

1 DOWNEY BRAND LLP
ANNIE S. AMARAL (Bar No. 238189)
2 AVALON J. FITZGERALD (Bar No. 288167)
621 Capitol Mall, 18th Floor
3 Sacramento, CA 95814
Telephone: (916) 444-1000
4 amaral@downeybrand.com
afitzgerald@downeybrand.com
5

6 Robert N. Weiner
Admitted *Pro Hac Vice*
7 Jeffrey L. Handwerker
Admitted *Pro Hac Vice*
8 R. Stanton Jones
Admitted *Pro Hac Vice*
9

10 ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, NW
Washington, DC 20001
11 Telephone: (202) 942-5000
robert.weiner@arnoldporter.com
12 jeffrey.handwerker@arnoldporter.com
stanton.jones@arnoldporter.com
13

14 *Attorneys for Plaintiff Pharmaceutical Research
and Manufacturers of America*
15

16 **UNITED STATES DISTRICT COURT**
17 **EASTERN DISTRICT OF CALIFORNIA**

18
19 PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA,

20 Plaintiff,

21 v.
22

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

25 Defendant.
26

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

**AMENDED COMPLAINT FOR
DECLARATORY AND INJUNCTIVE
RELIEF**

27 Plaintiff Pharmaceutical Research and Manufacturers of America (“PhRMA”), on behalf of
28 itself and its members, for its Complaint against Robert P. David, in his official capacity as Director

1 of the California Office of Statewide Health Planning and Development (“Defendant”), alleges as
2 follows:

3 **INTRODUCTION**

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

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

14 3. SB 17 provides that, if a manufacturer has increased a qualifying product’s
15 wholesale acquisition cost (“WAC”), a federally defined list price, by 16 percent or more
16 cumulatively over the prior two to three calendar years, including the proposed increase, then that
17 company may not increase its WAC list price unless it first provides registered purchasers and State
18 purchasers with 60 days’ advance notice. That means the manufacturer cannot increase its WAC
19 list price for qualifying drugs *anywhere* during the 60-day advance notice period. It is thus an
20 unconditional nationwide ban. In *Brown-Forman Distillers Corp. v. N.Y. State Liquor Authority*,
21 476 U.S. 573 (1986), the Supreme Court struck down an analogous ban on price changes. The New
22 York law there required distillers to file a monthly price list and to affirm that the listed prices were
23 no higher than those charged in other states. The law thus imposed a one-month nationwide ban on
24 decreasing prices below New York’s. The Court held that New York could not ban price changes
25 outside the state. California cannot do so either.

26 4. SB 17 in fact is more intrusive and problematic than the statute invalidated in
27 *Brown-Forman*. Not only does SB 17 *effectively* ban out-of-state pricing, it *overtly* prescribes
28 policy on drug pricing for the entire United States. The author of SB 17 proclaimed that it would

1 “set national health care policy, having an impact for consumers and providers in other states.”¹
 2 Because SB 17 seeks to regulate a national list price, these other states are saddled with California’s
 3 policy, even if they disagree with it. At least some states likely disagree, as SB 17 conflicts with
 4 key tenets of a free market economy, in particular, that market participants should not have to
 5 justify their pricing to the government or be compelled to make controversial public statements
 6 about their pricing. The extraterritorial dictates of the Act are even more pronounced and
 7 widespread because contract prices with wholesalers, hospitals, pharmacies, pharmacy benefit
 8 managers, payers, and others across the nation are typically based on a product’s WAC list price.

9 5. The Act further requires manufacturers to state in their announcement of the price
 10 increase whether it is justified on one ground—a change or improvement in the drug. While the
 11 asserted purpose of this provision is to “provide accountability” for price increases, the Act reflects
 12 openly acknowledged animus towards an industry that has developed—and continues to produce—
 13 life-saving and life-enhancing medicines. The author of the Act cited “[p]ublic anger at rising drug
 14 prices,”² and charged, among other things, that the pharmaceutical industry has earned “obscene
 15 profits at the expense of the entire healthcare system.”³ The Act singles out, in the author’s own
 16 words, the “greedy pharmaceutical companies,”⁴ forcing manufacturers to invite public
 17 condemnation for any price increases above California’s ordained threshold, even though myriad
 18 other participants in the supply chain significantly affect the cost of healthcare generally and
 19

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

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

1 prescription drugs specifically. Against this backdrop, it is clear that “accountability” means the
2 political assignment of blame, regardless of the facts, for prices the Legislature deems too high.

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

8 7. These infirmities render SB 17 unconstitutional, on multiple grounds. *First*, SB 17
9 violates the Commerce Clause by directly restricting the list price used nationwide—including
10 outside California. The author of the Act, in his own words, announced unconstitutional,
11 extraterritorial objectives to “set national health care policy” and “impact [] consumers and
12 providers in other states.”⁵ The Act implements these objectives by banning increases in the
13 WAC—a federally defined list price covering the entire nation—for drugs with a list price greater
14 than \$40 for a course of therapy for a period of 60 days after a manufacturer notifies registered
15 purchasers and State purchasers of the intent to increase the WAC for the product. The notice
16 required by SB 17, however, will signal to the statutorily specified purchasers nationwide that they
17 should attempt to buy in that window, creating a potential spike in purchasing—*i.e.*, stockpiling—
18 that could produce drug shortages harmful to many patients. Further, the Act permanently restricts
19 national prices by penalizing any manufacturer that raises the WAC for qualifying drugs by more
20 than California deems proper, regardless of whether that increase affects the price that customers in
21 California ultimately pay. The Commerce Clause prohibits California from foisting its policies onto
22 other states in this manner, and for good reason. California’s intrusion into the commerce among
23 other states will disrupt the drug market. The Commerce Clause also prohibits California from
24 imposing obligations that will result in stockpiling, opportunities for price coordination, and other
25 burdens on interstate commerce in return for making already public information more “transparent.”
26

27 _____
28 ⁵ Hernandez, *supra* note 1.

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

14 9. In compelling this speech, the Act discriminates based on speaker, content, and
15 viewpoint. It discriminates based on the speaker by singling out pharmaceutical manufacturers and
16 forcing them to disseminate California’s message that they alone are responsible for increases in the
17 prices of prescription drugs—a message that is simply not correct. SB 17 also dictates content by
18 forcing manufacturers to speak about drug pricing where they otherwise would not. And the Act
19 discriminates based on both content and viewpoint by forcing manufacturers to endorse and
20 disseminate the message the required statements unavoidably convey—that prescription drug prices
21 are too high and that only chemical changes or improvements to a drug can justify a 16-percent
22 increase in the WAC over a period of two to three years. SB 17 further reflects this discrimination
23 by imposing speech requirements, including the mandated self-condemnatory justifications, only
24 when a manufacturer *increases* prices, but not when the manufacturer lowers them.

25
26
27 ⁶ Sen. Ed Hernandez (@SenatorDrEd22), Twitter (Sept. 6, 2017, 12:23 PM),
28 <https://twitter.com/SenatorDrEd22/status/905511884241211393>.

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

10 11. *Third*, SB 17 is unconstitutionally vague. The statutory text offers no specifics on
 11 whether past WAC increases, as far back as January 2016, contribute toward the Act’s *de facto*
 12 price freeze—whether, for example, a 7-percent increase in June 2016 and a 6-percent increase in
 13 May 2017 would mean that a manufacturer could not raise the price of a prescription drug more
 14 than 3 percent of the initial price before June 2018 without triggering the public disclosures.
 15 Equally concerning, the Act does not state whether the 60-day notice requirement triggers prior to
 16 the presumed effective date of January 1, 2018. For example, if a manufacturer wants to increase
 17 the price of a drug above the threshold on January 2, 2018, could it do so if it did not provide notice
 18 on November 3, 2017—even though, as of the November 3 date, the statute was not effective and
 19 California’s Office of Statewide Health Planning and Development (“OSHPD”) had not even set up
 20 a process for providing such notices or a registration process for entities to receive such notices?
 21 Even though PhRMA asked OSHPD, the agency tasked with enforcing and thus interpreting SB 17,
 22 to clarify these ambiguities, OSHPD to date has not provided such guidance. Not knowing whether

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

25 ⁸ Sen. Ed Hernandez, *The Difference Between Life and Death for Diabetics*, Sacramento Bee
 26 (June 9, 2017), <http://www.sacbee.com/opinion/op-ed/soapbox/article155343174.html>; *see also*
 27 Alexei Koseff, *Your Drug Costs Might Drop If Lawmakers Can Agree on Why They’re So High*,
 28 Sacramento Bee (May 29, 2017), [http://www.sacbee.com/news/politics-government/capitol-
 alert/article152922344.html](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).

1 the State will adopt these improper interpretations, many manufacturers likely will either refrain
2 from price increases they are entitled to make or risk the State alleging violations of the statute and
3 potentially undertaking enforcement. The vagueness of the statute thus exacerbates the burdens
4 SB 17 imposes on interstate commerce and on speech.

5 12. These constitutional flaws directly harm PhRMA's members. For example, since the
6 advance notice requirement became effective on January 1, 2018, several of PhRMA's member
7 companies have each filed advance notices of price increases, thereby making statements to which
8 they object, but which SB 17 mandates. None of these member companies would have made these
9 statements had SB 17 not compelled them to do so. And some PhRMA member companies have
10 taken price increases on particular drugs over the last two years that exceed the 16 percent
11 threshold. If SB17 is interpreted to be retroactive—a point OSHPD to date has refused to clarify—
12 these companies could not take any price increase on these products, even to keep pace with
13 inflation, without triggering the requirement to make statements to which they object. Given the
14 studied ambiguity of OSHPD's position, the companies cannot take such increases now without
15 incurring the risk that OSHPD will later charge them with violating the statute. PhRMA member
16 companies will also make pricing changes in the future that trigger the burdens of SB 17, including
17 the 60-day notice requirement.

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

21 **PARTIES**

22 14. PhRMA is a non-profit corporation organized under Delaware law, with its
23 headquarters in Washington, D.C. PhRMA serves as the pharmaceutical industry's principal public
24 policy advocate, representing the interests of its members before Congress, the Executive Branch,
25 state regulatory agencies and legislatures, and the courts. Among other objectives, PhRMA seeks to
26 advance public policies that foster continued medical innovation and to educate the public about the
27 process for discovering and developing new drugs. PhRMA members are the leading research-
28

1 based pharmaceutical and biotechnology companies in America, devoted to discovering and
2 developing new medications that allow people to live longer, healthier, and more productive lives.⁹

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

8 JURISDICTION AND VENUE

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

11 17. Venue is proper in this district under 28 U.S.C. § 1391(b) because PhRMA's claims
12 arise in this judicial district and because Defendant resides and performs his official duties in this
13 district.

14 18. An actual controversy exists between the parties within the meaning of 28 U.S.C.
15 § 2201, and this Court has the authority under 28 U.S.C. §§ 2201–02 to grant PhRMA declaratory
16 and injunctive relief from Section 4 of SB 17.

17 FACTUAL ALLEGATIONS

18 *PhRMA Members Spend Enormous Sums on Research and Development*

19 19. PhRMA members develop life-saving and life-enhancing medicines that are
20 promoted, prescribed, and sold throughout the nation, including in California. Pharmaceutical
21 manufacturers, including PhRMA's members, invest huge sums in the research and development of
22 new medicines. "Since 2000, more than 475 new prescription medicines . . . have been approved
23 for use by the U.S. Food and Drug Administration" ("FDA").¹⁰ PhRMA members are responsible
24 for much of this innovation, including more than a third of the 34 novel drugs—those containing

25 ⁹ A list of PhRMA members is available at <http://www.phrma.org/about/members>.

26 ¹⁰ Genia Long, *The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development*,
27 Analysis Group (July 2017), at Executive Summary,
28 [http://www.analysisgroup.com/uploadedfiles/content/insights/publishing/the_biopharmaceutical_pi
peline_report_2017.pdf](http://www.analysisgroup.com/uploadedfiles/content/insights/publishing/the_biopharmaceutical_pipeline_report_2017.pdf).

1 “new molecular entities”—approved by FDA this year.¹¹ FDA has recognized that such drugs
2 “frequently provide important new therapies for patients.”¹²

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

11 21. The low likelihood of securing FDA approval magnifies the risk and multiplies the
12 cost of developing new drugs. Between 1988 and 2014, only 12 percent of drug candidates that
13 entered clinical testing were approved for use by FDA. Between 2002 and 2014, the failure rate for
14

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

17 ¹² *Id.*

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

20 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),
21 <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),
22 [https://www.theguardian.com/healthcare-network/2016/mar/30/new-drugs-development-costs-](https://www.theguardian.com/healthcare-network/2016/mar/30/new-drugs-development-costs-pharma)
23 [pharma](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”).

24 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
25 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),
26 <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
27 increase” from 2003).

28 ¹⁶ *Id.*

1 Alzheimer drugs was 99.6 percent; only one out of 244 compounds received FDA approval.¹⁷ Of
2 103 drugs tested for Melanoma between 1999 and 2015, only seven came to market.¹⁸ According to
3 an estimate focusing on the most prolific developers of new drugs, “95% of the experimental
4 medicines that are studied in humans fail to be both effective and safe.”¹⁹ Even when a product
5 reaches the market, the manufacturer may not earn back the cost of research and development.

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

16 23. As pharmaceutical companies build on new technologies and advances in scientific
17 knowledge, they continue to develop groundbreaking therapies to combat devastating diseases.

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

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

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

23 ²⁰ *Paving the Way for Personalized Medicine*, FDA 4 (Oct. 2013),
24 [https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PersonalizedMedicine/UCM37242](https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PersonalizedMedicine/UCM372421.pdf)
[1.pdf](https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PersonalizedMedicine/UCM372421.pdf).

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

27 ²² *What is Gene Therapy?* FDA,
28 <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm573960.htm>.

1 Pharmaceutical researchers are currently honing in on “disease-modifying treatments that may stop
2 or slow down disease progression [of Alzheimer’s],” developing almost 250 different medicines and
3 vaccines that use the immune system to combat cancer, and are “working on cutting-edge medicines
4 needed to bring new treatments to patients with mental illness.”²³ As of July, pharmaceutical
5 companies were pursuing more than 700 projects using gene therapy, more than 170 projects using
6 DNA or RNA therapies, and more than 180 projects using antibodies that join to chemotherapy
7 drugs and other agents to ensure those agents target specific cells (such as tumors).²⁴

8 ***Drug Pricing and the Pharmaceutical Supply Chain***

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

14 25. Manufacturers primarily sell their prescription drugs to wholesalers. Three
15 companies hold the vast majority of the wholesale market: AmerisourceBergen, Cardinal Health,
16 and McKesson Corporation, the last of which is headquartered in California. Approximately
17 90 percent of all pharmaceuticals distributed in the United States move through one of these
18 wholesalers.

19 26. Manufacturers sell to wholesalers at a price derived from the WAC. Federal law
20 defines the WAC as “the manufacturer’s list price” to wholesalers or direct purchasers, “not
21 including prompt pay or other discounts, rebates or reductions in price.” 42 U.S.C. § 1395w-

23 ²³ *Medicines in Development 2017 Update: Alzheimer’s Disease*, America’s Biopharmaceutical
24 Companies, http://phrma-docs.phrma.org/files/dmfile/MID-Alz-Update_FINAL.pdf; *Medicines in*
25 *Development: Immuno-oncology*, America’s Biopharmaceutical Companies, [http://phrma-](http://phrma-docs.phrma.org/files/dmfile/GoBoldlyImmuno_OncologyReport_2017.pdf)
26 [docs.phrma.org/files/dmfile/MentalIllness_MIDReport_2017.pdf](http://phrma-docs.phrma.org/files/dmfile/MentalIllness_MIDReport_2017.pdf).

26 ²⁴ Long, *supra* note 10, at 13.

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

1 3a(c)(6)(B). Manufacturers set the WAC for their drugs based on individualized, proprietary, and
2 highly subjective pricing methodologies. A drug’s WAC is uniform across the United States and is
3 already publicly available.

4 27. While a drug’s wholesale price is based on the WAC, what the wholesalers actually
5 pay depends on the items the statute excludes from the definition, such as discounts calculated as a
6 percentage of the WAC.²⁶ Wholesalers also charge manufacturers a negotiated fee, usually
7 calculated, again, as a percentage of the WAC, for a variety of distribution and logistics services.

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

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

20 30. Third-party payers typically pay pharmacies and healthcare providers a price derived
21 from the WAC. They also typically negotiate rebates from manufacturers, which are calculated as a

22 _____
23 ²⁶ Adam J. Fein, *McKesson’s Profit Shortfall: How Wholesalers Benefit from Rising Drug List
24 Prices*, Drug Channels (Jan. 26, 2017), <http://www.drugchannels.net/2017/01/mckessons-profit-shortfall-how.html>.

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

27 ²⁸ See Letter from James Cosgrove, Director of Health Care, Gov’t Accountability Office, to Rep.
28 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”).

1 percentage of the WAC. In exchange for the rebates, the payers provide access to, or preferred
2 placement on, the list of prescription drugs that the payer will reimburse, which is known as the
3 payer's formulary.

4 31. Many third-party payers also contract with Pharmacy Benefit Managers ("PBMs"),
5 which often negotiate larger rebates from manufacturers.²⁹ Three PBMs—CVS Caremark, Express
6 Scripts, and OptumRx—manage claims for well over half of the domestic healthcare market.³⁰

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

15 33. For these reasons, the "WAC neither reflect[s] the actual net revenue paid to
16 manufacturers nor the actual net prices paid by pharmacies . . . or health plans."³⁴ In considering
17 SB 17, the California Legislature acknowledged that "[t]he WAC price of a drug on the market, as
18 originally announced by the company[,] is also rarely the price paid by a payer."³⁵ It is "typically

19 ²⁹ Jessica Wapner, *Understanding the Hidden Villain of Big Pharma: Pharmacy Benefit Managers*,
20 *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*
21 *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%).

22 ³⁰ *Id.*

23 ³¹ 42 U.S.C. § 256b.

24 ³² 38 U.S.C. § 8126.

25 ³³ 42 U.S.C. § 1396r-8.

26 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

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

1 the contractual starting point for business-to-business contracts involving . . . key participants in the
2 pharmaceutical distribution system.”³⁶

3 34. Generally, the prices actually paid by insurers, pharmacies, healthcare providers, and
4 PBMs are significantly lower than the WAC, though the WAC is typically used in calculating those
5 negotiated discounts. Although invoice prices for patented drugs jumped 9.0 percent in 2016 and
6 6.9 percent in 2017, the average net price increase after rebates and other discounts was only 3.2
7 and 1.9 percent, respectively.³⁷ The price ultimately paid to the manufacturer is the “net effective
8 price” for the drug. Unlike the WAC, the net effective price is not transparent to the public and is
9 competitively sensitive.

10 ***Overview of California Senate Bill 17***

11 35. On May 30, 2017, the California State Senate passed SB 17. On September 11,
12 2017, the California State Assembly passed an amended version, which the Senate approved two
13 days later. On October 9, 2017, Defendant Governor Brown signed SB 17 into law.

14 36. Although the California Legislature states that it intended “to permit manufacturers
15 of a prescription drug to voluntarily make pricing decisions,” SB 17 § 4 (adding HSC
16 § 127675(b)(2)), proponents acknowledged that the Act’s true function was to name and shame
17 “greedy pharmaceutical companies”³⁸ into restricting the price of their innovative drugs “to avoid
18 public scorn.”³⁹ At the Act’s signing, one co-sponsor remarked that SB 17 “is not just transparency
19 for transparency’s sake, it is transparency with teeth” because it forces manufacturers to “think
20 twice before raising prices over the threshold that triggers additional reporting.”⁴⁰ Another co-
21 sponsor touted SB 17’s notice requirement because it “creates an incentive for price increases to fall

22 _____
³⁶ *Id.*

23 ³⁷ IMS Institute for Healthcare Informatics, National Sales Perspectives (Mar. 2016); IQVIA
24 Institute for Human Data Science, Medicine Use and Spending in the U.S.: A Review of 2017 and
Outlook to 2022, at 8 (Apr. 2018).

25 ³⁸ Issues, *supra* note 4.

26 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/>.

27 ⁴⁰ Anthony Wright (for Health Access California), Press Conference at 2:10 (Oct. 9, 2017),
28 <http://sd22.senate.ca.gov/video>.

1 below 10% [the reporting threshold in a previous version],”⁴¹ and others argued that “[r]eporting
2 requirements will dissuade excessive price hikes.”⁴² While Legislators acknowledged that such
3 innovative therapies were “protected by market exclusivity provisions granted by the U.S. Patent
4 and Trademark Office and the FDA,” this exclusivity was seen as a justification *for* imposing state
5 price controls to counteract this federal right.⁴³ For instance, Assembly member David Chiu, a co-
6 author of the law, claimed that SB 17 was warranted in part because pharmaceutical manufacturers
7 are “protect[ed] as monopolists because of the patents that they receive.”⁴⁴

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

13 38. Section 4 of SB 17 amends the California Health and Safety Code to add Chapter 9,
14 titled “Prescription Drug Pricing for Purchasers.” Chapter 9 imposes various notice, reporting, and
15

16
17 ⁴¹ Letter from A. Wright (Health Access Cal.) to Assemb. Gonzalez Fletcher (July 17, 2017),
18 attached as Exhibit G; *see also* Sen. Hernandez Author’s Bill File, *SB 17 (Hernandez) - Drug*
19 *Pricing Transparency* (April 17, 2017) (“Why Transparency? Transparency Works. When we’ve
20 required transparency in pricing on other sections of the industry, prices have stabilized or have
21 decreased.”), attached as Exhibit H.

22 ⁴² America’s Health Insurance Plans, *Assemb. Floor Alert re: S.B. 17 (Hernandez) - Support*
23 (Sept. 7, 2017), attached as Exhibit I.

24 ⁴³ State of Cal. Assemb. Comm. on Health, *Comm. Analysis of SB 17 (Hernandez)* at 6 (June 27,
25 2017), attached as Exhibit J; *see also* Ed Hernandez & Tom Steyer, *Require Drugmakers to Report*
26 *When They Raise Prices*, S.F. Chronicle (Apr. 18, 2017),
27 <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
28 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).

1 justification obligations on the manufacturer of a prescription drug “purchased or reimbursed” by
2 any of the following (collectively, “Purchasers”):

- 3 • “A state purchaser in California, including, but not limited to, the Public
4 Employees’ Retirement System, the State Department of Health Care Services,
5 the Department of General Services, and the Department of Corrections and
6 Rehabilitation, or an entity acting on behalf of a state purchaser”;
- 7 • “A licensed health care service plan”;
- 8 • “A health insurer holding a valid outstanding certificate of authority from the
9 Insurance Commissioner”;
- “A pharmacy benefit manager as defined in subdivision (j) of Section 4430 of the
Business and Professions Code.”

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

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

24 40. Given California’s size and robust healthcare industry, huge numbers of entities are
25 potentially eligible to receive a 60-day notice every time a drug’s WAC increases beyond the
26 16-percent threshold. Additionally, the Act requires each PBM that receives notice of a WAC
27 increase to “notify its large contracting public and private purchasers,” which the Act defines as any
28

1 “purchaser that provides coverage to more than 500 covered lives.” *Id.* § 4 (adding HSC
2 § 12677(e)).

3 41. Qualifying entities wishing to receive 60 days’ prior notice of a WAC increase must
4 register with OSHPD, which, in turn, will “make available to manufacturers a list of registered
5 purchasers for the purpose of this notification.” *Id.* § 4 (adding HSC § 127677(d)). In addition to
6 the date and amount of the planned WAC increase, each 60-day notice must include “a statement
7 regarding whether a change or improvement in the drug necessitates the price increase,” and, “[i]f
8 so, the manufacturer shall describe the change or improvement.” *Id.* § 4 (adding HSC § 127677(c)).

9 42. Because the Legislature did not expressly include an effective date for the 60-day
10 notice provisions, they went into effect on January 1, 2018. Cal. Const. art. IV, § 8 (newly enacted
11 statute “shall go into effect on January 1 next following the enactment date of the statute”).
12 However, it is unclear what this “effect” will be. The State could maintain that it is entitled to look
13 backward from the effective date and retroactively include WAC increases that occurred as early as
14 January 1, 2016 (*i.e.*, over “the two previous calendar years” before the Act’s effective date), in
15 calculating whether a drug’s list price has increased by more than the 16-percent threshold. This
16 interpretation would mean that for many drugs, *any price increase* subsequent to January 1, 2018,
17 would trigger SB 17, because pharmaceutical manufacturers already increased the drug’s WAC by
18 16 percent or more since January 1, 2016. Alternatively, the State could give SB 17 prospective
19 effect only by counting each WAC increase beginning January 1, 2018, toward the 60-day notice
20 requirement’s 16-percent threshold.

21 43. Likewise, the State could interpret SB 17 to require that price increases in January
22 2018 trigger the notice requirements, even though a 60-day advance notice of such a price increase
23 would not be possible unless the law required notice prior to its effective date, and prior to the
24 establishment of any process for providing such notice. Because there is no process for providing
25 advance notice of a January 2018 price increase, such an interpretation would effectively ban price
26 increases on a national basis before March 1, 2018. Alternatively, the State could determine that the
27 60-day notice requirement becomes effective January 1, 2018, such that price increases prior to
28 March 1, 2018, are not subject to a notice requirement.

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

- 5 • “A description of the specific financial and nonfinancial factors used to make the
6 decision to increase the [WAC] of the drug and the amount of the increase, including,
7 but not limited to, an explanation of how these factors explain the increase in [WAC]”;
- 8 • “A schedule of [WAC] increases for the drug for the previous five years if the drug was
9 manufactured by the company”;
- 10 • “If the drug was acquired by the manufacturer within the previous five years, all of the
11 following information: (A) The [WAC] of the drug at the time of acquisition and in the
12 calendar year prior to acquisition[;] (B) The name of the company from which the drug
13 was acquired, the date acquired, and the purchase price[; and] (C) The year the drug was
14 introduced to market and the [WAC] of the drug at the time of introduction”;
- 15 • “The patent expiration date of the drug if it is under patent”;
- 16 • “If the drug is a multiple source drug, an innovator multiple source drug, a non-
17 innovator multiple source drug, or a single source drug, as defined in [42 U.S.C.]
18 § 1396r-8(k)(7)(A)”;
- 19 • “A description of the change or improvement in the drug, if any, that necessitates the
20 price increase”; and
- 21 • “Volume of sales of the manufacturer’s drug in the United States for the previous year.”

22 SB 17 § 4 (adding HSC § 127679(a)). A “manufacturer may limit the information reported
23 [quarterly to the State] to that which is otherwise in the public domain or publicly available.” *Id.*
24 § 4 (adding HSC §§ 127679(b); 127681(c)).

25 45. SB 17 also requires a manufacturer to notify OSHPD of any newly introduced
26 prescription drug for which the WAC exceeds the threshold set for a specialty drug under Medicare
27 Part D, which was \$670 per month in 2017. The notification must occur either within three days of
28 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”;

- 1 • “If the drug was granted breakthrough therapy designation or priority review by [FDA] prior to final approval”; and
- 2 • “The date and price of acquisition if the drug was not developed by the manufacturer.”

3
4 *Id.* § 4 (adding HSC § 127681(b)).

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

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

12 ***OSHPD Fails to Clarify Whether SB 17 Applies Retroactively***

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

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

26 50. Neither OSHPD nor Defendant David provided the clarifications PhRMA requested.
27 Instead, on November 22, 2017, OSHPD issued a “Cost Transparency Rx Implementation Plan”
28 (“Plan,” attached as Exhibit C) on its website, which did not respond to PhRMA’s specific

1 inquiries. The Plan does not address whether manufacturers will be responsible for sending 60-day
 2 notices based on WAC increases that occurred between January 1, 2016, and January 1, 2018. The
 3 Plan states only that, “[b]eginning January 1, 2018, SB 17 requires OSHPD to make available a
 4 registry of public and private purchasers for purposes of the 60-day advance notice requirement for
 5 specified increases in the wholesale acquisition cost of a prescription drug. Public and private
 6 purchasers may register with OSHPD beginning December 1, 2017.” *Id.* OSHPD also offered the
 7 vague representation that it would “[b]egin outreach to stakeholders” between “January - March
 8 2018.” *Id.* Nor does the Plan address whether notices are required prior to the January 1, 2018
 9 presumed effective date, or how drug manufacturers should address price increases taken in January
 10 or February of 2018.

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

22 **SB 17’S CONSTITUTIONAL DEFECTS**

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

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

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

5 54. When a state “directly regulates” interstate commerce, the Supreme Court has
6 “generally struck down the statute without further inquiry.” *Brown-Forman Distillers Corp. v. N.Y.*
7 *State Liquor Auth.*, 476 U.S. 573, 579 (1986); *see also Edgar v. MITE Corp.*, 457 U.S. 624, 640
8 (1982) (plurality op.) (“The Commerce Clause, however, permits only *incidental* regulation of
9 interstate commerce by the States; direct regulation is prohibited.”); *NCAA v. Miller*, 10 F.3d 633,
10 638 (9th Cir. 1993) (statute that “directly regulates interstate commerce . . . violates the Commerce
11 Clause per se”); *Alliant Energy Corp. v. Bie*, 336 F.3d 545, 547 (7th Cir. 2003) (“[D]irect regulation
12 of interstate commerce is virtually per se unconstitutional.”).

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

20 56. SB 17 directly regulates out-of-state prices, just like the New York statute
21 invalidated in *Brown-Forman*. Indeed, SB 17 intrudes more significantly than the offending New
22 York law. The nationwide ban on price changes in *Brown-Forman* lasted one month. SB 17
23 imposes a 60-day nationwide ban on price increases. Further, in defending the law in *Brown-*
24 *Forman*, New York argued that it “addressed only . . . sales of liquor in New York.” *Id.* at 583. By
25 contrast, SB 17 was, in its author’s words, “a monumental achievement for the *entire nation*” and
26 would “set *national health care policy*, having an impact for consumers and providers *in other*
27
28

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

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

16 58. The Act’s quarterly reporting requirements requiring an explanation for price
17 increases constitute an additional burden. Violation of that requirement could subject a
18 manufacturer to fines of \$1,000 per drug, per day if the State deems a manufacturer’s “explanation”
19 incomplete. By forcing manufacturers to justify price increases, SB 17 imposes burdens on pricing
20 nationwide. A manufacturer of a qualifying drug that wishes to increase the WAC, which is a
21 nationwide list price, above the 16-percent threshold, must provide advance notices, must comply
22 with California’s reporting and justification requirements, and must engage in compelled and self-
23 disparaging speech (as discussed in detail below). And any failure to provide OSHPD with an
24 adequate justification for increases in the national list price subjects the manufacturer to fines in
25

26
27 ⁴⁷ Hernandez, *supra* note 1 (emphases added).

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

1 California. The purpose and effect of these requirements is to control prices in other states—again,
2 as the author of SB 17 proclaimed, to create a “national policy.”

3 59. Tying SB 17’s burdensome requirements and the threat of civil penalties to the WAC
4 list price necessarily regulates out-of-state conduct. The Act’s 60-day notice provision and the
5 uncertain (but potentially significant) economic risk surrounding its reporting requirements were
6 designed specifically to discourage manufacturers from increasing national prices to those deemed
7 excessive by California. Because the WAC is, by law, a national list price, manufacturers cannot
8 avoid the State’s intrusive regulations simply by altering their conduct in California. Notice and the
9 accompanying “explanation” are mandatory even where a registered Purchaser has negotiated
10 rebates that increase in proportion to the WAC. Manufacturers must refrain from increasing the list
11 price used in *every* state if they wish to avoid triggering SB 17, thereby giving the Act an
12 inescapable, impermissible, and intended extraterritorial effect. *See, e.g., Edgar*, 457 U.S. at 642–
13 43 (plurality op.) (“The Commerce Clause also precludes the application of a state statute to
14 commerce that takes place wholly outside of the State’s borders, whether or not the commerce has
15 effects within the State.”); *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1103 (9th Cir.
16 2013) (“States may not mandate compliance with their preferred policies in wholly out-of-state
17 transactions.”); *NCAA*, 10 F.3d at 639 (invalidating statute that required NCAA “to apply Nevada’s
18 procedures to enforcement proceedings throughout the country”). Moreover, the vague language of
19 SB 17 and OSHPD’s failure to clarify it compound the extraterritorial impact and impose an
20 additional burden on interstate commerce. Uncertain whether OSHPD will count price increases
21 from as far back as January 2016 in enforcing the Act or will apply the 60-day notice requirement
22 for a price increase taken within the first 60 days of 2018, manufacturers may refrain, nationwide,
23 from implementing even small increases in order to forestall potential exposure.

24 60. Manufacturers cannot avoid triggering SB 17 even by refusing to sell drugs in-state.
25 *See Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1323 (9th Cir. 2015) (invalidating state
26 law that applied to art transactions involving California residents, even if the resident conducted the
27 transaction entirely out of state and never brought the artwork to California), *cert. denied*, 136 S. Ct.
28 795 (2016). SB 17 applies not just to drugs purchased *in* California, but also to drugs that are

1 “purchased or reimbursed” by entities *licensed* in California, regardless of where the transaction
 2 actually occurs. SB 17 § 4 (adding § 127675(a)). In fact, the law appears to require manufacturers
 3 to give notice to health care plans and PBMs that merely solicit business in California, even if they
 4 are licensed elsewhere. *See id.* § 4 (adding HSC § 127675(a)); HSC § 1345; Cal. Bus. & Prof. Code
 5 § 4430. SB 17 also directs each PBM that receives notice to relay the information to every one of
 6 its contracting purchasers “that provide[] coverage to more than 500 covered lives,” without regard
 7 to whether those covered lives reside in or are otherwise connected to California. SB 17 § 4 (adding
 8 HSC § 127677(e)). This kind of attempt to “extend [a state’s] police power beyond its jurisdictional
 9 bounds” violates the Commerce Clause. *C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383,
 10 393 (1994). And, nothing in SB 17 prohibits those PBMs from sharing the advance notice with its
 11 affiliates, which in some cases include major national retail or specialty pharmacy chains. The
 12 parties receiving the information can disseminate it however they want. This further exacerbates
 13 the extraterritorial effects of the law.

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

19 62. SB 17 will generate substantial harmful economic effects that extend unavoidably
 20 beyond California, because pharmaceutical list prices and supply chains have an inherently national
 21 character. *See Nat’l Ass’n of Optometrists & Opticians v. Harris*, 682 F.3d 1144, 1148 (9th Cir.
 22 2012) (“[S]ignificant burdens on interstate commerce generally result from inconsistent regulation
 23 of activities that are inherently national or require a uniform system of regulation.”).

24 63. The 60-day notice also burdens interstate commerce by promoting price stabilization
 25 and potentially reducing competition.⁴⁹ The Federal Trade Commission, for example, has
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27 ⁴⁹ Ian Spatz, *California Takes on Drug Pricing: Real Progress or Illusion*, Health Affairs (Oct. 2,
 28 2017), <http://www.healthaffairs.org/doi/10.1377/hblog20171002.062240/full>.

1 questioned “transparency” laws such as SB 17, explaining: “Too much transparency can harm
 2 competition in any market, including in health care markets. . . . [W]hen information disclosures
 3 allow competitors to figure out what their rivals are charging, [it] dampens each competitor’s
 4 incentive to offer a low price, or increases the likelihood that they can coordinate on higher
 5 prices.”⁵⁰ In markets without such transparency, the FTC has recognized that “manufacturers have
 6 powerful incentives to bid aggressively for formulary position, because preferential formulary
 7 treatment may yield increased sales.”⁵¹

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

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 22 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>.

23 ⁵¹ Letter from James Cooper, Pauline M. Ippolito, & David P. Wales of the Fed. Trade Comm’n to
 24 Hon. James L. Seward (Mar. 31, 2009),
 25 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),
 26 <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/06-05-pricetransparency.pdf>.

27 ⁵² Spatz, *supra* note 49.
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1 65. Worse, SB 17 picks the winners and losers of this prescription-drug arbitrage. The
2 Act authorizes state purchasers, insurers, health plans, and PBMs—including presumably all retail
3 and specialty pharmacies owned by or affiliated with these entities, as well as “large purchasers”
4 who contract with eligible PBMs—to receive advance notice of an increase in the WAC list price
5 directly from the manufacturer. *See* SB 17 § 4 (adding §§ 127675(a), 127677(a) & (e)). Even if a
6 small, unaffiliated local pharmacy were capable of purchasing excess inventory during the 60 days
7 before a price increase takes effect, SB 17 gives its PBM-affiliated competitors a head start. SB 17
8 creates the temporal equivalent of a volume buying discount; those entities favored by the Act have
9 up to 60 additional days to take advantage of the lower list price. SB 17 thus discriminates between
10 market participants on the same level, specifically favoring certain select purchasers to the
11 detriment of others who do not have access to advance notices.

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

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

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⁵³ *See supra*, ¶¶ 4–7, 36–37.

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

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3 68. In addition to violating the Commerce Clause, SB 17 violates the First Amendment
4 by requiring manufacturers, and only manufacturers, to announce increases to WAC list prices for
5 qualifying drugs 60 days in advance and to explain whether the increase is attributable to factors
6 that California approves.

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

11 70. SB 17 violates the First Amendment by compelling pharmaceutical manufacturers to
12 communicate the information included in the 60-day notice and the OSHPD report; information that
13 manufacturers would not provide unless the Act compelled them to do so. “[T]he right of freedom
14 of thought protected by the First Amendment against state action includes both the right to speak
15 freely and the right to refrain from speaking at all.” *Wooley v. Maynard*, 430 U.S. 705, 714 (1977).
16 “‘Since *all* speech inherently involves choices of what to say and what to leave unsaid,’ one
17 important manifestation of the principle of free speech is that one who chooses to speak may also
18 decide ‘what not to say.’” *Hurley v. Irish-Am. Gay, Lesbian, & Bisexual Grp. of Boston*, 515 U.S.
19 557, 573 (1995) (quoting *Pac. Gas & Elec. Co. v. Pub. Utils. Comm’n of Cal.*, 475 U. S. 1, 11, 16
20 (1986) (plurality op.)). “Outside [the] context” of “commercial advertising,” the State “may not
21 compel affirmance of a belief with which the speaker disagrees.” *Id.* Put simply, “freedom of
22 speech prohibits the government from telling people what they must say.” *Rumsfeld v. Forum for*
23 *Academic & Inst. Rights*, 547 U.S. 47, 61 (2006).

24 71. The Supreme Court has repeatedly held that laws regulating “how sellers may
25 communicate their prices” are subject to First Amendment scrutiny. *Expressions Hair Design v.*
26 *Schneiderman*, 137 S. Ct. 1144, 1151 (2017). In particular, the First Amendment protects the free
27 “flow of prescription drug price information.” *Va. State Bd. of Pharmacy v. Va. Citizens Consumer*
28 *Council, Inc.*, 425 U.S. 748, 770 (1976). Decisions about when to announce a price increase, and

1 whether and how to explain that price increase, are inherently communicative. *See id.* at 761, 770
2 (pharmacist’s communication “I will sell you the X prescription drug at the Y price” was protected
3 by First Amendment). As SB 17 “regulat[es] the communication of prices rather than prices
4 themselves,” the law on its face implicates the First Amendment. *Expressions Hair Design*, 137 S.
5 Ct. at 1151.

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

19 73. The Act’s proponents ensured that these messages permeated the public discussion
20 of health care. They repeatedly denounced “drug companies” that “don’t tie price increases to
21 effectiveness.”⁵⁵ One proponent described the pharmaceutical industry as “a broken marketplace,
22 where patents are extended” and manufacturers “continue to raise prices on existing drugs once,
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26 ⁵⁴ Sen. Ed Hernandez, Press Conference, *supra* note 3, at 9:16 (noting SB 17 is triggered “when
27 drug companies increase prices in a way that would be shocking in any other industry, any other
28 segment of the healthcare industry.”).

⁵⁵ Sen. Ed Hernandez, Press Conference, *supra* note 3, at 8:35.

1 twice or even three times per year—and yet that new, higher price brings no additional value or
2 clinical benefit.”⁵⁶

3 74. Where a speech regulation discriminates based on the content of the communication,
4 favors a particular viewpoint, or favors or disfavors a particular speaker, courts apply heightened
5 judicial scrutiny. *See Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2227 (2015); *Sorrell v. IMS Health*
6 *Inc.*, 564 U.S. 552, 564-66 (2011). Heightened scrutiny applies to this case because SB 17
7 discriminates on all three bases: content, viewpoint, *and* speaker.

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

19 76. **Content Based Discrimination.** Laws that “[m]andate speech that a speaker
20 would not otherwise make” are content based, because forcing a speaker to convey a message
21 “necessarily alters the content of the speech.” *Riley*, 487 U.S. at 795. SB 17 dictates both when
22 pharmaceutical manufacturers must speak about their pricing decisions and what they must say. It
23 forces them to speak at a particular time (at least 60 days in advance of a price increase), to a
24 particular audience (at a minimum, drug purchasers, third-party payers, and the state of California),
25 with a particular message (that they are planning a price increase of a type that State officials have
26

27 ⁵⁶ Letter from T. Stark (Kaiser Permanente) to Assemb. Gonzalez Fletcher (July 10, 2017), attached
28 as Exhibit K.

1 disparaged repeatedly in the strongest terms, that the State presumptively disfavors, and that,
2 according to the State, can be justified only by a change or improvement in the drug). SB 17
3 compels manufacturers to “assist in disseminating” the messages the state entrenched in the public
4 consciousness: that drug prices are too high, that manufacturers are responsible, and that only
5 changes or improvement can justify an increase. Further, SB 17 requires manufacturers publicly to
6 “associate with speech with which [they] disagree.” *Pac. Gas & Elec. Co.*, 475 U.S. at 15 (plurality
7 op.).

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

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

1 79. SB 17 does not advance a legitimate, much less substantial, state interest.
2 California’s desire to “set national health care policy”⁵⁷ and reduce prescription drug prices
3 nationwide is not only illegitimate, it is also independently unconstitutional under the Commerce
4 Clause.

5 80. Even if regulating pharmaceutical prices nationwide were a legitimate state interest,
6 the State does not and cannot advance that interest by mandating speech about prices and then
7 regulating that speech as a backdoor means to achieve its regulatory objectives. *Lanphere &*
8 *Urbaniak v. State of Colo.*, 21 F.3d 1508, 1519 (10th Cir. 1994). Indeed, this is precisely what the
9 U.S. Government sought to do with regard to conflict minerals—resources extracted from a conflict
10 zone and sold to finance continued fighting. Rather than regulating use of possible conflict
11 minerals directly, the Dodd-Frank Act required disclosure about that use. The D.C. Circuit struck
12 down the law. As the Court observed, “Requiring a company to publicly condemn itself is
13 undoubtedly a more ‘effective’ way for the government to stigmatize and shape behavior than for
14 the government to have to convey its views itself, but that makes the requirement more
15 constitutionally offensive, not less so.” *Nat’l Ass’n of Mfrs. v. SEC*, 800 F. 3d 518, 530 (D.C. Cir.
16 2015). Compelling speech about pricing is not a legitimate alternative to regulating pricing directly.
17 The Supreme Court has made clear: “If the First Amendment means anything, it means that
18 regulating speech must be a last—not first—resort.” *Thompson v. W. States Med. Ctr.*, 535 U.S.
19 357, 373 (2002).

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

25 82. Even if SB 17 did directly advance a substantial state interest, the law still would not
26 survive because the “fit between the legislature’s ends and the means chosen to accomplish those

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28 ⁵⁷ Sen. Ed Hernandez, *supra* note 1.

1 ends” is incongruous. *Sorrell*, 564 U.S. at 572 (internal quotation marks omitted). The Act imposes
2 burdens on a single actor in a complex distribution system, ties its speech restrictions to a federally
3 required list price, and not only is unlikely to have the intended effect of lowering the cost of
4 prescription drugs, but may in fact spawn a host of market distortions, such as drug stockpiling and
5 reduced competition.⁵⁸

6 83. Furthermore, SB 17 is unconstitutionally vague because it “fails to provide a person
7 of ordinary intelligence fair notice of what is prohibited” and “is so standardless that it authorizes or
8 encourages seriously discriminatory enforcement.” *FCC v. Fox Television Stations, Inc.*, 567 U.S.
9 239, 253 (2012). Statutes that regulate speech are subject to particularly searching review for
10 vagueness. While vagueness is an outgrowth of due process rather than the First Amendment itself,
11 *United States v. Williams*, 553 U.S. 285 (2008), it is well recognized that “where a vague statute
12 abuts upon sensitive areas of basic First Amendment freedoms, it operates to inhibit the exercise of
13 those freedoms.” *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). Thus, “[w]hen speech is
14 involved, rigorous adherence to [due process] requirements is necessary to ensure that ambiguity
15 does not chill protected speech.” *Fox*, 567 U.S. at 253.

16 84. SB 17’s 60-day notice provision offends due process because the Act is silent on
17 which WAC increases determine whether a manufacturer has breached the statutory threshold of
18 increases over 16 percent during “the previous two calendar years prior to the current year.” SB 17
19 § 4 (adding HSC § 127677 (a)–(e)). Although SB 17 went into effect on January 1, 2018, Cal.
20 Const. art. IV, § 8, manufacturers cannot determine from the face of the Act whether that “effect” is
21 retroactive, such that OSHPD will include all price increases since January 1, 2016, in its
22 calculation, or prospective, such that OSHPD will count only WAC increases after January 1, 2018.
23 And OSHPD—the agency charged with enforcing and interpreting SB 17—has not responded to
24 PhRMA’s multiple direct requests to clarify this ambiguity.

25 85. If the Act applies retroactively, SB 17 will cause immediate harm to several PhRMA
26 members whose products’ list prices have increased since January 1, 2016—even though those prior

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28 ⁵⁸ See *supra*, ¶¶ 63–66.

1 price adjustments occurred without warning from California that the adjustments could subject the
2 manufacturer to burdensome notice requirements and compelled speech in 2018. Many of these
3 manufacturers will not increase the WAC of products at the same time and in the same manner that
4 they otherwise would without the risk of past increases triggering SB 17's 60-day notice provision.
5 The impact of this ambiguity on due process deserves intense scrutiny because it "abuts upon
6 sensitive areas of basic First Amendment freedoms" in two ways: not only does SB 17's vagueness
7 chill manufacturers' protected price communications, *Schneiderman*, 137 S. Ct. at 1151, but it does
8 so with the threat of compelled speech, *see Fox*, 567 U.S. at 253.

9 ***SB 17 Has Harmed and Will Continue to Harm PhRMA Members***

10
11 86. SB 17's notification requirements have harmed PhRMA's members and will
12 continue to do so. Members of PhRMA have already been forced to comply with the 60-day
13 advance notice requirement because of pricing changes, in violation of their constitutional rights.
14 Members of PhRMA will make pricing changes in the future that will force them to provide
15 additional 60-days' notice and will trigger the reporting requirements of SB 17.

16 87. SB 17's notification requirements have already harmed pharmaceutical companies.
17 As described in a published report, as of March 25, 2018, several pharmaceutical companies,
18 including a PhRMA member, had filed notices with California's Department of Health Care
19 Services regarding price increases above the threshold requirement for at least one of their
20 products.⁵⁹ Under SB 17, the article reports, those companies gave the 60-day advance notice to
21 registered purchasers, with an explanation of whether the price increases were justified by
22 improvements in the drug. The article also identifies a notice sent by another PhRMA member
23 company explaining a 49 percent increase in the price of one of its products. These companies
24 would not have made these statements, to which they object, had SB 17 not compelled them to do
25 so in violation of their First Amendment rights. Nor would they have waited 60 days between the
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27 ⁵⁹ Victoria Colliver, *California's drug transparency law yields early surprises*, Politico (Mar. 25,
28 2018), <https://www.politico.com/story/2018/03/25/california-drug-transparency-law-440090>.

1 announcement and the implementation of a price increase. Indeed, attached is an April 19, 2018
2 price increase notification from PhRMA Member A to registered purchasers pursuant to SB 17
3 regarding the expected increase of a particular drug. Exhibit L. The information provided in the
4 notification included the name of the product, and the current and planned WAC of the product, and
5 a statement that “[t]his planned price increase was not necessitated by a change or improvement in
6 the drug.” The notification was provided to registered purchasers despite the fact that the change in
7 the WAC was less than the threshold price. PhRMA Member A provided the notice because, due to
8 the vagueness of SB 17, it was unable to determine what is required under the law. Absent SB 17,
9 PhRMA Member A would not have sent such a notification and, in particular, would not have
10 included a justification for the increase in the product’s WAC. PhRMA Member A has thus been
11 directly harmed by SB 17’s unconstitutional provisions.

12 88. PhRMA members will make pricing changes in the future that will force them to
13 comply against their will and in violation of their constitutional rights with the 60-days’ notice and
14 reporting requirements of SB 17.

15 89. PhRMA members are also being harmed because the statute is vague; it is unclear
16 whether SB 17’s threshold calculations include 2016 and 2017 drug price increases. To this day,
17 OSHPD has refused to clarify whether the 60-day advance notification and reporting calculations
18 include price increases effectuated before the law went into effect on January 1, 2018. OSHPD has
19 indicated it will not implement clarifying regulations until January 1, 2019. For example, in a letter
20 dated March 22, 2018, one PhRMA member (“PhRMA Member B”) notified OSHPD that it would
21 not be able to provide advance notice of WAC increases as both a constitutional and a practical
22 matter, noting that the law not only imposes an excessive burden on interstate commerce, but also
23 creates inequities and disruptions in the drug supply that can severely limit patient access to drugs.
24 Exhibit M, at 3-4. PhRMA Member B reported that, even absent those factors, an increase in price
25 “may not be finally decided until less than 60 days in advance of its effective date, underscoring
26 further that [PhRMA Member B] is unable to implement a system to provide advanced notice at this
27 time.” *Id.* at 4.

1 **SECOND CLAIM FOR RELIEF**

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

4 95. Plaintiff re-alleges and incorporates by reference all prior and subsequent
5 paragraphs.

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

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

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

19 **THIRD CLAIM FOR RELIEF**

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

22 99. Plaintiff re-alleges and incorporates by reference all prior and subsequent
23 paragraphs.

24 100. A statute is unconstitutionally vague in violation of due process when it “fails to
25 provide a person of ordinary intelligence fair notice of what is prohibited” and “is so standardless
26 that it authorizes or encourages seriously discriminatory enforcement.” *Fox*, 567 U.S. at 253; *see*
27 *also* U.S. Const., Amend. XIV, § 1.
28

1 DATED: September 28, 2018
2

3 By: /s/ Annie S. Amaral

4 ANNIE S. AMARAL
5 AVALON J. FITZGERALD
6 DOWNEY BRAND LLP
7 621 Capitol Mall, 18th Floor
8 Sacramento, Ca 95814
9 Telephone: (916) 444-1000

10 ROBERT N. WEINER
11 JEFFREY L. HANDWERKER
12 R. STANTON JONES
13 ARNOLD & PORTER KAYE SCHOLER LLP
14 601 Massachusetts Avenue, NW
15 Washington, DC 20001
16 Telephone: (202) 942-5000

17 Attorney for Plaintiff Pharmaceutical Research
18 and Manufacturers of America
19
20
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