or savings for the projection period.

(G) The number of products covered by the information that incurred the excise tax paid by the health plan.

(4) (A) For covered prescription generic drugs excluding specialty generic drugs, prescription brand name drugs excluding specialty drugs, and prescription brand name and generic specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use, all of the following shall be disclosed:

(i) The percentage of the premium attributable to prescription drug costs for the prior year for each category of prescription drugs as defined in this subparagraph.

(ii) The year-over-year increase, as a percentage, in per-member, per-month total health plan spending for each category of prescription drugs as defined in this subparagraph.

(iii) The year-over-year increase in per-member, per-month costs for drug prices compared to other components of the health care premium.

(iv) The specialty tier formulary list.

(B) The plan shall include the percentage of the premium attributable to prescription drugs administered in a doctor's office that are covered under the medical benefit as separate from the pharmacy benefit, if available.

(C) (i) The plan shall include information on its use of a pharmacy benefit manager, if any, including which components of the prescription drug coverage described in subparagraphs (A) and (B) are managed by the pharmacy benefit manager.

(ii) The plan shall also include the name or names of the pharmacy benefit manager, or managers if the plan uses more than one.

(d) The information required pursuant to this section shall be submitted to the department on or before October 1, 2018, and on or before October 1 annually thereafter. Information submitted pursuant to this section is subject to Section 1385.07.

(e) For the purposes of this section, a "specialty drug" is one that exceeds the threshold for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)).

SEC. 3. Section 127280 of the Health and Safety Code is amended to read:

127280. (a) Every health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2, except a health facility owned and operated by the state, shall each year be charged a fee established by the office consistent with the requirements of this section.

(b) Commencing in calendar year 2004, every freestanding ambulatory surgery clinic as defined in Section 128700, shall each year be charged a fee established by the office consistent with the requirements of this section.

(c) The fee structure shall be established each year by the office to produce revenues equal to the appropriation made in the annual Budget Act or another statute to pay for the functions required to be performed by the office pursuant to this chapter, Article 2 (commencing with Section 127340) of Chapter 2, or Chapter 1 (commencing with Section 128675) of Part 5, and to pay for any other health-related programs administered by the office. The fee shall be due on July 1 and delinquent on July 31 of each year.

(d) The fee for a health facility that is not a hospital, as defined in subdivision (c) of Section 128700, shall be not more than 0.035 percent of the gross operating cost of the facility for the provision of health care services for its last fiscal year that ended on or before June 30 of the preceding calendar year.

(e) The fee for a hospital, as defined in subdivision (c) of Section 128700, shall be not more than 0.035 percent of the gross operating cost of the facility for the provision of health care services for its last fiscal year that ended on or before June 30 of the preceding calendar year.

(f) (1) The fee for a freestanding ambulatory surgery clinic shall be established at an amount equal to the number of ambulatory surgery data records submitted to the office pursuant to Section 128737 for encounters in the preceding calendar year multiplied by not more than fifty cents ($0.50).

(2) (A) For the calendar year 2004 only, a freestanding ambulatory surgery clinic shall estimate the number of records it will file pursuant to Section 128737 for the calendar year 2004 and shall report that number to the office by March 12, 2004. The estimate shall be as accurate as possible. The fee in the calendar year 2004 shall be established initially at an amount equal to the estimated number of records reported multiplied by fifty cents ($0.50) and shall be due on July 1 and delinquent on July 31, 2004.

(B) The office shall compare the actual number of records filed by each freestanding clinic for the calendar year 2004 pursuant to Section 128737 with the estimated number of records reported pursuant to subparagraph (A). If the actual number reported is less than the estimated number reported, the office shall reduce the fee of the clinic for calendar year 2005 by the amount of the difference multiplied by fifty cents ($0.50). If the actual number reported exceeds the estimated number reported, the office shall increase the fee of the clinic for calendar year 2005 by the amount of the difference multiplied by fifty cents ($0.50) unless the actual number reported is greater than 120 percent of the estimated number reported, in which case the office shall increase the fee of the clinic for calendar year 2005 by the amount of the difference, up to and including 120 percent of the estimated number, multiplied by fifty cents ($0.50), and by the amount of the difference in excess of 120 percent of the estimated number multiplied by one dollar ($1).

(g) There is hereby established the California Health Data and Planning Fund within the office for the purpose of receiving and expending fee revenues collected pursuant to this chapter.

(h) Any amounts raised by the collection of the special fees provided for by subdivisions (d), (e), and (f) that are not required to meet appropriations in the Budget Act for the current fiscal year shall remain in the California Health Data and Planning Fund and shall be available to the office in succeeding years when appropriated by the Legislature in the annual Budget Act or another statute, for expenditure under the provisions of this chapter, Article 2 (commencing with Section 127340) of Chapter 2, and Chapter 1 (commencing with Section 128675) of Part 5, or for any other health-related programs administered by the office, and shall reduce the amount of the

special fees that the office is authorized to establish and charge. In no event, however, shall those amounts be used for programs administered by the office pursuant to Sections 127676, 127679, 127681, 127683, and 127685, that become effective on or after January 1, 2019.

(i) (1) No health facility liable for the payment of fees required by this section shall be issued a license or have an existing license renewed unless the fees are paid. A new, previously unlicensed, health facility shall be charged a pro rata fee to be established by the office during the first year of operation.

(2) The license of any health facility, against which the fees required by this section are charged, shall be revoked, after notice and hearing, if it is determined by the office that the fees required were not paid within the time prescribed by subdivision (c).

(j) This section shall become operative on January 1, 2002.

SEC. 4. Chapter 9 (commencing with Section 127675) is added to Part 2 of Division 107 of the Health and Safety Code, to read:

CHAPTER 9. PRESCRIPTION DRUG PRICING FOR PURCHASERS

127675. (a) This chapter shall apply to a manufacturer of a prescription drug that is purchased or reimbursed by any of the following:

(1) A state purchaser in California, including, but not limited to, the Public Employees' Retirement System, the State Department of Health Care Services, the Department of General Services, and the Department of Corrections and Rehabilitation, or an entity acting on behalf of a state purchaser.

(2) A licensed health care service plan.

(3) A health insurer holding a valid outstanding certificate of authority from the Insurance Commissioner.

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

(b) For the purposes of this chapter, the term "office" shall mean the Office of Statewide Health Planning and Development.

127676. (a) The Legislature finds and declares that the State of California has a substantial public interest in the price and cost of prescription drugs. California is a major purchaser through the Public Employees' Retirement System, the State Department of Health Care Services, the Department of General Services, the Department of Corrections and Rehabilitation, and other entities acting on behalf of a state purchaser. California also provides major tax expenditures through the tax exclusion of employer sponsored coverage and tax deductibility of coverage purchased by individuals, as well as tax deductibility of excess health care costs for individuals and families.

(b) (1) It is the intent of the Legislature in enacting this chapter to provide notice and disclosure of information relating to the cost and pricing of

prescription drugs in order to provide accountability to the state for prescription drug pricing.

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

127677. (a) A manufacturer of a prescription drug with a wholesale acquisition cost of more than forty dollars ($40) for a course of therapy shall notify each purchaser described in Section 127675 if the increase in the wholesale acquisition cost of a prescription drug 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. For purposes of this section, a "course of therapy" is defined as either of the following:

(1) The recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the federal Food and Drug Administration for 30 days.

(2) The recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the federal Food and Drug Administration for a normal course of treatment that is less than 30 days.

(b) The notice required by subdivision (a) shall be provided in writing at least 60 days prior to the planned effective date of the increase.

(c) (1) The notice required by subdivision (a) shall include the date of the increase, the current wholesale acquisition cost of the prescription drug, and the dollar amount of the future increase in the wholesale acquisition cost of the prescription drug.

(2) The notice required by subdivision (a) shall include a statement regarding whether a change or improvement in the drug necessitates the price increase. If so, the manufacturer shall describe the change or improvement.

(d) The notice required by subdivision (a) shall be provided to each state purchaser and other purchasers described in paragraphs (2) to (4), inclusive, of subdivision (a) of Section 127675 if a purchaser registers with the office for the purpose of this notification. The office shall make available to manufacturers a list of registered purchasers for the purpose of this notification.

(e) If a pharmacy benefit manager receives a notice of an increase in wholesale acquisition cost consistent with subdivision (a), it shall notify its large contracting public and private purchasers of the increase. For the purposes of this section, a "large purchaser" means a purchaser that provides coverage to more than 500 covered lives.

127679. (a) On a quarterly basis at a time prescribed by the office and in a format prescribed by the office, commencing no earlier than January 1, 2019, a manufacturer shall report to the office all of the following information for each drug for which an increase in wholesale acquisition cost is described in Section 127677:

(1) A description of the specific financial and nonfinancial factors used to make the decision to increase the wholesale acquisition cost of the drug and the amount of the increase, including, but not limited to, an explanation of how these factors explain the increase in the wholesale acquisition cost of the drug.

(2) A schedule of wholesale acquisition cost increases for the drug for the previous five years if the drug was manufactured by the company.

(3) If the drug was acquired by the manufacturer within the previous five years, all of the following information:

(A) The wholesale acquisition cost 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.

(C) The year the drug was introduced to market and the wholesale acquisition cost of the drug at the time of introduction.

(4) The patent expiration date of the drug if it is under patent.

(5) If the drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug, as defined in subparagraph (A) of paragraph (7) of subdivision (k) of Section 1396r–8 of Title 42 of the United States Code.

(6) A description of the change or improvement in the drug, if any, that necessitates the price increase.

(7) Volume of sales of the manufacturer's drug in the United States for the previous year.

(b) The manufacturer may limit the information reported pursuant to subdivision (a) to that which is otherwise in the public domain or publicly available.

(c) The office shall publish the information provided to it pursuant to this section on its Internet Web site on no less than a quarterly basis. The information shall be published within 60 days of receipt from a manufacturer. The information shall be published in a manner that identifies the information that is disclosed on a per-drug basis and shall not be aggregated in a manner that would not allow identification of the drug.

(d) The office shall be responsible for the enforcement of this section.

(e) A manufacturer of a prescription drug subject to this chapter that does not report the information required pursuant to this section is liable for a civil penalty of one thousand dollars ($1,000) per day for every day after the reporting period described in this section that the required information is not reported.

(f) A civil penalty shall be assessed and recovered in a civil action brought by the office in the name of the people of the State of California. Assessment of a civil penalty may, at the request of any manufacturer of a prescription drug subject to this section, be reviewed on appeal, and the penalty may be reduced or waived for good cause.

(g) Any money received by the office pursuant to this section shall be paid into the Managed Care Fund.

127681. (a) A manufacturer of a prescription drug shall notify the office in writing if it is introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)). The notice shall be provided in writing within three days after the release of the drug in the commercial market. A manufacturer may make this notification pending approval by the federal Food and Drug Administration, if commercial availability is expected within three days of approval.

(b) No later than 30 days after notification pursuant to this section, a manufacturer shall report all of the following information to the office in a format prescribed by the office:

(1) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally.

(2) The estimated volume of patients that may be prescribed the drug.

(3) If the drug was granted breakthrough therapy designation or priority review by the federal Food and Drug Administration prior to final approval.

(4) The date and price of acquisition if the drug was not developed by the manufacturer.

(c) The manufacturer may limit the information reported pursuant to subdivision (b) to that which is otherwise in the public domain or publicly available.

(d) The office shall publish the information provided to it pursuant to this section on its Internet Web site on no less than a quarterly basis. The information shall be published in a manner that identifies the information that is disclosed on a per-drug basis and shall not be aggregated in a manner that would not allow identification of the drug.

(e) The office shall be responsible for the enforcement of this section.

(f) A manufacturer of a prescription drug subject to this chapter that does not report the information required pursuant to this section is liable for a civil penalty of one thousand dollars ($1,000) per day for every day after the notification period described in this section that the required information is not reported.

(g) A civil penalty shall be assessed and recovered in a civil action brought by the office in the name of the people of the State of California. Assessment of a civil penalty may, at the request of any manufacturer of a prescription drug subject to this section, be reviewed on appeal, and the penalty may be reduced or waived for good cause.

(h) Any money received by the office pursuant to this section shall be paid into the Managed Care Fund.

127683. (a) Funding for the actual and necessary expenses of the office to conduct the activities described in this section and in Sections 127676, 127679, 127681, and 127685, shall be provided, subject to appropriation by the Legislature, from transfers of moneys from the Managed Care Fund and the Insurance Fund.

(b) The share of funding from the Managed Care Fund shall be based on the number of covered lives in the state that are covered under plans

regulated by the Department of Managed Health Care, including covered lives under Medi-Cal managed care, as determined by the Department of Managed Health Care, in proportion to the total number of all covered lives in the state.

(c) The share of funding to be provided from the Insurance Fund shall be based on the number of covered lives in the state that are covered under health insurance policies and benefit plans regulated by the Department of Insurance, including covered lives under Medicare supplement plans, as determined by the Department of Insurance, in proportion to the total number of all covered lives in the state.

127685. (a) The office may adopt regulations or issue guidance for the implementation of this chapter. All information that is required to be reported to the office pursuant to this chapter shall be reported in a form prescribed by the office, commencing in the first calendar quarter of 2019.

(b) The office may consult with the Department of Managed Health Care, the Department of Insurance, the California State Board of Pharmacy, and any state purchaser of prescription drugs, or an entity acting on behalf of a state purchaser, in issuing guidance or adopting necessary regulations pursuant to subdivision (a), in posting information on its Internet Web site pursuant to this chapter, and in taking any other action for the purpose of implementing this chapter.

127686. (a) By January 1, 2022, the California Research Bureau shall report to the Legislature on the implementation of this chapter, including, but not limited to, this chapter's effectiveness in addressing the following goals:

(1) Promoting transparency in pharmaceutical pricing for the state and other payers.

(2) Enhancing understanding about pharmaceutical spending trends.

(3) Assisting the state and other payers in management of pharmaceutical drug costs.

(b) A report submitted pursuant to subdivision (a) shall be submitted in compliance with Section 9795 of the Government Code.

(c) Notwithstanding any other law, implementation of this chapter shall be subject to review by the appropriate policy committees of the Legislature. The review shall be performed as if this chapter were scheduled to be repealed on January 1, 2023.

(d) This section shall remain in effect only until January 1, 2024, and as of that date is repealed.

SEC. 5. Section 10123.205 is added to the Insurance Code, to read:

10123.205. (a) (1) A health insurer that reports rate information pursuant to Section 10181.3 or 10181.45 shall report the information described in paragraph (2) to the department no later than October 1 of each year, beginning October 1, 2018.

(2) For all covered prescription drugs, including generic drugs, brand name drugs, and specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use, all of the following shall be reported:

(A) The 25 most frequently prescribed drugs.

(B) The 25 most costly drugs by total annual plan spending.

(C) The 25 drugs with the highest year-over-year increase in total annual plan spending.

(b) The department shall compile the information reported pursuant to subdivision (a) into a report for the public and legislators that demonstrates the overall impact of drug costs on health care premiums. The data in the report shall be aggregated and shall not reveal information specific to individual health insurers.

(c) For the purposes of this section, a "specialty drug" is one that exceeds the threshold for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)).

(d) By January 1 of each year, beginning January 1, 2018, the department shall publish on its Internet Web site the report required pursuant to subdivision (b).

(e) After the report required in subdivision (b) is released, the department shall include the report as part of the public meeting required pursuant to subdivision (b) of Section 10181.45.

(f) Except for the report required pursuant to subdivision (b), the department shall keep confidential all of the information provided to the department pursuant to this section, and the information shall be protected from public disclosure.

SEC. 6. Section 10181.45 of the Insurance Code is amended to read:

10181.45. (a) For large group health insurance policies, each health insurer shall file with the department the weighted average rate increase for all large group benefit designs during the 12-month period ending January 1 of the following calendar year. The average shall be weighted by the number of insureds in each large group benefit design in the insurer's large group market and adjusted to the most commonly sold large group benefit design by enrollment during the 12-month period. For the purposes of this section, the large group benefit design includes, but is not limited to, benefits such as basic health care services and prescription drugs. The large group benefit design shall not include cost sharing, including, but not limited to, deductibles, copays, and coinsurance.

(b) (1) A health insurer shall also submit any other information required pursuant to any regulation adopted by the department to comply with this article.

(2) The department shall conduct an annual public meeting regarding large group rates within four months of posting the aggregate information described in this section in order to permit a public discussion of the reasons for the changes in the rates, benefits, and cost sharing in the large group market. The meeting shall be held in either the Los Angeles area or the San Francisco Bay area.

(c) A health insurer subject to subdivision (a) shall also disclose the following for the aggregate rate information for the large group market submitted under this section:

(1) For rates effective during the 12-month period ending January 1 of the following year, number and percentage of rate changes reviewed by the following:

(A) Plan year.

(B) Segment type, including whether the rate is community rated, in whole or in part.

(C) Product type.

(D) Number of insureds.

(E) The number of products sold that have materially different benefits, cost sharing, or other elements of benefit design.

(2) For rates effective during the 12-month period ending January 1 of the following year, any factors affecting the base rate, and the actuarial basis for those factors, including all of the following:

(A) Geographic region.

(B) Age, including age rating factors.

(C) Occupation.

(D) Industry.

(E) Health status factors, including, but not limited to, experience and utilization.

(F) Employee, and employee and dependents, including a description of the family composition used.

(G) Insureds' share of premiums.

(H) Insureds' cost sharing, including cost sharing for prescription drugs.

(I) Covered benefits in addition to basic health care services, as defined in Section 1345 of the Health and Safety Code, and other benefits mandated under this article.

(J) Which market segment, if any, is fully experience rated and which market segment, if any, is in part experience rated and in part community rated.

(K) Any other factor that affects the rate that is not otherwise specified.

(3) (A) The insurer's overall annual medical trend factor assumptions for all benefits and by aggregate benefit category, including hospital inpatient, hospital outpatient, physician services, prescription drugs and other ancillary services, laboratory, and radiology for the applicable 12-month period ending January 1 of the following year. A health insurer that exclusively contracts with no more than two medical groups in the state to provide or arrange for professional medical services for the health insurer's insureds shall instead disclose the amount of its actual trend experience for the prior contract year by aggregate benefit category, using benefit categories, to the maximum extent possible, that are the same or similar to those used by other insurers.

(B) The amount of the projected trend separately attributable to the use of services, price inflation, and fees and risk for annual policy trends by aggregate benefit category, including hospital inpatient, hospital outpatient, physician services, prescription drugs and other ancillary services, laboratory, and radiology. A health insurer that exclusively contracts with no more than two medical groups in the state to provide or arrange for professional medical

services for the insureds shall instead disclose the amount of its actual trend experience for the prior contract year by aggregate benefit category, using benefit categories that are, to the maximum extent possible, the same or similar to those used by other insurers.

(C) A comparison of the aggregate per insured per month costs and rate of changes over the last five years for each of the following:

(i) Premiums.

(ii) Claims costs, if any.

(iii) Administrative expenses.

(iv) Taxes and fees.

(D) Any changes in insured cost sharing over the prior year associated with the submitted rate information, including both of the following:

(i) Actual copays, coinsurance, deductibles, annual out of pocket maximums, and any other cost sharing by the benefit categories determined by the department.

(ii) Any aggregate changes in insured cost sharing over the prior years as measured by the weighted average actuarial value, weighted by the number of insureds.

(E) Any changes in insured benefits over the prior year, including a description of benefits added or eliminated as well as any aggregate changes as measured as a percentage of the aggregate claims costs, listed by the categories determined by the department.

(F) Any cost containment and quality improvement efforts made since the insurer's prior year's information pursuant to this section for the same category of health insurer. To the extent possible, the insurer shall describe any significant new health care cost containment and quality improvement efforts and provide an estimate of potential savings together with an estimated cost or savings for the projection period.

(G) The number of products covered by the information that incurred the excise tax paid by the health insurer.

(4) (A) For covered prescription generic drugs excluding specialty generic drugs, prescription brand name drugs excluding specialty drugs, and prescription brand name and generic specialty drugs dispensed at a pharmacy, network pharmacy, or mail order pharmacy for outpatient use, all of the following shall be disclosed:

(i) The percentage of the premium attributable to prescription drug costs for the prior year for each category of prescription drugs as defined in this subparagraph.

(ii) The year-over-year increase, as a percentage, in per-member, per-month total health insurer spending for each category of prescription drugs as defined in this subparagraph.

(iii) The year-over-year increase in per-member, per-month costs for drug prices compared to other components of the health care premium.

(iv) The specialty tier formulary list.

(B) The insurer shall include the percentage of the premium attributable to prescription drugs administered in a doctor's office that are covered under the medical benefit as separate from the pharmacy benefit, if available.

(C) (i) The insurer shall include information on its use of a pharmacy benefit manager, if any, including which components of the prescription drug coverage described in subparagraphs (A) and (B) are managed by the pharmacy benefit manager.

(ii) The insurer shall also include the name or names of the pharmacy benefit manager, or managers if the insurer uses more than one.

(d) The information required pursuant to this section shall be submitted to the department on or before October 1, 2016, and on or before October 1 annually thereafter. Information submitted pursuant to this section is subject to Section 10181.7.

(e) For the purposes of this section, a "specialty drug" is one that exceeds the threshold for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)).

SEC. 7. The provisions of this act are severable. If any provision of this act or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

SEC. 8. The Legislature finds and declares that Sections 1 and 5 of this act, which add Section 1367.243 to the Health and Safety Code and Section 10123.205 to the Insurance Code, respectively, impose a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

In order to protect proprietary, confidential information regarding health care service plan and health insurer prescription drug utilization and spending information that is specific to the plan or insurer and to protect the integrity of the competitive market, it is necessary that this act limit the public's right of access to that information.

SEC. 9. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Exhibit B

PhRMA RESEARCH • PROGRESS • HOPE
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October 13, 2017

Robert P. David
Director, Office of Statewide Health Planning and Development (OSHPD)
2020 West El Camino Avenue, Suite 1200
Sacramento, CA 95833

RE: Implementation of SB 17, Chapter 9, Prescription Drug Pricing for Purchasers

Dear Mr. David:

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), I am writing to discuss implementation of SB 17 (2017). PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. PhRMA would like to discuss the implementation of the law and request the State's interpretation of several provisions regarding manufacturer reporting of prescription drug pricing for purchasers pursuant to Sections 127677, 127679 and 127681 of SB 17 (2017).

Section 127677 Advance Notification of Price Increases to Purchasers

The statute is not clear regarding the effective date of Section 127677 pertaining to advance notification of price increases. Under Article IV, Section 8(c)(1) of the California Constitution, a statute enacted at a regular session shall generally go into effect on January 1 next following a 90-day period from the date of enactment of the statute.[1] If Section 127677 is effective January 1, 2018 (which is not clear to us), it is also not clear if notification is required for price increases that go into effect the first 60 days of 2018. If the State interprets Section 127677(b) to be effective January 1, 2018 and to require advance notification for price increases taken in the first 60 days of 2018, then notification prior to the effective date of the statute would be required, despite the presumption that laws do not have retroactive effect. Would you please clarify the effective date of Section 127677 and provide OSHPD's interpretation of how the advance notification requirements apply to price increases taken in the first 60 days of 2018?

If OSHPD interprets Section 127677(b) to apply prior to the effective date of the bill, PhRMA requests additional clarification on the purchaser notification process described in Section 127677(d). Section 127677(d) states, "The notice required by subdivision (a) shall be provided to each state purchaser and other purchasers described in paragraphs (2) to (4), inclusive, of subdivision (a) of Section 127675 if a purchaser registers with the office for the purpose of this notification. The office shall make available to manufacturers a list of registered purchasers for the purpose of this notification." If OSHPD interprets 127677(b) to require notification prior to the effective date of the law, the list of purchasers described in Section 127677(d) and regulations regarding the notification process will need to be made available 60 days prior to that date in order for manufacturers to comply with advance notification pursuant to Section 127677. Would you please clarify if the State will issue regulations for the purchaser registration and notification processes and when the list of purchasers described in Section 127677(d) will be made

[1] Cal. Const. art. IV, § 8(c)(1).

available? If the list will not be available by November 1, 2017 (60 days prior to January 1, 2018, assuming that is the State's view of the effective date), then what process, if any, should manufacturers follow to comply with the provisions outlined in Section 127677?

In addition, PhRMA requests clarification regarding calculation of the threshold that triggers reporting requirements. Section 127677(a) requires reporting "if the increase in the wholesale acquisition cost of a prescription drug 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." Again, 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. 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 1277677(a)?

Finally, Sections 127679 and 127681 provide OSHPD with the authority to enforce the reporting provisions through "civil action brought by the office in the name of the people of the State of California." However, Section 127677, which sets forth the advance notice requirements, does not contain the same language. Would you please clarify if the penalties described in Section 127679, Section 127681, or any other provision of California law apply to the advance notice to purchasers pursuant to Section 127677?

Sections 127679 OSHPD Transparency Reporting Requirements

Section 127679 (a) provides, "On a quarterly basis at a time prescribed by the office and in a format prescribed by the office, commencing no earlier than January 1, 2019, a manufacturer shall report to the office all of the following information for each drug for which an increase in wholesale acquisition cost is described in Section 127677." It is not clear if a manufacturer must report all price increases for a given quarter in a one-time report or if there is an indefinite quarterly reporting requirement to OSHPD for each drug with price increases above the threshold described in Section 127677. Could you please clarify if reporting must continue indefinitely?

Additionally, Section 127679 provides that reporting pursuant to Section 127679 will commence no earlier than January 1, 2019; however Section 127679 goes on to note that the reporting applies to "each drug for which an increase in wholesale acquisition cost is described in Section 127677." Could you please clarify whether the OSHPD transparency reporting requirements apply to price increases taken prior to January 1, 2019?

Section 127681 OSHPD Transparency Reporting for New Prescription Drugs

Section 127681(a) provides, "A manufacturer of a prescription drug shall notify the office in writing if it is introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program." The effective date for this reporting is not expressed in the Section. PhRMA interprets this Section to fall within OSHPD reporting that goes into effect on January 1, 2019. Would you please confirm that PhRMA's interpretation of the effective date of the notification for new products meeting the Medicare Part D Specialty Drug threshold is correct?

In addition, Section 127681 (b) provides, "No later than 30 days after notification pursuant to this section, a manufacturer shall report all of the following information to the office in a format prescribed by the office." When does the office plan to make the form available to manufacturers so that they may remain compliant with the requirement to submit transparency reporting pursuant to the Section?

Finally, "new prescription drug" is not defined in the statute or elsewhere in California law. PhRMA presumes that Section 127681 applies to drugs being introduced into the commercial market in the State of California for the first time. Would you please confirm that this is an accurate interpretation of the statute?

PhRMA and its member companies appreciate clarification of several provisions of the bill outlined above despite our ongoing concerns about the legality of SB 17. Thank you for your consideration of these clarifying questions and for providing guidance on the implantation of SB 17 (2017).

Sincerely,

Asher Lisec, MSPH
Senior Director, State Policy
PhRMA

Exhibit C

Office of Statewide Health Planning and Development
Senate Bill (SB) 17 (Chapter 603, Statutes of 2017)
Cost Transparency Rx Implementation Plan
November 2017

Beginning 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 at www.oshpd.ca.gov/CTRx.html.

Beginning January 1, 2019, drug manufacturers must notify OSHPD within three days of introducing a new drug at a wholesale acquisition cost that exceeds the specified threshold. Within 30 days of this notification, manufacturers must submit additional information to OSHPD. OSHPD will publish this information on its website quarterly.

Beginning after January 1, 2019, drug manufacturers are required to submit to OSHPD information on the rationale for cost increases for existing drugs that fall under the reporting requirement. OSHPD will collect this information beginning April 2019 and publish on its website within 60 days of receipt from each manufacturer on a quarterly basis.

The following implementation plan describes the provisions of SB 17 involving OSHPD. OSHPD will issue additional guidance in the coming weeks at www.oshpd.ca.gov/CTRx.html.

Projected Time Period	OSHPD Activities
November - December 2017	Compile a registry of state purchasers, healthcare service plans, health insurers, and pharmacy benefit managers that wish to receive 60-day notices of future increases, above the threshold specified, of the wholesale acquisition cost of prescription drugs.
December 1, 2017	Open portal on OSHPD website for purchasers to register to receive 60-day notice.
January 1, 2018	Registry to be available to drug manufacturers on OSHPD website.
January - March 2018	Begin outreach to stakeholders.
April - June 2018	Draft regulations that will take effect January 2019.
September - December 2018	Release information reporting requirements and information collection format to drug manufacturers.
January 2019	Begin collecting information related to new prescription drugs from drug manufacturers. OSHPD to publish this information quarterly on its website beginning Spring 2019.
April 2019	Begin collecting first quarter 2019 prescription drug cost increase information for existing drugs from drug manufacturers.
By June 2019	Publish first quarter 2019 drug cost increase information for existing drugs on OSHPD website.

Exhibit D

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November 30, 2017

Robert P. David
Director, Office of Statewide Health Planning and Development (OSHPD)
2020 West El Camino Avenue, Suite 1200
Sacramento, CA 95833

RE: Follow-up to PhRMA's October 13, 2017 Letter Regarding Implementation of SB 17

Dear Mr. David:

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), I am writing to follow-up on the letter I sent on October 13, 2017 and the implementation plan the Department published on November 22, 2017. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Thank you for publishing an implementation plan and clarifying regulations would be developed pursuant to Sections 127679 and 127681 of SB 17 (2017). While PhRMA appreciates the information published related to implementation of SB 17, there are still several questions that are unanswered from the October 13, 2017 letter related to implementation of Section 127677.

Section 127677 Advance Notification of Price Increases to Purchasers

PhRMA appreciates clarification that the registry of purchasers pursuant to Section 127677(d) will be available to manufacturers on January 1, 2018. Since 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?

In addition, PhRMA has not received clarification regarding calculation of the threshold that triggers reporting requirements. Section 127677(a) requires reporting "if the increase in the wholesale acquisition cost of a prescription drug 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." Again, 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. 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)?

In our letter dated October 13, 2017, PhRMA requested clarification regarding the enforcement provisions related to Section 127677. Sections 127679 and 127681 provide OSHPD with the authority to enforce the reporting provisions through "civil action brought by the office in the name of the people of the State of California." However, Section 127677, which sets forth the advance notice to purchaser requirements, does not contain the same language. PhRMA again asks for clarification of whether the penalties described in Section 127679, Section 127681, or any other provision of California law apply to the advance notice to purchasers pursuant to Section 127677.

Also, the November 2017 implementation plan states that between November and December 2017 OSHPD will "compile a registry of state purchasers, healthcare service plans, health insurers, and pharmacy benefit managers that wish to receive 60-day notices of future increases, above the threshold specified, of the wholesale acquisition cost of prescription drugs." Would you please clarify the criteria that will be used to determine if an entity is eligible to register for advance notification of price increases from manufacturers?

Sections 127679 OSHPD Transparency Reporting Requirements

In the letter dated October 13, 2017 we indicated that Section 127679 (a) provides, "On a quarterly basis at a time prescribed by the office and in a format prescribed by the office, commencing no earlier than January 1, 2019, a manufacturer shall report to the office all of the following information for each drug for which an increase in wholesale acquisition cost is described in Section 127677." It is not clear if a manufacturer must report all price increases for a given quarter in a one-time report or if there is an indefinite quarterly reporting requirement to OSHPD for each drug with price increases above the threshold described in Section 127677. Could you please clarify if reporting must continue indefinitely?

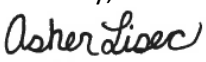
Additionally, Section 127679 provides that reporting pursuant to Section 127679 will commence no earlier than January 1, 2019; however Section 127679 goes on to note that the reporting applies to "each drug for which an increase in wholesale acquisition cost is described in Section 127677." Could you please clarify whether the OSHPD transparency reporting requirements apply to price increases taken prior to January 1, 2019?

Section 127681 OSHPD Transparency Reporting for New Prescription Drugs

"New prescription drug" is not defined in the statute or elsewhere in California law. PhRMA presumes that Section 127681 applies to drugs being introduced into the commercial market in the State of California for the first time. Would you please confirm that this is an accurate interpretation of the statute?

PhRMA and its member companies appreciate additional clarification related to several aspects of law and its implementation outlined above despite our ongoing concerns about the legality of SB 17. Our organization and its members also look forward to continued engagement throughout the regulatory development process. Thank you for your consideration of these clarifying questions related to the implementation of SB 17 (2017).

Sincerely,



Asher Lisec, MSPH
Senior Director, State Policy, PhRMA
1215 K Street, Suite 970
Sacramento CA, 95814

Exhibit E

Date of Hearing: August 23, 2017

ASSEMBLY COMMITTEE ON APPROPRIATIONS
Lorena Gonzalez Fletcher, Chair
SB 17 (Hernandez) – As Amended July 20, 2017

Policy Committee: Health Vote: 11 - 0

Urgency: No State Mandated Local Program: Yes Reimbursable: No

SUMMARY:

This bill establishes disclosure on prescription drug spending, a 60-day prior notification for prescription drug price increases that meet a certain threshold, and reporting to the state on prescription drug price information. Specifically, this bill:

Health Plan/Insurer Disclosure on Drug Spending

1) Requires health plans and insurers to report confidentially to Department of Managed Health Care (DMHC) and California Department of Insurance (CDI) on prescription drug spending, including the most frequently prescribed drugs, the most costly drugs, and the drugs with the highest year-over-year increase in spending.
2) Requires the DMHC and CDI to compile this information in an annual public report that demonstrates the impact of drug costs to health care premiums.
3) Adds, to existing rate information reported to DMHC and CDI, information about the contribution of prescription drugs to overall health spending, the percentage of the premium attributable to prescription drugs administered in a doctor's office that are covered under the medical benefit, and the plans' use of a pharmaceutical benefit manager (PBM).

Drug Pricing Purchaser Notification and Reporting

4) Applies notification and reporting requirements to any manufacturer of a prescription drug that is purchased by or reimbursed by a health plan, a health insurer, PBM, or a state purchaser in California, as specified.
5) Requires a prescription drug manufacturer to provide written notification, 60 days prior to a planned price increase of a drug with a wholesale acquisition cost (WAC) of $40 or more for a 30-day supply, to each state purchaser, health plan or insurer, and PBM, if the cumulative increase (including the proposed increase and any other increases over the prior two calendar years) is more than 10%.
6) Requires the Office of Statewide Health Planning and Development to maintain and provide a list of registered purchasers, for purposes of the advance pricing notification.
7) Requires a pharmacy benefit manager to notify its contracted large public and private purchasers of a price increase notification.
8) Requires manufacturers to report to OSHPD quarterly, and OSHPD to publicly report in turn, information including specific factors used to make a decision on a price increase, an explanation of how these factors relate to the price increase, drug marketing budgets,

information about drug acquisitions, sales volume, and other information, and allows information to be limited to what is in the public domain.

9) Requires manufacturers to notify OSHPD in writing if it is introducing a new prescription drug to market at a WAC that exceeds the threshold set for a specialty drug under Medicare Part D within three days of the release of the drug into the commercial market, and requires manufacturers to report specified related information, including marketing and pricing plans, estimated patient volume, and other information, and allows information to be limited to what is in the public domain.

10) Requires OSHPD to assess a civil penalty of $1,000 per day for every day after the applicable notification period, for failure to report required information, allows a review on appeal, and allows the penalty to be waived or reduced for good cause.

11) Allows OSHPD to issue regulations.

FISCAL EFFECT:

1) Costs to the DMHC in the range of $200,000 in 2017-18, $370,00 in 2018-19, and $350,000 ongoing to review, compile, and report on new rate filing information (Managed Care Fund).

2) Minor costs to CDI, not likely to exceed $15,000 ongoing, to review, compile, and report on new rate filing information (Insurance Fund).

3) Costs to enforce the reporting requirement and collect, coordinate, and publish information by the Office of Statewide Health Planning and Development (California Health Data and Planning Fund) estimated at $550,000 in 2018-19, $1.3 million in 2019-20 and 2020-21, and $1 million ongoing.

4) Unknown potential GF penalty revenues, based on enforcement and levels of noncompliance.

COMMENTS:

1) **Purpose.** According to the author, the introduction of new and innovative drugs is vital to our health care system, but these often high-priced treatments come with a multitude of challenges. The author contends high-priced drugs are a costly burden for patients, state programs, employers, and other payers, and that the public and policymakers need greater insight that will allow us to identify strategies to ensure prices do not threaten access to life-saving treatments.

2) **Drug Spending and Prices.** Prescription drug spending is estimated to account for around 10% of overall health care costs, yet spending has been growing rapidly. Public and policymaker interest in addressing high and growing costs has been piqued in recent years both by the introduction of new, innovative drugs at spectacular prices, such as the $84,000 breakthrough Hepatitis C drug Sovaldi, as well as opportunistic price increases of generic drugs, such as a 5,000% price increase in a decades-old drug called Daraprim.

   When developed, single-source drugs can be sold during a period of market exclusivity in order to reward innovation. After a drug loses its patent protection, it is considered a generic drug, and it may be manufactured by more than one company. Pricing and spending concerns in both the single-source and the more competitive generic market have been noted.

In the single-source market, the main issues are the high and increasing cost of new "specialty" drugs, and steadily increasing growth in overall costs that exceed the growth rate in other market segments. In the generic market, overall price trends are generally downward, but there are concerns about consolidation, short-term market manipulation, and exploitation that lead to seemingly arbitrary, excessive price spikes.

There is a high level of government intervention in the pharmaceutical market. Through state and federal laws, the government limits competition through patent protection, restricts the provision of drugs to those approved by the Food and Drug Administration (FDA) and prescribed by licensed professionals, finances drugs through government programs and subsidies, licenses manufacturers and pharmacies, requires tracking of drugs through the supply chain, requires medically necessary drugs to be provided by health plans and insurance, and caps the patient cost share for prescription drugs.

The prescription drug supply chain— how drugs physically get from manufacturers to patients— is quite complicated and has many intermediate players with different roles, including wholesalers, distributors, pharmacies, and health care providers. There are also a number of entities involved in negotiating the terms and prices under which drugs will be supplied—manufacturers may negotiate terms with payers like government agencies, labor trusts, and employers; purchasers like health plans and insurers; and in some cases, subcontractors like PBMs that manage drug benefits on behalf of numerous payers and purchasers.

Outpatient prescription drug coverage is a required benefit in the individual and small-group market under the federal Affordable Care Act, and is also provided by most large employer plans and through government health care programs. Under current law, health plans and PBMs attempt to meet patient needs for medication in a way that minimizes drug costs through negotiations with manufacturers, while meeting clinical standards of appropriate care. Formularies and different patient cost-sharing levels are used to drive utilization toward lower-cost drugs where possible.

Finally, entities concerned about increasing drug prices also recognize some level of pharmaceutical profits are invested in research and development that creates a pipeline of new, beneficial drugs that may be lifesaving or improve quality of life for consumers. It is generally recognized that the development costs and failure rates for new drugs are high. Also, in some cases, prescription drugs can substitute for more costly health care services, potentially offering a good value for the improvements they offer for a patient's health status, in spite of high sticker prices.

3) **Approach of this bill**. This bill attempts to help purchasers understand and plan for specific price increases by requiring advanced disclosure. It also requires reporting that will assist the state to track pricing factors and trends, and to analyze the impact of prescription drug spending more broadly.

4) **Support.** This bill has support from numerous payers and purchasers, including labor groups and trusts, health plans and insurers, business groups, PBMs, and CalPERS. Health care providers and health consumer advocates also support this bill. California Labor Federation, AFL-CIO (CLF) and Health Access California are cosponsors of this bill, who maintain notice and disclosure are important tools to provide transparency in health care and there is a

strong public policy interest to get basic information on prescription drug prices. A labor trust, the San Francisco Culinary, Bartenders, and Service Employees Welfare Fund, explains the advance price notification will help their trust fund to do the following: make changes to formularies; find alternatives to costly drugs; hold third-party purchasers accountable for prices and rebates; negotiate larger rebates and discounts; and prevent unnecessarily high payment for drugs, such as those with short-term price hikes where an alternative formulation can achieve the same result; and budget for price increases.

5) **Opposition.** Drug manufacturers oppose this bill, contending the reporting is burdensome and harmful to business interests. Member companies of the California Life Sciences Association (CLSA), the Biotechnology Innovation Organization (BIO), and Biocom write it will undermine investment in small and emerging biotechnology firms and that it will disrupt competitive market dynamics. In a joint letter the Pharmaceutical Research and Manufacturers of America (PhRMA), BIO, CSLA, and Biocom note concern about the high volume of reports and the potential administrative burden on OSHPD. They also note the bill requires the disclosure of commercially sensitive pricing information will undermine market competition, and suggest providing this information without confidentiality protections poses significant concerns about stockpiling and limited access, FDA regulation of manufacturer communications, and antitrust issues.

6) **Related Legislation.**

SB 790 (McGuire) prohibits a drug manufacturer or a wholesaler from offering or giving a gift, as defined, to a health care provider. SB 790 is pending on the Assembly Floor.

AB 265 (Wood) prohibits drug manufacturers from offering discounts or other reductions in an individual's out-of-pocket expenses associated with his or her insurance coverage, if a lower-cost therapeutically equivalent generic drug is available. AB 265 is pending on the Senate Floor.

AB 315 (Wood) requires PBMs to be licensed by DMHC and requires a PBM to disclose to a purchaser certain information. AB 315 is pending in the Senate Appropriations Committee.

7) **Prior Legislation.**

SB 1010 (Hernández), of the 2015-16 Legislative Session, was similar to this bill and was placed on the Assembly Floor Inactive File.

AB 2436 (Roger Hernández), of the 2015-16 Legislative Session, required carriers to provide at the time that a prescription drug is delivered or within 30 days of purchase, specified information related to the cost of the prescription drug. AB 2436 died on the Assembly Floor.

AB 463 (Chiu), of the 2015-16 Legislative Session, required pharmaceutical companies to file an annual report with OSHPD containing specified information regarding the development and pricing of prescription drugs. The Assembly Health Committee hearing was canceled at the request of the author.

AB 339 (Gordon), Chapter 619, Statutes of 2015, contains a variety of requirements about formularies and access to prescription drugs, and caps copayments for most health plans at

$250 for a supply of up to 30 days for an individual prescription, as specified.

Analysis Prepared by: Lisa Murawski / APPR. / (916) 319-2081

Exhibit F

SENATE COMMITTEE ON HEALTH
Senator Ed Hernandez, O.D., Chair

BILL NO:	SB 17
AUTHOR:	Hernandez
VERSION:	March 14, 2017
HEARING DATE:	April 19, 2017
CONSULTANT:	Melanie Moreno

SUBJECT: Health care: prescription drug costs

SUMMARY: Requires health plans and insurers that report rate information through the existing large and small group rate review process to also report specified information related to prescription drug pricing to Department of Managed Health Care (DMHC) and California Department of Insurance (CDI). Requires DMHC and CDI to compile specified reported information into a consumer-friendly report that demonstrates the overall impact of drug costs on health care premiums. Requires drug manufacturers to notify specified state purchasers, health plans, and health insurers, in writing at least 90 days prior to the planned effective date, if it is increasing the wholesale acquisition cost (WAC) of a prescription drug by specified amounts. Requires drug manufacturers to notify OSHPD within three days of commercial availability if it is introducing a new prescription drug to market at a WAC that exceeds the Medicare Part D specialty drug threshold. Requires drug manufacturers to provide specified information to the Office of Statewide Health Planning and Development related to the drug's price.

Existing law:

1) Establishes DMHC to regulate health plans and CDI to regulate insurers, including health insurers (referred to as "regulators").

2) Requires health plans and health insurers to file specified rate information with regulators, as applicable, for health plan contracts or health insurance policies in the individual or small group markets and for health plan contracts and health insurance policies in the large group market.

3) Requires, for large group health plan contracts and health insurance policies, plans and insurers to file with regulators the weighted average rate increase for all large group benefit designs during the 12-month period ending January 1 of the following calendar year, and to also disclose specified information for the aggregate rate information for the large group market.

4) Requires health plans and health insurers, for the small group and individual markets, to file with regulators, at least 60 days prior to implementing any rate change, specified rate information so that the departments can review the information for unreasonable rate increases.

5) Requires regulators to accept and post to their Internet Web sites any public comment on a rate increase submitted to the departments during the 60-day period.

6) Under federal law, requires drug manufacturers to obtain approval of new drugs from the federal Food and Drug Administration (FDA).

7) Establishes the Sherman Law, administered by Department of Public Health (DPH), which, among other things, regulates the packaging, labeling, and advertising of drugs and medical devices in California.

8) Prohibits, in the Sherman Law, the sale, delivery, or giving away of any new drug or new device unless it is either:

    a) A new drug, and a new drug application has been approved for it by the FDA, pursuant to federal law, or it is a new device for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under the FDA; or
    b) A new drug or new device for which DPH has approved a new drug or device application, and has not withdrawn, terminated, or suspended that approval.

9) Requires DPH to adopt regulations to establish the application form and set the fee for licensure and renewal of a drug or device license.

This bill:

Health Plan Reporting

1) Requires health plans and insurers that report rate information in the small and large group markets, beginning October 1, 2018, to annually report to regulators the following information about all covered drugs (categorized by generic drugs, brand name drugs, and specialty drugs):

    a) The 25 most frequently prescribed drugs;
    b) The 25 most costly drugs by total annual spending; and,
    c) The 25 drugs with the highest year-over-year increase in total annual spending.

2) Requires regulators to compile this information into a report, to be posted on their websites beginning on January 1, 2019, that demonstrates the overall impact of drug costs on health care premiums. Requires regulators to keep confidential all of the information provided pursuant to 1) above except for this report, and exempts this information from disclosure under the California Public Records Act.

3) Requires the data reported by regulators to be aggregated and to not reveal information specific to individual health plans/insurers.

4) Requires health plans and insurers, beginning October 1, 2018, to annually report, as part of the large group rate review process, to report the following (categorized by generic drugs, brand name drugs excluding specialty drugs, and specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use):

    a) The percentage of the premium attributable to prescription drug costs for the prior year for each category of prescription drugs;
    b) The year-over-year increase, as a percentage, in total spending for each category of prescription drugs;
    c) The year-over-year increase in per-member, per-month costs for drug prices compared to other components of the health care premium;
    d) The specialty tier formulary list;

e) The percentage of the premium attributable to prescription drugs administered in a doctor's office that are covered under the medical benefit as separate from the pharmacy benefit, if available; and,
f) Information on its use of a pharmacy benefit manager (PBM), if any, including its name and which components of the prescription drug coverage are managed by the PBM.

5) Requires the information reported under these provisions to be included as part of the public meeting that is required as part of the large group rate review process.

Prior notice of price increases for prescription drugs

6) Requires drug manufacturers to notify state purchasers (CalPERS, Medi-Cal, Department of Corrections and Rehabilitation, and Department of General Services), health plans and insurers, and PBMs at least 90 days prior to the planned effective date, of an increase in the WAC of a prescription drug as follows:

a) For drugs with a WAC below the Medicare Part D specialty drug threshold, when the increase is 25% or more over a three calendar year period; and,
b) For drugs with a WAC above the Medicare Part D specialty drug threshold, when the increase is 10% or more over a three calendar year period.

7) Requires this notice to include a statement of any changes or improvements to the clinical efficacy of the drug that explain the price increase. If there are no changes or improvements made to the clinical efficacy of the drug subject to the notice, requires the manufacturer to state that.

8) Requires a PBM, if it receives a price increase notice, to notify its large contracting purchasers of the increase.

9) Requires drug manufacturers, at the time that the price increase described above takes effect, to report to OSHPD all of the following:

a) A description of factors used to make the decision to increase the drug's price and the amount of the increase, including, but not limited to, an explanation of how these factors justify the increase in the WAC of the drug;
b) The previous year's marketing budget for the drug, including the budget for patient assistance programs specific to the drug; and,
c) A schedule of price increases for the previous five years if the drug was manufactured by the company.

10) Requires the drug manufacturer, if the drug was acquired by the manufacturer within the previous five years, to report all of the following:

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;
c) The year the drug was introduced to market and the WAC at the time of introduction;

d) The patent expiration date of the drug if it is under patent;
e) If the drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug;
f) Documentation of increased clinical efficacy of the drug, if any. If the drug does not exceed the clinical efficacy of existing treatments, the manufacturer must state that; and,
g) Volume of sales of the drug in the United States for the previous year.

Notice of introduction of new high-cost prescription drugs

11) Requires drug manufacturers to notify OSHPD within three days of commercial availability if it is introducing a new prescription drug to market at a WAC that exceeds the Medicare Part D specialty drug threshold.

12) Requires drug manufacturers, within 30 days of the notification above, to report to OSHPD all of the following:

a) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally;
b) The estimated volume of patients that may be prescribed the drug;
c) Any documentation showing increased efficacy of the drug compared to existing treatments. Requires manufacturers to state if there are no changes or improvements made to the clinical efficacy of the drug subject to the notice;
d) If the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval;
e) The expected marketing budget for the drug, including the budget for patient assistance programs; and,
f) The date and price of acquisition if the drug was not developed by the manufacturer.

13) Requires OSHPD to post this information on its website on a quarterly basis for price increases and on a monthly basis for new drugs in in a manner that identifies the information on a per-drug basis, and not be aggregated in a manner that would not allow identification of the drug.

FISCAL EFFECT: This bill has not been analyzed by a fiscal committee.

COMMENTS:

1) *Author's statement.* The introduction of new and innovative drugs is vital to our health care system, but these often high-priced treatments come with a multitude of challenges. Expensive drugs and steady price increases are becoming common-place with little transparency for astounding prices. This high-priced trend is a costly burden for patients, state programs, employers, and other payers, making it crucial that we understand what's behind the exploding prices. The public and policymakers need greater insight that will allow us to identify strategies to ensure prices do not threaten access to life-saving treatments. Additionally, data suggest that publically accessible price information in other sectors of the health care market encourage providers to offer more competitive pricing and thereby reduce excess health spending. Transparency-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. This bill will 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. 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.

2) *Health care costs.* According to the Centers for Medicare and Medicaid Services (CMS), in 2015, U.S. health care spending increased 5.8% to reach $3.2 trillion, or $9,990 per person. The coverage expansion that began in 2014 as a result of in the Affordable Care Act continued to have an impact on the growth of health care spending in 2015. Additionally, faster growth in total health care spending in 2015 was driven by stronger growth in spending for private health insurance, hospital care, physician and clinical services, and the continued strong growth in Medicaid and retail prescription drug spending. Health care costs continue to consume significantly large percentages of federal, state and personal budgets. Health care continues to grow at higher rates than inflation. In 2013, the U.S. spent far more on health care than other high-income countries. Higher spending is due to multiple factors including greater use of medical technology and higher health care prices, not necessarily more frequent doctor visits or hospital admissions.

3) *Drug costs.* According to CMS, although retail prescription drug spending slowed in 2015, it still increased by 9% to $324.6 billion. Although growth in 2015 was slower than the 12.4% growth in 2014, spending on prescription drugs outpaced all other services in 2015. The growth in spending for prescription drugs is attributed to increased spending on new medicines, price growth for existing brand name drugs, increased spending on generics, and fewer expensive blockbuster drugs going off-patent. A Kaiser Family Foundation analysis of data from CMS and Truven Health Analytics shows that while drugs account for 10% of U.S. health spending, it represents 19% of the cost of employer insurance benefits. Some speculate that this disparity exists because the $3 trillion in U.S. health spending is a broad catchall with includes hospital care, physician services, drugs, research, administrative costs, public health activities, and long-term care. Additionally, some of the people served by Medicare and Medicaid (whose spending is counted in the national totals) require many services not typically used by those covered by employer health plans. According to an analysis by the CEO of the Kaiser Family Foundation, even that 19% figure is understated because while it includes prescriptions that patients fill at pharmacies, it does not include many of the expensive drugs administered in physicians' offices or hospitals. In Medicare, for example, retail prescription drugs represent 13% of overall spending while drugs administered mainly by physicians add an additional 6%.

According to a Health Affairs Blog post from May 2016, one of the primary drivers of high drug costs is specialty drugs. Because of their extremely high costs, specialty drugs account for a disproportionate share of overall drug spending and have a corresponding effect on spending growth. In fact, spending on specialty medicines was responsible for 73% of overall medicine spending growth over the past five years. The prices of specialty drugs are also growing dramatically. For example, the Memorial Sloan Kettering Cancer Center reported that the median launch price of new cancer agents doubled in the last decade, from $4,500 per month to more than $10,000 per month. Similarly, the launch prices of new multiple sclerosis drugs increased from $8,000 to $12,000 per year in the 1990s to $50,000 to $65,000

per year today. Specialty drugs also often experience substantial price growth every year they are on the market. For example, the AARP Public Policy Institute's December 2016 Rx Price Watch report found that the retail prices of specialty drugs widely used by older Americans increased by almost 11% in 2013. Hefty increases are not limited to specialty drugs; prices for drugs that have been on the market for decades have also seen inexplicable increases. For example, over the past 20 years, the price of human insulin produced by two major manufacturers – Eli Lilly and Novo Nordisk – rose 450% after accounting for inflation, according to a 2016 Washington Post analysis of data from Truven Health Analytics. A single 10-milliliter vial of Eli Lilly's Humalog insulin, which is less than a month's supply for many adults, was listed at $254.80 last year, compared with $20.82 in 1996.

4) *Drug pricing.* Federal regulations prohibit the U.S. government from setting the price of pharmaceuticals, and patents on drugs, in effect, prohibit competition, at least initially. Countries without these restrictions generally buy drugs for a fraction of the U.S. price. Pharmaceutical companies argue that high drug prices are justified because of the enormous cost and risk associated with bringing a drug to market and that payment for current drugs fund future innovation. Developing a new drug costs an average of $1.2 billion and takes 10 to 15 years. When a new drug provides a cure for a disease, as opposed to only treating symptoms, drug companies claim that a high upfront cost is mitigated by not having to treat symptoms indefinitely. However, critics point to numerous examples of drug companies charging high prices for drugs with only marginal improvements over cheaper alternatives, or astounding increases in pricing for drugs that have been on the market for years.

5) *Price Benchmarks.* Knowing how much a drug costs is difficult; there are many different prices for each drug and different ways of expressing those prices. In the US, the two most common ways of stating drug prices are the WAC and average wholesale price (AWP). Neither one, though, is the actual price paid by a payer, nor are they what their names imply. Rather, they're standardized ways of expressing a price, thus allowing comparisons to be made from one drug to another. AWP is a benchmark that has been used for over 40 years for pricing and reimbursement of prescription drugs for both government and private payers. Initially, the AWP was intended to represent the average price that wholesalers used to sell medications to providers, such as physicians, pharmacies, and other customers. However, the AWP is not a true representation of actual market prices for either generic or brand drug products. AWP has often been compared to the "list price" or "sticker price," meaning it is an elevated drug price that is rarely what is actually paid. AWP is not a government-regulated figure, does not include buyer volume discounts or rebates often involved in prescription drug sales. As such, the AWP, while used throughout the industry, is a controversial pricing benchmark.

   The WAC price of a drug on the market, as originally announced by the company is also rarely the price paid by a payer. The actual price paid by any one payer is proprietary information, complicating discussions of value and cost to consumers. Drug companies negotiate with payers – Medicare, Medicaid, insurers, and PBMs – to set an initial gross sales price. Drug manufacturers pay rebates back to government entities, creating a difference between gross sales for a drug and net sales. The rebates are not publicly available, and vary highly among payers and for different drugs. Estimates put them between 2% for innovative new drugs and up to 60% for drugs that have several competitors or generics on the market.

   Federal law requires manufacturers to provide rebates to the Centers for Medicare and Medicaid Services and state Medicaid agencies. The program requires a drug

manufacturer to enter into, and have in effect, a national rebate agreement with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of most of the manufacturer's drugs. These rebates are paid by drug manufacturers on a quarterly basis to states and are shared between the states and the federal government to offset the overall cost of prescription drugs under the Medicaid program. According to DHCS, drug manufacturers are required to pay a Medi-Cal rebate for all outpatient drugs that are dispensed and paid for by the Medi-Cal program. In addition, some manufacturers have agreed to pay supplemental Medi-Cal rebates above the standard rebate. Federal law requires rebates for prescriptions offered through the AIDS Drug Assistance Program (ADAP), in part because of the high cost of HIV/AIDS medications. According to the Kaiser Family Foundation, drug manufacturer rebates account for 40% of the annual ADAP budget.

6) *Impact on state finances*. Medi-Cal provides health care coverage for nearly one-third of Californians. Combined with CalPERS, ADAP, state hospitals, and corrections, taxpayer liability for increasing drug costs is significant. For example, according to a December 2015 report published by the U.S. Senate Committee on Finance, Medi-Cal's fee-for-service system alone spent nearly $25 million treating roughly 340 patients with Sovaldi and Harvoni in 2014. However, Medi-Cal fee-for-service is only a fraction of the Medi-Cal population. Private health plans invoiced the state an additional $387.5 million for Sovaldi and Harvoni treatments for Medi-Cal managed care enrollees between July 2014 and November 2015 (for 3,624 patients) according to DHCS. Additionally, as a direct result of Sovaldi and Harvoni pricing, the 2015-16 California state budget allocated $228 million just for high cost drugs to DHCS and CDCR. In December 2015, it was reported that CalPERS spent $438 million on specialty drugs, an increase of 32% from the previous year. This represents one quarter of the total drug costs paid by CalPERS, while only 1% of the prescriptions filled.

7) *Related legislation.* SB 790 (McGuire) would prohibit a drug manufacturer or a wholesaler from offering or giving a gift, as defined, to a health care provider. Prohibits a drug manufacturer or an entity on behalf of a drug manufacturer from providing a fee, payment, subsidy, or other economic benefit to a health care provider in connection with the provider's participation in research, with some exceptions. Authorizes the Attorney General to bring an action to enforce a violation of these provisions and to seek injunctive relief and imposition of a civil penalty for each violation, as specified. Requires a health care professional, as defined, who is a member of a committee that sets formularies or develops clinical guidelines and who also serves as a speaker or commercial consultant for a drug manufacturer to disclose to the committee his or her relationship with the manufacturer, as specified. *SB 790 is set to be heard in the Senate Health Committee on April 26, 2017.*

   AB 265 (Wood) would prohibit, with some exceptions, prescription drug manufacturers from offering any discount,-repayment, product voucher, or other reduction in an individual's out-of-pocket- expenses associated with his or her insurance coverage, including, but not limited to, a copayment or deductible, for any prescription drug if a lower cost brand name or non-brand name prescription drug is available that is designated- as therapeutically equivalent to, or interchangeable with, the prescription drug. *AB 265 is pending in the Assembly Health Committee.*

8) *Prior legislation.* SB 1010 (Hernandez, 2016) was substantially similar to this bill. *SB 1010 was placed on the inactive file on the Assembly Floor.*

AB 2436 (Roger Hernández, of 2016) would have required carriers to provide at the time that a prescription drug is delivered or within 30 days of purchase, specified information related to the cost of the prescription drug. *AB 2436 failed passage on the Assembly Floor.*

AB 2711 (Chiu, of 2016) would have reinstated a previously repealed requirement for the Department of General Services to report to the Legislature on its prescription drug bulk purchasing program. *AB 2711 was held on the Assembly Appropriations Committee suspense file.*

AB 463 (Chiu, of 2015) would have required pharmaceutical companies to file an annual report with OSHPD containing specified information regarding the development and pricing of prescription drugs. *Hearing canceled at the request of author in the Assembly Health Committee.*

9) *Support.* According to the California Labor Federation (CLF), a cosponsor of this bill, Congress has investigated a number of arbitrary and outrageous drug price increases over the past year—from Sovaldi to Epipens and insulin. The Congressional reports detail how many price increases for drugs have little relation to improvements in the effectiveness of the drug or to the cost of research and development (R&D). Many price increases, such Mylan's steady upward trend for Epipen, were seemingly arbitrary. Others, such as insulin drugs, showed a pattern of three companies raising prices in lock-step. A U.S. Senate Finance Committee report found that the launch price of a drug like Sovaldi, to treat Hepatitis C, was set to maximize revenue and ensure an even higher launch price for the company's second Hepatitis C drug, Harvoni, which was in the pipeline. Drug companies argue that the costs of R&D for new medications justify the high prices. However, half of the new drugs approved in the U.S. from 1998 to 2007 resulted from research at universities and biotech firms, not drug companies. Drug companies spend 19 times as much on marketing for drugs than they do on R&D. In other cases, companies buy old drugs and raise prices as a profit driven business decision. According to Health Access California (HAC), a cosponsor of this bill, advance notice is routine in health care: health plans and insurers provide purchasers 60 days advance notice of rate increases; Covered California and other health plans offering coverage in the individual market provide six months advance notice of rate increases through the rate review process; and, hospitals are required to provide 75 days advance notice of a contract termination. Advance notice of 90 days gives purchasers, both public and private, time to adjust formularies, to negotiate price concessions, and to seek other alternatives, including obtaining alternative formulations of drugs for which there are therapeutic equivalents. Many purchasers have drug formulary committees that meet quarterly to review the drug formulary: while some would prefer longer notice, at least 90 days' notice allows time to adjust to price hikes. Kaiser Permanente (KP) contends that among the greatest threats to the affordability of health care coverage is the pharmaceutical industry's pricing of new and existing medication. KP states that the exorbitant prices of these important medications are leading to circumstances where consumers are having to shoulder a greater share of the burden of the overall cost of the drug, and public health may be jeopardized when treatments are out of reach because of their costs. The California Association of Health Plans states that rising prescription drug prices have been cited as a major driver of premium increases for CalPERS and Covered California, and six-figure price tags for new treatments and thousand-percent price hikes on decades-old medications are becoming the new normal, but no one really understands why this trend is so pervasive because there is no sunlight on how pharmaceutical companies price their products. Blue Shield of California writes that this bill takes an important step toward achieving prescription drug price transparency, by requiring

for the first time that the drug manufacturers take some level of responsibility for the impact of drug costs and their incessant price increases have on the affordability of health care. Epilepsy California writes that this bill assures that individuals with epilepsy will be provided greater transparency on prescription drug costs, and such assistance will assist both patients and their physicians in accessing appropriate drug therapy plans which will better control seizures. Epilepsy California states that shining a light on the costs of prescription drugs is a first step in reducing drug costs and saving the lives of 360,000 Californians with epilepsy. National Multiple Sclerosis Society writes that this bill is a good starting point and will be an important tool to help educate consumers about their prescription drug related expenses because lack of public information on price increases contributes to the burden of living with a chronic condition like MS. Western Center on Law and Poverty states that many consumers, particularly the low-income consumers they serve, have 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. Pacific Business Group on Health (PBGH) and Silicon Valley Employers Forum (SVEF) write last year, their members spent more than $12 billion dollars providing coverage to over three million California employees, retirees, and dependents. A significant—but ultimately unknown—proportion of this $12 billion can be directly attributed to the high and rising cost of pharmaceutical drugs. While retail and mail order medication filled through a separate pharmacy benefit comprise between 20 to 25% of health care spending for a typical PBGH or SVEF member, total drug costs are actually much higher given that many are administered in hospitals and clinics and paid for under an employee's medical benefit. More information on the most expensive and frequently utilized drugs is needed for public and private stakeholders trying to determine and implement value-based purchasing and policy strategies. The Los Angeles Area Chamber of Commerce writes that California has made significant gains in reducing our state's number of uninsured over the past several years, but to sustain this progress we must address affordability and the underlying costs that impact the price of coverage and this bill is a move toward transparency that can help further discussions over how we can address prices in the long term. Tenet Healthcare writes that this bill and its notification and other requirements would help to provide a new level of pragmatic transparency in a critical health care sector, and that the disclosures under this bill will begin to provide some much needed checks and balances for ongoing pharmaceutical cost trends, as well as important and overdue accountability.

10) *Oppose unless amended.* The Association for Accessible Medicines (AAM) writes that the generic industry's business model is similar to a commodities market where prices- sometimes at pennies a dose- fluctuate up and down regularly, and so under this bill, a generic drug could easily trigger this threshold numerous times, not because of rising drug prices, but because of normal business practices of the marketplace. AAM states that there is a genuine concern that when faced with this potential regulatory burden, a company would find it much easier to exit a market rather than dedicate resources to justify their pricing, and transparency legislation is a sure way to accomplish the opposite of what its authors intend. AAM believes that products below a certain cost should not be included and the legislation must allow for the differences between the brand and generics market when it comes to calculating increases and complying with the regulatory requirements.

11) *Opposition.* The Biotechnology Innovation Organization (BIO) writes that while this bill does not enact direct price caps on biopharmaceuticals, the bill is intended to impose a form of price control as the pre-notice and other reporting requirements are meant to discourage excessive price increases. BIO states that this "deterrent" would be imposed on nearly every

manufacturer of innovative biopharmaceutical therapies because the reporting threshold for medications that cost over $670 per month is 10% over three years, or an average of 3.33% per year, which is less than the medical CPI. BIO contends that this bill requires manufacturers to report marketing and pricing plans used in the launch of new drugs, specific factors used in determining price increase decisions, and acquisition prices of specific products, and they consider much of this information trade secrets and oppose requirements to publicly report information that will harm their members' ability to compete with other manufacturers and effectively negotiate with purchasers. BIO is also concerned that the advance notice provisions in this bill would have serious unintended consequences for the drug supply chain because the substantial advanced notice would provide enough time for wholesalers, hospitals, pharmacies, large provider networks, and buying groups to engage in stockpiling activity in advance of a price increase, which would disrupt the availability of medicines not only in California, but nationwide. The California Life Sciences Association (CLSA) asserts that this bill would create an incomplete and misleading picture of drug costs, and further from understanding drug costs in California and would also impose millions in new administrative costs, despite providing no meaningful benefits. CLSA states that this bill focuses almost entirely on prices and spending, which is not necessarily the same as cost, as cost should explicitly factor in offsets (e.g., rebates, discounts, and other price concessions, as well as other costs avoided). CLSA writes that looking outside of this bill for meaningful PBM information, which one must do, we grow increasingly concerned that there is not more alignment on recognizing PBMs' central role as legislative efforts move forward with a stated intent to achieve a better understanding of drug costs, and that the information required of biopharmaceutical companies, health plans, and insurers would create a highly inaccurate picture of how medicines affect overall healthcare costs, particularly in the absence of any cost information from PBMs. Pharmaceutical Research and Manufacturers of America (PhRMA) writes that requiring price notifications from manufacturers will not benefit patients, because access to care is primarily driven by insurance coverage and benefit design, and due to that benefit design, consumers' cost sharing for prescription medicines is disproportionately high relative to their cost share for other services. PhRMA states that patients pay for about 20% of their prescription drugs costs out-of-pocket compared to just 5% of their hospital costs and 15% of their overall health care costs. PhRMA contends that high cost sharing is associated with lower adherence to medicines, which can lead to poor health outcomes for patients and increased use of other medical services.

12) *Amendments.* The author has asked the Committee to approve the following amendments:

a) On page 4, delete lines 11-16 and replace with:

(f) Except for the report required pursuant to subdivision (b), the department shall keep confidential all of the information provided to the department pursuant to this section, and the information shall be protected from public disclosure.

b) On page 10, line 30, delete "of" and insert "after FDA approval"

c) On page 10, line 34, delete "Within 30 days of" and insert "No later than 30 days after"

SUPPORT AND OPPOSITION:

Support: California Labor Federation (co-sponsor)
Health Access California (co-sponsor)
AARP
American Federation of State, County and Municipal Employees, AFL-CIO
America's Health Insurance Plans
Anthem Blue Cross
Asian Law Alliance
Association of California Life and Health Insurance Companies
Blue Shield of California
California Alliance for Retired Americans
California Association of Health Plans
California Black Health Network
California Conference Board of the Amalgamated Transit Union
California Conference of Machinists
California Hospital Association
California Immigrant Policy Center
California Medical Association
California Nurses Association/ National Nurses United
California Optometric Association
California Pan-Ethnic Health Network
California Physicians Alliance
California Professional Firefighters
California Retired Teachers Association
California School Employees Association
California State Retirees
California Teachers Association
CALPIRG
Carson Chamber of Commerce
Children Now
City and County of San Francisco
Congress of California Seniors
Consumer Federation of California
Consumers Union
Engineers and Scientists of California, IFPTE Local 20
Epilepsy California
Fresno Chamber of Commerce
Greater Conejo Valley Chamber of Commerce
IATSE Local 80
International Longshore and Warehouse Union
Irwindale Chamber of Commerce
J. Glynn & Company
Justice in Aging
Kaiser Permanente
LIUNA Locals 777 & 792
Los Angeles Area Chamber of Commerce
Los Angeles County Professional Peace Officers Association
Molina Healthcare
Montebello Chamber of Commerce
National Health Law Program

National Multiple Sclerosis Society
NextGen Climate
Orange County Professional Firefighters Association, Local 3631
Pacific Business Group on Health
Pasadena Chamber of Commerce & Civic Association
Personal Assistance Services Council
Professional & Technical Engineers, Local 21, AFL-CIO
Project Inform
San Gabriel Valley Chamber of Commerce
SEIU California
Silicon Valley Employers Forum
The Silicon Valley Organization
Tenet Healthcare
United Food and Commercial Workers
UNITE HERE
United Nurses Associations of California/Union of Health Care Professionals
Utility Workers Union of America, Local 132
Western Center on Law & Poverty

Oppose: Association for Accessible Medicines (unless amended)
Biocom
Biotechnology Innovation Organization
California Life Sciences Association
Pharmaceutical Research and Manufacturers of America

-- END --

Exhibit G

HEALTH ACCESS CALIFORNIA

July 17, 2017

The Honorable Lorena S. Gonzalez Fletcher, Chair
Assembly Appropriations Committee
State Capitol Room 2114
Sacramento, CA 95814

Re: SB 17 (Hernandez): Co-Sponsor/Support
As amended July 5, 2017

Dear Assemblymember Gonzalez Fletcher,

Health Access California, the statewide health care consumer advocacy coalition committed to affordable, quality health care for all Californians, is pleased to co-sponsor and support SB 17 which, as amended July 5, 2017, would require transparency of prescription drug prices. SB 17 would provide advance notice to purchasers, both public and private, as well as make public information about pricing decisions, marketing, increased clinical efficacy, and impact on premiums and cost sharing for health insurance.

Advance Notice of Price Increases - 60 Days Triggered by Cumulative Price Increases:
SB 17 provides 60 days advance notice of increases in prescription drug prices if the cumulative price increase over the prior two years is more than 10%.

The notice goes to public purchasers, including CalPERS and Medi-Cal, as well as private purchasers, specifically health plans, health insurers and pharmacy benefit managers, who register with OSHPD to receive the notice.

This threshold for cumulative price increases creates an incentive for price increases to fall below 10%.

Advance notice is routine in health care:

- Health plans provide purchasers 60 days advance notice of rate increase.
- Covered California and CalPERS provide *six months* advance notice of rate increases through the rate review process.
- Hospitals are required to provide 75 days advance notice of a contract termination with a health plan

Advance notice of 60 days gives purchasers, both public and private, time to adjust formularies, negotiate price concessions, and seek other alternatives, including obtaining alternative formulations of drugs for which there are therapeutic equivalents.

Many purchasers have drug formulary committees that meet quarterly to review the drug formulary: while some would prefer longer notice, at least 60 days' notice allows time to adjust to price hikes.

Impact on Health Insurance Premiums and Cost Sharing:
SB 17 also requires health plans to disclose publicly the most costly drugs, the most frequently prescribed drugs, and the drugs with the highest cost increases.

SB 17 also requires public disclosure, through rate review, of the percentage of the premium attributable to prescription drug costs as well as the year over year increase in spending on drugs.

Transparency of Drug Pricing Information:
SB 17 requires pharmaceutical manufacturers to disclose information about drug pricing to the Office of Statewide Health Planning and Development. Since 1982, the Office of Statewide Health Planning and Development has been the central repository for health care cost and quality data for the State of California, providing detailed cost and quality information on hospitals, nursing homes, and other elements of the health care system. No public agency has provided comparable data on prescription drug costs which hampers efforts to manage these costs.

SB 17 would require pharmaceutical manufacturers to provide OSPHD information on:

- Factors used to make the decision to increase a drug's price
- Prior year's marketing budget for the drug
- Information on price increases for the prior five years
- Information on improved clinical efficacy of drug, if any
- Volume of sales
- Other information

For decades, California has made public information on costs and quality of health facilities because of the impact on purchasers, both public and private. SB 17 will help to fill the gap on prescription drug prices by making public information about pricing decisions and elements of drug costs.

Conclusion: Prescription drug prices, for both new and existing drugs, keep climbing year after year, driving up overall health care costs. The unit price of drugs and other health care costs are higher in this country than in other industrialized countries. SB 17 takes a very modest step toward transparency by providing advance notice of price increases and additional information about pricing and impacts on insurance rates. For this reason, we are pleased to co-sponsor and support this measure.

Sincerely,

Anthony Wright
Executive Director

CC: Members of the Assembly Appropriations Committee
Senator Ed Hernandez, author

WJ

Exhibit H

SB 17 (Hernandez) - Drug Pricing Transparency

Shining a Light on Drug Prices

SB 17 is a common-sense approach to providing transparency in drug pricing which will ensure affordable and accessible prescription drugs for California consumers.

Why Transparency?

- *Transparency works*. When we've required transparency in pricing on other sectors of the industry, prices have stabilized or have decreased.
- *Value of knowing*. It gives state purchasers and employers the tools to effectively negotiate with drug companies for fair prices.
- *Level the playing field*. We've required other big sectors to participate in transparency on cost drivers in order to help control cost increases – hospitals, plans, and providers all have transparency requirements. This is the only major sector of the health care system that doesn't have these types of requirements.

About SB 17

Sponsored by labor and consumers, this bill will promote transparency in the health care system by requiring drug makers to give prior notice to purchasers before raising prices and requiring health plans to report the proportion of the premiums that we pay which is spent on prescription drugs.

- **Ensures Advanced Notice for Pricing**
  - Drug makers must notify public and private purchasers before significant increase in prices
  - Drug makers must provide explanations about price increases and provide previous price increases for their products.
- **Records Drug Spending Information**
  - Health plans must report information on drugs purchasing trends, including the most prescribed, the most expensive, and the highest increases in spending.
  - Health plans must report the percentage of premiums spent on drugs and premium changes related to drug spending
- **Offers Access to Spending Data**
  - Regulators must issue public reports on cost drivers and drug spending
  - Regulators must inform public of significant price increases and new expensive drugs

Support A broad coalition has signed on in support of SB 17, including:
Consumer and Patient Groups AARP; Health Access California (sponsor); California State Retirees; CALPIRG; Children NOW; Congress of California Seniors; Consumer Federation of California; Consumers Union; Epilepsy California; National MS Society – CA Action Network; NextGen Climate; Project Inform
Health care Association of California Life and Health Insurance Companies; Blue Shield of California; California Association of Health Plans; California Hospital Association; California Medical Association; California Nurses Association; California Physicians Alliance; Kaiser Permanente, National Nurses United
Business Groups Los Angeles Area Chamber of Commerce; Pacific Business Group on Health; San Gabriel Valley Chamber of Commerce; Silicon Valley Employers Forum; Small Business Majority
Labor AFSME, AFL-CIO; California Labor Federation; AFL-CIO (sponsor); California Conference Board of the Amalgamated Transit Union; California Conference of Machinists; California Professional Firefighters; California School Employees Association; California Teachers Association; California Teamsters Public Affairs Council; Engineers and Scientists of California, IFPTE Local 20; International Alliance of Theatrical Stage Employees (IATSE), Local 80; International Longshore and Warehouse Union; LIUNA Locals 777 & 792; Professional and Technical Engineers, IFPTE Local; San Francisco Culinary, Bartenders and Service Employees Welfare Fund; SEIU California; UNITE HERE!; United Nurses Associations of California/Union of Health Care Professionals; Utility Workers Union of America
Local Government City and County of San Francisco; League of California Cities; School Employers Association of California; Small School Districts Association

What Others Are Saying

"Californians deserve to know why their medicine costs so much. With the ACA's health care gains under attack in Washington, D.C., we must do everything we can in California to fight real health care challenges like the skyrocketing costs of prescription drugs. This bill will help lift the veil on soaring drug prices so we can identify meaningful strategies to ensure access to life-saving treatments. I look forward to working this year with Sen. Hernandez and the broad coalition of advocates supporting SB 17." – **Assemblymember David Chiu** (Co-author)

"Behind closed doors, corporate pharmaceutical executives make life-and-death decisions for millions of Californians. This important legislation will help protect our families by introducing transparency and fairness to pricing of essential, lifesaving medicines. It is an essential first step to rein in skyrocketing prescription drug prices." – **NextGen Climate President Tom Steyer**

"With the President and Congress focused on tax and regulatory giveaways to Big Pharma rather than on any relief for consumers, it is more urgent than ever for California to take a lead on prescription drug price transparency. This legislation will provide purchasers with the information needed to better respond to prescription drug price hikes and negotiate better deals for patients." – **Health Access California Executive Director Anthony Wright** (Co-Sponsor)

"Skyrocketing prescription drug prices are hammering working people and driving up the cost of health care up for everyone. When someone is struggling with a life-threatening disease like cancer or diabetes, they should not have to make the choice between paying for treatment and paying the rent. SB 17 brings much-needed transparency to prescription drug pricing to help lower drug prices and contain health care costs." – **California Labor Federation Executive Secretary-Treasurer Art Pulaski** (Co-Sponsor)

"Data reported to the state by health plans proves that skyrocketing drug prices are the fastest growing driver of overall increases we pay for our healthcare. Moreover, the data proves that increases in prescription drugs are NOT related to usage, but are exclusively driven by PRICE inflation. We must get transparency from the drug industry to contain costs. That's why we support SB 17 by Senator Hernandez." – **UNITE HERE State Political Director Jack Gribbon**

"Like millions of other Americans, I'm a type 2 diabetic and need to take insulin regularly in order to survive. Insulin is a 95 year old drug for which there are no research and development costs - so why does the price keep climbing and climbing? Insulin is so expensive that on those months when I don't work enough hours to qualify for my union's health trust fund, my church has to help me buy insulin, which is literally life-saving for me." – **Alfy Youssef, a banquet barback at the Fairmont Hotel in San Francisco and a member of UNITE HERE Local 2**

"Pharmaceutical drug costs comprise a growing proportion of the more than $45 billion our members are spending on health care every year. SB 17 will help us promote value-based purchasing strategies that will return significant savings to millions of California consumers." – **Pacific Business Group on Health Senior Policy Manager Kristof Stremikis**

"Small businesses want to offer health benefits to their employees but the rising cost of prescription drugs is making it harder for them to do so. In fact, a scientific opinion poll conducted on behalf of Small Business Majority found small firms that offer health plans to their employees said the high cost of drugs is hurting their bottom lines. What's more, a vast 88 percent of small employers think drug prices are too high, while the same percentage said drug companies should disclose more information when it comes to setting prices for drugs. It's clear that small employers need help managing the cost of prescription drugs, and SB 17 should go a long way toward bringing California's job creators some needed relief." – **Small Business Majority California Director Mark Herbert**

"As a physician I see the impact high drug prices have on patients first hand. The price of prescription drugs continues to rise in the United States and have become a strain on patients and families. The reality is that the current market for drugs in the U.S. is broken. Price gouging in the prescription drug market has made prescription drugs less affordable and accessible. We view this as a threat to the health of our patients. This bill will bring much needed transparency to a broken market." – **Dr. Sameer Awsare, MD, FACP, Kaiser Permanente**

"Project Inform works to ensure people living with HIV and hepatitis C have access to the medications they need. An important piece of the access puzzle is drug pricing. Unfortunately, drug pricing is complex and often opaque. We applaud Senator Hernandez for highlighting this issue and working to bring transparency to our health care systems and, ultimately, to consumers." – **Project Inform Director of Federal & State Affairs and California Hepatitis Alliance Chair Emalie Huriaux, MPH**

"When the prices of basic medicines like EpiPens, insulin, and antibiotics skyrocket without warning, it's a burden on all Californians, not just patients relying on those drugs. Unjustifiably high drug prices lead to higher health insurance premiums and higher costs for taxpayers and businesses. SB 17 will arm purchasers and policymakers with information to help push back on outrageous prices and hold the industry accountable." – **CALPIRG Executive Director Emily Rusch**

"The California State Retirees – and our 35,000 members – strongly support SB 17 because it is time to do something about runaway drug prices. We thank Sen. Dr. Ed Hernandez for introducing the bill and leading this fight. High prescription drug prices are an extraordinary burden on state retirees and all health care consumers. SB 17 will bring transparency to drug pricing and give health care plans and consumers the tools they need to help control costs. SB 17 is an important step in getting a handle on high prescription drug prices. – **California State Retirees President Tim Behrens**

Exhibit I

America's Health Insurance Plans

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
Washington, DC 20004

202.778.3200
www.ahip.org

AHIP

SEP 0 7 2017

ASSEMBLY FLOOR ALERT

TO: MEMBERS OF THE CALIFORNIA STATE ASSEMBLY
FROM: America's Health Insurance Plans (AHIP)
RE: **S.B. 17 (Hernandez) – Support**

America's Health Insurance Plans (AHIP), the national trade association representing the health insurance community, urges you to vote "YES" on S.B. 17, which requires prescription drug manufacturers to provide advance notice on significant price increases and to report specified information about price increases.

- ***Prescription drugs account for more than 22 cents of every premium dollar.*** Prescription drugs represent the largest segment of health care spending – accounting for more than 22 percent of commercial premiums and 19 percent of all Medicare costs – and continues to rise much faster than any other sector. The primary driver of cost growth is ever-increasing launch prices for new drugs and astronomical increases on older medications that have been around for decades. **8 out of 10 Americans think drug prices unreasonable, and 9 out of 10 support policies that would require drug companies to report information about how they set their prices.**

- ***Advance notice on price increases will foster competition and help mitigate the shock of significant and unexpected hikes.*** Advance notice will arm state purchasers and other payers with vital information to negotiate better prices, foster competition in a highly protected industry, and create collective downward pressure on pricing. S.B. 17 will also allow purchasers to more appropriately plan budgets, better account for taxpayer dollars and employer spending, and set adequate rates in Medi-Cal, CalPERS, and private coverage.

- ***Reporting requirements will dissuade excessive price hikes while providing opportunity to explain necessary price increases.*** S.B. 17 will encourage more appropriate pricing and bring the pharmaceutical industry in line with nearly every other sector of health care. Policymakers and the public will be able to review price history and sales information on a quarterly basis as well as explanations on improvements made to pharmaceutical products that justify higher price tags.

- ***The bill protects manufacturers' confidential and proprietary information and is limited to new high-cost drugs and medications with excessive price increases.*** This bill allows manufacturers to limit their reported information to protect confidential or proprietary material. The vast majority of low-cost generic and brand name drugs, as well as drugs with only modest price increases, are exempt.

S.B. 17 will allow purchasers and payers to prevent and address out-of-control drug pricing and collect accurate and timely pricing information to foster competition and lower costs for California's consumers, businesses, and taxpayers.

PLEASE VOTE YES ON S.B. 17 (Hernandez)

Exhibit J

Date of Hearing: June 27, 2017

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
SB 17 (Hernandez) – As Amended April 25, 2017

SENATE VOTE: 28-10

SUBJECT: Health care: prescription drug costs.

SUMMARY: Requires health care service plans (health plans) and health insurers that report rate information through the existing rate review process to also report information related to covered prescription drugs, as specified, to the Department of Managed Health Care (DMHC) or California Department of Insurance (CDI), respectively. Requires DMHC and CDI to compile the data reported by health plans and insurers into a report that demonstrates the overall impact of drug costs on health care premiums. Requires drug manufacturers to notify specified state purchasers, health plans, and health insurers, in writing at least 90 days prior to the planned effective date, if it is increasing the wholesale acquisition cost (WAC) of a prescription drug by specified amounts. Requires drug manufacturers to notify the Office of Statewide Health Planning and Development (OSHPD) within three days of commercial availability if it is introducing a new prescription drug to market at a WAC that exceeds the Medicare Part D specialty drug threshold. Requires drug manufacturers to provide specified information to OSHPD related to the drug's price. Specifically, **this bill**:

Rate Reporting Information

1) Requires health plans to report to DMHC and insurers to report to CDI on an annual basis, rate information through existing group and individual rate review processes, beginning October 1, 2018, the following information about all covered drugs, including generic, brand name, and specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use:

   a) The 25 most frequently prescribed drugs;
   b) The 25 most costly drugs by total annual spending; and,
   c) The 25 drugs with the highest year-over-year increase in total annual spending.

2) Requires the DMHC and CDI to compile the data in 1) above into a report for to public and legislators that demonstrates the overall impact of drug costs on health care premiums. Requires the data in the report to be aggregated and prohibits information specific to individual health plans and insurers.

3) Defines a specialty drug as one that exceeds the threshold for a specialty drug under the Medicare Part D program.

4) Requires DMHC and CDI to publish on its Internet Website the report in 2) above by January 1 of each year, beginning on January 1, 2019.

5) Requires the information provided to DMHC and CDI, except for the report in 2) above, to remain confidential and protected from public disclosure.

6) Requires health plans and insurers, beginning October 1, 2018, to annually report, as part of the existing large group rate review process, the following information:

   a) Enrollee cost sharing, including cost sharing for prescription drugs as a factor affecting base rate described in existing law;
   b) For covered prescription drugs, including generic drugs, excluding specialty generic drugs, brand name drugs excluding specialty drugs, and brand name and generic specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use, all of the following:
      i) The percentage of the premium attributable to prescription drug costs for the prior year for each category of prescription drugs;
      ii) The year-over-year increase, as a percentage, in total spending for each category of prescription drugs;
      iii) The year-over-year increase in per-member, per-month costs for drug prices compared to other components of the health care premium;
      iv) The specialty tier formulary list;
      v) The percentage of the premium attributable to prescription drugs administered in a doctor's office that are covered under the medical benefit as separate from the pharmacy benefit, if available; and,
      vi) Information on its use of a pharmacy benefit manager (PBM), if any, including its name and which components of the prescription drug coverage described in b) above are managed by the PBM.

Prescription Drug Pricing for Purchasers

7) Applies all of the provisions below to any manufacturer of a prescription drug that is purchased or reimbursed by state purchasers, including, but not limited to the California Public Employees' Retirement System (CalPERS), Department of Health Care Services (DHCS), Department of General Services, Department of Corrections and Rehabilitation, or any entity acting on behalf of the state, health plans and insurers, and PBMs, as defined.

8) Requires a prescription drug manufacturer to provide notification, in writing at least 90 days prior to the planned effective date of the WAC increase, to each purchaser specified in 7) above if any of the following apply:

   a) The WAC is under the Medicare Part D specialty drug threshold and if the cumulative increase is more than 25% over the three calendar years prior to the current year; or,
   b) The WAC is above the Medicare Part D specialty drug threshold and if the cumulative increase is more than 10% over the three calendar years prior to the current year.

9) Requires this notice to include a statement of any changes or improvements to the clinical efficacy of the drug that explain the WAC increase. Requires the manufacturer to state if there are no changes or improvements made to the clinical efficacy of the drug subject to the notice.

10) Requires a PBM, if it receives a price increase notice, to notify its large contracting purchasers of the increase. Defines large purchasers as a purchaser that provides coverage to more than 500 covered lives.

11) Requires drug manufacturers, at the time that the price increase described in 8) above takes effect, to report to OSHPD all of the following:

a) A description of the specific financial and nonfinancial factors used to make the decision to increase the WAC and the amount of the increase, including, but not limited to, an explanation of how these factors justify the increase in the WAC of the drug;
b) The previous year's marketing budget for the drug, including the budget for patient assistance programs specific to the drug;
c) A schedule of WAC increases for the previous five years if the drug was manufactured by the company;
d) If the drug was acquired by the manufacturer within the previous five years, to report to OSHPD all of the following:
   i) The WAC of the drug at the time of acquisition and in the calendar year prior to acquisition;
   ii) The name of the company from which the drug was acquired, the date acquired, and the purchase price; and,
   iii) The year the drug was introduced to market and the WAC at the time of introduction;
e) The patent expiration date of the drug if it is under patent;
f) If the drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug as defined in federal law;
g) Documentation of increased clinical efficacy of the drug, if any. Requires the manufacturer to state if the drug does not exceed the clinical efficacy of existing treatments; and,
h) Volume of sales of the drug in the United States for the previous year.

12) Requires drug manufacturers to notify OSHPD in writing three days after federal Food and Drug Administration (FDA) approval of a new prescription drug to market at a WAC that exceeds the Medicare Part D specialty drug threshold. Allows a manufacturer to make this notification pending approval by the FDA, if commercial availability is expected within three days of approval.

13) Requires drug manufacturers, no later than 30 days of the notification above, to report to OSHPD all of the following:

a) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally;
b) The estimated volume of patients that may be prescribed the drug;
c) Any documentation showing increased efficacy of the drug compared to existing treatments. Requires manufacturers to state if there are no changes or improvements made to the clinical efficacy of the drug subject to the notice;
d) If the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval;
e) The expected marketing budget for the drug, including the budget for patient assistance programs; and,
f) The date and price of acquisition if the drug was not developed by the manufacturer.

14) Requires OSHPD to post information on its Website on a quarterly basis for price increases and on a monthly basis for new drugs in a manner that identifies the information on a per-drug basis, and not be aggregated in a manner that would not allow identification of the drug.

15) Establishes OSHPD enforcement responsibility in the provisions 11) to 14) above. Establishes a civil penalty of $1,000 per day for every day after the applicable notification period that the required information to specified purchasers is not reported. Requires a civil penalty to be assessed and recovered in a civil action brought by OSHPD. Permits OSHPD, upon request by a manufacturer, to review assessment of a civil penalty, and reduce or waive for good cause. Requires any money received by OSHPD be paid into the General Fund.

16) Finds and declares that that it is necessary for the Legislature to limit the public's right to information in order to protect proprietary, confidential information regarding health plan and insurer prescription drug utilization and spending information that is specific to a health plan or insurer to protect the integrity of the competitive market.

EXISTING LAW:

1) Requires, under federal law, drug manufacturers to obtain approval of new drugs from the FDA.

2) Sets forth, under federal law, the threshold for a specialty drug under the Medicare Part D program to qualify for placement on a specialty tier at $670 for a one-month supply of the drug for 2017.

3) Establishes the DMHC to regulate health plans and CDI to regulate health insurers (collectively referred to as regulators).

4) Requires health plans and health insurers to file specified rate information with regulators, as applicable, for health plan contracts or health insurance policies in the individual or small group markets.

5) Requires, for large group health plan contracts and health insurance policies, health plans and insurers to file with regulators the weighted average rate increase for all large group benefit designs during the 12-month period ending January 1 of the following calendar year, and to also disclose specified information for the aggregate rate information for the large group market.

6) Requires health plans and health insurers, for the small group and individual markets, to file with regulators, specified days prior to implementing any rate change, specified rate information so that DMHC and CDI can review the information for unreasonable rate increases.

7) Requires DMHC and CDI to accept and post on their Internet Websites any public comment on a rate increase submitted.

8) Establishes the Sherman Food, Drug, and Cosmetic Law (Sherman Law), administered by the Department of Public Health (DPH), which, among other provisions, regulates the packaging, labeling, and advertising of drugs and medical devices in California.

9) Prohibits, under the Sherman Law, the sale, delivery, or giving away of any new drug or new device unless it is either:

a) A new drug, and a new drug application has been approved for it by the FDA, pursuant to federal law, or it is a new device for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under the FDA; or
b) A new drug or new device for which DPH has approved a new drug or device application, and has not withdrawn, terminated, or suspended that approval.

10) Requires DPH to adopt regulations to establish the application form and set the fee for licensure and renewal of a drug or device license.

11) Establishes OSHPD and requires each organization that operates, conducts, or maintains a health facility to make and file with OSHPD certain specified reports, including a hospital discharge abstract data record that currently includes 19 elements of data per admission that are required to be included.

12) Requires OSHPD to compile and publish summaries of individual facility and aggregate data that do not contain patient-specific information for the purposes of public disclosure.

FISCAL EFFECT: According to Senate Appropriations:

1) One-time costs of $75,000 and ongoing costs of about $200,000 per year for review of drug pricing information submitted by health plans and that information to report to the Legislature by the DMHC (Managed Care Fund).

2) Likely ongoing costs in the low hundreds of thousands per year for review of drug pricing information submitted by health insurers and to report that information to the Legislature by CDI (Insurance Fund).

3) Likely ongoing costs in the hundreds of thousands per year for OSHPD to adopt regulations, collect information from drug manufacturers, publish that information, and take any necessary enforcement action for noncompliance by drug manufacturers (General Fund).

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, the introduction of new and innovative drugs is vital to our health care system, but these often high-priced treatments come with a multitude of challenges. Expensive drugs and steady price increases are becoming common-place with little transparency for astounding prices. This high-priced trend is a costly burden for patients, state programs, employers, and other payers, making it crucial that we understand what's behind the exploding prices. The public and policymakers need greater insight that will allow us to identify strategies to ensure prices do not threaten access to life-saving treatments. Additionally, data suggest that publicly accessible price information in other sectors of the health care market encourages providers to offer more competitive pricing and thereby reduce excess health spending.

   Transparency-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. This bill will 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. 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.

2) **BACKGROUND**.

a) **Health spending on prescription drugs.** A study published in the *Journal of the American Medical Association (JAMA)* in August 2016 reported that almost a quarter of 648 respondents to a 2015 poll reported that they or another family member did not fill a prescription in the last year because of cost. Data on national health expenditures reveal a similar pattern of rising costs. The Centers for Medicare and Medicaid Services (CMS) forecast summary indicates that for 2015-25, health spending is projected to grow at an average rate of 5.8% per year (4.8% on a per capita basis), which is 1.3% faster than the growth in the Gross Domestic Product (GDP) per year over this period. As a result, the health share of GDP is expected to rise from 17.5% in 2014 to 20.1% by 2025. Growth in health spending is expected to respond to changes in economic growth, faster growth in medical prices, and population aging. By the end of the projection, federal, state, and local governments are projected to finance 47% of national health spending (from 45% in 2014). With respect to prescription drugs, spending is projected to have grown 8.1% in 2015 and to have reached $321.9 billion, after a growth of 12.2% in 2014. CMS points out that this somewhat slower, but still relatively strong growth, is a result of the continued impact of newly approved and expensive drugs to treat conditions such as the hepatitis C virus (HCV) and cancer. Prescription drug spending is projected to grow an average of 6.7% per year for 2016 through 2025 as the influence on spending from newly approved drugs is expected to fade after two years of above average impacts. The point at which drug spending growth is projected to peak during the 10 year period is 2018; relatively fewer brand-name drugs are expected to lose patent protection and thus downward price pressure typically associated with the introduction of generic substitutes is somewhat mitigated.

b) **Prescription drug pricing.** According to the *JAMA* article, the primary reason for increasing drug spending is the high price of branded products protected by market exclusivity provisions granted by the U.S. Patent and Trademark Office and the FDA. The *JAMA* article reported that although brand-name drugs comprise only 10% of all dispensed prescriptions in the U.S., they account for 72% of drug spending. The *JAMA* article also stated that high prices have historically been limited to brand-name drugs that treat rare conditions, however, drugs that treat conditions affecting millions of individuals in the U.S. now also have high costs, for example many of the new oncology drugs. The *JAMA* article also stated that although brand-name drugs account for the greatest increase in prescription drug expenditures, another area that has captured the attention of the public and of policy makers is the sharp increase in the costs of some older generic drugs.

Due to the complexity and length of time invested in research, it is difficult for analysts and researchers to assess exactly how much it costs to bring one drug to market. The timeframe of development can last for decades, and may be a combination of efforts from multiple companies or previous research on other drugs. Beyond research and development costs, there are other business factors that manufacturers will take into account when determining the list price of a drug, including but not limited to marketing, sales, advertising, information

technology, legal defense, and the cost of raw materials. A June 2016 California HealthCare Foundation's Issue Brief contended that as a consequence of government benefits and restrictions, the favorable pricing for the Veterans Administration and Medicaid set the floor for the lowest prices that other purchasers may try to negotiate. Confounding this issue is the nondisclosure of net drug prices; purchasers have no method to calibrate the comparative value of the drugs they are purchasing since contracts remain confidential. Consequently, purchasers are prevented from comparison shopping net prices. The *JAMA* article also discussed the role of public and private payers during a drug's exclusivity period and the negotiating power of the payer as the primary counterweight against excessive pricing.

c) **State spending**. Typically, the state pays for prescription drugs under programs that provide health care or health insurance to certain state populations. For example, the state pays for prescription drugs through the health care coverage it provides to the state's low-income residents through the Medi-Cal program and to current and retired state employees through CalPERS.

In 2015-16, Medi-Cal spent over $3.7 billion on outpatient prescription drugs, which represents 4.2% of the DHCS $87 billion 2015-16 Budget. The Governor's 2017-18 Budget estimates that pharmacy fee-for-service spending (including prescribed drugs, medical supplies, and durable medical equipment) will be over $3.89 billion or 3.6% of the DHCS $102.6 billion Medi-Cal budget. These amounts do not include expenditures on prescription drugs made by Medi-Cal managed care plans.

In its 2015 Legislative Report, CalPERS described pharmacy trends and projected costs contributing significantly to the overall rates for the 2016 plan year. As a percentage of the overall rate increases for both the HMO and PPOs, about 45% is attributed to pharmacy; approximately 20% of the total pharmacy spending was attributable to each carrier's top 10 drugs. The balance is attributed to medical expenses, federal Patient Protection and Affordable Care Act fees, and administrative fees. Additionally, a September 2016 presentation to the CalPERS Board of Administration entitled, "Prescription Drugs Utilization and Cost Trends," included an analysis of claims data demonstrating that costs for prescription drugs continue to rise. The 2015 total prescription drug costs for drugs obtained through mail-order and at retail pharmacies for all CalPERS plans were $2.1 billion, which represented nearly a 10% increase over the costs of $1.9 billion in 2014. The top 10 non-specialty drugs accounted for $213 million spending or 14% of the total non-specialty drug cost in 2015.

d) **Assembly Health Informational Hearing.** In an effort to understand the factors that lead to unexpected drug price increases and offer meaningful solutions that assure patient access while controlling costs, this Committee held a series of informational hearings on prescription drug pricing. The first informational hearing entitled, "Understanding the Pharmaceutical Supply Chain: What is Driving Up the Cost of Drugs," was held on October 31, 2016, and provided a historical perspective on drug pricing, discussed the economics of drug pricing, and included an overview of the pharmaceutical supply chain. The second hearing entitled, "Impact of Rising Drug Costs on Public and Private Payers," focused on the impact of prescription drug costs to public and private payers and how this influences the total cost of health care delivery in California. The hearing explored how the public and private sectors obtain prescription drugs, discuss trends in drug pricing, develop formularies, and various steps that payers are utilizing to address the escalating prices of prescriptions drugs.

e) **Other states.** Other states have enacted legislation to address concerns relating to high prescription drug spending. For example, Vermont enacted legislation that requires state officials to identify 15 drugs for which "significant health care dollars" are spent, and

where WAC rose by 50% or more over the previous five-year period. Alternatively, they must identify list prices for 15 medicines that rose 15% or more over a 12-month period. Afterwards, the state attorney general must contact each drug maker to obtain justification for price hikes. The companies must submit information concerning all factors that contributed to the price increases, including detailed cost breakdowns. Ultimately, this information is collected in a report and posted on a public Website. Each violation carries a $10,000 penalty. The Vermont law requires state officials to identify 15 drugs for which "significant health care dollars" are spent, and where list prices rose by 50% or more over the previous five-year period. Alternatively, they must identify list prices for 15 medicines that rose 15% or more over a 12-month period. Maryland became the first state to enact legislation that outlaws "price gouging" in the generic drug market. Maryland's law, enacted on May 27, 2017, has two components: i) a prohibition on price gouging; and, ii) a mechanism for reporting, investigating, and penalizing price gouging in the state's Medicaid program. Lastly, Nevada signed into law legislation requiring pharmaceutical companies to release insulin prices. The Nevada law mandates pharmaceutical companies to disclose how they set insulin prices, manufacturing costs, research investments and projects annually.

3) **SUPPORT**. Health Access California (HAC), a cosponsor of this bill, states that California for decades has made public information on costs and quality of health facilities because of the impact on purchases. HAC contends that his bill will help to fill the gap on prescription drug prices. California Labor Federation, also a cosponsor of this bill, writes that according to insurers' 2016 filings with state regulators, prescription drug costs are expected to rise at a greater rate than overall medical costs, with increases as high as 18%. Small Business Majority states that this bill will bring more stability to the pricing of health coverage in the marketplaces, which is beneficial to small employers, health insurers and the health care system overall.

4) **OPPOSITION**. Biotechnology Innovation Organization is concerned that this bill is intended to impose a form of price control that will scare away investors and disproportionately harm small biotech companies. Sanofi contends that this bill's mandates interfere with the robust market forces that dictate the environment around pharmaceutical company business practices without adequately protecting proprietary information or directly benefiting the consumer. The Pharmaceutical Research and Manufacturers of America (PhRMA) contends that the disclosed information in this bill would paint a misleading and inaccurate portrait of actual drug prices to health plans. PhRMA states that this bill would ignore the significant negotiated rebates and discounts payers and large provider groups can obtain from manufacturers.

5) **COMMITTEE AMENDMENTS.** To address concerns, the Committee proposes to amend this bill as follows:

   a) Reduce advance notice to purchasers from 90 days to 60 days;
   b) Eliminate tiers so there is only one percentage increase trigger for notice;
   c) Narrow scope by inserting a floor in the trigger to exempt some drugs;
   d) Narrow scope by reducing the three year look-back to two years;
   e) Include a mechanism so that drug companies have a known, limited list of entities to report to; and,
   f) Increase confidentiality by providing some limits on pricing information that is reported.

6) RELATED LEGISLATION.

a) SB 790 (McGuire) prohibits a drug manufacturer or a wholesaler from offering or giving a gift, as defined, to a health care provider. Prohibits a drug manufacturer or an entity on behalf of a drug manufacturer from providing a fee, payment, subsidy, or other economic benefit to a health care provider in connection with the provider's participation in research, with some exceptions. Authorizes the Attorney General to bring an action to enforce a violation of these provisions and to seek injunctive relief and imposition of a civil penalty for each violation, as specified. Requires a health care professional, as defined, who is a member of a committee that sets formularies or develops clinical guidelines and who also serves as a speaker or commercial consultant for a drug manufacturer to disclose to the committee his or her relationship with the manufacturer, as specified. SB 790 is pending in the Assembly Health Committee.

b) AB 265 (Wood) prohibits prescription drug manufacturers from offering discounts or other reductions in an individual's out-of-pocket expenses associated with his or her insurance coverage, if a lower cost therapeutically equivalent generic drug is available. AB 265 is pending in the Senate Health Committee.

c) AB 315 (Wood) requires PBMs to be licensed by DMHC; requires a PBM to periodically disclose to a purchaser certain information such as drug acquisition cost, rebates received from pharmaceutical manufacturers, and rates negotiated with pharmacies; and applies these provisions to a contract or contractual relationship between a PBM and a purchaser that is entered into, issued, amended, renewed, or delivered on or after January 1, 2018. AB 315 is pending in the Senate Health Committee.

7) PREVIOUS LEGISLATION.

a) SB 1010 (Hernandez) of 2016 was substantially similar to this bill. SB 1010 was placed on the inactive file on the Assembly Floor.

b) AB 2436 (Roger Hernández) of 2016 would have required carriers to provide, at the time that a prescription drug is delivered or within 30 days of purchase, specified information related to the cost of the prescription drug. AB 2436 died on the Assembly Floor.

c) AB 2711 (Chiu) of 2016 would have reinstated a previously repealed requirement for the Department of General Services to report to the Legislature on its prescription drug bulk purchasing program. AB 2711 was held on the Assembly Appropriations Committee suspense file.

d) AB 463 (Chiu) of 2015 would have required pharmaceutical companies to file an annual report with OSHPD containing specified information regarding the development and pricing of prescription drugs. The Assembly Health Committee hearing was canceled at the request of the author.

e) AB 339 (Gordon), Chapter 619, Statutes of 2015, requires carriers that provide coverage for outpatient prescription drugs to have formularies that do not discourage the enrollment of individuals with health conditions, and requires combination antiretroviral drug treatment coverage of a single-tablet that is as effective as a multitablet regimen for treatment of HIV/AIDS, as specified. AB 339 places in state law, federal requirements related to pharmacy and therapeutics committees, access to in-network retail pharmacies,

standardized formulary requirements, formulary tier requirements similar to those required of health plans and insurers participating in Covered California and copayment caps of $250 and $500 for a supply of up to 30 days for an individual prescription, as specified.

f) SB 1052 (Torres), Chapter 575, Statutes of 2014, requires health plans and insurers to use a standard drug formulary template to display their drug formularies and to post their formularies on their Internet Websites and requires Covered California to provide links to the formularies.

REGISTERED SUPPORT / OPPOSITION:

Support

California Labor Federation (cosponsor)
Health Access California (cosponsor)
UNITE HERE (cosponsor)
AARP
AFSCME Local 1001
America's Health Insurance Plans
American Academy of Pediatrics
American Association of Retired Persons-California
American Federation of State, County and Municipal Employees, AFL-CIO
Anthem Blue Cross
APLA Health
Association of California Life & Health Insurance Companies
Blue Shield of California
California Academy of Family Physicians
California Chapter of the American College of Physicians
California Alliance for Retired Americans
California Association of Health Plans
California Association of Health Underwriters
California Black Health Network
California Conference Board of the Amalgamated Transit Union
California Conference of Machinists
California Health Professional Student Alliance
California Hospital Association
California Immigrant Policy Center
California LGBT Health & Human Services Network
California Nurses Association
California Optometric Association
California Pan-Ethnic Health Network
California Pharmacists Association
California Physicians Alliance
California Professional Firefighters
California Public Employees' Retirement System
California Retired Teachers Association
California School Employees Association
California State Retirees

California Teachers Association
California Teamsters Public Affairs Council
CALPIRG
Carson Chamber of Commerce
Children Now
City and County of San Francisco
Congress of California Seniors
Consumer Federation of California
Consumers Union
Courage Campaign
Engineers and Scientists of California
Epilepsy California
Equality California
Fresno Chamber of Commerce
Gilroy Chamber of Commerce
Greater Conejo Valley Chamber of Commerce
Health Net
Hollywood Chamber of Commerce
I.A.T.S.E. Local 80
International Longshore and Warehouse Union
Irwindale Chamber of Commerce
J. Glynn & Company
Justice in Aging
Kaiser Permanente
Kaiser Permanente
Kern County Hispanic Chamber of Commerce
Latino Coalition for a Healthy California
League of California Cities
LIUNA Locals 777 & 792
Livermore Valley Chamber of Commerce
Los Angeles Area Chamber of Commerce
Los Angeles County Professional Peace Officers Association
Manteca Chamber of Commerce
Molina Healthcare of California
Montebello Chamber of Commerce
National Association of Social Workers – California Chapter
National Health Law Program
National Multiple Sclerosis Society
NextGen Climate
Oakland Chamber of Commerce
Orange County Hispanic Chamber of Commerce
Orange County Professional Firefighters Association, Local 3631
Pacific Business Group on Health
Pajaro Valley Chamber of Commerce and Agriculture
Pasadena Chamber of Commerce & Civic Association
Personal Assistance Services Council
Professional & Technical Engineers, Local 21
Professional & Technical Engineers, Local 21, AFL-CIO
Professional Assistance Services Council

Project Inform
Regional Chamber of Commerce – San Gabriel Valley
Sacramento Metropolitan Chamber of Commerce
San Mateo Chamber of Commerce
San Ramon Chamber of Commerce
Santa Clara County Office of Education
School Employers Association of California
Service Employees International Union, SEIU Local 1000
Service Employees International Union - California
Silicon Valley Employers Forum
Small Business Majority
Small School Districts' Association
Tenet Healthcare
The Black Chamber of Silicon Valley
The Silicon Valley Organization
United Food and Commercial Workers Union – Western States Council
United Nurses Association of California/ Union of Health Care Professionals
Utility Workers Union of America, Local 132
Western Center on Law & Poverty
Several individuals

Opposition

Biocom
Biotechnology Innovation Organization
California Hepatitis C Task Force
California Life Sciences Association
California's Senior Advocates League
Eli Lilly & Company
Pharmaceutical Research and Manufacturers of America
Plasma Protein Therapeutics Association
Sanofi

Analysis Prepared by: Kristene Mapile / HEALTH / (916) 319-2097

Exhibit K

KAISER PERMANENTE®

July 10, 2017

The Honorable Lorena Gonzalez Fletcher
Chair, Assembly Appropriations Committee
State Capitol, Room 2114
Sacramento, CA 95814

RE: SB 17 (Hernandez) – SUPPORT

Dear Assemblymember Gonzalez Fletcher:

Kaiser Permanente is pleased to support SB 17 (Hernandez) which will bring much needed transparency and accountability around drug pricing, providing important advanced notice and justification to purchasers about price increases. This bill will help inform the very robust public dialogue about high drug prices by shining a light on what is behind the skyrocketing prices of drugs.

High-priced drugs and their growing portion of health spending is a crisis in need of immediate attention.

Among the greatest threats to the affordability of health care coverage is the pharmaceutical industry's pricing of new and existing medication. The exorbitant prices of these important medications are leading to circumstances where consumers are having to shoulder a greater share of the burden of the overall cost of the drug. Furthermore, the public health may be jeopardized when treatments are out of reach because of their cost.

New drugs are being approved and marketed with higher prices than their predecessor treatment, often with no difference in efficacy. Drugs that have been on the market for years are seeing double digit price increases each year, with no explanation.

Pricey specialty drugs now account for 1% of prescriptions, but 31% of drug spending. This problem is only going to get worse, with spending on specialty drugs expected to quadruple in just five years. Unchecked, this trend will bankrupt public and private payors alike. Even common drugs that have been around for many years are seeing unexplainable, staggering price increases. Here are just a few recent examples:

- Isuprel – For asthma, bronchitis. Increased 525%, from $215.46 to $1,346.62
- EpiPen – For severe allergic reactions. Increased 520%, from $49.02 to $304.31 per syringe (over $600 for 2 pack)
- Nitropress – For congestive heart failure and life-threatening high blood pressure. Increased 212%, from $257.80 to $805.61
- Insulin – for diabetes - average price has increased 300%.

Government Relations
1215 K Street, Suite 2030
Sacramento, CA 95814
Phone: 916-448-4912
Fax: 916-973-6476

Despite national public outrage and backlash against their pricing tactics, pharmaceutical manufacturers have continued the same egregious behavior.

Drug manufacturers continue to assert that "market forces" will work to keep drugs affordable. But in a broken marketplace, where patents are extended and price competition is virtually non-existent, this is a pipe dream. Even in the face of damning headlines and growing bi-partisan criticism of their pricing behavior, pharma continues their tone deaf behavior. They launch new drugs at outrageously high prices that seem to bear no relationship to the cost to develop and manufacturer them. They 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. This would never be acceptable in any other industry and is simply unsustainable; therefore policymakers have no choice but to insist on transparency around these pricing actions.

It is high time for pharmaceutical manufacturers to publicly explain the price of their products and to share responsibility for maintaining access and affordability.

Because individuals are required to buy health care, and public and private purchasers are required to cover all FDA approved medication, there is a compelling public interest for drug manufacturers to be required to provide a rationale as to how they arrived at particular price. Health plans and insurers are required to go through a similar process in the state, and are also required to spend a certain amount of every dollar on medical services as opposed to what goes to administrative services or on profit. Price transparency is quickly becoming the norm in the health care industry in order to contain costs and encourage healthy competition.

Kaiser Permanente is appreciative of the innovation in pharmaceuticals that makes a profoundly better quality of life available to our patients. But a medication's benefits will not help anyone if it is priced out of reach and will ultimately bankrupt the system.

SB 17 will ensure that drug makers who do business in California are held accountable for the prices they charge and will also help purchasers and policymakers better plan for this large and growing expense.

Sincerely,

Teresa Stark

Teresa Stark
Director, State Government Relations

cc: The Honorable Ed Hernandez, O.D.
Members, Assembly Appropriations Committee
Lisa Murawski, Assembly Appropriations Committee
Peter Anderson, Assembly Republican Caucus

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Pharmaceutical Research and Manufacturers of America

(b) County of Residence of First Listed Plaintiff District of Columbia
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Downey Brand LLP
621 Capitol Mall, 18th Floor
Sacramento, CA 95814

DEFENDANTS
Edmund Gerald Brown, Jr., and Robert P. David, in their official capacities

County of Residence of First Listed Defendant Sacramento
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff, and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

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Habeas Corpus:
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- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS - Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
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- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multi-district Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity):*
28 USC § 2201
Brief description of cause:
Plaintiff seeks declaratory judgment that California Senate Bill 17 is unconstitutional.

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P. **DEMAND $**
CHECK YES only if demanded in complaint: **JURY DEMAND:** ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY *(See instructions):* JUDGE DOCKET NUMBER

DATE 12/8/2017 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY
RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. **(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

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Attorneys for Plaintiff Pharmaceutical Research and Manufacturers of America

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.

CORPORATE DISCLOSURE STATEMENT OF PLAINTIFF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Pursuant to Federal Rule of Civil Procedure 7.1, the Plaintiff in this action, Pharmaceutical Research and Manufacturers of America, states that it has no parent corporations and that no publicly held corporations own 10 percent or more of its stock.

DATED: December 8, 2017

DOWNEY BRAND LLP

By: */s/ Annie S. Amaral*
ANNIE S. AMARAL
Attorney for Plaintiff
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA