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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JANE DOE, *et al.*,

Plaintiffs,

v.

ROB BONTA, in his Official Capacity as Attorney General of California, *et al.*,

Defendants.

Case No. 8:19-cv-2105-DOC(ADSx)

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE THE TESTIMONY OF EXPERT WITNESS LAURENCE J. FREEDMAN, ESQ.

Date: May 2, 2022
Time: 8:30 AM
Place: Courtroom 9D

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I. INTRODUCTION

The State identifies no valid basis for excluding Mr. Freedman from offering his expert opinions on the federal Beneficiary Inducement Statute and Advisory Opinion 97-1 ("AO 97-1") issued by the Office of Inspector General ("OIG"). The Court is entitled to consider Mr. Freedman's testimony in considering AO 97-1's safe harbor and whether AB 290 subjects AKF to risk of enforcement under the Beneficiary Inducement Statute by the U.S. Department of Justice ("DOJ").

Mr. Freedman is qualified to testify about these issues based on his 13-year service as an attorney at DOJ, including seven years as an Assistant Director of the Civil Fraud Division, over which time OIG consulted with DOJ to issue approximately 121 advisory opinions. Contrary to the State's assertion, Mr. Freedman's opinions are formed from reliable documents, data, and analysis. His opinions concerning HIPP are also directly relevant to whether AB 290 creates substantial risk and impediment to AKF's administration of HIPP in California.

The State is wrong that the "entirety" of Mr. Freedman's testimony is about an "ultimate legal issue." To the contrary, after describing AB 290's requirements and AO 97-1's safe harbor, Mr. Freedman explains why AB 290's requirements would require AKF to deviate from the requirements underlying AO 97-1's safe harbor. He likewise will testify about why that state of affairs would expose AKF and HIPP to significant risk unless AKF exits California. Such testimony is both proper and likely to prove helpful to the Court in considering the issues at hand in this case. Accordingly, the State's Motion should be denied.[1]

II. FACTUAL BACKGROUND

A. Mr. Freedman's Background and Experience

Laurence J. Freedman has decades of experience with the federal Beneficiary

[1] The Court need not rule on the State's Motion in order to grant Plaintiffs' motion for summary judgment. Plaintiffs rely on Freedman in only one paragraph of their Statement of Undisputed Facts. *See* Dkt. 132-1 ¶ 97.

Inducement Statute, health care providers, and health care policy more broadly. Mr. Freedman worked in the Fraud Section of DOJ's civil division from 1991 until 2004, including as an Assistant Director from 1997 to 2004. Freedman Rep. ¶ 4[2]; Leland Decl. Exh. 1, at 11 (Freedman Depo. at 35:11–16). In that role, Mr. Freedman oversaw investigations of health care providers and assessed providers' compliance with federal laws, including the Beneficiary Inducement Statute. Freedman Rep. ¶¶ 5, 8–9. Mr. Freedman was also responsible for the Fraud Section's relationship with the OIG in the U.S. Department of Health and Human Services ("HHS"). *Id.* ¶ 6. During Mr. Freedman's tenure at the Fraud Section, the OIG issued approximately 121 advisory opinions, including AO 97-1. *Id.* ¶ 7.

At the Fraud Section, Mr. Freedman assessed whether health care providers complied with the Beneficiary Inducement Statute or operated within safe harbors created by OIG advisory opinions. *Id.* ¶ 9. The Fraud Section considered such safe harbors to be "bar[s] to enforcement" against those providers. *Id.*

Mr. Freedman is currently a Member in the Health Law Section of Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C. *Id.* ¶ 10. Among other healthcare issues, Mr. Freedman focuses on compliance with the Beneficiary Inducement Statute and related OIG advisory opinions. *Id.* ¶¶ 11–12. Mr. Freedman also writes and speaks regarding those issues. *Id.* ¶ 12.

B. Mr. Freedman's Expert Testimony

Mr. Freedman's expert testimony has two main components. *See* Freedman Rep. ¶¶ 18–25; Leland Decl. Exh. 1, at 21–22 (Freedman Depo. at 63:04–64:01). *First*, Mr. Freedman draws on his experience at DOJ and in the private sector to explain the advisory opinion process, including HHS's interactions with DOJ and DOJ's oversight and enforcement related to advisory opinions. Freedman Rep. ¶¶ 18–19; Leland Decl. Exh. 1, at 21–22 (Freedman Depo. at 63:13–21; 64:06–09). *Second*, Mr. Freedman

[2] Freedman's expert report and the appendices thereto are filed at Dkt. 142-1, at 5–60.

draws on that same experience to explain why AB 290's requirements would, as a factual matter, force AKF to take steps inconsistent with the certifications it made to the OIG when requesting AO 97-1. In addition, he explains the serious risks to AKF that would follow if it was forced to operate outside the safe harbor. *See* Freedman Rep. ¶¶ 20–25; Leland Decl. Exh. 1, at 21–22 (Freedman Depo. at 63:04–12, 64:02–05).

The Advisory Opinion Process. Mr. Freedman explains the specialized framework of the federal Beneficiary Inducement Statute, HHS OIG advisory opinions, and DOJ's enforcement procedure in circumstances where parties operate outside of Advisory Opinion certifications. To set the stage, Mr. Freedman explains that section 231(h) of the Health Insurance and Portability and Accountability Act of 1996 ("HIPAA") created a new statutory prohibition on providing inducements to beneficiaries enrolled in certain health care programs (the "Beneficiary Inducement Statute"). *See* Freedman Rep. ¶¶ 36–38. Mr. Freedman goes on to explain the "three safety valves" within this framework that "ensure that health care providers could engage in conduct beneficial to patients" without risking liability. *Id.* ¶ 39. OIG's advisory opinion process is one such "safety valve[]." *Id.*; *see also id.* ¶¶ 45, 51–53.

Mr. Freedman explains that the "advisory opinion process" allows individuals and entities "to seek guidance from the OIG" regarding (1) "whether the [B]eneficiary [I]nducement [S]tatute . . . applies to the requestor's specific proposed arrangement," and (2) whether the arrangement "poses a low level or risk and has adequate safeguards to avoid inducement or kickback issues[.]" *Id.* ¶ 18; *see also id.* ¶ 52. Mr. Freedman highlights that "any advisory opinion is explicitly limited to the requestor(s) and the specific conduct disclosed to the OIG" and that an advisory opinion does not bind any agency besides HHS. *Id.* ¶ 48; *see also id.* ¶ 56. Mr. Freedman clarifies DOJ's and OIG's understanding that "OIG has no authority to advise as to any state law[.]" *Id.* ¶ 49. And Mr. Freedman explains that OIG considers whether "the proposed conduct will benefit patients" when evaluating requests for advisory opinions. *Id.* ¶ 45.

Mr. Freedman next details the "rigorous requirements for seeking and obtaining

a formal and valid advisory opinion." *Id.* ¶ 54. "A requestor must certify that it is operating the program at issue or intends to do so[.]" *Id.* A requestor must provide a "complete and specific description of all relevant information" that bears on the arrangement and on the circumstances of the conduct. *Id.* And a requestor must provide "complete copies of all operative documents" and other materials. *Id.* OIG relies on these materials, along with the requestor's description of the material facts, to issue advisory opinions. *Id.* ¶ 55. Mr. Freedman also explains that OIG issues advisory opinions "in consultation" with DOJ. *Id.* ¶¶ 57–61.

AB 290 Removes AKF from Advisory Opinion 97-1's Safe Harbor. Mr. Freedman opines, based on his experience at DOJ, that the requirements of AB 290 will take AKF out of AO 97-1's safe harbor and subject AKF to a "substantial risk" of facing enforcement from federal agencies. *Id.* ¶¶ 92–93. Mr. Freedman first explains the scope and content of AO 97-1. *See id.* ¶¶ 62–69. Importantly, he states that the OIG has *never* taken steps to rescind or modify AO 97-1. *Id.* ¶ 72; *see also id.* ¶ 70 (explaining OIG has rescinded or modified 14 of the 32 advisory opinions on proposed patient assistance programs it has issued). Drawing on his expertise, Mr. Freedman explains how AB 290 will remove AKF from AO 97-1's safe harbor:

- Section 3(c)(2) of AB 290 compels AKF to disclose the identities of HIPP beneficiaries to private insurers, which conflicts with AO 97-1's requirement that patients not be informed whether their dialysis provider donates to AKF. *Id.* ¶ 74.
- Section 3(e)(1) reduces reimbursement payments to dialysis providers that donate to AKF, and likely reduces payments from patients to their providers, thus creating a financial incentive for patients to seek treatment from certain providers. *Id.* ¶¶ 75–76. This conflicts with AO 97-1's foundational premise that patient assistance would not induce beneficiaries to select particular providers. *Id.* ¶ 77; *see also id.* ¶ 78.
- Sections 3(d)(1) and 5(d)(1), the "grandfathering" clauses, would cause patients to receive different financial benefits depending on when they sign up for

insurance. This conflicts with AO 97-1 requirement that all patients be treated equally. *Id.* ¶¶ 80–81; *see also* Leland Decl. Exh. 1, at 31–36 (Freedman Depo. at 113:12–117:07).

- Sections 3(b)(2) and 5(b)(2) require AKF to "agree not to condition financial assistance on eligibility for, or receipt of, any surgery, transplant, procedure, drug, or device." Freedman Rep. ¶ 82. This conflicts with HIPP as it existed when OIG issued AO 97-1. *Id.* ¶ 83.
- Additionally, AB 290 would shift some coverage costs from private insurers to Medicare—a circumstance OIG did not consider when it issued AO 97-1. *Id.* ¶ 84.

Mr. Freedman further explains that section 7, which allows AKF or dialysis providers to seek a new advisory opinion, does not alleviate the above conflicts. *Id.* ¶¶ 86–91. Specifically, drawing on his experience, Mr. Freedman explains that OIG has "no authority, no history, and no expertise" reconciling or construing state law. *Id.* ¶ 88. More fundamentally, an entity cannot request an advisory opinion unless it can certify that it will pursue the program authorized by the OIG, which AKF cannot do. *Id.* ¶ 89; *see also* Leland Decl. Exh. 1, at 36–38 (Freedman Depo. at 117:17–119:19, 120:07–25) (explaining risks of requesting new advisory opinion).

Mr. Freedman concludes by opining that, if AKF leaves the safe harbor created by AO 97-1, it may face "substantial risk" and "uncertainty" from an enforcement perspective. Freedman Rep. ¶ 93.

III. LEGAL STANDARD

"A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts

of the case." Fed. R. Evid. 702. Further, "[a]n [expert] opinion is not objectionable just because it embraces an ultimate issue." Fed. R. Evid. 704.

IV. ARGUMENT

A. Mr. Freedman Is Qualified to Testify About the Interplay Among AKF, HIPP, and AO 97-1.

Mr. Freedman is highly qualified to testify in this case based on his "knowledge," "experience," and "training." Fed. R. Evid. 702. Mr. Freedman has 13 years of experience in the Fraud Division of DOJ, including seven years as Assistant Director. Freedman Rep. ¶¶ 4. At DOJ, Mr. Freedman oversaw countless investigations of health care providers (including dialysis providers) in connection with fraud and abuse matters. Freedman Rep. ¶¶ 4–5; *see also* Leland Decl. Exh. 1, at 14 (Freedman Depo. at 40:23–24) ("[E]verything I did involved health care."). As Assistant Director, Mr. Freedman oversaw DOJ's relationship with OIG over a period where it issued 121 advisory opinions. Freedman Rep. ¶¶ 6–7. In this capacity, Mr. Freedman assessed the applicability of safe harbors in the OIG's advisory opinions. *Id.* ¶¶ 8–9. And Mr. Freedman performs related work to this day. *Id.* ¶¶ 10–12; *see also* Leland Decl. Exh. 1, at 38–39 (Freedman Depo. at 119:20–120:06) (explaining Mr. Freedman has requested "half a dozen" advisory opinions). Moreover, Mr. Freedman is familiar with the DOJ's "vigorous[] enforce[ment]" of the Beneficiary Inducement Statute, *id.* ¶ 50, so he is qualified to speak to the risk AKF will face if it leaves AO 97-1's safe harbor. At bottom, Mr. Freedman's years of experience at DOJ and intimate familiarity with the inner workings of the advisory opinion process and DOJ's enforcement of the Beneficiary Inducement Statute make him an appropriate expert to opine on these matters.

The State argues that Mr. Freedman's experience is not "specific" enough to support his conclusions. *See* Mot. 4, 6, 9–10. The State first objects that Mr. Freedman had no direct involvement with Advisory Opinion 97-1. Mot. 6. That argument is easily cast aside. As shown above, Mr. Freedman has years of pertinent experience with the

advisory opinion process, health care providers' compliance with the Beneficiary Inducement Statute, and DOJ's enforcement in relation to those issues. *See supra* pp. 1–2. The State similarly objects that Mr. Freedman lacks the experience to testify about the "risks" to AKF resulting from AB 290 going into effect. Mot. 9. But Mr. Freedman is qualified to testify about such "risks" because he has specific experience related to the risks similarly situated entities have faced—Mr. Freedman supervised "hundreds of allegations, investigations, and litigations" against entities that left the safe harbors of the Beneficiary Inducement Statute or an OIG advisory opinion. Freedman Rep. ¶¶ 5, 8–9, 13. As a result of this experience, Mr. Freedman knows *exactly* the risks AKF faces if it leaves AO 97-1's safe harbor.

B. Mr. Freedman's Testimony Is Reliable.

The State argues that portions of Mr. Freedman's testimony are unreliable. *See* Mot. 7–10. Its arguments are meritless. Mr. Freedman's proffered testimony satisfies the requirements of Rule 702.

1. Mr. Freedman Satisfies the Requirements of Rule 702.

An expert's testimony must be "based on sufficient facts or data," "the product of reliable principles and methods," and the "reliabl[e] appli[cation] [of] the principles and methods to the facts of the case." Fed. R. Evid. 702(b)–(d). Moreover, an experiential expert "must explain how that experience leads to the conclusions reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig.*, 978 F. Supp. 2d 1053, 1067 (C.D. Cal. 2013) (emphasis removed) (quoting Fed. R. Evid. 702, 2000 advisory committee note). Mr. Freedman's proffered testimony readily clears these hurdles.

Mr. Freedman reviewed "sufficient facts [and] data" in reaching his expert opinions. Fed. R. Evid. 702(b). In addition to drawing on his decades of experience working with DOJ and personal knowledge of the advisory opinion process, Mr. Freedman reviewed AO 97-1, AB 290, the California Legislative Counsel Bureau's

analysis of the two, other advisory opinions, factual declarations, and pleadings in this case and the related *Fresenius* case (among other things). *See* Freedman Rep. App'x D. Mr. Freedman's review is more than "sufficient" to opine on the advisory opinion process and the interaction between AO 97-1 and AB 290. Further, Mr. Freedman reliably applied his decades of experience to arrive at his conclusions. *E.g.*, Freedman Rep. ¶¶ 4–12, 17, 22, 92 (describing experience and linking conclusions to experience); Leland Decl. Exh. 1, at 9–10 (Freedman Depo. at 33:12–34:08) (explaining how experience with explanations of benefits supports his conclusions); *id.* at 112:11–19 (explaining how OIG analyses support his conclusion about patient incentives); *see also id.* at 48:22–49:19 (describing methodology). Mr. Freedman's analyses of the advisory opinion process, the AO 97-1 request, the ways in which AB 290 would take AKF outside of AO 97-1's safe harbor, and the responses by DOJ to modifications to the program are all reliable.

2. The State's Arguments to the Contrary Fail.

The State raises a grab-bag of "methodological" arguments. *See* Mot. 7–10. All the State's arguments apply to a narrow subset of Mr. Freedman's opinions. Each argument is based on a misapprehension of Mr. Freedman's testimony, a misunderstanding of the law, or both.

The State first asserts that Mr. Freedman cannot permissibly opine regarding how third parties will "react" to the enactment of AB 290. Mot. 7. Specifically, the State claims that Mr. Freedman delves into "the subjective state of mind" and the "probable behavior" of other parties. *Id.* (citing Freedman Rep. ¶¶ 23, 78). But Mr. Freedman's analysis is not premised on guesswork regarding anyone's state of mind; rather, it is based on the text of AO 97-1, AB 290, and regulatory and sub-regulatory materials, as well as his considerable experience as a DOJ official and defense attorney investigating and defending health care fraud allegations. Far from purporting to read minds, Mr. Freedman testified that "20-plus years of OIG analysis" explains that "patients . . . make choices for health care based on financial obligation[.]" Leland Decl. Exh. 1, at 31–32

(Freedman Depo. at 112:11–113:04). The Beneficiary Inducement Statute and AO 97-1 also operate under this same understanding. *See* 42 U.S.C. § 1320a-7a(a)(5); Dkt. 29-2 (RJN Exh. 2, at 23–24). Mr. Freedman need not delve into anyone's "subjective state of mind" to opine from experience about on how federal authorities react to parties that fail to comply with a safe harbor created by an advisory opinion. Mot. 7; Freedman Rep. ¶ 23.

The State next argues that Mr. Freedman "is in no better position than the Court" to determine how other parties will react to the enactment of AB 290. Mot. 8. This argument fails at the outset because—as a result of his substantial government experience—Mr. Freedman *does* possess expertise relevant to assessing compliance with AO 97-1 and the investigations and enforcement actions to which AKF could be exposed if it deviated from that safe harbor. *See supra* pp. 1–2. The State's scattershot legal authority does not help its case. In *Beech Aircraft Corp. v. United States*, the court affirmed the exclusion of two experts who interpreted the content of reconstructed audio tapes, holding that "hearing is within the ability and experience of the trier of fact." 51 F.3d 834, 841–42 (9th Cir. 1995) (per curiam). Mr. Freedman's observations about the consequences AKF may experience if AB 290 is enacted are not comparable to basic senses like hearing or taste. *United States v. Finley* is even less on-point, as Mr. Freedman does not testify as to any personal involvement in the issuance of AO 97-1 or his personal experience regarding the application of AO 97-1 to AKF or HIPP. Therefore, he is not "reciting . . . allegation[s]" of a witness in the guise of an expert opinion. 301 F.3d 1000, 1009 (9th Cir. 2002). And *Wendler & Ezra, P.C. v. American International Group, Inc.*—a case in which the Seventh Circuit excluded an expert with "specialized technical knowledge" because his affidavit "d[id] not say what software he used, what data he fed it, what results it produced, and how alternative explanations . . . were ruled out," 521 F.3d 790, 791 (7th Cir. 2008) (per curiam)—does not stand for the cited proposition at all, *see* Mot. 8 (arguing "because Mr. Freedman possesses no special expertise, he is in no better position than the Court" to make certain determinations).

The State's shaky arguments that Mr. Freedman's testimony lacks "intellectual rigor" collapse under scrutiny. Mot. 8; *see also id.* 8–10. The State appears to argue that Freeman's testimony is not based on sufficient facts or data. *See* Mot. 8–9; Fed. R. Evid. 702(b). But, as shown, Mr. Freedman's opinions are based on his review of an identified body of documents, and he has applied deep experience to explain how federal agencies operate in this area of enforcement and the risk of a federal fraud investigation. Moreover, the State makes no effort to explain how conducting "interview[s]" or reviewing "scientific literature" would have altered Mr. Freedman's opinions. *See S. Yuba River Citizens League v. Nat'l Marine Fisheries Serv.*, 257 F.R.D. 607, 616 (E.D. Cal. 2009) ("The fact that additional information was available does not itself demonstrate that the information considered was '[in]sufficient' absent a showing that the considered information cannot support the opinion or that other information would have raised serious issues." (alteration in original) (citation omitted)). Even if the State could make such a showing, challenges regarding "materials that [Mr. Freedman] did not review go to weight, not admissibility." *In re Toyota Motor Corp.*, 978 F. Supp. 2d at 1073.

The State next faults Mr. Freedman for relying on the declaration of LaVarne Burton, AKF's CEO. Mot. 9. This argument fails as well. Rule 703 allows an expert to rely on facts and data that "experts in the particular field would reasonably rely on[.]" Here, Mr. Freedman relied on the same type of information OIG relied on to issue AO 97-1. *See* Dkt. 29-2 (RJN Exh. 2, at 19) ("In issuing this opinion, we have relied solely on the facts and information you presented to us."); Leland Decl. Exh. 1, at 27–28 (Freedman Depo. at 70:23–71:02) (acknowledging "OIG relies on the requestor's description of the material facts"); *see also id.* at 66:13–14 (explaining Mr. Freedman saw no facts "to the contrary" in the record).[3]

[3] None of the State's cases are on point. In *United States v. Jawara*, the Ninth Circuit found that the district court's denial of a pre-trial *Daubert* hearing without making an explicit finding that the expert's testimony was reliable was harmless error. 474 F.3d

Finally, the State argues that Mr. Freedman's "nonspecific assertions of expertise" are a methodological failing. Mot. 9–10. As shown, Mr. Freedman has the requisite experience. *See supra* pp. 6–7. Par for the course, the State's cases are not on point. The court in *Toyota Motor Corp.* excluded the testimony of an *attorney-consultant* because he failed to explain how his experience supported his conclusion that "[Office of Defect Investigations] *engineers* and *scientists* are biased" toward certain conclusions. 978 F. Supp. 2d at 1068 (emphasis added). In *Zenith Electronics Corp. v. WH-TV Broadcasting Corp.*, the court excluded the testimony of an expert who used "intuition" rather than "the empirical toolkit of the social sciences" to calculate damages. 395 F.3d 416, 419 (7th Cir. 2005). Here, by contrast, Mr. Freedman's experience with healthcare fraud and the OIG actually relates to his opinions, and Mr. Freedman explains as much. *See supra* pp. 6–7.

C. Mr. Freedman's Testimony Is Relevant.

Expert testimony is relevant if it "will assist the trier of fact to understand or determine" an issue in the case. *Cooper v. Brown*, 510 F.3d 870, 942 (9th Cir. 2007) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591–92 (1993)); *see also Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 738 F.3d 960, 969 (9th Cir. 2013),

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565, 581–82 (9th Cir. 2006), *as amended* (Jan. 19, 2007). It simply does not stand for the proposition that the Court must make special findings of reliability and relevance when expert testimony is "premised on hearsay," as the State represents. Mot. 9. The State's two automobile accident cases from the 1980s involved opinion testimony premised on eyewitness reports instead of physical investigations. *Faries v. Atlas Truck Body Mfg. Co.*, 797 F.2d 619, 622–24 (8th Cir. 1986); *Dallas & Mavis Forwarding Co. v. Stegall*, 659 F.2d 721, 721–22 (6th Cir. 1981). Both decisions are based on the fact that the advisory committee notes to Rule 703 *specifically mention* that eyewitness testimony cannot be used in accident reconstruction because of its unreliability. *Faries*, 797 F.2d at 624; *Dallas*, 659 F.2d at 722. Neither case supports the State's proposition that "self-serving" materials are *per se* unreliable. Mot. 9. And the court in *In re "Agent Orange" Products Liability Litigation* excluded medical expert testimony based on symptom "checklists" because "no reputable physician" would rely on such materials. 611 F. Supp. 1223, 1246 (E.D.N.Y. 1985). The "checklists" are nothing like the material Mr. Freedman relies on here.

as amended (June 19, 2013) ("Expert opinion testimony is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry." (internal quotation marks omitted)).

Here, there is little doubt that Mr. Freedman's testimony is relevant and will assist the Court. Indeed, the State does not appear to challenge the relevance of Mr. Freedman's testimony at all. *First*, Mr. Freedman explains the framework of the Beneficiary Inducement Statute and the OIG's advisory opinion process. *See* Freedman Rep. ¶¶ 36–49. Of note, Mr. Freedman highlights the advisory opinion process as one of the statute's "safety valves" (*id.* ¶¶ 39–41; *see also* ¶¶ 51–53), explains that OIG evaluates whether proposed arrangements will "benefit patients" (*id.* ¶ 47), explains the limitations of the process (*id.* ¶¶ 48–49, 55–56), and lays out the requirements for obtaining an advisory opinion (*id.* ¶ 54). This testimony provides the Court with relevant contextual information about the complicated advisory opinion process at the center of this case. *See also infra* section IV.D.2.

Second, Mr. Freedman explains how AB 290 will take AKF out of the safe harbor created by AO 97-1. *See supra* pp. 5–6 (citing Freedman Rep. ¶¶ 74–91). This testimony is, of course, highly relevant to the question whether AB 290 is preempted by AO 97-1.

Third, Freedman explains the effects and consequences of noncompliance with AO 97-1. Based on his experience at DOJ, Mr. Freedman explains that "[t]he Department of Justice . . . has vigorously enforced the [B]eneficiary [I]nducement [S]tatute in recent years[.]" Freedman Rep. ¶ 50; *see also id.* ¶¶ 57–61 (describing DOJ's role in advisory opinion process). Mr. Freedman thus concludes that, "[f]rom a [DOJ] and OIG enforcement perspective," AKF would face "substantial risk" and "uncertainty" if it operated HIPP outside the safe harbor of AO 97-1. *Id.* ¶ 93. This testimony will help the Court understand why AKF cannot comply with AB 290.

D. Mr. Freedman Does Not Provide Impermissible Legal Opinions.

The State argues that Mr. Freedman "opine[s] on an ultimate issue of law."

Mot. 5. But Mr. Freedman renders no such opinion. Even if he did, Mr. Freedman's testimony remains admissible because it explains a complex and specialized legal framework.

1. Mr. Freedman Does Not Offer Improper Legal Conclusions.

The State argues that "the entirety of Mr. Freedman's report should be stricken" because "[t]he entirety of Mr. Freedman's opinion is the conclusion that there is no way for AKF to comply with both AO 97-1 and AB 290," which the state claims is an improper legal conclusion. Mot. 5. The State mischaracterizes Mr. Freedman's report and the opinions contained within it. Rather than presenting an impermissible opinion on the ultimate legal issues before the Court, Mr. Freedman permissibly draws on his experience to identify certain key provisions from AB 290 and to evaluate the practical effect that those provisions will have on AKF's ability to operate HIPP under the current AO 97-1 regime. For example, Mr. Freedman explains that if AB 290 goes into effect:

- AKF will be compelled to disclose to private insurers the identities of patients receiving charitable premium assistance, which means that "patients will be made aware that their dialysis providers contribute to AKF." *See* Freedman Rep. ¶ 74.
- Patients will owe reduced payments to their providers if their providers donate to AKF, which may create a financial incentive for patients to seek services from a provider that donates to AKF. *See id*. ¶¶ 75–76.
- Patients who signed up for the same insurance plan in the same state at a different time can possibly receive different financial benefits, whereas "AO 97-1 requires AKF to use objective criteria to determine patient eligibility for assistance." *See id*. ¶¶ 80–81.
- AKF must "agree not to condition financial assistance on eligibility for, or receipt of, any surgery, transplant, procedure, drug, or device" even though AKF currently provides premium assistance *for ESRD patients* in the manner that it certified to OIG when it requested AO 97-1. *See id*. ¶¶ 82–83.

This testimony explains what will happen if AKF complies with AB 290, notwithstanding the requirements of AO 97-1 (in this case, significant legal risk).

To the extent that the State purports to criticize Mr. Freedman for referring to the language of AB 290 or AO 97-1, that is not a basis for excluding his report. As the State's own case law makes clear, "it is sometimes impossible for an expert to render his or her opinion on a subject without resorting to language that recurs in the applicable legal standard." *United States v. Diaz*, 876 F.3d 1194, 1198 (9th Cir. 2017); *see also Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1017 (9th Cir. 2004) (admitting expert testimony that relied on expert's "understanding of the requirements of state law" because "'a witness may refer to the law in expressing an opinion'" (quoting *Specht v. Jensen*, 853 F.2d 805, 809 (10th Cir. 1998)). Mr. Freedman likewise cannot render his expert opinions in this case without addressing the requirements of AO 97-1 and AB 290. Like the expert testimony in *Diaz* admitted by the Ninth Circuit, Mr. Freedman's report does not use terms that have "a specialized meaning in law," nor does Mr. Freedman "instruct [the Court] on the law, or how to apply the law to the facts of the case." *See Diaz*, 876 F.3d at 1199; Mot. 6 (noting that Mr. Freedman, in his deposition, described AB 290 as creating "legal risks" but agreeing that "it was the province of the Court . . . to determine whether AKF has in fact operated" in compliance with AO 97-1).

To be sure, Mr. Freedman's conclusions may "support[] a finding" that AB 290 is preempted. But it is settled that such testimony does not render Mr. Freedman's opinion impermissible. *Hangarter*, 373 F.3d at 1016; *see also Haitayan v. 7-Eleven, Inc.*, Nos. CV 17-7454 DSF (ASx), CV 18-5465 DSF (ASx), 2021 WL 1034152, at *1 (C.D. Cal. Mar. 8, 2021) ("While Lafontaine's testimony embraces the ultimate issue of whether Plaintiffs are employees or independent contractors, it offers testimony in the form of opinion as to the business model and roles of the parties."); *Soria v. U.S. Bank N.A.*, No. SACV 17-00603-CJC(KESx), 2019 WL 8167925, at *6 (C.D. Cal. Apr. 25, 2019) (finding expert testimony that defendant's policies complied with the Fair

Debt Collection Practice Act permissible because "[w]hether [defendant's] policies and procedures were *designed* to comply with the law and industry standards is a distinct issue from whether U.S. Bank actually *violated* any statutes in this case").

The State's other arguments are meritless. *See* Mot. 5–6. The State objects that Mr. Freedman reviewed only "pleadings, statutes, and other legal information." Mot. 5. But Mr. Freedman also reviewed factual declarations, the California Legislative Bureau's internal analysis of AB 290 and AO 97-1, and the California Assembly's Floor Analysis of AB 290, among other materials. *See* Freedman Rep., App'x D. Further, the materials Mr. Freedman reviewed have no bearing on whether his *opinion* reaches an impermissible legal conclusion. Unable to show Mr. Freedman renders an improper legal opinion, the State instead points out that Mr. Freedman is a lawyer. *See id.* (observing that Mr. Freedman "spoke to . . . an associate at Mintz," "was retained in his capacity as a Mintz attorney," and "submitted his bills through his law firm"). Nowhere do the federal rules prohibit a lawyer from serving as an expert witness. The State's arguments regarding Mr. Freedman's lack of "specific . . . experience" are debunked above. *See supra* pp. 6–7.

2. Mr. Freedman's Testimony Regarding the Advisory Opinion Process Is Proper.

The State's Motion also fails because it ignores the second major facet of Mr. Freedman's testimony. *Compare* Mot. 5 ("The entirety of Mr. Freedman's opinion is the conclusion that there is no way for AKF to comply with both AO 97-1 and AB 290 . . . .") *with* Leland Decl. Exh. 1, at 21–22 (Freedman Depo. at 63:06–64:01) (explaining testimony has "*two* parts" (emphasis added)). As shown above, Mr. Freedman also explains the OIG advisory opinion process. *See supra* pp. 3–4.

Mr. Freedman's testimony is proper because it explains a "highly complex" and "technical" legal regime. *Flores v. Arizona*, 516 F.3d 1140, 1166 (9th Cir. 2008), *as amended on denial of reh'g* (Apr. 17, 2008). Specifically, Mr. Freedman explains how OIG's advisory opinions fit into the broader framework of the federal Beneficiary

Inducement Statute (Freedman Rep. ¶¶ 37–43, 45–46, 51–53), the scope and limitations of OIG advisory opinions (*id.* ¶¶ 48–49, 56), and the facts and materials OIG considers before issuing advisory opinions (*id.* ¶¶ 47, 54–55). This is exactly the sort of testimony regarding complex or specialized legal regimes that courts in this Circuit have found permissible. *E.g.*, *Marshall v. Northrop Grunman Corp.*, No. 16-cv-06794-AB-JCx, 2019 WL 6354371, at *2 (C.D. Cal. Oct. 16, 2019) (allowing expert testimony regarding "the complicated factual and legal issues presented by ERISA's fiduciary requirements"); *In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2017 WL 6523833, at *6 (D. Ariz. Dec. 21, 2017) (allowing expert testimony regarding "how the 510(k) process works, how a manufacturer navigates the process, and how the FDA renders a decision based on the process"); *United States v. Pac. Gas & Elec. Co.*, No. 14-cr-00175-TEH, 2016 WL 3268994, at *1 (N.D. Cal. June 15, 2016) (finding "expert testimony on the Pipeline Safety Act is necessary"); *Stambolian v. Novartis Pharms. Corp.*, No. CV 12-04378 BRO (FMOx), 2013 WL 6345566, at *8 (C.D. Cal. Dec. 6, 2013) (allowing expert testimony regarding "the complex regulatory framework governing the approval, labeling, advertising, and marketing of pharmaceutical medical products" and "the FDA process for determining efficacy and safety of pharmaceutical drugs"). Even if this Court finds that Mr. Freedman's "conflict" opinion should be excluded—and it should not—it should still allow Mr. Freedman to testify regarding the advisory opinion process. Such testimony does not offer any improper legal conclusions.

V. CONCLUSION

For the foregoing reasons, Plaintiffs urge the Court to deny the State's motion to exclude the testimony of Laurence J. Freedman.

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Dated: April 1, 2022

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