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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JANE DOE; STEPHEN ALBRIGHT; AMERICAN KIDNEY FUND, INC.; and DIALYSIS PATIENT CITIZENS, INC.,

Plaintiffs,

v.

ROB BONTA, in his Official Capacity as Attorney General of California; RICARDO LARA in his Official Capacity as California Insurance Commissioner; SHELLY ROUILLARD in her official Capacity as Director of the California Department of Managed Health Care; and TOMAS ARAGON, in his Official Capacity as Director of the California Department of Public Health,

Defendants.

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

REPLY IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Date:	May 2, 2022
Time:	8:30 a.m.
Courtroom:	10A
Judge:	The Honorable David O. Carter
Trial Date:	July 12, 2022
Action Filed:	November 1, 2019

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INTRODUCTION

The California Legislature enacted Assembly Bill 290 to address steering of patients into commercial insurance by financially interested providers, such as DaVita, Fresenius, and US Renal, for their own financial benefit and to the detriment of their patients. Plaintiffs argue that AB 290 should be struck down, in large part because Defendants supposedly have "identifie[d] no evidence of steering." ECF No. 156 [Opp'n] at 1. Plaintiffs suggest that the only way that Defendants can substantiate that providers have engaged in steering is by identifying a "California dialysis patient who was directed into a commercial insurance plan to their detriment." Opp'n 8. They go on to say that a "handful" of such complaints would also be insufficient. *Id.* at 9 (citing *United States v. Playboy Entm't Grp., Inc.*, 529 U.S. 803, 821-22 (2000)).

Plaintiffs' narrow conception of the evidence that Defendants may rely on to establish California's substantial interests reflects a fundamental misunderstanding of Defendant's burden. To be sure—as this Court has observed—AB 290 must address harms that are "real." *Edenfield v. Fane*, 507 U.S. 761, 762 (1993). But the Supreme Court long ago made clear that *Edenfield* does not prescribe a one-size-fits-all approach to satisfying this standard: speech restrictions can be justified "by reference to studies and anecdotes pertaining to different locales altogether, or even, in a case applying strict scrutiny, [by] history, consensus, and simple common sense." *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 628 (1995) (internal citations and quotation marks omitted). Indeed, "[n]othing in *Edenfield*, a case in which the State offered *no* evidence or anecdotes in support of its restriction, requires more." *Id.*

Here, Defendants have presented a robust federal rulemaking record, a nearby state's thorough investigation and enforcement action, and Plaintiffs and providers' own internal documents and witnesses—among other evidence of steering. *See* ECF No. 128-1 [Mot.] at 15-17. Plaintiffs casually brush aside this evidence,

Opp'n 9 (labeling it a "paucity"), but it is more than enough to show that AB 290 "targets a concrete, nonspeculative harm." *Fla. Bar v. Went For It,* 515 U.S. at 629.

It follows that Plaintiffs' First Amendment claim fails. AB 290's steering prohibition permissibly regulates commercial speech while providing fair notice of the prohibited conduct. Plaintiffs fail to show that AB 290's reimbursement cap, which applies only to AKF's contributors, infringes on AKF's right of association; nor is that right violated by AB 290's anti-discrimination provision, which merely requires AKF not to withhold financial assistance from an ESRD patient who chooses a treatment other than dialysis. AB 290's disclosure provisions require only the truthful disclosure of factual information, and thus do not unlawfully coerce speech. And none of Plaintiffs' First Amendment rights, including the right to petition, are violated by AB 290's provision permitting—but not compelling—AKF to request an updated advisory opinion from the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG).

Plaintiffs' preemption claims should also be rejected. Neither the federal Beneficiary Inducement Statute nor Advisory Opinion 97-1 preempts AB 290 because they do not impose a mandate with the force of federal law. Nor does the Medicare Secondary Payer Act (MSPA) preempt AB 290. Plaintiffs forgo a portion of that claim, Opp'n 25 (abandoning argument that AB 290 violates the MSPA's "take into account" provision), and they not only fail to explain how AB 290 presents an obstacle to the MSPA's "non-differentiation" provision, but misread *DaVita Inc. v. Amy's Kitchen, Inc.*, 981 F.3d 664, 670-71 (9th Cir. 2020), which forecloses their argument.

Defendants' motion for summary judgment should be granted.

ARGUMENT

I. AB 290 DOES NOT VIOLATE PLAINTIFFS' FIRST AMENDMENT RIGHTS

A. AB 290's Steering Prohibition Is Constitutionally Sound

1. AB 290's Steering Prohibition Permissibly Regulates Commercial Speech

AB 290's steering prohibition, which provides that a chronic dialysis clinic or financially interested entity cannot "steer, direct, or advise" a patient toward a specific coverage option or health care plan, regulates commercial speech. AB 290, §§ 2(a), 3(b)(4). Speech may be "characterized as commercial when (1) the speech is admittedly advertising, (2) the speech references a specific product, and (3) the speaker has an economic motive for engaging in the speech." *Am. Acad. of Pain Mgmt. v. Joseph*, 353 F.3d 1099, 1106 (9th Cir. 2004) (citing *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66-67 (1983)). A finding that the speech is commercial is strengthened by a combination of these factors, but it is not necessary for "each of the characteristics" to "be present in order for speech to be commercial." *Bolger*, 463 U.S. at 67 n.14.

As detailed in Defendants' moving papers, the steering prohibition meets the latter two *Bolger* factors. Mot. 14. It primarily regulates the interactions of social workers and insurance counselors with dialysis patients about a specific product—commercial insurance—for which "reimbursement rates [] are many times the cost associated with providing care." AB 290, § 1(g). Expert evidence, documents in the legislative record, shareholder communications, and provider training documents together establish an economic motive for these commercial transactions between providers and patients. Mot. 14 (citing ECF No. 128-5, SUF 23-26). Plaintiffs do not contest that this evidence is sufficient to show that commercial speech is at issue, but instead mistakenly claim that the steering prohibition restricts AKF's charitable solicitation. Opp'n 6-7 (citing *Vill. of Schaumburg v. Citizens for a Better Env't*, 444 U.S. 620 (1980) and *Riley v. Nat'l Fed'n of the Blind of N.C.,*

Inc., 487 U.S. 781 (1988)). Yet the steering prohibition does not regulate charitable activities, and thus the cases they rely on are inapposite.

Because the steering prohibition regulates commercial speech, intermediate scrutiny applies: AB 290 must directly advance a substantial governmental interest and do so in a manner that is not more extensive than necessary. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980). Defendants have met this standard. Mot. 15-19. Plaintiffs wrongly conclude that Defendants have presented "no evidence" of steering or its attendant harms, Opp'n 8; they do so only by dismissing the compelling record presented here, on which the steering prohibition would satisfy any level of scrutiny.[1]

Plaintiffs' myopic view of the evidence that Defendants can rely on to defend AB 290 disregards longstanding Supreme Court and circuit precedent. It is well established that evidence showing a substantial governmental interest can take many forms. *See, e.g.*, *Fla. Bar v. Went For It*, 515 U.S. at 628; *Minority Television Project, Inc. v. FCC*, 736 F.3d 1192, 1199 (9th Cir. 2013) (en banc). Where the interest is "intuitive," *Williams-Yulee v. Fla. Bar*, 575 U.S. 433, 445 (2015), or evident from "an impressive historical pedigree" of "public disapproval" of the prohibited conduct, *Coyote Publ'g Inc. v. Miller*, 598 F.3d 592, 604 (9th Cir. 2010), little, if any, evidence is required. In other circumstances, it is "apparent from the face of the statute and its legislative history" that the interest is substantial. *United States v. Chovan*, 735 F.3d 1127, 1139 (9th Cir. 2013). And in many cases, "studies in the record or cited in pertinent case law," *Fyock v. Sunnyvale*, 779 F.3d 991, 1000 (9th Cir. 2015) (citation and quotation marks omitted), or other evidence outside the legislative record, *see, e.g.*, *Fla. Bar v. Went For It*, 515 U.S. at 626-28 (relying on survey data, newspaper editorials, and anecdotes), are critical in

[1] Plaintiffs both acknowledge that Defendants argue that the steering prohibition satisfies any level of scrutiny, Opp'n 7-8, and in the same breath, assert that "the words 'strict scrutiny' do not even appear" in Defendants' moving papers, *id.* at 5. To be clear, intermediate scrutiny applies, but the steering prohibition would also survive a strict scrutiny analysis.

establishing the interest. The upshot is that courts do not impose "'an unnecessarily rigid burden of proof . . . so long as whatever evidence the [government] relies upon is reasonably believed to be relevant to the problem that the [government] addresses.'" *Jackson v. City and Cty. of San Francisco*, 746 F.3d 953, 965 (9th Cir. 2014) (quoting *City of Renton v. Playtime Theatres, Inc.*, 475 U.S. 41, 50-52 (1986)).

Under this standard, the record of steering here readily satisfies intermediate scrutiny. The comprehensive rulemaking record prepared by HHS's Centers for Medicare & Medicaid Services (CMS)—which provided a strong basis for the California Legislature to enact legislation, *see, e.g.*, AB 290, § 1 (legislative findings mirroring the evidence in the CMS record)—describes not only the widespread existence of steering but the urgent need to regulate this practice to protect vulnerable patients and the broader public. Mot. 3-5 (citing SUF 1-17).[2] Plaintiffs fail to substantively address this record or to acknowledge the agency's institutional knowledge that informed the findings within, and instead mischaracterize it as a "handful of complaints" of "out-of-state activities." Opp'n 9. The entirety of the CMS rulemaking record consists of not only the over 800 public comments gathered from patients, providers, and other stakeholders, Mot. 4 (citing SUF 10), but also CMS's considerable expertise on this issue. *See, e.g.*, ECF 128-3 (Ex. 1c) at 56 (stating that "HHS's own data" contributed to the finding that steering is likely accelerating over time). And Plaintiffs have not produced any evidence suggesting that California was immune from the concerning trends detailed in the rulemaking record—indeed, the opposite is true. *See* Wise Decl.,

[2] That the urgency did not satisfy the technical "good cause" requirements for bypassing notice and comment under the Administrative Procedures Act, *Dialysis Patient Citizens v. Burwell*, No. 4:17-CV-16, 2017 WL 365271, *5, has no bearing on the intermediate scrutiny analysis in this case. The decision enjoining the interim final rule did, however, create the need for states, like California, to take immediate action in the absence of federal oversight. *See* Declaration of R. Matthew Wise (Wise Decl.), Ex. 26 (CA2592); SUF 18.

Ex. 27 (CA1841) (comment from DaVita social worker who worked at two Sacramento clinics describing the "unethical practice" of "educat[ing]" Medi-Cal patients about enrolling in commercial insurance without confirming that they would not incur high out-of-pocket expenses).[3]

In any event, Defendants may rely on "anecdotes pertaining to different locales altogether" to support California's substantial interest in the steering prohibition. *Fla. Bar v. Went For It*, 515 U.S. at 628. Such evidence includes not only comments in the rulemaking record from patients and provider staff across the country, but additional evidence referenced in the legislative record, such as the attempt by a DaVita insurance coordinator in the State of Washington, Cary Ancheta, "to sign up approximately 30 kidney dialysis patients, most of whom [we]re receiving Medicaid," for commercial insurance. Mot. 15 (citing SUF 27-28). Plaintiffs object that this evidence is not "relevant" largely based on the notion that the Legislature cannot rely on out-of-state evidence to enact legislation, Opp'n 9, but their position is out of step with First Amendment jurisprudence addressing this issue. *See, e.g.*, *Fla. Bar v. Went For It*, 515 U.S. at 628; *Dream Palace v. Cty. of Maricopa*, 384 F.3d 990, 1015 (9th Cir. 2004) (government reasonably relied on studies from multiple states in enacting regulation, and citing *Ctr. For Fair Public Policy v. Maricopa Cty.*, 336 F.3d 1153, 1168 (9th Cir. 2003)); *World Wide Video of Wash., Inc. v. City of Spokane*, 368 F.3d 1186, 1192 (9th Cir. 2004), as amended

[3] Plaintiffs also object that findings within the rulemaking record are "inadmissible hearsay," even for uncontroversial propositions, such as the fact that ESRD is irreversible and permanent. ECF No. 156-2, Pls.' Objections to Evid., at 1. They would prefer that the Court rely instead on the one-sided testimony of their fact witnesses. *See* ECF No. 132-1, Pls.' SUFCL (relying almost exclusively on fact declarations of plaintiffs' witnesses). But it is black letter law that a public record containing the factual findings of a public agency is "clearly admissible under Rule 803(8)(A)(iii)." 2 Robert E. Jones et al., *Federal Civil Trials & Evidence (The Rutter Group Practice Guide)* ¶ 8:2837 (2021); *see, e.g.*, *Owens v. Republic of Sudan*, 864 F.3d 751, 792 (D.C. Cir. 2017) (State Department report, including its factual findings and conclusions, "fit squarely within the public records exception) (vacated in part on other grounds by *Opati v. Republic of Sudan*, 140 S. Ct. 1601 (2020)). Plaintiffs' objections to the rulemaking record thus go to the weight, not the admissibility, of the evidence contained therein. *See Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 168 (1988).

on denial of reh'g and reh'g en banc (July 12, 2004) (First Amendment does not require government to conduct new studies or produce new evidence so long as there is a reasonable belief that the outside evidence relied on is relevant to the problem sought to be addressed by the regulation).

Plaintiffs' objections to Defendants' other evidence of steering are similarly misguided. They dispute what is obvious—that DaVita's Medicaid Opportunity program and Fresenius's incentive plans for insurance coordinators, as described in internal documents and by their own witnesses, were tools the provider plaintiffs used to steer Medicare and Medicaid eligible patients toward commercial insurance. Mot. 15-16 (citing SUF 30-36).[4] This is not the first time that Plaintiffs, in denying such conduct, have made up a "definition of 'steering'—as legal communications with ESRD patients—[that] is not . . . what a reasonable person would understand that statement to mean." *See Peace Officers' Annuity and Benefit Fund of Ga. v. DaVita Inc.*, 372 F. Supp. 3d 1139, 1154 (D. Colo. 2019). This Court should reject Plaintiffs' spin and find that Plaintiffs' "communications with patients were not solely for the purpose of education, but rather for persuasion." *See id.*

Plaintiffs also object to Defendants' references to similar cases, news articles, and investigative reports describing this industry scheme. Opp'n 9-10; *see* Mot. 16-17 (citing SUF 37-39). They argue that this evidence should be dismissed entirely, implying that it should be subject to the rigorous evidentiary standards applicable in a criminal trial. Yet those standards are not operative in this First Amendment case. *See Pena v. Lindley*, 898 F.3d 969, 979 (9th Cir. 2018) (citing *Minority Television Project*, 736 F.3d at 1199). This evidence, which documents the public's concerns about the dialysis industry's practices in the years leading up to AB 290's enactment, bolsters California's substantial interest in regulating steering, and it

[4] Former DaVita insurance specialist Laura Fiallos corroborated the existence and purpose of the "Medicaid Opportunity" scheme at a legislative hearing on AB 290, testifying that she had "watched DaVita increasingly push to have more commercially insured patients in their clinics" through this program. ECF No. 153-2, SAMF 79.

should be considered by this Court. *See Mahoney v. Sessions*, 871 F.3d 873, 882 (9th Cir. 2017) (relying in part on "the joint findings of fact and conclusions of law approved by the district judge" in another case to find a substantial governmental interest); *Fla. Bar v. Went For It*, 515 U.S. at 627 (relying in part on "newspaper editorial pages" criticizing the practice targeted by the challenged law to find that the law advanced a substantial governmental interest).[5]

While Plaintiffs and their provider friends suggest that all this smoke is just a mirage, Opp'n 9 (citing Mot. 17); *see also Fresenius v. Bonta*, No. 8:19-cv-2130-DOC-ADS, ECF No. 176 at 8-9, the only plausible explanation is the presence of an actual fire—the "real" problem of patient steering. *See Edenfield*, 507 U.S. at 771.

As described in Defendants' moving papers, steering injures patients in at least three ways: (1) by negatively impacting patients' determination of readiness for a kidney transplant, (2) by potentially exposing patients to additional costs for health care services, and (3) by putting patients at significant risk of a mid-year disruption in health care coverage. Mot. 4 (citing SUF 14); *id.* at 17-18 (citing SUF 41-43). Plaintiffs do not seriously dispute, on the merits, that steering causes these harms; they argue instead that there is "no evidence of steering" and that the report of Defendant's expert, Dr. Amy Waterman, discusses the same harms observed by the Legislature and CMS. Opp'n 11. But as shown above, Dr. Waterman's testimony is reasonably based on the factual predicate that steering is a real problem, and the fact that her findings are consistent with those in the CMS record, including the concerns raised in a comment by her colleague, Dr. Teri Browne, only strengthens

[5] That the report of California-based Congresswoman Katie Porter was issued "*after* AB 290 was enacted" is irrelevant, particularly because, as Plaintiffs admit, Opp'n 10, much of what is referenced in the report—the CMS record, securities lawsuits, and *New York Times* article, among other evidence—addresses conduct that occurred *before* AB 290's enactment. And either way, the report documents a problem that is real.

the foundation for her testimony. *See* ECF No. 161, Defs.' Opp'n to Pls.' Mot. to Exclude Expert Opinions and Testimony of Dr. Amy Waterman, at 8.

Steering also harms the public by distorting the insurance risk pool, causing health insurance premiums to rise. Mot. 18 (citing SUF 44). Plaintiffs again challenge the factual predicate that steering is real, Opp'n 11, but fail to grapple with the undisputed conclusion of all researchers and groups to examine this problem: that an increase in commercially-insured ESRD patients results in higher insurance premiums for everyone in the market. Mot. 18 (citing SUF 44).

Plaintiffs do not contest that AB 290 will directly advance these substantial governmental interests by "remov[ing] a potential conflict of interest" from staff-patient interactions and by helping "patients to make informed decisions and minimize their potential exposure to financial liabilities." Mot. 18-19 (SUF 45-46). Instead, they second-guess whether the Legislature "could have accomplished its goals through any number of less restrictive alternatives." Opp'n 12. Again, Plaintiffs misconstrue Defendants' burden. The Legislature need not achieve "a fit that is [] necessarily perfect, but reasonable." *Coyote Publ'g*, 598 F.3d at 610 (quoting *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 188 (1999)). Thus, in the face of difficult policy choices, "'[a court] must allow the government to select among reasonable alternatives in its policy decisions.'" *Pena*, 898 F.3d at 980 (quoting *Peruta v. Cty. of San Diego*, 824 F.3d 919, 944 (9th Cir. 2016) (en banc) (Graber, J., concurring)).

Here, Plaintiffs provide no explanation as to how the approaches they suggest "would serve the state's compelling interest" in addressing steering and its attendant harms "with the same level of effectiveness" as AB 290. *Victory Processing, LLC v. Fox*, 937 F.3d 1218, 1228 (9th Cir. 2019). As explained below, *post* Argument I.A.2, the steering prohibition carefully addresses the various forms of persuasion used by providers to enroll patients in commercial insurance; a narrower ban would risk allowing some of these methods to continue unabated.

And had state anti-fraud laws sufficiently deterred providers from steering patients, then regulators, lawmakers, and courts would not have taken notice of, and needed to address, this mushrooming problem. Even if more vigorous enforcement of anti-fraud laws were successful in somewhat diminishing the prevalence of steering and its impact, "[t]he First Amendment does not require that a regulatory regime single-mindedly pursue one objective to the exclusion of all others to survive the intermediate scrutiny applied to commercial speech regulations." *Coyote Publ'g*, 598 F.3d at 610. As Dr. Waterman put it, AB 290 serves unique and important purposes as part of a "larger fabric of regulatory changes occurring nationwide." SAMF 81. There is nothing constitutionally suspect about this approach.

2. AB 290's Steering Prohibition Is Not Void for Vagueness

AB 290's steering prohibition—specifically the word "advise"—is sufficiently definite to "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly." *Edge v. City of Everitt*, 929 F.3d 657, 664 (9th Cir. 2019) (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972)). Plaintiffs erroneously assert that Defendants have treated "advise" as indistinguishable from "steer." Opp'n 14. Defendants have, instead, observed that "advise" should be read in harmony with the entire provision—that taken together, "steer, direct, or advise" covers the forms of encouragement prohibited by AB 290. Mot. 19-20. When "used in combination," these terms "provide sufficient clarity." *Edge*, 929 F.3d at 665 (quoting *Gammoh v. City of La Habra*, 395 F.3d 1114, 1120 (9th Cir. 2005). Nothing more is required for the steering prohibition to defeat a vagueness challenge.[6]

Plaintiffs' citation to their preferred definition of "advise" in the *Merriam Webster* dictionary—"to give information or notice to" or to "inform"—does not

[6] Contrary to Plaintiffs' claim, Opp'n 15, representatives of the California Department of Managed Health Care and the California Department of Insurance have not taken a formal position on the meaning of "advise" because the departments they represent have not officially adopted any interpretation of that term. SAMF 78.

help their argument. Opp'n 15 (quoting *Merriam-Webster's Third New International Dictionary* 32 (2002). The more common meaning of "advise" is "to give advice to" or "counsel" (was *advised* to try a warmer climate"), to "caution" or "warn" ("*advised* him of the danger"), and to "recommend" ("*advise* going slow"). *Merriam-Webster* 32. Another definition of "advise" is "to give advice" or to "offer counsel"—for example, "an article written to inform, not to *advise*." *Id.* Given the Legislature's deliberate placement of "advise" directly after "steer" and "direct," it is evident that the term, "when read in context with the entire provision," means to recommend a particular course of action, not merely to inform a patient of their options. *Hunt v. City of Los Angeles*, 638 F.3d 703, 714 (9th Cir. 2011).

B. AB 290's Reimbursement Cap and Anti-Discrimination Provision Do Not Violate AKF's Right of Association

Like the steering prohibition, AB 290's reimbursement cap, which limits the reimbursement rate for those patients receiving third-party premium assistance, is constitutionally sound. AB 290, §§ 3(e)(1) & 5(e)(1). Plaintiffs argue that the reimbursement cap infringes on AKF's right to associate with dialysis providers by "imped[ing]" providers from donating to AKF. Opp'n 13. As explained in Defendants' moving papers, Mot. 20, Plaintiffs' claim is foreclosed by *Interpipe Contracting, Inc. v. Becerra*, 898 F.3d 879 (9th Cir. 2018). There, the Ninth Circuit observed that the Supreme Court has never "establish[ed] an independent constitutional right of recipients"—such as AKF—"to 'amass' funds." *Id.* at 892. Plaintiffs cannot meaningfully distinguish *Interpipe*, and thus "ignore[] this bedrock principle." *Id.* And to the extent Plaintiffs' argument is an attempt to "advance [the providers'] purported First Amendment interests," rather than those of AKF, it is similarly misplaced. *Id.* at 893 n.11.

Plaintiffs also claim that AKF's right of association is infringed by AB 290's requirement that a financially interested entity "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). AKF misconstrues this provision, arguing that it "would impermissibly require AKF to abandon its central mission" by interfering with AKF's ability to provide financial assistance to an ESRD patient for a "procedure" (e.g., dialysis) or "transplant." Opp'n 13-14. Hyperbole aside, the provision merely requires entities that offer premium assistance, such as AKF, not to discriminate against an ESRD patient who chooses the best course of treatment—even if that treatment is not dialysis. Thus, the provision has no effect on Plaintiffs' associational rights.

C. AB 290's Disclosure Provisions Do Not Unlawfully Compel Speech

AB 290 also includes a number of disclosure provisions that assist ESRD patients in making informed decisions about financing for their care. Mot. 21 (citing SUF 60). AB 290 requires a financially interested entity like AKF to inform HIPP recipients of "all available health coverage options, including but not limited to, Medicare, Medicaid, individual market plans, and employer plans," AB 290, §§ 3(b)(3) & 5(b)(3), and it prohibits a financially interested entity from making a third-party premium payment unless it provides an annual statement of compliance with the law and discloses to a health insurer the name of each insured patient who will receive premium assistance, *id.*, § 3(c). While Plaintiffs mistakenly apply the First Amendment tests for speech restrictions to these provisions, Opp'n 3-4 (conflating the standards for AB 290's steering prohibition and the disclosure provisions), these are the sort of disclosure requirements long held to be permissible under *Zauderer* and its progeny. *See, e.g.*, Mot. 20-23.

In *Zauderer*, the Supreme Court held that requirements to disclose "factual and uncontroversial information" to a consumer do not implicate First Amendment concerns as long as they "are reasonably related to the State's interest in preventing deception of consumers." *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985). Consistent with *Zauderer*, the Court has

repeatedly acknowledged the government's authority to require disclosures of factual information that promote transparency. *See* Mot. 21-22 (citing *Riley*, 487 U.S. at 799 n.11 & 800, among other cases). The Court's recent decision in *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) [*NIFLA*] did not undermine this precedent; it merely affirmed that the compelled disclosure must involve "purely factual and uncontroversial" information and clarified that the government's interest in the disclosure must be "substantial." *Id.* at 2372, 2375. The Court further required that the disclosure "relate to the product or service that is provided by an entity subject to the requirement." *CTIA—The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 845 (9th Cir. 2019) (citing *NIFLA*, 138 S. Ct. at 2372).

Here, the disclosure provisions require a financially interested entity, specifically AKF, to make truthful and neutral disclosures about a patient's health coverage options and receipt of premium assistance. AB 290, §§ 3(b)(3) & 5(b)(3); *id.* § 3(c). These disclosures do not "t[ake] sides in a heated political controversy," and they relate directly to the HIPP assistance that AKF provides patients to cover their insurance premiums. *CTIA*, 928 F.3d at 845.

With little explanation, Plaintiffs contend otherwise. Opp'n 7 (citing *NIFLA*). But *NIFLA* "plainly contemplates applying *Zauderer* to 'purely factual and uncontroversial disclosures *about commercial products*,'" and AB 290's disclosure provisions "fall[] squarely within this category." *CTIA*, 928 F.3d at 848 (quoting *NIFLA*, 138 S. Ct. at 2376, and adding emphasis). Given that the disclosure provisions are reasonably related to California's substantial interest in ensuring both that patients are informed of their coverage options and that the law is effectively implemented, Mot. 22, they permissibly regulate commercial speech.[7]

[7] Plaintiffs also cite *Americans for Prosperity Foundation v. Bonta*, 141 S. Ct. 2373, 2382 (2021), for the proposition that "compelled disclosure of affiliation with groups engaged in advocacy" restrains freedom of association. Opp'n 14. Yet they fail to explain how, or for whom, disclosing the names of HIPP patients to

D. AB 290's Provision Allowing AKF to Request an Updated Advisory Opinion Does Not Abridge AKF's Right to Petition

Plaintiffs argue that Section 7 of AB 290, which delays the law's effective date if AKF seeks a new advisory opinion, abridges AKF's right to petition. Opp'n 15. But they rely on cases that are inapposite. *See, e.g.*, *Agency for Int'l Dev. v. Alliance for Open Soc'y*, 570 U.S. 205, 221 (2013) (holding, in a Spending Clause case, that a policy compelling as a condition of federal funding the affirmation of a certain belief violated the First Amendment); *Garrity v. New Jersey*, 385 U.S. 493 (1967) (holding that police officers under investigation for obstructing justice who were forced to choose between incriminating themselves or forfeiting their jobs suffered a violation of their Fourteenth Amendment rights). Section 7 merely provides AKF the *option* to request an updated advisory opinion; the choice is entirely up to AKF, which faces no penalty either way. Plaintiffs fail to explain how a provision that does not compel them to do anything at all could violate their right to petition, or any First Amendment right.

II. AB 290 IS NOT PREEMPTED BY FEDERAL LAW

Plaintiffs also allege that AB 290 is preempted by federal law. Having abandoned their original position that AB 290 is preempted by Advisory Opinion 97-1 alone, *see* ECF No. 1, Compl. ¶ 85, Plaintiffs now assert that AB 290 is preempted by the federal Beneficiary Inducement Statute, 42 U.S.C. §§ 1320a-7a, *et seq*.—as interpreted by Advisory Opinion 97-1.[8] Plaintiffs separately claim that AB 290 presents an obstacle conflict to the Medicare Secondary Payer Act (MSPA). Neither claim has merit.

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health insurers would have a "chilling effect." *Ams. for Prosperity*, 141 S. Ct. at 2382. Indeed, Plaintiffs already effectively disclose such information when they convey grant payments to insurers. SAMF 85 (AKF patient handbook states that "[w]hen possible, AKF will send grant payments directly to the insurance company").

[8] This Court should reject Plaintiffs' attempt to oppose summary judgment on grounds not raised in their complaint. *Wasco Prods., Inc. v. Southwall Techs., Inc.*, 435 F.3d 989, 991 (9th Cir. 2006).

A. Neither the Beneficiary Inducement Statute Nor Advisory Opinion 97-1 Preempts AB 290

Plaintiffs argue that the Beneficiary Inducement Statute preempts AB 290 because, in their view, AKF would fall outside of Advisory Opinion 97-1's safe harbor, and would risk violating the Beneficiary Inducement Statute, by complying with AB 290. Opp'n 19. Plaintiffs' argument, which this Court need not consider because it is untethered to their complaint, fails for two additional reasons. AKF can comply with both AB 290 and the Beneficiary Inducement Statute because (1) no provision in the Beneficiary Inducement Statute requires AKF's Health Insurance Premium Program (HIPP) to operate in any particular manner, or even at all, and (2) Advisory Opinion cannot create preemptive effect and does not conflict with AB 290.

1. The Beneficiary Inducement Statute Does Not Require AKF to Operate HIPP at All, or in Any Particular Form

The Beneficiary Inducement Statute, which Plaintiffs claim is in conflict with AB 290, prohibits medical providers from providing certain remuneration to federal health care program beneficiaries. Opp'n 16 (citing 42 U.S.C. § 1320a-7a(a)(5)). The Beneficiary Inducement Statute does not require HIPP to exist in any particular form—or to exist at all—and thus, it does not preempt AB 290.

The drug-labeling cases cited by Plaintiffs provide an instructive contrast to this case because in those cases, impossibility preemption resulted from a federal *requirement* that directly conflicted with state law. In *Merck Sharp & Dohme Corp. v. Albrecht*, the Supreme Court held that to establish preemption of a state law drug labeling claim, there must be "clear evidence" that the Food and Drug Administration—which was required to approve the drug label in question—would not approve the drug label as compelled by state law. 139 S. Ct. 1668, 1676-80 (2019). Similarly, in *PLIVA, Inc. v. Mensing*, the Court found impossibility preemption where federal laws required generic drug manufacturers to conform

their labels with those of the name-brand drug, while state regulations imposed additional requirements on generic labeling. 564 U.S. 604, 618 (2011); *see also Mutual Pharm. Co. Inc. v. Bartlett*, 570 U.S. 472, 480 (2013) (same). In each of these cases, it was clear that federal law placed affirmative requirements on drug manufacturers to label their products in certain ways, and that state laws imposing conflicting requirements should be preempted. Here, in contrast, there is no federal requirement for AKF to run a charitable program like HIPP, and thus no requirement that would make it impossible for AKF to comply with both federal law and AB 290. *Merck*, 139 S. Ct. at 1678 (refusing to find clear evidence of impossibility "where the laws of one sovereign permit an activity that the laws of the other sovereign restrict or even prohibit").

Section 7 of AB 290 does not, as Plaintiffs claim, Opp'n 19, 24, "recognize[]" a conflict by allowing AKF to seek a new advisory opinion. Section 7 was an attempt to address concerns raised by AKF in the legislative process. The provision's mere existence does not suggest that compliance with federal law is impossible.

Plaintiffs' related argument that AKF's choice to cease providing services in California is akin to the "stop selling" rationale that the Supreme Court rejected in *PLIVA* and *Mutual Pharmacy*, Opp'n 19-21, also fails. Those cases involved product liability claims brought by plaintiffs based on state law standards that deviated from the FDA's expansive regulatory scheme for drug labeling. *PLIVA*, 564 U.S. at 618; *Mutual Pharm*, 570 U.S. at 488. Here, the Beneficiary Inducement Statute does not institute a similar regulatory scheme that dictates how AKF must operate HIPP—and that would conflict with AB 290's requirements.

Finally, Plaintiffs misconstrue the opinion of the California Legislative Counsel, claiming that it "acknowledged" a conflict between AB 290 and Advisory Opinion 97-1. Opp'n 23. Legislative Counsel opined that, based on the available facts, AKF "would remain in compliance with the arrangement approved in

Advisory Opinion 97-1" if AB 290 were enacted and AKF "complies with the changes enacted by that bill." SUF 66. Just as it did in a legislative hearing on AB 290, ECF No. 153-3, RJN in Support of Defs.' Opp'n, Ex. 2, AKF refuses to accept this conclusion.

2. Advisory Opinion 97-1 Cannot Create Preemptive Effect and Does Not Conflict with AB 290

Advisory Opinion 97-1 is not the result of notice-and-comment rulemaking, and thus, lacks the force of federal law. Mot. 9-10. Plaintiffs argue that the Opinion effectively amends the Beneficiary Inducement Statute to create preemptive effect. Opp'n 21. This implausible theory is unsupported by any case law.

The Supreme Court rejected a similar argument in *Wyeth v. Levine*, 555 U.S. 555 (2009). There, the Court held that an FDA opinion expressed in the preamble to a regulation did not have preemptive effect. *Id.* at 580. The Court contrasted the FDA opinion with the formal rulemaking in *Geier v. American Honda Motor Co.*, 529 U.S. 861, which preempted state law. *Wyeth*, 555 U.S. at 580. Plaintiffs resist the comparison, Opp'n 21 n.6, but cite no contrary authority.[9]

In any event, the express terms of Advisory Opinion 97-1 are limited to AKF's payment of Medicare Part B and Medigap premiums. Mot. 10 (citing SUF 65). The Opinion does not regulate reimbursement of premiums for Qualified Health Care Programs, Covered California, employer group plans, and private insurance, all which are not considered "federal health care programs" for the purposes of the Opinion. SUF 72.[10]

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[9] Nor do Plaintiffs have an answer to Defendants' observation that interpretations in opinion letters lack the force of law. Mot. 9-10 (citing *Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000), among other cases). Plaintiffs instead mistakenly rely on *Wyeth*, implicitly comparing Advisory Opinion 97-1 to a regulation issued after notice and comment.

[10] Indeed, at the time it was issued, the Opinion could not have addressed premiums for certain types of coverage, such as Qualified Health Care Programs, that did not exist. *See* ECF No. 128-4, Ex. 6, ¶ 34.

Plaintiffs nonetheless claim that Advisory Opinion 97-1 contemplates HIPP assistance for the payment of premiums for other types of insurance. Opp'n 22. Not so. Plaintiffs' argument misreads the Opinion, which only expressly covers payments for Medicare Part B and Medigap premiums. SUF 72. This is evident from even a cursory reading of the Opinion. *See, e.g.*, ECF No. 128-3 (Ex. 1a) at 18 (stating that "once in possession of *Medicare Part B or Medigap coverage*, a beneficiary will be able to select any provider of his or her choice") (emphasis added). Plaintiffs provide no authority that would expand Advisory Opinion 97-1's safe harbor to cover the payment of premiums for private insurance.[11]

Even if Advisory Opinion 97-1 could be construed to apply to such premium payments, it still would not conflict with AB 290. Mot. 11-12. Plaintiffs assert that, if implemented, AB 290's disclosure and reimbursement cap provisions would cause patients to learn that their providers are donors to AKF, which they assert is in conflict with the Opinion. Opp'n 18-19. As Defendants' expert, Randolph Pate, observed—in testimony essentially unchallenged by Plaintiffs—this argument necessarily assumes that patients will connect a lower reimbursement rate appearing on their billing statements with donations to AKF made by their provider. SUF 74. Even if this speculative chain of events were to come to fruition, a HIPP recipient would already have chosen a provider without undue influence, as required by Advisory Opinion 97-1. SAMF 87. In short, Plaintiffs have not shown that "compliance with both federal and state regulations is a physical impossibility." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (internal quotation marks and citation omitted).

B. The Medicare Secondary Payer Act Does Not Preempt AB 290

Plaintiffs' contention that there is an obstacle conflict between AB 290 and the MSPA also fails. Mot. 12-13. Plaintiffs first walk away from their argument that

[11] Plaintiffs note that Congress has amended the advisory opinion process since the time that Advisory Opinion 97-1 was issued, Opp'n 17 n.5, but again, cite no authority that would expand the Opinion's scope.

AB 290 is preempted by the MSPA's "take into account" provision. Opp'n 25. They then attempt to save their argument that AB 290 is preempted by the MSPA's "non-differentiation" provision by contending that the Ninth Circuit's recent decision in *DaVita Inc. v. Amy's Kitchen, Inc.*, "does not speak to whether AB 290 is preempted by [the non-differentiation provision] of the MSPA." Opp'n 25 (citing *Amy's Kitchen*, 981 F.3d at 667). That is wrong. *Amy's Kitchen* squarely addresses the non-differentiation argument brought by DaVita in that case, and the Court's reasoning is equally applicable here.

In *Amy's Kitchen*, an employee retirement plan was modified to cap the dialysis reimbursement rate for employees, and DaVita alleged that the plan's provisions were preempted by the MPSA. *Id.* at 667. The Ninth Circuit held that neither the MPSA's "take into account" provision, *id.* at 669-70, nor the MPSA's "non-differentiation" provision, *id*. at 670-78, preempted the plan's provisions.

The same result is warranted here. Plaintiffs have not shown that AB 290 would require health plans to provide "*different benefits for persons with ESRD*." *Id.* at 674-75. No provision in AB 290 requires differentiation between patients based on their ESRD status; a plan can "provide[] identical benefits to someone with ESRD as to someone without ESRD" and thus "not 'differentiate' between those two classes." *Id.* at 678. This binding circuit precedent precludes Plaintiffs' obstacle preemption claim.

CONCLUSION

This Court should grant Defendants' motion for summary judgment.

Dated: April 18, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

Case Name: ***Jane Doe, et al v. Rob Bonta, et al.***

Case No.: **8:19-cv-02105-DOC-ADS**

I hereby certify that on April 18, 2022, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

1. **REPLY IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**
2. **[REDACTED] DEFENDANTS' RESPONSE TO PLAINTIFFS' OBJECTIONS TO EVIDENCE OFFERED IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**
3. **DECLARATION OF R. MATTHEW WISE IN SUPPORT OF REPLY [with EXHIBITS 26-34]**
4. **DECLARATION OF RANDOLPH WAYNE PATE**
5. **DECLARATION OF DR. AMY WATERMAN**
6. **DECLARATION OF JOHN BERTKO**

I certify that **all** participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

I declare under penalty of perjury under the laws of the State of California and the United States of America the foregoing is true and correct.

Executed on April 18, 2022, at San Francisco, California.

Vanessa Jordan	*Vanessa Jordan*
Declarant	Signature