No. 20-15014

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Plaintiff-Appellant,

v.

XAVIER BECERRA, in his official capacity as Attorney General of the State of California,

Defendant-Appellee.

On Appeal from the United States District Court
for the Eastern District of California,
No. 2:19-cv-02281-TLN-DB

BRIEF OF AMERICAN MEDICAL ASSOCIATION AND CALIFORNIA MEDICAL ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT-APPELLEE

MATTHEW L. CANTOR
Counsel of Record
CONSTANTINE CANNON LLP
335 Madison Ave.
New York, New York 10017
(212) 350-2700
mcantor@constantinecannon.com

ARI M. YAMPOLSKY
CONSTANTINE CANNON LLP
150 California Street, Suite 1600
San Francisco, California 94111
(415) 639-4001
ayampolsky@constantinecannon.com

Attorneys for *Amici Curiae*

CORPORATE DISCLOSURE STATEMENT

Pursuant to the Federal Rules of Appellate Procedure, there are no parent corporations or publicly held corporations that own 10% or more of the stock in the *amici* organizations.

TABLE OF CONTENTS

TABLE OF AUTHORITIES iv

INTEREST OF AMICI CURIAE 1

INTRODUCTION 2

ARGUMENT 3

I. Pay-for delay deals hinder the ability of physicians to provide quality patient care. 3

A. Pharmaceutical manufacturers have used "pay-for-delay" settlements to increase drug prices. 3

B. Pay-for-delay deals often interfere with the ability of physicians to provide access to care in accordance with their ethical obligations. 7

C. Assembly Bill 824 ensures more effective, cost-competitive treatment of patients. 8

II. Assembly Bill 824 is a legally valid mechanism that protects the ability of physicians to provide quality patient care and does not offend due process. 10

A. California's antitrust laws are an appropriate vehicle to protect health care consumers, payers, and providers from the anticompetitive effects of abusive pay-for-delay deals 10

B. Pay-for-delay deals may be anticompetitive because they substantially raise prices on health care consumers and payers. 14

C. Pay-for-delay deals may be anticompetitive because they result in lower quality care and patient harm. 16

D. Pay-for-delay deals may be anticompetitive because they harm the ability of physicians to provide quality care to patients consistent with their ethical obligations. 18

CONCLUSION 20

CERTIFICATE OF SERVICE 22

TABLE OF AUTHORITIES

Cases

Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Company,
20 Cal. 4th 163 (1999) 11

Cianci v. Super. Ct.,
40 Cal. 3d 903 (1985) 10, 12

Comedy Club, Inc. v. Improv W. Assocs.,
553 F.3d 1277 (9th Cir. 2009) 11

CVS Pharmacy Inc. v. Pfizer Inc., et al.,
No. 18-cv-12437 (D.N.J. Aug. 3, 2018) 16

FTC v. Cephalon, Inc.,
No. 08-cv-2141 (E.D. Pa. Feb. 13, 2008) 15

In re Cipro Cases I & II,
61 Cal. 4th 116 (2015) 8, 9, 13

In re Cipro Cases I & II,
No. S198616, 2012 WL 503757 (Cal. Jan. 13, 2012) 15

In re Cipro Cases I & II, *Karyn McGaughey, et al., v. Bayer Corporation, et al.*,
No. D056361, 2010 WL 3232362 (Cal. Ct. App. July 1, 2010) 14

In re Ciprofloxacin Hydrochloride Antitrust Litigation,
544 F.3d 1323 (Fed. Cir. 2008) 14

New York Medscan LLC v. New York Univ. Sch. of Med.,
430 F. Supp. 2d 140 (S.D.N.Y. 2006) 11

New York v. Actavis PLC,
787 F.3d 638 (2d Cir. 2015) 12

New York v. Actavis, PLC,
No. 14-cv-7473, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014) 12

Palmyra Park Hosp., Inc. v. Phoebe Putney Mem'l Hosp.,
604 F.3d 1291 (11th Cir. 2010) 11

Statutes

Cal. Bus. & Prof. Code § 17200 11

Cal. Health & Safety Code § 134002 .....9, 10

Other Authorities

AARP Public Policy Institute, *Rx Price Watch Report: Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update*, Sept. 2019 5

AMA Code of Medical Ethics Opinion 11.1.2, *Physician Stewardship of Health Care Resources* 7, 8, 19

AMA Principles of Medical Ethics.....8, 19

Association for Accessible Medicines, *The Case for Competition, 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report*, May 2019 5

Brendan Pierson, *U.S. court upholds AstraZeneca, Ranbaxy win in Nexium antitrust trial*, REUTERS, Nov. 21, 2016 15

Cal. Dep't of Managed Health Care, "Prescription Drug Cost Transparency Report, Measurement Year 2018," Jan. 10, 2020 .....4, 5

California Health Care Foundation, "California Personal Health Care Spending | A supplement to CHCF's Health Care Costs 101" (2017 ed.), Sept. 2017 4

Center for Medicare and Medicaid Services, "CMS Office of the Actuary releases 2017-2026 Projections of National Health Expenditures," Feb. 14, 2018.....4

Consumer Reports, *Sluggish Economy Forces Americans to Cut Corners to Pay for Medications: Those without Prescription Drug Coverage Nearing Crisis Point*, Sept. 2012 17

Federal Trade Commission, "Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2016, A Report by the Bureau of Competition".....9

Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, Jan. 2010 .....7, 14

John George, *Hurdles Ahead for Cephalon*, PHILADELPHIA BUSINESS JOURNAL, March 17, 2006.....15

Letter from John E. Dicken, Dir., Health Care, U.S. Gov't Accountability Office to Sen. Orrin G. Hatch, Committee on Finance, Jan. 31, 2012.....5

Linda L. Barrett, AARP Knowledge Management, *Prescription Drug Use Among Midlife and Older* Americans, Jan. 2005 17

Micah Hartman, et al., *National Health Care Spending in 2016: Spending and Enrollment Growth Slow After Initial Coverage Expansions*, HEALTH AFFAIRS, Jan. 2018.....3

Prepared Statement of the Federal Trade Commission before the Committee on the Judiciary of the United States Senate, *Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution*, Jan. 17, 2007.....5

R. McCarthy, *The price you pay for the drug not taken*, BUS. HEALTH., Oct. 1998 18

Statement for the Record, American Medical Association before the Subcomm. on Commerce, Trade, and Consumer Protection for the House Committee on Energy and Commerce, *Impact of "Pay-for-Delay" Settlements On Patient Access to Affordable Generics and Overall Health Care System Costs*, April 13, 2009.....18

Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67026 (Oct. 28, 2011) 12

United States Department of Justice and Federal Trade Commission, *Statements of antitrust enforcement policy in health care*, Aug. 1996.....12

United States Public Interest Research Group, *Top Twenty Pay-For-Delay Drugs: How Drug Industry Payoffs Delay Generics, Inflate Prices and Hurt Consumers*, July 11, 2013..... 6, 15, 16

William H. Shrank, et al., *The epidemiology of prescriptions abandoned at the pharmacy*, ANNALS OF INTERNAL MEDICINE, Nov. 16, 2010..... 17, 18

INTEREST OF AMICI CURIAE

The American Medical Association (AMA) and the California Medical Association (CMA) respectfully submit this brief as *amici curiae* in support of Defendant-Appellee.[1]

The AMA is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups, seated in the AMA's House of Delegates, substantially all US physicians, residents, and medical students are represented in the AMA's policy making process. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health.

The CMA is a non-profit, incorporated professional association for physicians with approximately 46,000 members throughout the state of California. For more than 160 years, CMA has promoted the science and art of medicine, the care and wellbeing of patients, the protection of public health, and the betterment of the medical profession. CMA's physician members practice medicine in all specialties and settings throughout California.

Amici submit this brief on its own behalf and as a representative of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state, plus the District of Columbia, whose purpose is to represent

[1] Counsel for all parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No persons other than the *amici* or their counsel made a monetary contribution to this brief's preparation or submission.

the viewpoint of organized medicine in the courts.

The AMA and CMA have strong interests in this case. California Assembly Bill 824, Cal. Health & Safety Code §§ 134000–134002, the recently enacted statute Plaintiff-Appellant challenges, imposes important restrictions on so-called "pay-for-delay" agreements. Such agreements often harm health care consumers and payers by driving up the cost of pharmaceutical drugs, putting necessary medications out of reach for consumers who cannot afford them, and dissipating scarce health care resources. These agreements often work further harm on health care providers by interfering with physicians' ethical obligations to provide access to care, which includes consideration of the patient's ability to afford treatment options, for vulnerable patient populations. In addition, CMA supported Assembly Bill 824, the law Plaintiff-Appellant challenges in this appeal, when the California Legislature considered the legislation.

Amici respectfully submit that this Court should affirm the district court's denial of AAM's motion for preliminary injunction.

INTRODUCTION

Amici agree with the District Court and Defendant-Appellee Attorney General Becerra that California Assembly Bill 824 withstands the challenges Plaintiff-Appellant Association for Accessible Medicines (AAM) brings to it. *Amici* write separately to emphasize how this law enhances physicians' ability to care for their patients.

State and federal antitrust laws are appropriate vehicles to protect health care consumers, payers, and providers from the anticompetitive effects of many pay-for-delay deals. For several years, California courts applying antitrust scrutiny to

pay-for-delay deals have recognized that they can cause substantial anticompetitive effects. These include:

- increased prices for critical drugs for health care consumers and payers;
- reduced quality of patient care and resultant patient harm; and
- harm to the ability of physicians to provide quality care to patients.

The presumptions Assembly Bill 824 sets forth are consistent with established California jurisprudence, which casts a wary eye on pay-for-delay deals.

ARGUMENT

I. Pay-for delay deals hinder the ability of physicians to provide quality patient care.

A. Pharmaceutical manufacturers have used "pay-for-delay" settlements to increase drug prices.

Skyrocketing prescription-drug costs are a matter of fundamental concern to California and the United States. In 2016, the United States spent $3.337 trillion, or 17.9 percent of the gross domestic product, on national health expenditures; of this amount, the nation spent $329 billion on retail prescription drugs.[2] *See* Micah Hartman, et al., *National Health Care Spending in 2016: Spending and Enrollment Growth Slow After Initial Coverage Expansions*, HEALTH AFFAIRS, Jan. 2018, at 150, 155, *available at* https://bit.ly/3a6oZdC.[3] In 2014, Californians spent approximately $38 billion on prescription drugs and related services. *See* California Health Care Foundation, "California Personal Health Care Spending | A

[2] The category of "retail prescription drugs" excludes drugs purchased directly from physicians or hospitals, such as infusion drugs.

[3] All websites cited in this brief were last visited on March 2, 3020.

supplement to CHCF's Health Care Costs 101" (2017 ed.), Sept. 2017, *available at* https://bit.ly/3a99qS7.

Beyond that, prescription drugs are a significant driver in increases in health care costs. Economists expect retail prescription-drug costs to grow 6.1% per year during the ten-year period ending in 2027; that will make spending for prescription drugs the fastest growth category in health care, consistently outpacing growth in all other health care spending categories. *See* Center for Medicare and Medicaid Services, "CMS Office of the Actuary releases 2017-2026 Projections of National Health Expenditures," Feb. 14, 2018, *available at* https://go.cms.gov/3aaTVcJ. According to the California Department of Managed Health Care, which regulates the vast majority of commercial health plans, health plans paid nearly $9.1 billion for prescription drugs in 2018, over $400 million more than in 2017; this 4.7 percent increase eclipsed the 2.7 percent increase in health plans' medical expenses during the same period. *See* Cal. Dep't of Managed Health Care, "Prescription Drug Cost Transparency Report, Measurement Year 2018," Jan. 10, 2020, at 6 ("DMHC Report") (Table 1), *available at* https://bit.ly/3cnZczi. Extraordinary price increases for pharmaceutical drugs impede the ability of consumers in California to access necessary medications. They also interfere with the ability of physicians in California to provide quality patient care.

Competition from generic drugs is the most effective means to slow the spiraling cost of pharmaceuticals. Generic drugs, which are bioequivalent copies of brand-name drugs whose patents have expired, typically sell for a fraction of the cost of their brand-name counterparts. For example, the average cost of a brand-name drug was 18.6 times higher than its generic equivalent in 2017. *See* AARP Public Policy Institute, *Rx Price Watch Report: Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update*,

Sept. 2019, at 6–7 (stating the average cost of 535 widely used generic drugs indicated for treating chronic conditions in 2017 was $365 for a year of therapy, compared with $6,798 for brand-name drugs), *available at* https://bit.ly/380Yi8G. Remarkably, the size of that gap has more than tripled since 2013. *See id*. at 8 (reporting that average annual cost of generic drugs was $751 in 2013, compared to $4,308 for branded drugs). Unsurprisingly, brand drugs drive prescription drug spending. In 2018, for example, brand drugs accounted for about 13 percent of all prescribed drugs in California, but approximately 78 percent of the total annual spending on prescription drugs in the state. *See* DMHC Report, at 8.

The entry of generic-drug competitors to brand-name drugs unquestionably results in enormous consumer savings. *See* Prepared Statement of the Federal Trade Commission before the Committee on the Judiciary of the United States Senate, *Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution*, Jan. 17, 2007, at 4 (successful patent challenges to just four major brand-name drugs—Prozac, Zantac, Taxol and Platinol—have saved consumers more than $9 billion), *available at* https://bit.ly/2uv03gx; *see also* Letter from John E. Dicken, Dir., Health Care, U.S. Gov't Accountability Office to Sen. Orrin G. Hatch, Committee on Finance, Jan. 31, 2012, at 4 (competition between generics and brand-name pharmaceuticals in traditional drug markets has saved consumers over $1 trillion since 1984), *available at* https://bit.ly/2PjTFA3; Association for Accessible Medicines, *The Case for Competition, 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report*, May 2019, at 4 (estimating that generics saved consumers $293 billion in 2018 alone), *available at* https://bit.ly/3a0DLCk.

However, delays in the introduction of generic drugs can, and often do, hinder the ability of generics to drive down the costs of pharmaceuticals. Both

brand-name and generic drug manufacturers have used, and continue to use, so-called "pay-for-delay" settlements (also called "reverse settlements") to stifle competition from lower-cost generic manufacturers.

At their core, pay-for-delay deals involve an agreement not to compete. They are used to dispose of legal challenges that generic-drug manufacturers have brought against the brand manufacturers who hold pharmaceutical patents. Instead of litigating the validity of its patent, the brand-name manufacturer pays the generic manufacturer cash or other consideration to drop the patent challenge. In exchange, the generic manufacturer permits the brand manufacturer to exclusively sell the brand drug for a period of time—despite the generic drug manufacturer's former claims that the brand manufacturer's patents are invalid or unenforceable—during which the generic manufacturer agrees to not enter the market. In short, a brand manufacturer in a pay-for-delay deal pays a would-be generic competitor *not* to bring lower-cost alternatives to market, blocking generic competition to the branded drug and extending the brand manufacturer's monopoly pricing power, sometimes for years.

The consequences of abusive pay-for-delay deals pass through the health care system, and their anticompetitive effects are plain. Pay-for-delay deals increase drug prices for health care consumers. *See* United States Public Interest Research Group, *Top Twenty Pay-For-Delay Drugs: How Drug Industry Payoffs Delay Generics, Inflate Prices and Hurt Consumers*, July 11, 2013, at 1 ("U.S. PIRG Report") (finding that pay-for-delay deals related to twenty "blockbuster" drugs used by patients with serious medical conditions—ranging from cancer and heart disease to depression and bacterial infection—thwarted generic competition for five years on average; resulted in brand-name drugs that cost ten times as much on average than their generic equivalents; and earned brand manufacturers an

estimated $98 billion in total sales while the generic versions were delayed), *available at* https://bit.ly/2ViyFgV. In 2010, for example, the Federal Trade Commission (FTC) estimated that pay-for-delay deals cost Americans about $3.5 billion in higher health care costs each year. Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, Jan. 2010, at 10 ("FTC Pay-for-Delay Report"), *available at* https://bit.ly/2HVmwXh.

By thwarting price reductions from generic drugs, pay-for-delay deals can keep affordable medications used to treat serious or chronic conditions out of the hands of patients who need them most.

B. Pay-for-delay deals often interfere with the ability of physicians to provide access to care in accordance with their ethical obligations.

Apart from the harmful impact on patients, pay-for-delay deals can compromise the ability of AMA and CMA physician-members to provide access to affordable care to suffering patients, in a manner consistent with their ethical obligations. *See* discussion *infra* § II.C.

Under ethical precepts that guide the profession, physicians must not only attempt to provide effective treatment to patients, but as a practical matter, must also consider the costs of treatment when doing so. Obstacles that limit a patient's ability to comply with the physician's determination of what care will result in the best medical outcome hinder a physician's ability to effectively treat her patients. The AMA Code of Medical Ethics, for instance, states that a physician's "primary ethical obligation is to promote the well-being of individual patients." AMA Code of Medical Ethics ("AMA Code") Opinion 11.1.2, *Physician Stewardship of Health Care Resources*, *available at* https://bit.ly/2HSLPcs. "A physician shall, while caring for a patient, regard responsibility to the patient as paramount." AMA

Principles of Medical Ethics ("AMA Principles"), Principle VIII, *available at* https://bit.ly/2SXh5NK.

Apart from tending to the needs of individual patients, a physician is also required to "support access to medical care for all people," *id*. Principle IX, and to "promote public health and access to care," AMA Code Opinion 11.1.2. In order to do so, a physician must be a "prudent steward[] of the shared societal resources with which [she is] entrusted," "for the benefit of all patients." *Id*.

When patients cannot afford drugs that physicians determine are necessary to their treatment and health, physicians may be effectively barred from providing treatment most likely to achieve a patient's health care goals. *Id*. The effects of many pay-for-delay deals—skyrocketing drug costs and shrinking patient access of affordable treatment options—compromise the ability of AMA physician-members to treat suffering patients in line with their professional ethical duties.

C. Assembly Bill 824 ensures more effective, cost-competitive treatment of patients.

Following the United States Supreme Court's landmark decision in *Federal Trade Commission v. Actavis, Inc.*, 570 U.S. 136 (2013), the California Supreme Court held in *In re Cipro Cases I & II* that pay-for-delay deals can be challenged under California's antitrust laws as unreasonable restraints on trade. 61 Cal. 4th 116, 160 (2015). As *Cipro* recognized, pay-for-delay deals enable a brand-drug patent holder to use monopoly profits to avoid the possibility that a generic-drug patent challenger will prove its patents are invalid or not infringed. *Id*. at 130. Reflecting the Court's skeptical stance, *Cipro* observed that, where the interests of the patentee and the generic manufacturer "align in favor of maximizing their combined wealth by extending the monopoly for as long as

possible," pay-for-delay deals can "effectively establish a cartel." *Id*. at 135, 155. And because "[a]ntitrust law condemns the purchase of freedom from competition," pay-for-delay deals that engineer such illicit purchases should not stand. *Id*. at 159.

Yet even after *Cipro*, drug manufacturers continued to enter into abusive pay-for-delay deals. In 2016, for example, drug manufacturers entered into thirty settlements that contained both explicit compensation from a brand manufacturer to a generic manufacturer, and a restriction on the generic manufacturer's ability to market its product in competition with the brand drug. *See* Federal Trade Commission, "Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2016, A Report by the Bureau of Competition," at 1, *available at* https://bit.ly/2vhJsx1. Regardless of whether the parties to these agreements were California companies, *all* agreements that thwart drug-cost reductions in California and diminish access to critical drugs to California patients necessarily harm California health care consumers, payers, and providers.

Responding to the persistence of anticompetitive pay-for-delay deals, California became the first state in the nation to legislatively ban them. Under Assembly Bill 824, which California Governor Gavin Newsom signed into law in October 2019, a settlement agreement between two drug companies in which a brand manufacturer compensates a rival to delay sales of competing generic drugs for a certain period of time is presumptively anticompetitive under California antitrust laws. *See* Cal. Health & Safety Code § 134002(a)(1). Assembly Bill 824 allows parties to these deals to overcome the presumption by showing that either (a) the brand's settlement payment to the generic was not made to delay the

generic's entry into the marketplace, because the payment or consideration is fair and reasonable compensation for goods and services the generic has promised to provide, or (b) the procompetitive benefits of the agreement outweigh its anticompetitive effects. *See id*. § 134002(a)(3)(A)–(B).

Assembly Bill 824 reflects California's interests in promoting competition and reining in the costs of prescription drugs. It also manifests California's concern with protecting health care consumers, providers, and payers, which include employers, insurers, and government payers, such as Medicaid and Medicare. And Assembly Bill 824's presumption that pay-for-delay settlements violate the state's antitrust laws is consistent with empirical evidence that demonstrates the anticompetitive effects of many such settlements.

II. Assembly Bill 824 is a legally valid mechanism that protects the ability of physicians to provide quality patient care and does not offend due process.

Plaintiff-Appellant AAM argues that Assembly Bill 824 violates the due-process rights of drug manufacturers because it presumes that pay-for-delay deals are always anticompetitive under California law. (*See* Pl.-Appellant's Opening Br. at 52–55 (Dkt. No. 10).) The Court should reject AAM's argument.

A. California's antitrust laws are an appropriate vehicle to protect health care consumers, payers, and providers from the anticompetitive effects of abusive pay-for-delay deals.

California antitrust law is a unique antitrust vehicle that reaches well beyond federal law. The Cartwright Act, California's general antitrust statute, for example, is "broader in range and deeper in reach than the Sherman Act." *Cianci v. Super. Ct.*, 40 Cal. 3d 903, 920 (1985). Similarly, California Business and Professions Code section 16600, which is "independent of and supplemental to the Cartwright

Act," *Comedy Club, Inc. v. Improv W. Assocs.*, 553 F.3d 1277, 1293 n.17 (9th Cir. 2009), invalidates "every contract by which anyone is restrained from engaging in a lawful profession, trade, or business of any kind"; section 16600 has no equivalent in federal law.

California has also enacted unfair competition laws that render certain business practices impermissible, even when they do not fall within the scope of traditional antitrust analysis. California's Unfair Competition Law (UCL), Cal. Bus. & Prof. Code § 17200, for example, prohibits "any unlawful, unfair or fraudulent business act or practice." Under the UCL, "unfair" practices are those that "threaten[] an incipient violation of an antitrust law, or violate[] the policy or spirit of one of those laws because its effects are comparable to or the same as a violation of the law, or otherwise significantly threaten[] or harm[] competition." *Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Company*, 20 Cal. 4th 163, 187 (1999).

Antitrust laws are an appropriate vehicle to protect health care consumers, payers, and providers from the anticompetitive effects of abusive pay-for-delay deals. Practices in the health care industry that result in "higher prices and fewer choices for [health care] consumers" are "precisely the type of harm that we allow plaintiffs to vindicate through the antitrust laws." *See Palmyra Park Hosp., Inc. v. Phoebe Putney Mem'l Hosp.*, 604 F.3d 1291, 1303 (11th Cir. 2010) (affirming denial of motion to dismiss).[4] And government enforcers have long viewed higher

[4] *See also New York Medscan LLC v. New York Univ. Sch. of Med.*, 430 F. Supp. 2d 140, 148 (S.D.N.Y. 2006) (noting that "courts have repeatedly held that a decline in quality is among the injuries that the antitrust laws were designed to prevent," including in the context of the provision of health care services) (citing *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc.*, 996 F.2d 537, 546 (2d Cir. 1993); *Aventis Envtl. Sci. USA LP v. Scotts Co.*, 383 F. Supp. 2d 488,

prices and lower quality care as anticompetitive harms that the antitrust laws could remedy. *See Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program § 1*, 76 Fed. Reg. 67026 (Oct. 28, 2011) (antitrust analysis of ACO applicants by the Federal Trade Commission and the Department of Justice recognizes that "under certain conditions ACOs could reduce competition and harm consumers through higher prices or lower quality of care.").[5] Moreover, anticompetitive harms to health care consumers that can make out antitrust violations include the deterioration of "medically significant innovation." *New York v. Actavis PLC*, 787 F.3d 638, 659 (2d Cir. 2015).

Relatedly, the California Supreme Court expressly rejected the contention—which AAM again presses with respect to Assembly Bill 824—that *Actavis* preempts the "structured" rule-of-reason analysis announced in *Cipro*. (*See* Pl-Appellants Opening Br. at 39–48 (Dkt. No. 10).) This Court should reject AAM's

503 (S.D.N.Y. 2005); *Nilavar v. Mercy Health Sys. W. Ohio*, 142 F. Supp. 2d 859, 874 (S.D. Ohio 2000)); *cf. Cianci*, 40 Cal. 3d at 918 ("Consumer welfare is a principal, if not the sole, goal of [California's] antitrust laws.").

[5] *Cf.* United States Department of Justice and Federal Trade Commission, *Statements of antitrust enforcement policy in health care*, Aug. 1996, at 81 (Statement 8 - Physician Network Joint Ventures) ("In assessing the likelihood that efficiencies will be realized, the [Department of Justice and the Federal Trade Commission] recognize that competition is one of the strongest motivations for firms to lower prices, reduce costs, and provide higher quality."), *available at* https://bit.ly/2PqgtxV; *see also New York v. Actavis, PLC*, No. 14-cv-7473, 2014 WL 7015198, at *41 (S.D.N.Y. Dec. 11, 2014), *aff'd sub nom. New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) (recognizing anticompetitive harm when "patients [have to] pay [] higher co-payments or have to switch medications").

entreaty, as *Cipro*—which AAM's opening brief barely mentions on this point—controls.

State antitrust law, *Cipro* noted, "ordinarily is fully compatible with federal law," which is intended only "'to supplement, not displace, state antitrust remedies.'" 61 Cal. 4th at 160 (quoting *California v. ARC America Corp.*, 490 U.S. 93, 102 (1989)). Because federal law does not dictate or establish "a special rule limiting antitrust scrutiny of reverse payment settlements in order to preserve the incentives created by the patent system," *Actavis* made clear that pay-for-delay deals must be "examined for unjustified anticompetitive effects," with reference "solely to antitrust considerations." *Id*. at 161. Moreover, *Actavis* "offered only broad outlines" for a rule-of-reason analysis and "explicitly left to other courts the task of developing a framework for analyzing the competitive effects of reverse payment patent settlements." *Id*. at 160.

Cipro's structured analysis, dubious as it is of pay-for-delay deals, does not "fall prey to obstacle preemption" because it is "consistent with, not an obstacle to, congressional patent and health care goals." *Id*. at 160, 162. In line with congressional objectives, *Cipro*'s rule "ferret[s] out anticompetitive agreements that limit generic market entry and sustain costly monopolies" and promotes generic approvals "designed to make available more low cost generic drugs and reduce costs for consumers and government-funded health care alike." *Id*. at 162 (citations and internal quotation marks omitted).

In sum, California's antitrust laws are an appropriate vehicle to protect health care consumers, payers, and providers from the anticompetitive effects of abusive pay-for-delay deals. Situated in a line of authority that recognizes the role of state-based antitrust enforcement, Assembly Bill 824 properly seeks to protect

California health care consumers and payers from higher costs and lower quality care. Assembly Bill 824 is also a fitting means to safeguard physicians' ability to provide quality care consistent with their ethical obligations and medical judgment.

B. Pay-for-delay deals may be anticompetitive because they substantially raise prices on health care consumers and payers.

Pay-for-delay deals have led to skyrocketing prices of critical drugs that doctors need to provide appropriate care to patients. As noted, the FTC has estimated that pay-for-delay deals cost Americans about $3.5 billion annually in increased prescription-drug costs. *See* FTC Pay-for-Delay Report at 10. But analysis of the aggregate effects of pay-for-delay deals fails to capture their impact at the level of the individual patient with specific prescription-drug needs. The following examples illustrate the harms pay-for-delay deals work on health care consumers and payers.

- Cipro is a common antibiotic used to treat a number of bacterial infections. Cipro's brand manufacturer, Bayer, paid approximately $400 million to its rivals to keep generic competition off the market for over six years. *See In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323, 1130 nn.7&8 (Fed. Cir. 2008) (noting that settlements in January 1997 included payments totaling $398 million and agreements to delay generic from entry until January 2004). During the delayed period, Bayer allegedly earned revenues of approximately $5.7 billion and profits of approximately $4.9 billion from sales of Cipro tablets. *See* Brief of Appellants, *In re Cipro Cases I & II*, *Karyn McGaughey, et al., v. Bayer Corporation, et al.*, No. D056361, 2010 WL 3232362, at *20 (Cal. Ct. App. July 1, 2010). A single Cipro pill cost consumers upwards of $5.30, while that same pill should have cost only $1.10 with generic competition. *See* Brief of Attorney

General as Amicus Curiae, *In re Cipro Cases I & II*, No. S198616, 2012 WL 503757, at *3 (Cal. Jan. 13, 2012).

- Provigil is a stimulant used to treat narcolepsy and sleep apnea. Cephalon, Provigil's brand manufacturer, allegedly provided over $200 million to four generic companies to delay entry of a generic competitor by approximately six years, until 2012. *See* Complaint at 2, *FTC v. Cephalon, Inc.*, No. 08-cv-2141 (E.D. Pa. Feb. 13, 2008), *available at* https://bit.ly/2w35Jig. On the heels of the settlement with generic competitors, Cephalon's CEO bragged: "We were able to get six more years of patent protection. That's $4 billion in sales that no one expected." John George, *Hurdles Ahead for Cephalon*, PHILADELPHIA BUSINESS JOURNAL, March 17, 2006 (quoting Cephalon CEO Frank Baldino), *available at* https://bit.ly/384YuE1. The default dose and quantity of the brand drug cost $1,213, while the generic version reportedly costs $520. *See* U.S. PIRG Report at 3.

- Nexium is a drug used to treat gastroesophageal reflux disease. AstraZeneca, the brand manufacturer, allegedly paid generic manufacturer Ranbaxy $700 million to abandon its patent challenge for approximately six years. *See* Brendan Pierson, *U.S. court upholds AstraZeneca, Ranbaxy win in Nexium antitrust trial*, REUTERS, Nov. 21, 2016 (reporting that class action lawsuit filed in 2012 accused AstraZeneca of paying Ranbaxy nearly $700 million to drop a challenge to AstraZeneca's patents on Nexium and delay launching a generic version of the drug), *available at* https://reut.rs/2wOkBBx. The default dose and quantity of the brand drug cost $222; the generic version reportedly runs $56. *See id*. at 3.

- Lipitor lowers the level of cholesterol and triglycerides in the blood. Pfizer, the brand manufacturer, allegedly provided generic manufacturer Ranbaxy "hundreds of millions of dollars" of value for delaying generic entry for over two years. *See* Complaint ¶ 219, *CVS Pharmacy Inc. v. Pfizer Inc., et al.*, No. 18-cv-12437 (D.N.J. Aug. 3, 2018) (alleging that Pfizer gave Ranbaxy substantial financial consideration, including the settlement and effective forgiveness of Pfizer's claims against Ranbaxy for damages in those parties' patent litigation over Accupril, a different Pfizer drug, in exchange for Ranbaxy's agreement not to launch generic Lipitor until November 30, 2011), *available at* https://bit.ly/2wORoXd. While the default dose and quantity of brand-name Lipitor costs $205, the generic version is priced at $18. *See* U.S. PIRG Report at 3.

As these examples show, while pay-for-delay deals can be a windfall for drug manufacturers, they can also unequivocally harm consumers forced to pay skyrocketing costs in the form higher premiums and out-of-pocket costs.

C. Pay-for-delay deals may be anticompetitive because they result in lower quality care and patient harm.

The reduction of low-cost treatment options that results from the delayed entrance of affordable generic drugs harms the well-being of patients and the ability of physicians to offer effective health care services. The price of a brand drug can be prohibitive for uninsured patients who do not have help covering the cost of their prescription drugs. And for insured patients on fixed or limited incomes, a generic option is often the difference between access to treatment and no treatment at all.

When patients cannot afford necessary drugs, they may simply decline to fill a prescription, making it more difficult for the physician to treat the patient and help her recover from her ailment. According to an AARP study, one in four Americans over the age of fifty who use prescription drugs say they did not fill a prescription their doctor wrote in the past two years, and report that cost is the main reason. *See* Linda L. Barrett, AARP Knowledge Management, *Prescription Drug Use Among Midlife and Older* Americans, Jan. 2005, at 2, a*vailable at* https://bit.ly/39bS1YU.

This phenomenon, sometimes known as "abandonment," has been on the rise. For example, a Consumer Reports survey found that 18% of people with prescription-drug coverage declined to fill prescriptions in 2012 because of cost, up from 16% in 2011, and 45% of people without prescription-drug coverage skipped a refill due to costs, up from 27% in 2011. *See* Consumer Reports, *Sluggish Economy Forces Americans to Cut Corners to Pay for Medications: Those without Prescription Drug Coverage Nearing Crisis Point*, Sept. 2012, *available at* https://bit.ly/3a1FIP9.

Another study found that patients abandoned 3.3 percent of 10.35 million prescriptions pharmacists filled in a three-month period in 2008. *See* William H. Shrank, et al., *The epidemiology of prescriptions abandoned at the pharmacy*, ANNALS OF INTERNAL MEDICINE, Nov. 16, 2010, at 633, *available at* https://bit.ly/380YS6m. Out-of-pocket costs played a big role in predicting which drugs patients abandoned. Patients did not pick up from the pharmacy a drug with a copayment of $10 or less just 1.3 percent of the time; but when the cost to the patient exceeded $50, the abandonment rate tripled, to 4.5 percent. *See id*. at 636; *see also id*. at 637 ("Copayments charged to patients were the strongest predictors of abandonment, suggesting that patients experience 'sticker-shock' at the

pharmacy and choose not to fill those prescriptions."). Researchers further found that a large concentration of abandoned prescriptions were brand drugs, and that patients commonly picked up low-cost generics. *See id*. at 636.

When patients do not take medications as their physicians direct because no financially feasible options are available, their conditions can worsen, resulting in a higher cost of care over time; that, in turn, may necessitate providing more complex and costly treatments than initially required. *See* Statement for the Record, American Medical Association before the Subcomm. on Commerce, Trade, and Consumer Protection for the House Committee on Energy and Commerce, *Impact of "Pay-for-Delay" Settlements On Patient Access to Affordable Generics and Overall Health Care System Costs*, April 13, 2009. Researchers estimate that 125,000 deaths per year in the United States are due to medication nonadherence, which is caused by high costs, among other factors. *See* R. McCarthy, *The price you pay for the drug not taken*, BUS. HEALTH., Oct. 1998, at 27–28, 30, 32–33.

Pay-for-delay deals that increase health care costs for consumers reverberate throughout the entire health care system, harming the well-being of patients and the ability of physicians to provide effective treatment.

D. Pay-for-delay deals may be anticompetitive because they harm the ability of physicians to provide quality care to patients consistent with their ethical obligations.

Medical ethics require physicians to attempt to effectively treat their patients. They also require physicians to promote access to care, which includes consideration of their patients' ability to afford treatment options. Barriers that limit a physician's ability to provide care and promote access to care conflict with a physician's ethical responsibilities.

A physician's "primary ethical obligation is to promote the well-being of individual patients"; in addition, a physician must "promote public health and access to care." AMA Code Opinion 11.1.2, *Physician Stewardship of Health Care Resources*, *available at* https://bit.ly/2HSLPcs; *see also* AMA Principles, Preamble ("As a member of this profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self."), *available at* https://bit.ly/2SXh5NK; *id*. Principle VIII ("A physician shall, while caring for a patient, regard responsibility to the patient as paramount."); *id*. Principle IX ("A physician shall support access to medical care for all people."). To do so, a physician is required to be a "prudent steward[] of the shared societal resources with which [she is] entrusted," "for the benefit of all patients." AMA Code Opinion 11.1.2, *Physician Stewardship of Health Care Resources*, *available at* https://bit.ly/2wNuQGi. This involves basing recommendations and treatment decisions on patients' medical needs; endorsing treatment options likely to achieve a patient's health care goals; and choosing treatments that requires fewer resources when the alternatives offer a similar anticipated benefit but cost more. *Id*.

By making necessary drugs unaffordable for patients—particularly patients who are uninsured, under-insured, or saddled with high deductibles, co-insurance, and co-payments they cannot afford—pay-for-delay deals have frequently compromised the ability of AMA physician-members to adequately treat suffering patients. A physician cannot effectively allocate scarce health care resources when the only treatment option available for her patients costs many times more than a clinically equivalent alternative, which is unavailable solely because a pay-for-delay deal keeps it off the market. Equally, a physician cannot effectively promote the well-being of her patient by recommending a treatment likely to achieve the

patient's goals when the physician knows the patient will be unable to access the drug at the center of the treatment plan because of its high cost.

CONCLUSION

This Court should affirm the district court's denial of Plaintiff-Appellant's motion for preliminary injunction.

Dated: March 3, 2020

Respectfully submitted,

CONSTANTINE CANNON LLP

By: /s/ Matthew L. Cantor

MATTHEW L. CANTOR
Counsel of Record
CONSTANTINE CANNON LLP
335 Madison Ave.
New York, New York 10017
(212) 350-2700
mcantor@constantinecannon.com

ARI M. YAMPOLSKY
CONSTANTINE CANNON LLP
150 California Street, Suite 1600
San Francisco, California 94111
(415) 639-4001
ayampolsky@constantinecannon.com

Attorneys for Amici Curiae
American Medical Association and California Medical Association

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

Instructions for this form:
http://www.ca9.uscourts.gov/forms/form08instructions.pdf

9th Cir. Case Number(s) 20-15014

I. I am the attorney or self-represented party.

II. **This brief contains 5,657 words,** excluding the items exempted by Fed. R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6).

III. I certify that this brief *(select only one)*:

[ ] complies with the word limit of Cir. R. 32-1.

[ ] is a **cross-appeal** brief and complies with the word limit of Cir. R. 28.1-1.

[X] is an **amicus** brief and complies with the word limit of Fed. R. App. P. 29(a)(5), Cir. R. 29-2(c)(2), or Cir. R. 29-2(c)(3).

[ ] is for a **death penalty** case and complies with the word limit of Cir. R. 32-4.

[ ] complies with the longer length limit permitted by Cir. R. 32-2(b) because *(select only one)*:
- [ ] it is a joint brief submitted by separately represented parties;
- [ ] a party or parties are filing a single brief in response to multiple briefs; or
- [ ] a party or parties are filing a single brief in response to a longer joint brief.

[ ] complies with the length limit designated by court order dated _____.

[ ] is accompanied by a motion to file a longer brief pursuant to Cir. R. 32-2(a).

Signature /s/ Matthew L. Cantor **Date** March 3, 2020
*(use "*s/[typed name]*" to sign electronically-filed documents)*

CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of March 2020, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ Ari M. Yampolsky
ARI M. YAMPOLSKY