XAVIER BECERRA, State Bar No. 118517
Attorney General of California
RENU R. GEORGE, State Bar No. 262310
Supervising Deputy Attorney General
KARLI EISENBERG, State Bar No. 281923
Deputy Attorney General
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-7913
Fax: (916) 324-5567
E-mail: Karli.Eisenberg@doj.ca.gov
Attorneys for Defendant Xavier Becerra, in his official capacity as Attorney General of the State of California

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

Association for Accessible Medicines, Plaintiff, **v.** **Xavier Becerra, in his official capacity as Attorney General of the State of California,** Defendant.	2:19-cv-02281-TLN-DB **DEFENDANT'S OPPOSITION TO PLAINTIFF'S MOTION FOR INJUNCTION PENDING APPEAL** Judge: The Honorable Troy L. Nunley

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INTRODUCTION

On December 31, 2019, this Court issued a thorough decision denying plaintiff Association for Accessible Medicines' (AAM's) motion for a preliminary injunction, explaining that AAM is not likely to succeed on the merits, has not demonstrated irreparable harm, and has not shown that the balance of hardships tips in AAM's favor. As AAM concedes, the standard for whether to grant a stay pending appeal "'is similar to that employed by district courts in deciding whether to grant a preliminary injunction.'" Mot. at 1-2 (quoting *Klamath-Siskiyou Wildlands Ctr. v. Grantham*, No. 2:18-cv-02785-TLN-DMC, 2019 WL 2325555, at *1 (E.D. Cal. May 31, 2019), appeal filed, Case No. 19-16133 (9th Cir. June 4, 2019)). Indeed, in considering a motion for an injunction pending appeal, the Court must consider the same four factors it considered at the preliminary injunction stage: (1) whether the stay applicant has made a strong showing that it is likely to succeed on the merits; (2) whether the stay applicant will be irreparably injured absent a stay; (3) whether issuance of a stay will substantially injure other interested parties; and (4) where the public interest lies. *Id*. AAM has not met any of these factors and thus does not warrant an injunction pending appeal.

As to the likelihood of success, AAM's cursory motion primarily hinges on its assertion that it is entitled to bring a pre-enforcement as-applied Dormant Commerce Clause challenge—an assertion it raised in its preliminary injunction motion and which this Court properly rejected. Indeed, AAM does not dispute this Court's order and the Ninth Circuit authority relied upon therein that to bring a pre-enforcement as-applied challenge, AAM must demonstrate: (1) a concrete plan to violate the law; (2) a communicated threat of prosecution; and (3) a history of past prosecution or enforcement of the challenged law. AAM has not met these prerequisites. Rather than address this binding authority, AAM relies on out-of-circuit authority. However, the Ninth Circuit is bound by its own caselaw. Moreover, AAM is essentially seeking an advisory opinion from the Court as to the contours of a law that has not been applied, that AAM has no "concrete plan" to violate, and without any threat of prosecution. AAM nevertheless asks this Court to assume a chain of speculative events that may or may not ever occur so that the Court

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can rule on an as-applied pre-enforcement Dormant Commerce Clause claim. No Ninth Circuit authority supports AAM's position.

With regard to irreparable harm, AAM simply "renews" the arguments it made in its preliminary injunction motion. *Cf. Klamath-Siskiyou Wildlands Ctr.*, 2019 WL 2325555, at *6 (granting motion for injunction pending appeal where defendant-appellant government put forth additional evidence explaining irreparable harm to the government absent a stay pending appeal). For those reasons outlined in this Court's order denying the preliminary injunction, this Court should conclude that AAM has not demonstrated irreparable harm.

The final two prongs of the stay analysis also weigh in favor of California. California residents and state entities will suffer substantial harm if a stay is issued and AB 824 is enjoined. As numerous declarants explained, generic drugs entering the marketplace lower drug prices and that is extremely important both at the individual consumer level and at the Statewide agency purchaser level. Moreover, as the Supreme Court concluded, pharmaceutical companies can and do enter settlement agreements without pay-for-delay provisions, *FTC v. Actavis*, 570 U.S. 136, 158 (2013), and as this Court noted, the latest Federal Trade Commission "report indicates the majority of patent settlements do not contain a reverse payment at all." Order at 24 (citing *Overview of Agreements Filed in FY 2016*, A Report by the FTC Bureau of Competition). As to the public interest prong, the California Legislature is entitled to deference when it comes to the health and welfare of its residents. Here, the Legislature concluded that 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 manufactures of generic drugs compete with each other, prices can be up to 90% less than what the band name drug cost originally." RJN Exh. B at 1.

STANDARD OF REVIEW

A "stay is an 'intrusion into the ordinary processes of administration and judicial review,' and accordingly 'is not a matter of right.'" *Nken v. Holder*, 556 U.S. 418, 427 (2009) (citations and quotations omitted); *Lair v. Bullock*, 697 F.3d 1200, 1203–04 (9th Cir. 2012) ("A stay is not a matter of right. . . . It is instead 'an exercise of judicial discretion' . . . [that] 'is dependent upon the

circumstances of the particular case.'"). AAM bears the heavy burden of "showing that the circumstances justify an exercise of [the Court's] discretion." *Nken*, 556 U.S. at 433-434. In determining whether a stay should issue, the Court considers "four factors: '(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.'" *Id*. at 434 (quoting *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987)). Of these factors, the first two "are the most critical." *Lair*, 697 F.3d at 1203.

Here, AAM seeks any injunction "pending appeal of a preliminary injunction." *Lopez v. Heckler*, 713 F.2d 1432, 1436 (9th Cir. 1983). Thus, "in order to determine whether [AAM has] raised serious legal questions or […] show a probability of success on the merits," this Court "must evaluate [AAM's] arguments for overturning [this Court's order denying a] preliminary injunction on appeal." *Id*. The Ninth Circuit "'review[s] the district court decision to grant or deny a preliminary injunction for abuse of discretion,'" *BOKF, NA v. Estes*, 923 F.3d 558, 561 (9th Cir. 2019) (quoting *Sw. Voter Registration Educ. Project v. Shelley*, 344 F.3d 914, 918 (9th Cir. 2003) (en banc), and this Court's factual findings are reviewed for clear error, *adidas Am., Inc. v. Skechers USA, Inc.*, 890 F.3d 747, 753 (9th Cir. 2018).

ARGUMENT

I. AAM'S MOTION FOR AN INJUNCTION PENDING APPEAL SHOULD BE DENIED

AAM's motion fails on the merits. As discussed in full in this Court's injunction order, this Court has determined that AAM's claims are not likely to succeed, that AAM has failed to establish irreparable harm, and that the balance of hardships does not tip in favor of AAM. ECF No. 29, Order on Preliminary Injunction (Order), at 7-23, 23-24, 25. For these same reasons, this Court should conclude that AAM has not satisfied its burden of showing that a stay pending appeal is justified.[1]

[1] AAM's motion is also procedurally defective. This Court's local rules plainly state that: "*all* motions *shall* be noticed on the motion calendar of the assigned Judge." L.R. 230(b). Local Rule 230 further provides that "[t]he moving party shall file a notice of motion . . . in support of the motion." *Id*. "Motions defectively noticed shall be filed, but not set for hearing; the Clerk

A. AAM Is Not Entitled to a Stay Because It Is Seeking Appellate Review

AAM's argument that it is entitled to an injunction pending appeal "given its efforts to seek an immediate and expedited appeal of this Court's preliminary injunction ruling" is meritless. Mot. at 1. As noted above, AAM must demonstrate that (1) it has made a strong showing that it is likely to succeed on the merits; (2) it will be irreparably injured absent a stay; (3) issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies. *Nken*, 556 U.S. at 434. It is not enough that AAM is seeking "immediate and expedited appeal."

B. AAM Has Not Shown a Likelihood of Success on its Dormant Commerce Clause Claim

AAM's motion appears to only challenge this Court's decision on AAM's Dormant Commerce Clause claim. ECF No. 30, AAM's Motion for Injunction Pending Appeal (Mot.). Once again, AAM asserts that it can bring a pre-enforcement as-applied challenge. But, as this Court noted, the Ninth Circuit has been clear that pre-enforcement as-applied challenges require three things: (1) a concrete plan to violate the law; (2) a communicated threat of prosecution; and (3) a history of past prosecution or enforcement of the challenged law. Order at 10 (citing *Clark v. City of Seattle*, 899 F.3d 802 (9th Cir. 2018); *Molando v. Morales*, 556 F.3d 1037, 1044 (9th Cir. 2009)). AAM "has made no attempt to establish these three constitutional elements nor to discuss the prudential concerns." Order at 10. In its pending motion, AAM does not discuss this Ninth Circuit authority or attempt to cure these constitutional infirmities. As such, this Court should deny AAM's motion.

Moreover, rather than address the Ninth Circuit authority cited by this Court, AAM relies on out-of-circuit authority, asserting that "[t]here is a substantial question here whether the Ninth Circuit will agree with this Court that further factual development (or State enforcement) is

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shall immediately notify the moving party of the defective notice and of the next available dates and times for proper notice, and the moving party shall file and serve a new notice of motion setting for the proper time and date." *Id*. Moreover, Judge Nunley's standard information states "[p]lease file your motion(s) in accordance with the Local Rules." To the extent AAM wanted to expedite briefing on its motion for injunction pending appeal, it could have reached out to Defendant to arrange for a stipulated briefing schedule or filed a motion with this court to expedite a ruling on its motion for injunction pending appeal. AAM did none of these things and instead simply flouted the rules of this Court.

necessary." Mot. at 2. However, numerous Ninth Circuit opinions hold that a Ninth Circuit panel is bound by decisions of prior Ninth Circuit panels unless an en banc decision, Supreme Court decision, or subsequent legislation undermines those decisions. *Grove v. Wells Fargo Financial Cal., Inc.*, 606 F.3d 577, 580 (9th Cir. 2010); *U.S. v. State of Wash.*, 872 F.2d 874, 880 (9th Cir. 1989); *Montana v. Johnson*, 738 F.2d 1074, 1077 (9th Cir. 1984); *United States v. Depaoli*, 139 F.2d 225, 226 (9th Cir. 1943). As this Court rightly concluded, the Ninth Circuit has repeatedly required that a plaintiff bringing a pre-enforcement as-applied challenge meet each of the three threshold requirements. *See Thomas v. Anchorage Equal Rights Com'n*, 220 F.3d 1134, 1139 (9th Cir. 2000) (en banc) (court must evaluate the "genuineness of a claimed threat of prosecution" by determining whether (1) "plaintiffs have articulated a 'concrete plan' to violate the law in question, [(2)] whether the prosecuting authorities have communicated a specific warning or threat to initiate proceedings, and [(3)] the history of past prosecution or enforcement under the challenged statute"); *Clark*, 899 F.3d at 812-813; *Molando*, 556 F.3d at 1044; *Haw. Newspaper Agency v. Bronster*, 103 F.3d 742, 746-47 (9th Cir. 1996). No en banc decision, Supreme Court decision, or relevant subsequent legislation undermines this binding Ninth Circuit authority.

AAM's argument is a veiled attempt to obtain an advisory opinion that outlines the contours of AB 824—a law that has not yet taken affect. But overwhelming authority prohibits courts from issuing advisory opinions. *See Golden v. Zwickler*, 394 U.S. 103, 108 (1969) ("federal courts established pursuant to Article III of the Constitution do not render advisory opinions"); *Thomas*, 220 F.3d at 1138 ("Our role is neither to issue advisory opinions nor to declare rights in hypothetical cases").

AAM's reliance on the fact that it is bringing a claim under 42 U.S.C. § 1983 to support its pre-enforcement as-applied challenge, is misplaced. Mot. at 3-4. Specifically, AAM argues that this Court's decision is contrary to the "fundamental purpose of 42 U.S.C. § 1983," will "effectively defeat[ ] federal review," and will force "a party regulated by a state law that may well be unconstitutional [ ] [to] wait for that law to be applied against it before it may complain." Mot. at 3-4. Not so. While Section 1983 permits certain suits against state officials, it does not

permit a plaintiff to obtain a decision defining the scope of a law that has not yet taken effect and where the plaintiff has not met the "constitutional elements" to bring a pre-enforcement as-applied challenge. Indeed, both *Clark* and *Malonado*—cases cited by this Court in its injunction order—involved Section 1983 claims. *Clark*, 899 F.3d at 808 (explaining that § 1983 plaintiffs had not established requirements to bring pre-enforcement as-applied challenge and purported injury "hinge[s] on a prospective chain of events that have not yet occurred, and may never occur"); *Maldonado*, 556 F.3d at 1044-45 (§ 1983 action challenging constitutionality of California law was ripe where plaintiff alleged current conduct violated the California law and the state issued citations against plaintiff). Contrary to AAM's assertion, a party regulated by a state law need not "wait for that law to be applied against it before it may complain." Mot. at 3. However, as noted, the Ninth Circuit has delineated three "constitutional elements" that must be met before it will adjudicate a pre-enforcement as-applied challenge. *See supra* at 3, 4; *San Diego Cnty. Gun Rights Comm. v. Reno*, 98 F.3d 1121, 1126 (9th Cir. 1996) (rejecting plaintiffs' contention that "they need not wait for the government to enforce the criminal provisions" to bring suit because "the mere existence of a statute, which may or may not ever be applied to plaintiffs, is not sufficient to create a case or controversy within the meaning of Article III"). Again, AAM does not address or dispute this binding authority.

Moreover, adopting AAM's argument would not only ignore that Ninth Circuit precedent, it would open the courthouse doors to countless lawsuits from entities that will claim to have some type of speculative injury or harm from a law that has yet to take effect. Such suits will make the same request: Define and limit the boundaries of the law that has not taken effect and for which the parties do not know how it will be applied, if at all, to plaintiff.

C. AAM Has Not Demonstrated Irreparable Injury

With regard to irreparable harm, AAM simply "renews its argument(s)" (Mot. at 4) and reiterates its unsupported assertions that its members will need to "reorder their affairs." Mot. at 5. There are a number of problems with this recycled argument.

As a threshold matter, AAM does not cite *any* record evidence that *any* AAM member will need to "reorder its affairs." *Herb Reed Enterprises, LLC v. Florida Entertainment*

Management, Inc., 736 F.3d 1239, 1251 (9th Cir. 2013) ("those seeking injunctive relief must proffer evidence sufficient to establish a likelihood of irreparable harm"). Without any evidence of irreparable harm, AAM is not entitled to injunctive relief pending appeal.

Second, AAM's vague assertion of harm is based on a purely speculative chain of events. Such speculation is insufficient for an injunction; there must be a *likelihood* that irreparable harm will occur. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008); *Am. Trucking Associations, Inc. v. City of Los Angeles*, 559 F.3d 1046, 1052 (9th Cir. 2009) ("injunction cannot issue merely because it is possible that there will be irreparable injury to the plaintiff; it must be likely that there will be"); *Goldie's Bookstore, Inc. v. Superior Court of State of Cal.*, 739 F.2d 466, 472 (9th Cir. 1984) ("speculative injury does not constitute irreparable injury"); *Kaplan v. Bd. of Educ. of City School Dist. of City of New York*, 759 F.2d 256 (2d Cir. 1985) (community school board members failed to establish irreparable harm would result in the absence of a preliminary injunctive relief since their predictions of havoc and unrest of school-board members were too speculative to constitute a clear showing of immediate irreparable harm).

Third, "reordering affairs" is hardly the type of irreparable harm that warrants granting an injunction. *See Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 545 (1987) (Harm is irreparable when it cannot "be adequately remedied"). Indeed, AAM fails to cite to a case that has held that a business's decision to "reorder [its] affairs" constitutes irreparable injury.

Fourth, nothing in AB 824 requires AAM members to "reorder" their affairs. As this Court noted, AB 824 only "creates a presumption that 'reverse payment' settlement agreements regarding patent infringement claims between brand-name and generic pharmaceutical companies are anti-competitive and unlawful." Order at 2; *see also* Order at 24 (AAM "overstates the changes AB 824 makes to established jurisprudence in the areas of antitrust and patent law. The presumption raised by AB 824 is stronger and the burden shift may be sharper but both federal and state antitrust caselaw provides for a similar presumption and burden shift in the context of reverse payment settlement agreements"). In short, pay-for-delay agreements are already unlawful under federal and state antitrust law. Thus, AAM members' purported injury does not

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stem from AB 824; it is entirely self-inflicted.[2] A "movant does not satisfy the irreparable harm criterion when the alleged harm is self-inflicted." *Fiba Leasing Co., Inc. v. Airdyne Indus., Inc.*, 826 F.Supp. 38, 39 (D. Mass. 1993); *Lee v. Christian Coal. of Am., Inc.*, 160 F. Supp.2d 14, 33 (D.D.C. 2001); *San Francisco Real Estate Investors v. Real Estate Inv. Trust*, 692 F.2d 814, 818 (1st Cir. 1982) ("any 'harm' caused by investor apprehension over the litigation would seem largely self-inflicted; it was not only not irreparable in the absence of the district court's order, but entirely avoidable").

D. AAM Fails to Acknowledge that a Stay Will Injure California Residents and California State Agencies

AAM ignores that "any time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1301 (2012). Furthermore, as both the California Legislature and the Federal Trade Commission (FTC) have found, pay-for-delay settlement agreements harm patients and cost Californians and California state agencies hundreds of millions of dollars. RJN Exh. B at 1 (citing FTC report that "these anticompetitive deals cost consumers and taxpayers $3.5 billion in high drug costs every year"); Doe Decl. ¶ 4 (explaining the California Department of Corrections and Rehabilitation spends over $300 million per year on pharmaceuticals and that amount would be significantly reduced the more that generic equivalent products enter the market); McPherson Decl. ¶ 7 (the average older adult takes 4.5 prescription medications and 73% of AARP members did not fill a prescription due to cost); Cantwell Decl. ¶¶ 4, 11-12; Moulds Decl. ¶¶ 6, 9.

E. The Public Interest Does Not Weigh in Favor of AAM

The public interest does not weigh in favor of staying implementation of AB 824. AAM's motion for injunction pending appeal does not squarely address the public interest. Rather, AAM asserts that it merely "renews its arguments." Mot. at 4. But, as this Court correctly concluded

[2] As this Court noted, "AB 824 does not prohibit patent settlement agreements; the claim that AB 824 will force Plaintiff's members to either violate the law or litigate to judgment, both at great expense is therefore based on speculation of how companies will choose to react to AB 824's implementation." Order at 24.

(and contrary to AAM's assertions otherwise), "parties to pharmaceutical patent litigation *can* settle in the aftermath of AB 824." Order at 24. Thus, the parade of horribles described in AAM's motion for a preliminary injunction regarding AB 824 are without merit as they all hinge on the notion that pharmaceutical companies cannot settle patent litigation and thus will be forced to litigate all patent suits to judgment.

Moreover, States have broad discretion to legislate in the area of health and welfare. Here, the California Legislature concluded that AB 824 would help curb the high costs of prescription drugs that affect not only healthcare patients, but also payors such as employers and the Medicare and Medicaid programs. RJN Exh. B at 1; *see also* Cressman Decl. ¶¶ 3-8; MacEdon Decl. ¶¶ 4-9. As noted, the Legislature concluded that 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 manufactures of generic drugs compete with each other, prices can be up to 90% less than what the band name drug cost originally." RJN Exh. B at 1. The Legislature explained that AB 824 "preserves consumer access to affordable drugs by prohibiting brand name and generic drug manufacturers from entering into these agreements by making them presumptively anticompetitive." *Id*. The legislative history further reflects that AB 824 was passed in recognition of the fact that "brand-name drug companies had made an estimated $98 billion in total sales of these drugs while generic versions were delayed." *Id*. In short, "[p]ay for delay agreements take money out of workers' pockets to unfairly increase drug company profits." *Id*.

Such legislative conclusions should be afforded deference in weighing purported competing public interest factors. *See Winter*, 555 U.S. at 27 (discussing deference owed to government officials in reviewing the public interest prong) (citing Wright & Miller § 2948.2, at 167-168 ("The policy against the imposition of judicial restrains prior to an adjudication of the merits becomes more significant when there is reason to believe that the decree will be burdensome"). Indeed, the Ninth Circuit expressly explained that deference is appropriate when considering a broad equitable question such as whether to grant a preliminary injunction, including deference to states judgments "concerning interests in health and welfare." *Sierra*

Forest Legacy v. Sherman, 646 F.3d 1161, 1185-86 (9th Cir. 2011) (citing *Massachusetts v. EPA*, 549 U.S. 497, 519-20 (2007)).

II. AAM'S ALTERNATIVE RELIEF REQUESTED SHOULD LIKEWISE BE DENIED

Despite the fact that AAM has not demonstrated a likelihood of success on the merits, has not demonstrated irreparable harm, and has not demonstrated that the balance of hardships tips in AAM's favor, it nevertheless, asks this Court to "enjoin enforcement of AB 824 *as applied* to out-of-state settlement agreements during the pendency of AAM's appeal." Mot. at 4. This "alternative" request suffers from the same constitutional defects already identified by this Court with regard to AAM's Dormant Commerce Clause claim. Furthermore, as this Court noted, this relief is not warranted given that AAM's declarants make mere "generalized statements." Order at 11. "No declarant claims its company has a concrete plan to violate the terms of AB 824." *Id.* And no declarant "submitted evidence of a currently pending reverse payment settlement negotiation in which the parties would not settle as a result of AB 824 or feared prosecution under AB 824." *Id.*

CONCLUSION

AAM's motion for an injunction pending appeal should be denied in its entirety.

Dated: January 6, 2020

Respectfully Submitted,

XAVIER BECERRA
Attorney General of California
RENU R. GEORGE
Supervising Deputy Attorney General

/S/ Karli Eisenberg
KARLI EISENBERG
Deputy Attorney General
Attorneys for Defendant Xavier Becerra, in his official capacity as Attorney General of the State of California

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