

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 AMICI CURIAE AARP AND AARP FOUNDATION
IN SUPPORT OF DEFENDANT-APPELLEE**

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CORPORATE DISCLOSURE STATEMENT

The Internal Revenue Service has determined that AARP is organized and operated exclusively for the promotion of social welfare pursuant to Section 501(c)(4) of the Internal Revenue Code and is exempt from income tax. The Internal Revenue Service has determined that AARP Foundation is organized and operated exclusively for charitable purposes pursuant to Section 501(c)(3) of the Internal Revenue Code and is exempt from income tax. AARP and AARP Foundation are also organized and operated as nonprofit corporations under the District of Columbia Nonprofit Corporation Act.

Other legal entities related to AARP and AARP Foundation include AARP Services, Inc., and Legal Counsel for the Elderly. Neither AARP nor AARP Foundation has a parent corporation, nor has either issued shares or securities.

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INTERESTS OF AMICI CURIAE¹

AARP is the nation's largest nonprofit, nonpartisan organization dedicated to empowering Americans 50 and older to choose how they live as they age. With nearly 38 million members and offices in every state, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, AARP works to strengthen communities and advocate for what matters most to families, with a focus on health security, financial stability, and personal fulfillment. AARP's charitable affiliate, AARP Foundation, works to end senior poverty by helping vulnerable older adults build economic opportunity and social connectedness.

AARP and AARP Foundation advocate for access to affordable prescription drugs by, among other things, participating as Amici Curiae in state and federal courts. *See, e.g., FTC v. Actavis, Inc.*, 570 U.S. 136 (2013); *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015).

Amici have a strong interest in ensuring that all consumers, and older adults in particular, have access to affordable prescription drugs. Prescription drug prices continue to skyrocket each year, with the prices of brand name drugs increasing at

¹ Amici Curiae certify that no party or party's counsel authored this brief in whole or in part, or contributed money intended to fund its preparation or submission. Amici Curiae also certify that only Amici Curiae provided funds to prepare and submit this brief. All parties have consented to the filing of this brief.

an exorbitant rate. In 2018, retail prices for 267 widely used brand name prescription drugs increased by 5.8 percent, more than twice the rate of inflation. Stephen W. Schondelmeyer and Leigh Purvis, *Rx Price Watch, Brand Name Drug Prices Increase More than Twice as Fast as Inflation in 2018*, AARP Pub. Pol’y Inst., 1 (Nov. 2019) [*AARP Brand Name Drugs Report*].² For over a decade, annual brand name drug price increases have exceeded the general inflation rate by two-fold to more than 100-fold. *Id.*

These ever-escalating prices disproportionately harm older adults, as they typically take more prescription drugs than younger adults and live on fixed or lower incomes. Older adults take an average of 4.5 prescription medications each month on a chronic basis. *Id.* Eighty-nine percent of Americans over 65 and seventy-five percent of Americans age 50-64 take prescription medication. Ashley Kirzinger, et al., *Data Note: Prescription Drugs and Older Adults*, Kaiser Fam. Foundation (Aug. 9, 2019).³ The high price of drugs forces many of these older adults to sacrifice their health and welfare by not filling their prescriptions, skipping doses, or cutting pills in half. *Id.*

² <https://www.aarp.org/content/dam/aarp/ppi/2019/11/brand-name-drug-prices-increase-more-than-twice-as-fast-as-inflation.doi.10.26419-2Fppi.00073.005.pdf>.

³ <https://www.kff.org/health-reform/issue-brief/data-note-prescription-drugs-and-older-adults/>.

Amici’s participation will help the Court understand that “pay-for-delay” patent settlements harm consumers by delaying the entry of lower-cost generic drugs into the market. It will also help the Court understand that enjoining California from enforcing its pay-for-delay law is not in the public interest. Amici urge this Court to affirm the district court’s decision denying the preliminary injunction.

SUMMARY OF ARGUMENT

California’s legislature passed its pay-for-delay settlement bill (“AB 824”) in response to the public health crisis caused by the ever-escalating price of prescription drugs. AB 824 creates a presumption that “pay-for-delay” patent settlements are anticompetitive. AB 824, California 2019-2020 Regular Session (2019).⁴ The Act also provides exceptions to the presumption when the agreement promotes competition. *Id.* In brief, the Act protects consumers by prohibiting pharmaceutical companies from keeping cheaper generic drugs off the market through anticompetitive pay-for-delay settlements.

Pay-for-delay settlements, also known as “reverse payment” agreements, involve a brand manufacturer maintaining exclusivity over a brand name drug by

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https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201920200AB824.

paying a competitor to delay selling a less expensive generic version as part of a patent litigation settlement. Jordan Canedy, *Pay-for-Delay: A Costly Practice in the Pharmaceutical Industry*, Harvard Health Policy Review, January 12, 2014.⁵

Concerns about pay-for-delay settlements in the pharmaceutical industry trace back more than a decade. See Natasha Singer, *Deals to Restrain Generic Drugs Face a Ban*, N.Y. Times, Jan. 10, 2010.⁶ These concerns are warranted because generic competition is one of the few time-tested ways to control prescription drug prices.

In 2018, generic drugs reduced the cost of prescription drugs by \$293 billion. Association for Accessible Medicines, *The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report*, 4 (2019) [*The Case for Competition*].⁷ Access to generic drugs benefits all consumers, but particularly older adults as they take more medications and often live on fixed or lower incomes. The high price of prescription drugs forces many older adults to forgo life-saving medication or take less than the prescribed amount. See Kirzinger, *supra*. Thus, having access to lower-cost generic drugs is critical to

⁵ <http://www.hhpronline.org/articles/2016/11/12/pay-for-delay-a-costly-practice-in-the-pharmaceutical-industry>.

⁶ <https://www.nytimes.com/2010/01/13/business/13generic.html>.

⁷ <https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf>.

preserving older adults' health and financial wellbeing. Any anticompetitive activity that limits generic competition makes drugs less affordable and threatens their lives.

The district court's denial of a preliminary injunction should be affirmed. California enacted its pay-for-delay law to address the health and affordability crisis caused by the ever-escalating price of prescription drugs. This law is in the public interest because it promotes competition while helping consumers gain timely access to lower-cost generic drugs. Thus, a decision enjoining the law would neutralize a key weapon in the government's arsenal to combat anticompetitive conduct that harms consumers.

ARGUMENT

I. Delaying Generic Drugs from Entering the Market Harms Consumers by Preventing Competition.

Anticompetitive pay-for-delay settlements cause significant and unnecessary delays in consumer access to less costly generic drugs. Prescription drug spending in the United States has skyrocketed over the last decade. *AARP Brand Name Drugs Report, supra*, at 1. Most alarming, many brand name prescription drugs prices are increasing so quickly that they are outpacing inflation. In 2018, retail prices for 267 widely used brand name prescription drugs increased by 5.8 percent, more than twice the rate of inflation. *Id.* at 2.

When clinically appropriate for a consumer, using a generic drug over a branded product is key to slowing the spiraling price of prescription drugs. Generic drugs typically sell for a fraction of the price of their branded counterparts and quickly capture the majority of unit sales. For example, a recent AARP study found that in 2017, while the average annual cost of therapy for widely used brand name drug products was \$6,798, the average annual cost of therapy for widely used generic drug products was \$365. Stephen W. Schondelmeyer and Leigh Purvis, *Rx Price Watch Report, Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update*, AARP Pub. Pol’y Inst., 3, 4 (Sept. 2019).⁸

Moreover, in that same year, the retail prices for 390 generic drugs widely used by older adults fell by an average of 9.3 percent. *Id.* at 3-4. In contrast, the retail brand name drug prices for 267 brand name prescription drugs widely used by older adults increased by an average of 8.4 percent. *Id.* at 3.

These cost savings are vital to older adults because doctors prescribe them more prescription drugs than other populations. Kirzinger, *supra*. Older adults take an average of 4.5 prescription medications each month. *AARP Brand Name Drugs*

⁸ <https://www.aarp.org/content/dam/aarp/ppi/2019/09/trends-in-retail-prices-of-prescription-drugs-widely-used-by-older-americans.doi.10.26419-2Fppi.00073.003.pdf>.

Report, supra, at 1. Yet nearly 25 percent of adults above age 65 have trouble affording their prescription drugs. Kirzinger, *supra*. That number is much higher for older adults in fair or poor health (45 percent). *Id.* In addition, over 20 percent of older adults report not filling a prescription, substituting an over-the-counter product for the prescribed product, or splitting pills due to cost. *Id.* For these consumers, access to lower-cost generic drugs can be life-saving. See Ken Alltucker, *Struggling to stay alive: Rising insulin prices cause diabetics to go to extremes*, USA Today (Mar. 27, 2019).⁹

Prescription drugs are critical to curing or managing disease, maintaining health, and improving quality of life. As a result, a patient's inability to comply with a drug regimen due to its cost often leads to bad therapeutic outcomes: substantial worsening of disease, increased health care costs, and even death. Jane E. Brody, *The Cost of Not Taking Your Medicine*, N.Y. Times (April 17, 2017).¹⁰ In fact, around 125,000 people die each year as a result of not taking their medication as prescribed. *Id.*

⁹ <https://www.usatoday.com/in-depth/news/50-states/2019/03/21/diabetes-insulin-costs-diabetics-drug-prices-increase/3196757002/>.

¹⁰ <https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html>.

Patients' inability to adhere to their drug regimens also costs the U.S. health care system an estimated \$100 billion to \$300 billion annually. Ctrs. for Disease Ctrl. & Prevention, *Overcoming Barriers to Medication Adherence for Chronic Diseases*, 5 (Feb. 21, 2017).¹¹ Some of those costs come from avoidable hospitalizations; 33 percent to 69 percent of hospital admissions are due to non-adherence with medication orders. *Id.*

Moreover, when patients cannot afford their medication, their disease—which may otherwise have been controllable—worsens. Costs then go up for: (1) obtaining health care services (doctor visits, emergency room and urgent care visits, and visits to treatment facilities such as nursing homes, hospice, or dialysis centers); (2) pharmacy costs for new therapies as the patient's comorbid conditions progress; and (3) diagnostic testing that the patient could have avoided if they had been able to control their primary illness. Aurel O. Iuga and Maura J. McGuire, *Adherence and Health Care Costs*, 7 RISK MGMT. AND HEALTHCARE POL'Y, 35-44 (2014). In short, access to generic drugs does not just save consumers money; it saves consumers' lives.

The use of generic drugs, in particular, provides significant savings to the U.S. health care system. An Association for Accessible Medicines (AAM) report

¹¹ <https://www.cdc.gov/grand-rounds/pp/2017/20170221-presentation-medication-adherence-H.pdf>.

showed that in 2018 alone, consumer access to generic drugs saved the U.S. health care system nearly \$293 billion. *The Case for Competition, supra*, at 9. Since 2010, generic drugs have saved the system \$2 trillion. *Id.* at 10. Furthermore, even though nine out of every ten prescriptions dispensed are generic drugs, generic drugs only accounted for twenty-two percent of prescription drug spending. *Id.* at 8.

As these studies show, consumers and the entire U.S. health care system benefit from having access to generic drugs on the market. Recognizing this, Congress sought to speed up generic entry by enacting the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355, also known as the Hatch-Waxman Act. This Act “institutionalize[d] and provide[d] incentive for a system of attacks on presumptively valid patents[,]” by generic manufacturers. *Innovation and Patent Law Reform: Hearings on H.R. 3285, H.R. 3286, and H.R. 3605 Before the Subcomm. on Courts, Civil Liberties, and the Admin. of Justice of the H. Comm. on the Judiciary, 98th Cong. 2d Sess., Part 1, at p. 445 (1984).*¹²

In creating the incentive to challenge patents, Congress was not seeking to enrich generic drug manufacturers. Hatch-Waxman challenges were supposed to

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https://ipmall.law.unh.edu/sites/default/files/hosted_resources/lipa/patents/Innovation%20and%20Patent%20Law%20Reform,%20Subcomm.%20%28March%2028,%20April%2026,%20June%206,%20201984%29%20Part%20A3.pdf

be vehicles for earlier entry of generic drugs into the marketplace, thus giving consumers earlier access to lower-priced prescription drug alternatives. H.R. Rep. No. 98-857, pt. 1, at 1 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647 (explaining that the purpose of the Hatch-Waxman Act “is to make available more low cost generic drugs by establishing a generic drug approval procedure”). Indeed, generics make up nearly 90 percent of drugs dispensed today, yet constituted only 19 percent of prescription drugs dispensed before the Hatch-Waxman Act. PhRMA, *What is Hatch-Waxman?* (June 2018).¹³

Unfortunately, some pharmaceutical companies abuse the system. They enter into agreements to delay the entry of generic drugs that dramatically affect competition and prescription drug prices. *See, e.g., FTC v. Actavis, Inc.*, 570 U.S. 136 (2013); *FTC v. Cephalon, Inc.*, 36 F. Supp. 3d 527 (E.D. Pa. 2014). On average, these agreements delay the entry of generic drugs by an average of seventeen months, costing billions of dollars in consumer savings. Fed. Trade Comm’n, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, 2, 8-10 (Jan. 2010).¹⁴

¹³ https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Fact-Sheet_What-is-Hatch-Waxman_June-2018.pdf.

¹⁴ <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>.

States have wide latitude to address problems concerning “the protection of the lives, limbs, health, comfort, and quiet of all persons.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (quoting *Metro Life Ins. Co. v. Mass.*, 471 U.S. 724, 256 (1985)). This includes their power to regulate medicine and public health. *See Green Atl. & Pac. Tea Co., Inc. v. Cottrell*, 424 U.S. 366, 371 (1976). States also have the power to promote competition through their own antitrust laws and combat unfair business practices. *Lewis v. BT Inv. Mgrs., Inc.*, 447 U.S. 27, 36 (1980); *see* Cal. Bus. & Prof. Code §§ 16700-16770 (“Cartwright Act”).

Here, the State of California is exercising its power to protect citizens from harm caused by anticompetitive activity. Through its law, California aims to stop pharmaceutical companies from entering into anticompetitive agreements that delay access to generic drugs. AB 824. It does so by placing the burden on the parties to the agreement to show that it is not anticompetitive. *Id.* This law complements existing state and federal antitrust law. *See, e.g.*, Hatch-Waxman Act, *supra*; Cartwright Act, *supra*; *FTC v. Actavis*, 570 U.S. 136 (2013); *In re Cipro Cases I & II*, 348 P.3d 845 (Cal. 2015). It focuses on promoting robust competition in the drug market, a practice that has been time-tested to lower the cost of drugs.

Simply put, California had to act because current prescription drug price trends are unsustainable. With total prescription medication spending at near-record highs, ensuring quick access to generic drugs is a critical factor in

controlling cost and ensuring consumer access to life-saving medication. Not surprisingly, consumers agree. In a February 2019 Kaiser Family Foundation poll, 88 percent of respondents favored making it easier for generics to come to market as a way to lower prescription drug prices. Kaiser Fam. Foundation, *KFF Health Tracking Poll* (Feb. 2019).¹⁵

In the end, it is consumers, and not the parties to the settlements, who ultimately pay for anticompetitive activities delaying generic drugs from entering the market. Higher prices and less competition lead to fewer consumer options, expensive medications, and, most importantly, poor patient adherence to prescribed regimens because they cannot afford their medication. AB 824 thus protects consumers by getting them timely access to the lower-cost generics they need.

II. Enjoining Enforcement of California’s Pay-For-Delay Law Is Not in the Public Interest Because It Will Place Californians at Risk of Harm from Anticompetitive Conduct.

The district court did not abuse its discretion when it denied AAM’s motion for a preliminary injunction. A court considering a plaintiff’s request for a preliminary injunction must examine, among other factors, whether the injunction

¹⁵ <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>

is in the public interest. *See All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1138 (9th Cir. 2011). Here, the preliminary injunction should be denied because, among other reasons, it is not in the public interest.¹⁶ *See, e.g., Sw. Voter Registration Educ. Project v. Shelley*, 344 F.3d 914, 919 (9th Cir. 2003). Instead, the injunction would harm California residents as it would rebuff the protections that the California Legislature sought with the law.

Like the rest of the country, California is experiencing a crisis because of ever-escalating prescription drug prices. Even drugs for common conditions have become increasingly unaffordable. For example, take three drugs for conditions that affect millions of older Californians: cancer, diabetes, and heart disease.

AARP, *How Californians Are Impacted By High Rx Costs* (Sept. 2019).¹⁷

Between 2012 and 2017, the retail price of:

- Revlimid, used to treat cancer, increased from \$147,413 per year to \$247,496 per year;
- Lantus, used to treat diabetes, increased from \$2,907 per year to \$4,702 per year; and

¹⁶ Amici agree with the arguments set forth in the Appellee's Answering Brief and do not repeat them here. App. Br. 22-61, Dkt. No. 20.

¹⁷ <https://www.aarp.org/content/dam/aarp/politics/advocacy/2019/09/rx-state-infographic-three-issues-california.pdf>.

- Aggrenox, a heart disease medication, increased from \$3,030 per year to \$5,930 per year.

Id.

The high prices of these and other drugs affect millions of Californians, and particularly older adults, because they don't have the resources to absorb these rapidly escalating costs. In California, the average annual cost of prescription drug treatment increased by 57.8 percent between 2012 and 2017, while the annual income for Californians only increase by 12.5 percent. AARP, *Rx Price Gouging v. 50+ Income* (July 2019).¹⁸ As a result, in 2017, more than 8 million Californians stopped taking life-saving medications because of their high costs. *Id.* And, as discussed above, the inability to afford life-saving medication inflicts a human toll. It leads to worsening health conditions, increased health care costs, and avoidable hospitalizations. Iuga, *supra*, at 35-44.

Amicus AARP collected stories from California residents ages 50 and older about the price of prescriptions drugs. Their responses echoed the statistics – the high price of drugs and other derivative costs are crushing them. Here are a few

¹⁸ <https://www.aarp.org/politics-society/advocacy/info-2019/prescription-drugs-state-fact-sheets.html>;
<https://www.aarp.org/content/dam/aarp/politics/advocacy/2019/07/california-rx-state-factsheet-final.pdf>; <http://statehealthcompare.shadac.org/>.

examples:

- M. A., Paso Robles, CA: I am a 80-year-old widow living on a very limited income. My monthly income is less than \$2000 a month. Because of the fact that I have atrial fibrillation (a-fib) I have to take Xarelto or possibly die from a stroke or heart [a]ttack. This drug has caused me to do without groceries so that I can survive. Please help me!
- B. B., Orange, CA: I use an inhaler for my asthma. The doctor prescribed that I use it twice each day. Because of the very high price of the med (over \$500/month if used as directed), I opted to use it just once each day. I can already tell that my asthma is not behaving as well as it did when I used the medication twice each day as prescribed.
- M. S., Merced, CA: I have had to put off filling prescriptions because I did not have the money. I skip taking medication some days to make it last longer. I fear seeing a doctor in case I need some additional prescription. I skimp on my pets' vet care, and feel guilty about it, because I need to pay for prescriptions for myself. I do not eat out, go to movies or do much of anything fun that costs money because I have to pay for prescriptions. I am retired, but I am seeking employment in my "golden years" just to pay for my daily needs.

It was amid this growing crisis that the California Legislature passed its pay-for-delay bill to ensure that lower-cost generics get to market as soon as possible. As the legislature noted, pay-for-delay agreements "hurt consumers twice—once by delaying the introduction of an equivalent generic drug that is almost always cheaper than the brand name and second by stifling additional competition because . . . when multiple manufacturers of generic drugs compete with each other, prices can be up to 90% less than what the brand name drug cost originally." *Hearing on AB 824 before the Assembly Committee on Health, California 2019-2020 Regular*

Session (March 26, 2019) (statement of bill’s purpose). This law is in the public interest.

Consumers benefit significantly from robust competition between manufacturers of brand name and generic drugs. AB 824 promotes the availability of generics by dissuading anticompetitive agreements. Thus, allowing the law to remain intact while the parties litigate the case serves the public interest. It ensures that Californians are being protected from harm while the case proceeds.

CONCLUSION

For the reasons described above, Amici respectfully urge the Court to affirm the district court’s decision.

Dated: March 5, 2020

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify:

(1) That this brief complies with the page limit set forth in Circuit Rule 29-2(c)(2). The brief contains 3,173 words.

(2) That this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6), because it has been prepared using Microsoft Office Word and is set in 14-point Times New Roman font.

March 5, 2020

/s/ Maame Gyamfi

CERTIFICATE OF SERVICE

I certify that on March 5, 2020, I filed the foregoing amicus curiae brief via CM/ECF system and served the foregoing via the CM/ECF system on all counsel who are registered CM/ECF users.

/s/ Maame Gyamfi