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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JANE DOE, *et al.*

Plaintiffs,

v.

XAVIER BECERRA, *et al.*

Defendants.

Case No. 8:19-cv-02105-DOC-SDA

PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR A PRELIMINARY INJUNCTION

Date: December 9, 2019
Time: 8:30 a.m.
Place: Courtroom 9D

TO THE COURT AND DEFENDANTS AND THEIR ATTORNEYS:

PLEASE TAKE NOTICE that, on December 9, 2019, at 8:30 a.m., or as soon thereafter as the matter can be heard, in Courtroom 9D, located within the Ronald Reagan Federal Building, United States Courthouse, 411 West Fourth Street, Santa Ana, California, Plaintiffs Jane Doe, Stephen Albright, (collectively, the "Patients"), American Kidney Fund, Inc. ("AKF"), and Dialysis Patient Citizens, Inc. ("DPC") will, and hereby do, move pursuant to Federal Rule of Civil Procedure under Federal Rule of Civil Procedure 65(a) and Local Rule 65-1 for a preliminary injunction, enjoining Defendants Xavier Becerra, Ricardo Lara, Shelly Rouillard, and Sonia Angell, each in his or her official capacity an agent of the State of California, from enforcing or otherwise implementing California Assembly Bill 290 ("AB 290" or "Act"). *See* Act of Oct. 13, 2019, ch. 862, 2019 Cal. Stat. ___ (2019) (to be codified at Cal. Health & Safety Code §§ 1210, 1367.016, 1385.09 and Cal. Ins. Code §§ 10176.11, 10181.8).

Plaintiff's Motion for Preliminary Injunction is made on the grounds:

1. AB 290 conflicts with federal law and is thus void under the Supremacy Clause; and

2. Enforcement of AB 290 would deprive Plaintiffs of their rights of free speech, association, and petitioning under the First and Fourteenth Amendments.

Dated: November 8, 2019

KING & SPALDING LLP

By: */s/Joseph N. Akrotirianakis*
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INTRODUCTION

If allowed to go into effect, AB 290 will result in many California patients being unable to afford their health care, putting them at significant risk for health complications and even death. It will jeopardize a nation-wide program of financial support for thousands of very sick individuals. The drastic harm does not end there, however. AB 290 also violates federal law and the U.S. Constitution. Plaintiffs therefore request that this Court preliminarily enjoin the State from implementing AB 290 while this lawsuit is pending.

BACKGROUND

A. End-Stage Renal Disease and American Kidney Fund's Health Insurance Premium Program

End-stage renal disease ("ESRD"), or kidney failure, is a painful, chronic, and often fatal disease of the kidneys. Declaration of LaVarne A. Burton ("AKF Decl.") ¶ 14. To those who suffer from it, it causes a wide range of significant health problems, ranging from heart disease to cancer, and if it is left untreated, it is invariably fatal through a slow and agonizing process. *Id.*; Declaration of Jane Doe ¶ 5; Declaration of Stephen Albright ¶ 7. While dialysis, a process by which patients' blood is filtered, can mitigate ESRD's impacts for a time, ESRD patients ultimately need a kidney transplant. AKF Decl. ¶ 14.; Doe Decl. ¶ 4; Albright Decl. ¶ 8. Transplants involve significant surgical and recovery complications, in addition to delays due to a shortage of transplantable kidneys; many patients either cannot receive one promptly or are not medically suitable at all. AKF Decl. ¶ 14. The end result is that dialysis, though an imperfect solution, is the only option for many ESRD patients. *Id.* ¶ 14.

But dialysis is physically and financially challenging for ESRD patients. The filtering process requires multiple, hours-long sessions each week, either at home or, more often, at a clinic. Doe Decl. ¶¶ 6, 8; Albright Decl. ¶ 7. The time required for

these appointments can make employment difficult for many ESRD patients who must also cope with the symptoms of ESRD and the draining side effects of dialysis. AKF Decl. ¶ 21; Doe Decl. ¶ 10; Albright Decl. ¶ 5.

Plaintiffs Jane Doe and Stephen Albright personify these complications. Mr. Albright, through immense personal effort and discipline, has managed to remain employed despite his ESRD diagnosis. Albright Decl. ¶ 6. But he must undergo dialysis every night overnight. *Id.* ¶ 7. And while he and his significant other both work and are covered by her employer-provided health insurance, the premiums for that insurance have pushed them to the financial edge. Albright Decl. ¶ 9. Jane Doe, for her part, has lost everything that she has worked for due to ESRD. Doe Decl. ¶ 11. Her illness has forced her to cease working and steadily depleted her savings until she was forced out of her home. *Id.* Her finances are already desperately tight, and her treatment must come first if she is to stay alive. *Id.* ¶¶ 12-13.

Both AKF and DPC are keenly aware of these costs. *See* AKF Decl. ¶¶ 21-33; Declaration of Hrant Jamgochian ("DPC Decl.") ¶ 4. More than twenty years ago, AKF undertook to alleviate the immense financial burdens faced by dialysis patients through its Health Insurance Premium Program ("HIPP"). AKF Decl. ¶¶ 20, 36. HIPP provides financial assistance to 75,000 ESRD patients in the United States, and 3,756 in California, for the health insurance that they have already selected and obtained but are unable to pay for alone. *Id.* ¶¶ 18, 27. The program is strictly need based, focusing on patients' incomes. *Id.* ¶ 41. AKF does not consider any other factors, such as a patient's age, place of residency, or dialysis provider. *Id.* Founded in 2004, and with 28,000 members, DPC serves as an advocate for ESRD patients on dialysis. DPC Decl. ¶ 5.

B. Advisory Opinion 97-1

A key provision of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. No. 104-191, 110 Stat. 1936, authorizes the U.S. Department of Health & Human Services ("HHS") Office of Inspector General

("OIG") to seek civil monetary penalties against any entity offering remuneration to a Federal health care program beneficiary with knowledge that such remuneration is likely to influence that individual's choice of a health care provider. *See* HIPAA §231(h), codified at 42 U.S.C. § 1320a-7a(a)(5) (the "Beneficiary Inducement Statute"). Such "remuneration" includes "transfers of items or services for free or for other than fair market value." 42 U.S.C. § 1320a-7a(i)(6).

Congress also enacted an advisory opinion process to provide guidance on the statute, empowering OIG to opine on "whether any activity or proposed activity constitutes grounds for the imposition of a sanction under . . . [the Beneficiary Inducement Statute] . . . ." *See* HIPAA § 205, codified at 42 U.S.C. § 1320a-7d(b)(2)(E). A favorable advisory opinion acts as a safe harbor against a federal enforcement action. *See* 42 U.S.C. § 1320a-7d(b)(4)(A).

Following HIPAA's enactment, AKF and certain dialysis provider donors proactively sought an advisory opinion addressing HIPP. *See* Advisory Opinion 97-1; AKF Decl. ¶ 36. They did so to make sure that the HIPP program did not run afoul of HIPAA's prohibition on offering remuneration. *Id.* The OIG concluded that HIPP did not "constitute grounds for the imposition of civil monetary penalties under Section 231(h) of HIPAA." Advisory Op. at 1. The OIG first found that the dialysis providers' donations to AKF do not constitute impermissible "remuneration" because "the interposition of AKF, a bona fide, independent, charitable organization, and its administration of HIPP provides sufficient insulation so that the premium payments should not be attributed to the [provider] Companies." Advisory Op. at 6 (emphasis in original). The OIG noted that, once in possession of coverage, beneficiaries will likely have already selected a provider before applying for assistance, concluding, "[s]imply put, AKF's payment of premiums will expand, rather than limit, beneficiaries' freedom of choice." *Id.* at 7. Finally, the OIG noted that AKF provides "[a]ssistance . . . to all eligible patients on an equal basis." *Id.* at 3.

Advisory Opinion 97-1 provides a safe harbor only so long as "the arrangement in practice comports with the information provided," *id.* at 8; *see also* 42 C.F.R. § 1008.43. Should HIPP change in any material way, AKF will lose its safe harbor and face potential exposure under the Beneficiary Inducement Statute.[1] For over 20 years, AKF has operated HIPP in strict compliance with Advisory Opinion 97-1. AKF Decl. ¶¶ 34-42. As a charitable organization, AKF cannot take the business, legal, and reputational risk of losing this critical safe harbor. *Id*. ¶ 42.

C. The Medicare Secondary Payer Act

In 1972, Congress extended special Medicare coverage to ESRD patients requiring dialysis or transplantation, regardless of age or disability. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, tit. II, § 299I, 86 Stat. 1329, 1463 (codified as amended at 42 U.S.C. § 426-1(a)). Time and again, Congress has reaffirmed its commitment to ESRD patients, including through the Medicare Secondary Payer Act ("MSPA"), 42 U.S.C. § 1395y(b) by:

1) Lengthening the amount of time that Medicare will be secondary payer behind a private plan, Social Security Amendments of 1972, Pub. L. No. 92-603, § 299I, 86 Stat. 1330, 1463–64 (1972); Omnibus Budget Reconciliation Act ("OBRA") of 1990, Pub. L. No. 101-508, tit. IV, § 4203, 104 Stat. 1388, 1388-107–108; Balanced Budget Act of 1997, Pub. L. 105-33, tit. IV, § 4631, 111 Stat. 251, 486, codified as amended at 42 U.S.C. § 1395y(b)(1)(C); and

2) Prohibiting insurers from differentiating based on or "taking into account" a patient's ESRD diagnosis, OBRA 1989, Pub. L. No. 101-239, tit. VI, § 6202(b), 103 Stat. 2106, 2231; OBRA 1989, § 6202(b), codified at 42 U.S.C. § 1395y(b)(3).

[1] *See*, *e.g.*, Rescinded Advisory Opinion 06-04 (rescinding favorable opinion related to non-AKF charitable premium and cost-sharing assistance because "Requestor failed to comply with certain factual certifications it made to OIG . . . [that] were material to OIG's conclusions."), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf.

D. The Provisions of AB 290

For years, the commercial health insurance industry and its labor union allies have lobbied the California legislature to impose restrictions on HIPP. In 2018, the legislature did so, but then-Governor Jerry Brown vetoed the bill and suggested that "all stakeholders . . . find a more narrowly tailored solution that ensures patient access to coverage."[2] Undeterred, opponents of HIPP succeeded in passing Assembly Bill 290 ("AB 290"), signed by Governor Gavin Newsom on October 13. Unless enjoined by this Court, AB 290 will take effect on January 1, 2020.

In no sense is AB 290 a "narrowly tailored solution" ensuring "patient access to coverage." The Legislature intended AB 290 to focus on AKF, its HIPP program, and its donors: The Act mentions AKF by name, *see* AB 290 § 1(j), and AKF and "large dialysis organizations" are the explicit targets of the legislation, *see id.* §§ 1(g), 1(h), 1(i). AB 290's central purpose is to destroy AKF's premium assistance program in California. *See id.* § 1(h) (legislative findings targeting AKF and its donors); *see also* AB-290 Ca. Assembly Floor Analysis, at 2 (Sept. 9, 2019) (statement of Assemblyman Jim Wood singling out AKF and its donors).

AB 290 regulates three groups of entities: (1) insurance companies and health benefit plans, AB 290 §§ 3(h)(3), 5(h)(2); (2) dialysis providers, *id.* §§ 3(h)(2)(A), 3(h)(4), 5(h)(1)(A), 5(h)(4); and (3) "[f]inancially interested entities," meaning AKF, *id.* §§ 3(h)(2)(B), 5(h)(1)(B). In particular, two interrelated mechanisms are uniquely harmful to AKF's and DPC's mission of assisting vulnerable ESRD patients with high health care costs.

First, AB 290 compels AKF to "[d]isclose[] to the health care service plan, prior to making the initial payment, the name of the enrollee for each health care service plan contract on whose behalf a third-party premium payment described in this section will be made." *Id.* § 3(c)(2); *see also id.* § 5(c)(2). AB 290 changes how

[2] *See* https://leginfo.legislature.ca.gov/faces/billStatusClient.xhtml?bill_id=201720180SB1156.

AKF operates by obligating it to turn over the names of the patients it assists to private insurers—information that it otherwise would not reveal. AKF Decl. ¶ 45.

Second, AB 290 sharply reduces providers' reimbursement rates for HIPP patients. Starting on January 1, 2022, if AKF makes a premium assistance payment to a health care service plan on behalf of a patient, the reimbursement for any "contracted financially interested provider" will be cut to the higher of either the Medicare rate or a rate determined by a "rate determination" process, if sought by the provider or heath care plan. *Id.* §§ 3(e)(1), 5(e)(1). Out-of-network providers will see a similar reimbursement decrease. *See id.* §§ 3(e)(2), 5(e)(2). Providers are also prohibited from billing the beneficiary for the balance; instead, they may attempt to collect only a cost-sharing percentage related to the insurance payment actually received. *Id.* §§ 3(e)(1), 3(e)(2), 5(e)(1), 5(e)(2).

In sum, the above provisions work in tandem: the first forces AKF to hand over patient names to insurers so that they can implement the second provision, penalizing providers that donate to AKF by cutting their reimbursement. These provisions will irreparably damage AKF's charitable efforts in California (and possibly nationwide) and upset the delicate balance Congress intended when it passed the MSPA, 42 U.S.C. § 1395y(b).

Third, AB 290 requires that AKF inform a patient of "all available health coverage options," including Medicare and Medicaid. AB 290 §§ 3(b)(3), 5(b)(3); *see also id.* §§ 3(b)(1), 5(b)(1). The State is attempting to conscript AKF into delivering the State's chosen message to patients. But, under the terms of Advisory Opinion 97-1, AKF currently plays no role in patients' insurance selection decision—patients come to AKF only after they have insurance in place. AKF Decl. ¶¶ 41, 50.

The compelled speech required by the third provision is exacerbated by a fourth provision. AKF must "agree not to steer, direct, or advise the patient into or away from a specific coverage program." AB 290 §§ 3(b)(4), 5(b)(4). Thus, AB

290 forces AKF into a bind: AKF must assume the role of insurance navigator, yet AKF cannot "advise" patients on the insurance options it is forced to discuss.

Finally, and perhaps most outrageously, AB 290 forces AKF "not to condition financial assistance on eligibility for, or receipt of, any surgery, *transplant*, *procedure*, drug, or device." *Id.* §§ 3(b)(2), 5(b)(2) (emphasis added). But HIPP assistance is limited to patients on dialysis (a "procedure") or those who within the past year have received a kidney transplant. AKF Decl. ¶ 16. This provision would frustrate AKF's ability to fulfill its nearly 50-year-old mission of serving ESRD patients, transforming it into an all-purpose medical charity in violation of its articles of incorporation.

E. AB 290 Threatens Irreparable Harm

The Act creates a severe disincentive for AKF's donors: if a provider donates to AKF, it is punished by a much lower rate of reimbursement for its services within the State of California.

With fewer donations for HIPP, AKF will be able to assist fewer patients across the United States. In turn, those patients will be forced from their insurance plans. *See*, *e.g.*, Doe Decl. ¶ 16; Albright Decl. ¶ 11. Although some will be eligible for Medicare, the majority of patients AKF assists cannot afford even Medicare's modest premium or the 20% Medicare does not cover. This out-of-pocket cost of treating ESRD can be as much as $7,000 for dialysis patients. AKF Decl. ¶ 21. Patients who can afford Medicare will nonetheless generally face a 3-month waiting period. For indigent patients who are ineligible for Medicare and who cannot avail themselves of Medi-Cal (California's Medicaid program with its own stringent requirements), emergency room treatments are often the only option. AKF Decl. ¶ 32. This disruption to insurance coverage will imperil the lives of countless ESRD patients by subjecting them to inferior treatment options (or none at all, which would result in death), additional financial burdens, and further stress and uncertainty. *See*, *e.g.*, Doe Decl. ¶¶ 16-17; Albright Decl. ¶¶ 11-14.

These consequences will be especially severe in California because AB 290 will force AKF to halt HIPP within that State. AKF Decl. ¶¶ 47, 52. The safe harbor of Advisory Opinion 97-1 is contingent on AKF strictly adhering to the terms of the program OIG approved. AB 290, however, would require material changes to HIPP, and, as California's Legislative Counsel Bureau concluded, "remove the legal protection afforded by Opinion 97-1." Ca. Legislative Counsel Bur., Assembly Bill No. 290: Dialysis Providers: Charitable Donations - #1916414, at 6 (June 28, 2019). For this reason, unless this Court enjoins AB 290, AKF must withdraw from California entirely on or before January 1, 2020. AKF Decl. ¶ 47. A cascade of irreparable harms will quickly follow.

ARGUMENT

A preliminary injunction is necessary and appropriate to prevent the dire consequences that will follow the State's implementation of AB 290 in contravention of the U.S. Constitution. Such relief is appropriate when the movant has shown that "(1) it is 'likely to succeed on the merits,' (2) it is 'likely to suffer irreparable harm in the absence of preliminary relief,' (3) 'the balance of equities tips in [its] favor,' and (4) 'an injunction is in the public interest.'" *Disney Enters., Inc. v. VidAngel, Inc.*, 869 F.3d 848, 856 (9th Cir. 2017) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). "Under [the Ninth Circuit's] 'sliding scale' approach, 'the elements of the preliminary injunction test are balanced, so that a stronger showing of one element may offset a weaker showing of another.'" *Hernandez v. Sessions*, 872 F.3d 976, 990 (9th Cir. 2017) (citation omitted). As a result, "[a] preliminary injunction may also be appropriate if a movant raises 'serious questions going to the merits' and the 'balance of hardships . . . tips sharply towards' it, as long as the second and third *Winter* factors are satisfied." *Disney Enters., Inc.*, 869 F.3d at 856 (citation omitted).

For the following reasons, all four of the *Winter* factors strongly support entry of a preliminary injunction in this case.

A. Plaintiffs Will Likely Succeed on the Merits.

Plaintiffs will likely succeed on the merits of this case because AB 290 is unlawful in two crucial respects. *First*, AB 290 is preempted by federal health care law because it removes AKF's safe harbor for operating the HIPP program, and it presents obstacles to Congress' objectives in the Medicare Secondary Payer Act. *Second*, AB 290 infringes Plaintiffs' First Amendment rights to free speech, petition, and association.

1. *AB 290 Is Preempted by Federal Law.*

Plaintiffs are likely to succeed on their claim that AB 290 is preempted by federal law. AB 290 conflicts with both the safe harbor in Advisory Opinion 97-1, as well as Congress's carefully calibrated structure for reimbursement of ESRD treatments. "Conflict preemption exists where 'compliance with both state and federal law is impossible,' or where 'the state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'"" *Oneok, Inc. v. Learjet, Inc.*, 135 S. Ct. 1591, 1595 (2015) (quoting *California v. ARC Am. Corp.*, 490 U.S. 93, 100, 101 (1989)). "In either situation, federal law must prevail." *Id.*

Several preemption principles are relevant here. Impossibility preemption exists when it is "not lawful under federal law for [affected parties] to do what . . . state law require[s] of them." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011). "The question for 'impossibility,'" then, "is whether the private party c[an] independently do under federal law what state law requires of it." *Id.* at 620. It is not enough to "imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it." *Id.* (emphasis in original). Indeed, Congress could always rewrite federal law to follow state law, *id.* at 620-21, but unless and until it does, state law must yield to federal law.

Obstacle preemption occurs when state law "present[s] an obstacle to the

variety and mix of [regulatory approaches]" selected by Congress. *Geier v. American Honda Motor Co.*, 529 U.S. 861, 881 (2000). Among the "special features" of federal law that may require obstacle preemption, *English v. Gen. Elec. Co.*, 496 U.S. 72, 87 (1990), is a specialized federal enforcement regime that would be thwarted by state legislation, *see Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 144 (1990).

a. AB 290 Requires AKF to Operate Outside the Federally Approved Safe Harbor of Advisory Opinion 97-1 and Must Be Preempted.

On its face, AB 290 demands that AKF act in a manner that is inconsistent with Advisory Opinion 97-1. Advisory Opinion 97-1 serves as a critical safe harbor for AKF, which, as a charitable organization, cannot take the business, legal, and reputational risk of losing that safe harbor. AKF Decl. ¶ 42. As approved by the OIG, HIPP is carefully structured to avoid conflict with the Beneficiary Inducement Statute. First, AKF accepts voluntary donations from providers, but in approving assistance does not consider whether the patient-applicant is using a provider that donated to HIPP. Second, beneficiaries receiving premium assistance are unaware of whether their specific providers donated to HIPP. And finally, HIPP treats all eligible patients equally on a first-come, first-served basis, so long as funding is available.

AB 290 is a direct assault on this structure. It requires AKF to inform insurers of those patients for whom it provides premium assistance, so that the insurers can reduce reimbursement rates to providers for those patients. *See* AB 290 §§ 3(c)(2), 3(e), 5(c)(2), 5(e). When HIPP participants receive their Explanations of Benefits reflecting lower payments, they will know their provider is a HIPP donor and may feel bound to stay only with providers who donate to HIPP. AB 290 also requires HIPP to treat patients in California differently from patients in other states who are not subject to AB 290. It even requires HIPP to treat certain "grandfathered" ESRD

patients in California differently from those patients who are not grandfathered, and both differently from patients who were formerly grandfathered.[3]

These AB 290-enforced notifications, coupled with the compulsory patient differentiation, are also improper under the terms of Advisory Opinion 97-1: first, AB 290 requires AKF to notify insurers of patients participating in HIPP; second, patients receive access to the identities of providers that donated to AKF; and third, AB 290 creates different classes of patients. Advisory Op. at 3. Thus, AB 290 requires AKF to deviate from the facts upon which the OIG issued Advisory Opinion 97-1 and puts AKF at serious—and intolerable—risk of claims under the Beneficiary Inducement Statute, which prohibits remuneration (here, free premium assistance) that may to influence an individual's choice of health care provider. *See* 42 U.S.C. § 1320a-7a(a)(5); *see also* AKF Decl. ¶¶ 34-42. The California Legislative Counsel Bureau agreed: "Because th[e] disclosure requirements [contemplated by AB 290] were not part of the arrangement considered by OIG when it issued Opinion 97-1, that opinion would not ensure that the version of the patient assistance program operated by AKF in compliance with AB 290 would be immune from OIG sanctions." Ca. Legislative Counsel Bur., Assembly Bill No. 290: Dialysis Providers: Charitable Donations - #1916414, at 6 (June 28, 2019). The Bureau concluded: "*the changes in the premium assistance program required by AB 290 would remove the legal protection afforded by Opinion 97-1*." *Id.* (emphasis added).[4]

[3] *See* AB 290 §§ 3(d)(1), 5(d)(1) (grandfathering against name disclosure and rate reductions for beneficiaries receiving premium assistance prior to October 1, 2019); §§ (3)(d)(2)–(3), 5(d)(2)–(3) (removing grandfathered status if those beneficiaries change their insurance plan on or after March 1, 2020); §§ 3(c)(2), 3(e), 5(c)(2), 5(e) (requiring name disclosure and reduction of patient rates for all others).

[4] Nonetheless, the Legislative Counsel Bureau illogically concluded that AKF "would remain in compliance with the arrangement approved in Advisory Opinion 97-1," *id.* at 9, even as it also acknowledged that "this would be a factual determination made by the OIG and could involve a consideration of facts not

These facts establish impossibility preemption under Supreme Court precedent. For instance, in *PLIVA,* the Supreme Court found impossibility preemption when state tort law demanded a stricter warning label than federal law, which required that generic manufacturers adopt an exact, invariable warning label for their drugs. *PLIVA*, 564 U.S. at 618-19. The Court explained: "It was not lawful under federal law for the Manufacturers to do what the state law required of them. . . . Thus, it was impossible . . . to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." *Id.* at 618.

So too here. The OIG, charged with interpreting the Beneficiary Inducement Statute, has indicated in Advisory Opinion 97-1 that the safe harbor is available only if AKF complies strictly with its terms. AB 290 requires that AKF operate HIPP without those safeguards. The result is that it "[i]s not lawful under federal law for [AKF] to do what the state law required of [it]." *PLIVA*, 564 U.S. at 618.

The very text of AB 290 concedes the preemption issue. By "inducing" AKF to seek a new advisory opinion by delaying the effective date of the statute, California recognizes that AKF cannot simultaneously comply with AB 290 and Advisory Opinion 97-1. *See* AB 290 § 7. As the Supreme Court explained in *PLIVA*, however, "[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." 564 U.S. at 620. The Court then made short shrift of a proposal that new, non-conflicting labeling requirements could be obtained from HHS:

> We can often imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it. In these cases, it is certainly possible that, had the Manufacturers asked the FDA for help, they might have eventually been able to strengthen their warning label. Of course, it is also *possible* that the Manufacturers

available to [it]," *id.* at 8.

> could have convinced the FDA to reinterpret its regulations in a manner that would have opened the CBE process to them. Following [the plaintiffs'] argument to its logical conclusion, it is also *possible* that, by asking, the Manufacturers could have persuaded the FDA to rewrite its generic drug regulations entirely or talked Congress into amending the Hatch-Waxman Amendments.

Id. at 620-21 (emphasis original). That AKF might convince the OIG to issue a new advisory opinion is therefore irrelevant to the preemption analysis. "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *PLIVA*, 564 U.S. at 623–24. Rather than allaying the preemption problem, Section 7 strongly confirms it.

California also ignores the deep practical difficulties that would accompany an effort by AKF to obtain a new advisory opinion. It is impossible for AKF to request a new advisory opinion because it cannot certify in good faith under 42 C.F.R. § 1008.43 that it will enact AB 290's scheme. AKF Decl. ¶ 49. It must, after all, treat all patients equally under the HIPP program, and to assure compliance would need to adopt AB 290's requirements throughout the country. AKF also believes that compliance with AB 290 would expose it to claims under the Beneficiary Inducement Statute, and AKF cannot and will not risk a program that last year helped 75,000 desperately ill patients across the country. *Id.* ¶ 18. Instead, if AB 290 is not enjoined, AKF will have no choice but to cease its grant assistance operations within California to safeguard the interests of its operations and patients elsewhere. *Id.* ¶¶ 47, 52.

Driving HIPP from California would not, however, alleviate the preemption concerns. In *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013), the Supreme Court rejected an argument that a generic drug manufacturer could comply

with federal law by simply halting sale of the drug within a state requiring stronger warning labels, writing "if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'" *Id.* at 488. The same logic is compelling here.

b. AB 290 Presents a Significant Obstacle to Congress's Objectives for Medicare Coverage of Individuals with ESRD.

Congress passed, and then several times amended, the MSPA, 42 U.S.C. § 1395y(b), to ensure that private health plans share in the cost of treating ESRD. AB 290 precludes this system from functioning as intended, allowing insurers to skirt their fair share of the burden, and therefore presents a clear obstacle to Congress's "accomplishment and execution of . . . important means-related federal objectives." *Geier*, 529 U.S. at 881.

The MSPA and its implementing regulations require that group insurers treat ESRD patients the same as non-ESRD patients, and plans cannot pay providers less for the same service for individuals with ESRD than without. 42 U.S.C. § 1395y(b)(1)(C)(i); 42 C.F.R. § 411.161(b)(2)(iv). AB 290 impermissibly does just that. For example, a healthcare provider (for instance, a cardiologist) who contributes to AKF becomes a "financially interested provider" under AB 290 §§ 3(h)(2)(A), 5(h)(1)(A). That contributor would therefore receive differing reimbursement pursuant to AB 290 §§ 3(e) and 5(e) for services provided: one amount for HIPP recipients (who necessarily have ESRD) and another amount for everyone else. Such a scheme cuts directly against Congress's mandate that ESRD patients receive equal treatment as all other patients.

2. *AB 290 Tramples Plaintiffs' First Amendment Rights.*

AB 290 tramples free expression in almost too many ways to count. It singles out disfavored speakers, prohibits communications by those disfavored speakers based on content, and coerces those speakers to tout a state-approved message. It

burdens the right of association in numerous ways and punishes the acts of giving and receiving charitable donations. It coerces AKF to file a petition with OIG for a result it opposes. Its violation of the First Amendment is not a close call.

The Act specifically targets AKF for extensive speech restrictions because it is a "financially interested entity" that makes "third-party premium payments."[5] These oppressive speech restrictions include:

- AKF "shall inform an applicant . . . of *all available health coverage options*, including, but not limited to, Medicare, Medicaid, individual market plans, and employer plans, if applicable." (§§ 3(b)(3), 5(b)(3) (emphasis added).)
- In so informing HIPP applicants, however, AKF must "agree" (although the Act is unclear how it must agree or with whom) "not to steer, direct, or advise the patient into or away from a specific coverage program option or health care service plan contract." (§§ 3(b)(4), 5(b)(4).)
- AKF must annually provide "a statement to the health care service plan that it meets" these and other requirements. (§§ 3(c)(1), 5(c)(1).)
- And, before making the initial payment on behalf of any beneficiary, AKF must disclose "to the health care service plan . . . the name of the enrollee for each health care service plan contract on whose behalf a third-party premium payment described in this section will be made." (§§ 3(c)(2), 5(c)(2).)[6]

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[5] The Act deems AKF "financially interested" because AKF "receives the majority of its funding from one or more financially interested providers." (§§ 3(h)(2)(B), 5(h)(1)(B).) "Financially interested providers" here include the Provider Plaintiffs, who are "large dialysis clinic organization[s]," (§§ 3(h)(2)(C), 5(h)(1)(C)), as well as any "provider of health care services that receives a direct or indirect financial benefit from a third-party premium payment," (§§ 3(h)(2)(A), 5(h)(1)(A).)

[6] Use of passive voice in this provision creates an ambiguity: Must AKF disclose only those payments *AKF* is making, or is it also obligated to report premium payments made by *any other* third party? If the latter, this provision is also overbroad and unworkable.

Failure by AKF to make the report required by sections 3(c) and 5(c) will expose it to substantial liabilities to the health care service plan. *Id.* §§ 3(i), 5(i).[7]

Any provider that contributes to AKF, and then treats a patient receiving assistance from HIPP, will suffer a dramatic reduction in reimbursement. The predictable (and no doubt intended) consequence of these provisions is to deter any "financially interested" provider, a term which encompasses AKF's primary donors, from donating to AKF. Each of these restrictions is subject to heightened judicial scrutiny, and none can pass any version of that test. *See* Part A.2.d below.

a. AB 290 Violates the First Amendment by Restricting AKF's Speech.

Sections 3(b)(3), 5(b)(3). By policy and practice, AKF does not discuss coverage options with patients. It simply pays for coverage submitted by the patients. The Act forces a change in these practices by compelling AKF to inform patients of "*all available health coverage options,*" including government options. AB 290 §§ 3(b)(3), 5(b)(3).[8] These provisions also offend the First Amendment by imposing a State-favored speech requirement on a disfavored speaker. They "compel[] speech" in violation of the First Amendment. The difference between "compelled speech and compelled silence . . . in the context of protected speech . . . is without constitutional significance." *Riley v. National Fed. of the Blind*, 487 U.S.

[7] The penalties include payment to the health care service plan of 120 percent of the difference between (i) the actual payment to the provider for provided services and (ii) the amount to which the provider would have been entitled under the rate control provisions imposed on services provided to participants in HIPP. The penalty to AKF could be tens of thousands of dollars for a single beneficiary in a year.

[8] AKF cannot possibly know "all" such options that might be available, and it would incur considerable expense to gather such information. The provision is both vague and overbroad. "Vague laws may not only trap the innocent by not providing fair warning or foster arbitrary and discriminatory application but also operate to inhibit protected expression by inducing citizens to steer far wider of the unlawful zone . . . than if the boundaries of the forbidden areas were clearly marked." *Buckley v. Valeo*, 424 U.S. 1, 41 n. 48 (1976) (citation and internal quotation marks omitted).

781, 796 (1988) (rejecting effort by North Carolina to require certain disclosures by professional fundraisers). Both offend the First Amendment.

As in *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2371 (2018) ("*NIFLA*"), the Act requires AKF to deliver "a government-drafted script about the availability" of public and private coverage, and "plainly 'alters the content' of [AKF's] speech." In *NIFLA*, the Court reversed the refusal to grant a preliminary injunction against a statute that required a pro-life organization to inform patients about state-sponsored abortion services. The Court deemed the required statements "content-based regulation of speech," *id*. at 2371, which "[a]s a general matter . . . 'are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests.'" *Id*. (citation omitted). As in *NIFLA*, Plaintiffs are "likely to succeed on the merits of [their] claim that [AB 290] violates the First Amendment." *Id.* at 2378.

Sections 3(b)(4), 5(b)(4). Having compelled AKF to communicate with the aid recipients, even when it would not otherwise, the Act then prohibits AKF from "steer[ing], direct[ing], or advis[ing]" any patient with regard to any "specific coverage program option or health care service plan contract." These provisions fail for two reasons. *First*, they are void because they do not give "ordinary people [] 'fair notice' of the conduct [they] proscribe[]." *Sessions v. Dimaya*, 138 S. Ct. 1204, 1212 (2018). Indeed, lacking definition of "steer, direct, or advise," AKF is left to guess at the meaning of those terms. Because sections 3(b)(5) and 5(b)(5) already specifically prevent AKF from conditioning premium assistance on "specific coverage type[s]," sections 3(b)(4) and 5(b)(4) must be intended to restrict AKF's freedom to inform patients, for example, of Medicare costs and deductibles, or to state its view that particular types may better fit a patient than other plan types, or to "advise" patients about the availability of better, more appropriate, or less expensive coverage. For unsophisticated or uninformed patients, this information could be immensely valuable.

Because these provisions restrict AKF's speech, they offend the First Amendment. In *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011), the Supreme Court struck down a Vermont statute that prohibited sale of certain prescription data to pharmaceutical marketers, called "detailers," but did not restrict sale of the data to other persons. Even assuming Vermont had a "significant interest" in medical privacy and in untainted prescription decisions, *id.* at 557, the Court noted that the statute "has the effect of preventing detailers—and only detailers—from communicating with physicians in an effective and informative manner." *Id.* at 564. Like AB 290, the statute was "designed to impose a specific, content-based burden on protected expression," and required "heightened judicial scrutiny." *Id.* at 565. *See also id.* at 567 ("[b]oth on its face and in its practical operation, Vermont's law imposes a burden based on the content of speech and the identity of the speaker"). Like Vermont, California has infringed the First Amendment by targeting a specific group of disfavored speakers and imposing restrictions on their communications about medical and public health information.

Sections 3(c)(1), 5(c)(1). These provisions compel AKF to provide an annual statement certifying compliance with the whole of Sections 3(b) and 5(b) to the health insurer. Insurers may use these certifications to detect violations, and then seek a 120% bounty from AKF if they detect any violations. Again, these provisions are content-based speech regulations targeting disfavored speakers and are subject to heightened scrutiny. This "compelled speech" is also offensive to the First Amendment. *See Riley*, 487 U.S. at 795. "Mandating speech that a speaker would not otherwise make necessarily alters the content of the speech. We therefore consider the Act as a content-based regulation of speech." *Id.* at 795. *See also NIFLA*, 138 S. Ct. at 2371 ("plainly 'alters the content'" of [] speech). Indeed, "the government, even with the purest of motives, may not substitute its judgment as to how best to speak for that of speakers and listeners." *Riley*, 487 U.S. at 791.

Sections 3(c)(2), 5(c)(2). These provisions compel AKF to disclose patient

names, and by implication (because they are receiving assistance) their health and financial status. For the reasons set forth above, this compelled speech offends the First Amendment.

b. AB 290 Abridges the First Amendment Right of Association.

By imposing mandatory and prohibitory restraints on the relationships among patients, dialysis providers, and AKF, AB 290 abridges their individual and collective rights of association. AB 290 burdens Plaintiffs' ability to associate in pursuit of that goal in several ways. *First and foremost*, it strikes directly at the heart of AKF's 50-year mission by requiring AKF to "agree not to condition financial assistance on eligibility for, or receipt of, any surgery, transplant, procedure, drug, or device." AB 290 §§ 3(b)(2), 5(b)(2). Yet HIPP assistance is intentionally limited to patients on dialysis (a "procedure") or those who within the past year have received a kidney transplant. AKF Decl. ¶ 16. Through this provision, AKF will be inhibited from associating with the ESRD patients it desires to serve, since its resources will be depleted by the requirement to serve a broader audience, and with the donors who desire to support the fight against kidney disease.

Second, the Act punishes providers for donating to AKF by dramatically reducing reimbursement for treatments provided to any HIPP recipient. The reports AKF must submit to the insurers allow the insurers to reduce reimbursement for services provided by AKF's donors to HIPP beneficiaries.

A provider is penalized the same for any amount of contribution to AKF, large, small, or even minute. A $10 donation to AKF by a provider draws the same penalty as a $10 million donation; in both instances the provider's reimbursement for treating any and all HIPP participants is dramatically reduced, a draconian penalty with no function other than to deter donations. Like political contributions, charitable giving is associational activity protected by the First Amendment. *See Kamerling v. Massanari*, 295 F.3d 206, 214 (2d Cir. 2002) ("contributions, in both

political and charitable contexts . . . are speech entitled to protection under the First Amendment."). Accordingly, restrictions on contributions must be "'closely drawn' to match a 'sufficiently important interest.'" *Nixon v. Shrink Missouri PAC*, 528 U.S. 377, 387-88 (2000).

In *Randall v. Sorrell*, 548 U.S. 230, 247 (2006) (Breyer, J., announcing judgment of the Court), the Court struck down Vermont's political contribution limits as offensive to the First Amendment because they were "sufficiently low as to generate suspicion that they are not closely drawn." *Id.* at 249. The Court found "nowhere in the record any special justification that might warrant a contribution limit so low or so restrictive as to bring about the serious associational and expressive problems that we have described." *Id.* at 261. AB 290 unabashedly punishes any provider who makes any donation to AKF in any amount, at any time, for any reason. This is not a "closely drawn" statute.

The Act also burdens AKF's right to associate with patients by imposing mandatory and prohibitory speech restrictions on how AKF communicates with them, and by requiring AKF to disclose their identities, along with their medical and financial status, to the insurance companies. Thus, the burden on ESRD patients of associating with AKF is disclosure of intensely personal information; this burden on their right of association is an affront to the First Amendment.

Finally, the Act burdens the right of patients to associate with the dialysis providers of their choice. It does so by allowing more generous reimbursement for providers who do not donate to AKF than for providers that do.

c. AB 290 Infringes the First Amendment Right of Petition.

As a condition for delaying its effective date beyond July 1, 2020, the Act requires AKF to petition for revision of the Advisory Opinion. AB 290 § 7. As shown (p. 12, above), the purpose of the putative petition would be to change the Advisory Opinion in a way that will allow the Act to avoid preemption and become effective. Because the State is not covered by the Advisory Opinion, and cannot

seek the revision on its own, the Act seeks to force one of the entities to whom the Advisory Opinion was issued to do so.

To forestall the effective date of the Act and avoid its numerous injuries, AKF would be required to submit a new advisory opinion request to the OIG, state an intention to comply with AB 290, and ask OIG to revise the Advisory Opinion in ways that would allow compliance with the Act. This provision attempts to force AKF to submit a petition advocating a result it vigorously opposes. By doing so, it violates the petition clause. *See Wayte v. United States*, 470 U.S. 598, 610 n.11 (1985) ("Although the right to petition and the right to free speech are separate guarantees, they are related and generally subject to the same constitutional analysis.").

d. The State's Purported Interests Cannot Justify These Restraints.

Under any version of heightened First Amendment scrutiny, AB 290 fails. The Act states its "intent" as "protect[ing] the sustainability of risk pools," "shield[ing] patients from potential harm caused by being steered into coverage options" not in their best interests, and "correct[ing] a market failure that has allowed large dialysis organizations . . . to inflate commercial reimbursement rates and unjustly drive up the cost of care." (§ 1(i)). The State must show that these concerns are "real, not merely conjectural," *Turner Broadcasting System v. FCC*, 512 U.S. 622, 664 (1994), and bears the burden of showing that the remedy it has adopted does not "'burden substantially more speech than is necessary,'" *id.* at 665 (citation omitted). Here, the Act fails these tests.

If the goal is to avoid "steer[ing]" patients into inappropriate coverage, the restrictions are "wildly underinclusive" to protect patients, thus casting doubt on whether the state has any legitimate interest in them. The Act imposes these restrictions on AKF, but not on insurance brokers, hospitals, physicians, or numerous other categories of individuals and entities that might come into contact

with ESRD patients. AKF receives no commission and has no financial interest in insurance policies. In stark contrast, the insurance industry, which aggressively supported AB 290, *does* have such a financial interest, but remains unrestricted by AB 290 and free to "steer, direct, or advise" patients in whatever manner it wants. In *NIFLA*, 138 S. Ct. at 2375, the Court rejected California's asserted interest in "providing low-income women with information about state-sponsored services" because the statute was "wildly underinclusive" to serve that interest; it did not include other clinics, for example. *Id*. at 2375 (citation omitted). As in *NIFLA*, "[s]uch '[u]nderinclusiveness raises serious doubts about whether the government is in fact pursuing the interest it invokes, rather than disfavoring a particular speaker or viewpoint." *Id.* 138 S. Ct. at 2376 (citation omitted).

If the goal is to combat rising health care costs, the Act's means of doing so are obtuse. By deterring donations to AKF, fewer patients will have the benefit of private insurance provided by HIPP and thus will be forced to participate in government programs (at greater cost to the taxpayers), and perhaps insurers will save money by covering fewer ESRD patients. Or perhaps the hope (however unlikely) is that providers, notwithstanding the Act, will continue to donate to AKF, the same number of patients will continue to participate in HIPP, the Act will reduce reimbursement by the insurers to the donating provider for treating HIPP beneficiaries, and insurers will again save money. Notably, the Act does not require the insurers to share any savings with policyholders. This is an approach to cost control only Rube Goldberg could understand. As the Court noted in *Nixon,* "[w]e have never accepted mere conjecture as adequate to carry a First Amendment burden." 528 U.S. at 392.

In short, no credible state interest can support AB 290's extensive assault on the First Amendment rights of the Plaintiffs.

B. AB 290 Will Cause Immediate, Irreparable Harm.

Plaintiffs' likelihood of success notwithstanding, final relief will come too

late. On January 1, 2020, AB 290 will begin to work severe and irreversible harm to AKF and the vulnerable patients it supports, causing AKF to withdraw HIPP from California.

To begin, AB 290 will deprive Plaintiffs of their First Amendment freedoms, a loss that "unquestionably constitutes irreparable injury." *Manning v. Powers*, 281 F. Supp. 3d 953, 964 (C.D. Cal. 2017) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)); *see also*, *e.g.*, *Sammartano v. First Judicial Dist. Court*, 303 F.3d 959, 973-74 (9th Cir. 2002) (explaining irreparable harm follows if the plaintiff has raised "a colorable First Amendment Claim"), *abrogated on other grounds by Winter*, 555 U.S. 7. Accordingly, the manifold constitutional harms laid out above themselves justify preliminary injunctive relief. *See, e.g.*, *Weaver v. City of Montebello*, 370 F. Supp. 3d 1130, 1138 (C.D. Cal. 2019); *Serv. Emps. Int'l Union v. City of L.A.*, 114 F. Supp. 2d 966, 975 (C.D. Cal. 2000).

In addition, and more importantly, implementation of AB 290 will permanently upturn the lives of current AKF beneficiaries and substantially burden future ESRD patients' access to life-saving dialysis and kidney transplants. Plaintiffs Doe, Albright, and numerous members of DPC suffer constant anxiety about their health care needs and expenses. Doe Decl. ¶ 17; Albright Decl. ¶ 13; DPC Decl. ¶ 19. Losing AKF's assistance will make it impossible for them to afford their current health insurance coverage. Doe Decl. ¶ 16; Albright Decl. ¶ 11; DPC Decl. ¶ 15. As the result of even a short lapse in AKF's operations, Ms. Doe, Mr. Albright, and many DPC members will see their health care needs come to dominate their lives and livelihoods. Doe Decl. ¶ 16; Albright Decl. ¶¶ 11-14; DPC Decl. ¶ 19. Some may even be delayed in receiving necessary kidney transplants as the result of disruptions in their health insurance coverage. AKF Decl. ¶ 22; DPC Decl. ¶ 18. These are precisely the types of hardship courts routinely avoid through preliminary relief. *See M.R. v. Dreyfus*, 697 F.3d 706, 729, 732 (9th Cir. 2012); *Harris v. Bd. of Supervisors*, 366 F.3d 754, 766 (9th Cir. 2004); *Lopez v. Heckler*,

713 F.2d 1432, 1437 (9th Cir. 1983); *see also Beltran v. Myers*, 677 F.2d 1317, 1322 (9th Cir. 1982) ("Plaintiffs have shown a risk of irreparable injury, since enforcement of the California rule may deny them needed medical care."); *United Steelworkers of Am. v. Fort Pitt Steel Casting*, 598 F.2d 1273, 1280 (3d Cir. 1979) (recognizing that "the possibility [of being] denied adequate medical care as a result of having no insurance" is an irreparable injury).

Economic harms of this nature can support preliminary relief because of the interim injury and because Plaintiffs are unable to recover damages from the state. *Cal. Pharmacists Ass'n v. Maxwell-Jolly*, 563 F.3d 847, 852 (9th Cir. 2009), *vacated on other grounds by Douglas v. Indep. Living Ctr. of S. Cal.*, 565 U.S. 606 (2012). Damages years from now could not make them whole anyway, *cf. Zepeda v. INS*, 753 F.2d 719, 727 (9th Cir. 1983) (recognizing the inadequacy of money damages to retroactively cure a constitutional violation). Indeed, no form of relief could restore Plaintiffs to their current position once AB 290 goes into effect. The need for dialysis and maintaining adequate coverage for a transplant is ongoing and cannot be put on hold.

C. The Equities and Public Interest Favor an Injunction.

Finally, the heavy support for preliminary relief has no counterweight. The State will suffer no loss from preliminary relief, and the public will benefit from this Court's maintenance of the status quo.

Although the balance of equities and the public interest are normally two separate considerations, those considerations merge when an injunction would run against the government. *See Nken v. Holder,* 556 U.S. 418, 435 (2009). And it is always in the public interest to prevent state officials from breaking federal law and violating constitutional rights. *E.g. Az. Dream Act Coalition v. Brewer*, 757 F.3d 1053, 1069 (9th Cir. 2014); *Melendres v. Arpaio*, 695 F.3d 990, 1002 (9th Cir. 2012); *Cal. Pharmacists*, 563 F.3d at 852–53; *cf. Rodriguez v. Robbins*, 715 F.3d 1127, 1145 (9th Cir. 2013) (the government "cannot suffer harm from an injunction that

merely ends an unlawful practice").

That is all Plaintiffs ask for here. Far from burdening the public, an injunction would thus *serve* the public by protecting its most vulnerable members from illegal privations. *See Rodde v. Bonta*, 357 F.3d 988, 999 (9th Cir. 2004) (recognizing the public's interest in providing health care to the needy); *cf. Texas v. EPA*, 829 F.3d 405, 435 (5th Cir. 2016) (holding the public's immediate need for affordable electricity paramount to the potential long-term benefits of a new government policy). This Court has recognized the aptness of preliminary relief in similar circumstances. *See, e.g.*, *Weaver*, 370 F. Supp. 3d at 1139; *Gebin v. Mineta*, 239 F. Supp. 2d 967, 969 (C.D. Cal. 2002). It should reaffirm that principle here.

CONCLUSION

For the foregoing reasons, Plaintiffs urge this Court to enjoin the State from implementing AB 290 while this lawsuit is pending.

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