APPENDIX

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APPENDIX A

United States Court of Appeals, Ninth Circuit.

UNITED STATES of America, Plaintiff -Appellee,

v.

Mark SCHENA, Defendant - Appellant.

No. 23-2989

Argued and Submitted February 11, 2025 Honolulu, Hawaii

Filed July 11, 2025

Appeal from the United States District Court for the Northern District of California, Edward J. Davila, District Judge, Presiding, D.C. No. 5:20-cr-00425-EJD-1

Sofia M. Vickery (argued), Attorney, Appellate Section, Criminal Division; Jeremy R. Sanders, Trial Attorney; Lisa H. Miller, Deputy Assistant Attorney General; Nicole M. Argentieri, Principal Deputy Assistant Attorney General; United States Department of Justice, Washington, D.C.; Laura Connelly, Trial Attorney, Fraud Section, Criminal Division; Merry J. Chan and Christina Liu, Assistant United States Attorneys; Jacob Foster, Principal Deputy Assistant Chief; Ismail J. Ramsey, United States Attorney; Office of the United States Attorney; United States Department of Justice, San Francisco, California; for Plaintiff-Appellee.

Leah Spero (argued), Spero Law Office, San Francisco, California, for Defendant-Appellant.

Before: Sidney R. Thomas, Daniel A. Bress, and Ana de Alba, Circuit Judges.

OPINION

BRESS, Circuit Judge:

To combat fraud and abuse in the healthcare industry, the Eliminating Kickbacks in Recovery Act (EKRA) criminalizes, among other things, the payment of "remuneration ... to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory." 18 U.S.C. § 220(a)(2)(A). We interpret this 2018 law for the first time, as to a laboratory operator who allegedly made payments to marketing intermediaries to induce referrals for medically dubious allergy tests. We hold that the defendant's challenged conduct is within the scope of the EKRA statute and that the evidence supported the EKRA charges.[1]

I

We describe the facts most relevant to the EKRA counts, construing the evidence presented at trial in the light most favorable to the government. *See United States v. Nevils*, 598 F.3d 1158, 1163–64 (9th Cir. 2010) (en banc).

Mark Schena operated Arrayit, a medical testing laboratory in Northern California. A small business staffed with his wife and other family members and friends, Arrayit initially focused on selling equipment

[1] We address the other issues in this appeal in an accompanying memorandum disposition. In total, we affirm the defendant's convictions and affirm in part and vacate and remand in part the district court's restitution order.

to other laboratories. Schena, who had an "obsession" with medical billing codes, wanted a way to make large amounts of money from billing insurers. To that end, he decided to transition Arrayit to conduct clinical diagnostics on its own.

Arrayit's testing focused on blood tests for allergies. Typically, allergists use skin tests and only use blood tests as a secondary measure when a skin test cannot be performed due to a patient's skin problems. But Schena marketed the blood tests as superior, in large part because he believed he could bill patients' insurance providers up to $10,000 for each full suite of tests. The tests only cost Arrayit a small fraction of the amount billed. Arrayit conducted tests for 120 allergens, not because this was medically necessary (some of the tested allergens were rare), but because it was the most its machine could process. Evidence at trial indicated that for most patients, testing for the full 120 allergens was not warranted.

Key to Schena's plan to gain insurance proceeds was maintaining a steady flow of patient samples to test. That, in turn, required finding doctors who would steer their patients to Arrayit. Schena tasked a series of marketers with pitching Arrayit's services to medical professionals. Marketers were not paid a salary or given written contracts; instead, marketers were paid a percentage of the revenue that they were able to bring in.

The evidence at trial showed that Schena orchestrated a scheme in which his marketers, most prominently Marc Jablonski, misrepresented Arrayit's services, and the need for those services, to doctors and other medical professionals, with the goal

of inducing patient referrals. Schena instructed his marketers to pitch the blood tests to "naïve" doctors who lacked allergy experience (such as chiropractors and naturopaths), even though allergists considered skin testing to be superior and 120 allergen tests per person were usually not necessary. Schena's marketers "stayed away from the allergists because they didn't believe in the tests." Marketing agents misleadingly told the less sophisticated doctors that Arrayit's blood testing was "highly accurate" and "far superior" to skin tests, even though Arrayit's blood tests could not assess whether the patient had an allergy (as opposed to having been exposed to an allergen).

The marketers' undue influence extended beyond their misrepresentations. At trial, Jablonski—who himself pleaded guilty to conspiring to defraud the United States through kickbacks—testified that marketers "controlled" which lab the blood samples would be sent to. Another marketer testified that Arrayit's financial incentives ensured that marketers would push blood tests and not mention skin tests as an option.

When the COVID-19 pandemic began in 2020, Arrayit's testing volume fell dramatically as patients stayed home and did not get their blood tested. So, Schena transitioned to COVID testing. As with allergies, Arrayit utilized a blood test (which tested for antibodies) rather than the "gold standard" PCR test (which could detect active infections). Despite this limitation, Schena had Arrayit marketers hawk his COVID test as equal or superior to PCR tests. Schena also directed marketers to mislead doctors about how quickly the COVID test results would be available.

Schena further used marketing agents to secure blood tests through the COVID tests. To be able to test the blood for allergies (and to bill for these more lucrative tests), Schena instructed marketers to bundle allergy tests with COVID tests. In addition, Arrayit marketers falsely claimed that according to Dr. Anthony Fauci, COVID and allergies could be confused, requiring tests for both. If doctors only ordered a COVID test, Schena directed lab employees to run allergy tests anyway. In one case, when a patient wrote on the test form that she wanted a "COVID test only," Arrayit ran an allergy test as well—and billed her insurance nearly $5,300 for it.

Arrayit's billing practices allowed it to bill far more per patient than comparable providers. An analysis of Arrayit's billings to Medicare showed that the company billed an average of $5,200 per patient—more than any other laboratory in the country and over $4,000 more than the average laboratory billing per beneficiary. In aggregate, between October 2018 and June 2020, Arrayit billed more than $77 million to public and private insurers. But insurers paid only around $2.7 million, as many claims were denied or paid at a lower rate.

For this scheme along with other misconduct, the government charged Schena with one count of conspiracy to commit healthcare fraud, 18 U.S.C. § 1349; two counts of healthcare fraud, 18 U.S.C. §§ 2, 1347; one count of conspiracy to violate EKRA, 18 U.S.C. § 371; two counts of EKRA violations, 18 U.S.C. §§ 2, 220(a)(2); and three counts of securities fraud, 15 U.S.C. §§ 78j, 78ff; 17 C.F.R. 240.10b-5; 18 U.S.C. § 2. The EKRA counts were based on two payments made to Jablonski.

Schena moved to dismiss the EKRA counts, arguing that his conduct did not violate the statute as a matter of law because the percentage payments were made only to marketing intermediaries, not to the persons who themselves were making referrals, i.e., doctors. The district court denied the motion.

The jury convicted Schena on all counts. The district court sentenced Schena to 96 months in prison and ordered him to pay more than $24 million in restitution. This appeal follows.

II

A

Congress passed EKRA in 2018 to further curb fraud and abuse by healthcare providers. *See* Pub. L. No. 115-271, 132 Stat. 3894 (2018); Laura F. Laemmle-Weidenfeld, *Navigating the Rocky Waters of the Eliminating Kickbacks in Recovery Act*, in Health L. Handbook 12 (Alice G. Gosfield ed., 2022). The Anti-Kickback Statute, 42 U.S.C. § 1320a–7b, already prohibited certain kickbacks for medical services reimbursed through Medicare and other federal programs. *See United States v. Hong*, 938 F.3d 1040, 1047 (9th Cir. 2019); Chinelo Diké-Minor, *The Untold Story of the United States' Anti-Kickback Laws*, 20 Rutgers J.L. & Pub. Pol'y 103, 108–13 (2023). In EKRA, Congress sought to impose a similar prohibition for certain covered services, for patients with private insurance. Diké-Minor, *Untold Story*, 20 Rutgers J.L. & Pub. Pol'y at 155–60.

Highlighting in bold italics the key language at issue in this case, the relevant text of EKRA reads as follows:

> [W]hoever, with respect to services covered by a health care benefit program, in or affecting interstate or foreign commerce, knowingly and willfully--
>
> > (1) solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or
> >
> > (2) *pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind*--
> >
> > > (A) *to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory*; or
> > >
> > > (B) in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory,
>
> shall be fined not more than $200,000, imprisoned not more than 10 years, or both, for each occurrence.

18 U.S.C. § 220(a) (emphasis added).

The statute also includes a few safe-harbor provisions. Most notably, "a payment made by an employer to an employee or independent contractor ...

for employment" is permitted so long as the "employee's payment is not determined by or does not vary by (A) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory; (B) the number of tests or procedures performed; or (C) the amount billed to or received from" a patient's insurance company. 18 U.S.C. § 220(b)(2).

In this case, several points are not in dispute. Arrayit is a "laboratory" within the meaning of the statute. It is clear from the record that Schena paid remuneration to the marketers. And the payments did vary based on the number of tests or procedures performed, so the § 220(b)(2) safe-harbor provision does not apply.

The disagreement between Schena and the government rests on two other aspects of § 220(a)(2)(A): (1) whether EKRA applies to payments made to marketing intermediaries, as opposed to the referring doctors or persons who otherwise interact directly with patients, and, (2) if payments to marketing intermediaries are covered, what it means to "induce a referral" in the context of that type of payment relationship. To answer these questions, we apply our usual tools of construction, interpreting the statutory text based on its plain and natural meaning and with a view to the statute as a whole. *See, e.g.*, *Davis v. Michigan Dep't of Treasury*, 489 U.S. 803, 809, 109 S.Ct. 1500, 103 L.Ed.2d 891 (1989); *San Francisco Herring Assoc. v. U.S. Dep't of the Interior*, 33 F.4th 1146, 1152 (9th Cir. 2022).

B

The first question is whether 18 U.S.C. § 220(a)(2)(A) covers payments to marketers designed to induce referrals, or whether the provision is limited to payments made to the persons who are doing the actual patient referrals, most typically doctors and other medical professionals. Schena maintains it is the latter. And if payments to marketers are to be covered, he maintains they are covered only if the marketers directly engage with patients. We disagree and hold that 18 U.S.C. § 220(a)(2)(A) covers marketing intermediaries who interface with those who do the referrals. Under EKRA, there is no requirement that the payments be made to a person who interfaces directly with patients.

The basic rejoinder to Schena's position is that the statute does not create the limitation he seeks. The statute penalizes one who "pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind-- ... to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory." 18 U.S.C. § 220(a)(2)(A). Nothing in this provision, including the term "kickback," limits its reach to payments made specifically to persons who have the authority to refer patients or who directly interact with patients. One could "induce a referral" by paying someone who could in turn effect a referral, even if the person who received the payment did not himself have the ability to order a laboratory test or refer a patient to a treatment facility. That the statutory language applies to anyone who pays remuneration "directly or *indirectly*" to induce a referral further supports this reading. *See United States v. Prasad*, 18 F.4th 313, 325 (9th Cir. 2021)

(explaining that the phrasing "directly or indirectly" "reaches broadly"). We therefore agree with the district court that "[t]he plain meaning of 'to induce a referral of an individual' includes situations where a marketer causes an individual to obtain a referral from a physician."

In *S&G Labs Hawaii, LLC v. Graves*, 2021 WL 4847430 (D. Haw. Oct. 18, 2021), another district court in our circuit reached a different conclusion on this point.[2] Observing that EKRA refers to the induced referral "of an individual," the district court in *S&G* determined that EKRA did not apply when a marketing employee interfaced with doctors and other treatment providers, because the " 'client' accounts they serviced were not individuals whose samples were tested at" S&G's lab. *Id.* at *11.

In our respectful view, *S&G*'s interpretation was incorrect because the phrase "to induce a referral of an individual" means merely that the ultimate object of the inducement must be a natural person to whom covered medical services would be provided. It does not follow, as the *S&G* court determined, that 18 U.S.C. § 220(a)(2)(A) is limited to payments made to persons who are "working with" such individual patients. *S&G Labs Hawaii, LLC*, 2021 WL 4847430, at *11. As we have explained above, the statute does not impose that requirement. While it is true that the doctors' offices to whom a marketer pitches services are not "individuals" under the statute, a third party

[2] The *S&G* appeal, No. 24-823, was also assigned to this panel and was argued before us in coordination with this case.

such as a marketer could still induce a patient referral through a doctor or other medical professional.

Our interpretation of EKRA is in accord with the circuits that have interpreted an analogous provision in the Anti-Kickback Statute. *See* 42 U.S.C. § 1320a–7b(b)(2)(A) ("Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program ... shall be guilty of a felony.").

In *United States v. Shoemaker*, 746 F.3d 614 (5th Cir. 2014), the Fifth Circuit considered a case in which a nurse staffing business bribed the chairman of the board of a Mississippi hospital to use its contract nurses. *Id.* at 617. The chairman, in turn, authorized a $50,000 raise for the chief operating officer to compensate him for his participation in the scheme. Id. In upholding the convictions of both defendants, the Fifth Circuit rejected the contention that Anti-Kickback "liability cannot attach unless the 'person' who receives such remuneration is a 'relevant decisionmaker' with formal authority to effect the desired referral or recommendation." *Id.* at 627. Holding otherwise, the Fifth Circuit reasoned, "would be tantamount to re-writing the statutory text" and would mean that "if a bribe-giver wanted to avoid liability, he could simply identify the individual with direct operational authority over the desired decision, and bribe a manager who is at least one level removed in the chain of command." *Id.* at 629; *see also United*

States v. Miles, 360 F.3d 472, 480 (5th Cir. 2004) (noting that there are "certain situations where payments to non-doctors would fall within the scope of the" Anti-Kickback Statute); *United States v. Polin*, 194 F.3d 863, 866–67 (7th Cir. 1999) (holding that 42 U.S.C. § 1320a–7b(b)(2)(A) applied to payments made to a marketing intermediary because the provision "do[es] not distinguish between physicians and lay-persons").

Similar problems would arise in the EKRA context under Schena's proposed reading. To evade EKRA, the recipient of unlawful payments from a provider would need only to enlist a subordinate or other agent to pressure a patient into using the provider's services. Once again, nothing in the text of 18 U.S.C. § 220(a)(2)(A), or the statute as a whole, supports that reading. We thus conclude that the reference to "an individual" in § 220(a)(2)(A) requires that the renumeration generally contemplate the referral of a patient for an EKRA-covered service. But the statute imposes no requirement that the recipient of the renumeration directly interact with an "individual" patient for § 220(a)(2)(A)'s prohibition to apply.

Applying that understanding to this case, a reasonable jury could find that Schena was paying marketers with the goal that individuals would be referred to Arrayit. Even though the marketers did not directly interface with patients, Schena does not (and cannot) dispute that the marketers' ultimate objective was to cause patients to use Arrayit's services.

C

We now turn to the connection between the payments and the goal of obtaining referrals. That connection turns on the statutory language "to induce."

If a payment is made directly to a person who is making the referral, such as a doctor, the payment induces the referral by the very fact of the payment itself. Such a payment is by definition unlawful under EKRA. But we must consider what it means to "induce a referral" in the context of a case such as this, in which the defendant is alleged to have made payments to a marketing agent "to induce a referral of an individual." We conclude that a percentage-based compensation structure for marketing agents, without more, does not violate 18 U.S.C. § 220(a)(2)(A). But the evidence is sufficient to show wrongful inducement when, as here, the defendant pays remuneration to a marketing agent to have him unduly influence doctors' referrals through false or fraudulent representations about the covered medical services.

The starting point for our analysis is the key word in § 220(a)(2)(A): "induce." EKRA does not define that term. But "induce" has a "longstanding history" in criminal law. *United States v. Hansen*, 599 U.S. 762, 778, 143 S.Ct. 1932, 216 L.Ed.2d 692 (2023). Although "[i]n ordinary parlance, 'induce' means [t]o lead on; to influence; to prevail on; to move by persuasion or influence," it has a "specialized, criminal-law" meaning that "incorporat[es] common-law liability for solicitation and facilitation." *Id.* at 774, 143 S.Ct. 1932 (internal quotations omitted). Criminal solicitation "is the intentional encouragement of an unlawful act," and criminal

facilitation (also known as aiding and abetting) "is the provision of assistance to a wrongdoer with the intent to further an offense's commission." *Id.* at 771, 143 S.Ct. 1932. We take from *Hansen* that the term "induce" connotes not mere causation, but wrongful causation. And it makes sense to read EKRA as incorporating the "well-established legal meaning[ ]" of "induce," because "when Congress 'borrows terms of art in which are accumulated the legal tradition and meaning of centuries of practice, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word.'" *Id.* at 774, 143 S.Ct. 1932 (quoting *Morissette v. United States*, 342 U.S. 246, 263, 72 S.Ct. 240, 96 L.Ed. 288 (1952)).

Although no circuit court has interpreted "induce" in 18 U.S.C. § 220(a)(2)(A), case law from the Anti-Kickback Statute context is once again informative (as Schena himself agrees). In that context, we have said that "mere encouragement would not violate the statute." *Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995). Instead, " 'to induce' ... connotes an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business." Id. (internal quotations omitted). Such conduct is not merely influence; we understand *Hanlester*, based on the facts of the case, to require undue influence. *Id.* at 1399.

A more robust body of Anti-Kickback Statute precedent from the Fifth Circuit is also illuminating. In *Miles*, the Fifth Circuit considered the scope of the Anti-Kickback Statute in the case of defendants who ran a home health service provider and paid a marketing firm to distribute literature and business

cards to local medical offices, along with the occasional plate of cookies. 360 F.3d at 479–80. The marketers were paid $300 for every patient who ultimately signed up. *Id.* at 479.

Reversing the convictions, the Fifth Circuit held that the marketers "simply engaged in advertising activities" on behalf of the defendant's company, and "[t]here was no evidence that [the marketer] had any authority to act on behalf of a physician in selecting the particular home health care provider." *Id.* at 480. But Miles cautioned that it would have been different had the intermediary "ma[de] the decision as to which service provider to contact." *Id.* (citing *Polin*, 194 F.3d at 865).

That warning proved prescient in *Shoemaker*, where the Fifth Circuit upheld the convictions before it. 746 F.3d at 631. In that case, which involved the bribery of hospital executives, the payor "was not asking for a brochure bearing his company's name to be distributed to [the hospital's] staff; rather, enough evidence showed that he wanted [the hospital board's chairman] to exploit his personal access to [hospital] executives." *Id.* at 629. The key difference from *Miles* was the presence of "undue influence" over the referrals. *Id. Miles* was therefore distinguishable:

> Where advertising facilitates an independent decision to purchase a healthcare good or service, and where there is no evidence that the advertiser "unduly influence[s]" or "act[s] on behalf of" the purchaser, the mere fact that the good or service provider compensates the advertiser following each purchase is

> insufficient to support the provider's conviction for making a payment "to refer an individual to a person" under 42 U.S.C. § 1320a–7b(b)(2)(A).

Id. (quoting *Miles*, 360 F.3d at 480); *see also United States v. Marchetti*, 96 F.4th 818, 827 (5th Cir. 2024) (explaining that in the case of payments to marketers, the government under the Anti-Kickback Statute must prove that the defendant "intended 'improperly [to] influence[ ]' those who make healthcare decisions on behalf of patients") (quoting *Miles*, 360 F.3d at 481) (brackets in original).

We interpret "induce" similarly in the EKRA context. Given the criminal law heritage of the term "induce" and the past treatment of that concept under the Anti-Kickback Statute, we do not think the mere fact of a percentage-based marketing arrangement, without more, would constitute a per se violation of EKRA. As the Fifth Circuit has explained in the Anti-Kickback Statute context, in the case of payments to marketing agents "[t]he structure of the contract alone is not sufficient evidence to produce a conviction." *Marchetti*, 96 F.4th at 826. And at oral argument, the government itself agreed that a percentage-based payment to a marketer is not per se unlawful under EKRA. All marketing efforts are intended to influence the recipient. In the absence of a clearer indication in the statute, we are hard-pressed to read EKRA to criminalize (with major federal penalties) a standard payment structure for marketing personnel, even when the marketing personnel are persuasive in driving business. *See id.* at 827 (observing under the Anti-Kickback Statute

that "not every sort of influence is improper. (What are advertisers hired to do anyway?)").[3]

Future cases will be needed to give content to the specific circumstances in which payments to a marketing agent reflect a wrongful effort to unduly influence the decisions of doctors and medical professionals making referrals. Given that reality, and although fraudulent conduct risks implicating other criminal statutes, companies and marketing agents seeking to steer clear of EKRA may consider whether it is preferable to structure their compensation arrangements in accordance with the statute's safe harbor. *See* 18 U.S.C. § 220(b)(2).

At the same time, this case does not require us to reach the potentially more difficult questions in this area. We agree that when a marketing intermediary effectively takes over the role of the referring physician, payments to the marketer would "induce a referral" under 18 U.S.C. § 220(a)(2)(A). *See Polin*, 194 F.3d at 866 (upholding Anti-Kickback Statute conviction where marketing agent "would call [the provider] and arrange for the patient's follow-up himself"). But contrary to Schena's suggestion, that is not the only way that a payment to a marketing agent could induce a referral. Instead, we conclude that at a minimum, when percentage-based payments are made to marketing agents who are directed to mislead those making the referrals about the nature of and need for the covered medical services, those payments

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[3] That a percentage-based marketing arrangement is not, standing alone, a *per se* violation of EKRA explains our result in the coordinated *S&G* appeal. *See ante* at n.2. There, in a separate memorandum disposition, we conclude that the counterclaim-plaintiff's employment contract did not violate EKRA.

would violate EKRA. This is not a necessary set of circumstances for establishing undue influence, but it is sufficient. Construing the evidence in the light most favorable to the verdict, *see Nevils*, 598 F.3d at 1163–64, that type of undue influence occurred here.

Schena directed his marketers to mislead and deceive doctors about Arrayit's blood testing services, in an effort to cause them to make referrals to his lab. In particular, Schena directed that marketers should target doctors that were less knowledgeable about allergies and claim that Arrayit's blood tests were superior to skin tests, even though Arrayit's tests had significant limitations and allergists considered skin testing to be the "gold standard." Schena also had all patients tested for 120 allergens, not because it was medically necessary, but because it was the most the machine could process. When the COVID pandemic hit, Schena's marketers misrepresented the speed and efficacy of the company's blood tests compared to PCR tests; falsely claimed that allergies and COVID could be confused; and had patients who requested COVID testing also tested for allergies, even when they declined the allergy test. The jury also heard from one of Schena's marketers who testified that he effectively "controlled" which lab a sample would be sent to.

Although the doctors may have nominally referred patients to Arrayit, a jury could have found that Schena directed marketers to engage in deceitful conduct that gave the marketers undue influence over the referrals. In that sense, Schena paid marketing agents to induce referrals to his lab.

* * *

For these reasons and those set forth in our accompanying memorandum disposition, we affirm Schena's EKRA and other convictions. As to the restitution order, and as detailed in our memorandum disposition, we affirm in part, and vacate and remand in part.

AFFIRMED IN PART, VACATED AND REMANDED IN PART.

APPENDIX B

United States Court of Appeals, Ninth Circuit.

UNITED STATES of America, Plaintiff - Appellee,

v.

Mark SCHENA, Defendant - Appellant.

No. 23-2989

Argued and Submitted February

11, 2025 Honolulu, Hawaii

FILED JULY 11, 2025

Appeal from the United States District Court for the Northern District of California, Edward J. Davila, District Judge, Presiding, D.C. No. 5:20-cr-00425-EJD-1

Before: S.R. THOMAS, BRESS, and DE ALBA, Circuit Judges.

MEMORANDUM*

Mark Schena appeals his convictions for one count of conspiracy to commit healthcare fraud, 18 U.S.C. § 1349; two counts of healthcare fraud, 18 U.S.C. §§ 2, 1347; one count of conspiracy to violate the Eliminating Kickbacks in Recovery Act (EKRA), 18 U.S.C. § 371; two counts of EKRA violations, 18 U.S.C. §§ 2, 220(a)(2); and three counts of securities fraud, 15 U.S.C. §§ 78j, 78ff; 17 C.F.R. 240.10b-5; 18

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

U.S.C. § 2. Schena also appeals his restitution order. In an accompanying opinion, we hold that Schena's conduct fell within the scope of EKRA. In this memorandum disposition, we reject Schena's remaining challenges to his convictions. But as to his restitution order, we affirm in part, vacate in part, and remand for further consideration.

1. Schena contends that his EKRA convictions should be reversed because the district court improperly allowed expert and lay witnesses to offer legal opinions about EKRA's scope. We review preserved evidentiary objections for abuse of discretion and unpreserved objections for plain error. *United States v. Alahmedalabdaloklah*, 94 F.4th 782, 835–36 (9th Cir. 2024). In this case, it is not apparent that Schena objected to much of the challenged testimony. But even assuming he did, there was no reversible error.

In the case of the expert witnesses, Quindoza and Kondratenko, some of the testimony in question concerned either basic background on healthcare fraud based on the witnesses' training and experience, or else the witnesses' views on Medicare policy. To the extent their testimony veered into impermissible legal conclusions, Schena for the most part did not object. And in the context of the trial as a whole—which involved extensive evidence of healthcare fraud—the experts' allegedly objectionable testimony did not materially affect the verdict. Even assuming the government bore the burden given the lack of objections, it has demonstrated that "it is more probable than not that the jury would have reached the same verdict" absent the disputed testimony. *United States v. Wells*, 879 F.3d 900, 923–24 (9th Cir.

2018). In addition, and further minimizing any prejudice, the district court instructed the jury on the law, and we presume that jurors followed the court's instructions. *See United States v. Ovsepian*, 113 F.4th 1193, 1201–02 (9th Cir. 2024).

In the case of the lay witness testimony, that testimony was relevant to showing Schena's wrongful intent. The lay witnesses testified that they knew about EKRA and shared their concerns about possible EKRA violations with Schena. The statute requires the government to prove that Schena acted "willfully," 18 U.S.C. § 220(a), which means that the government must show that Schena had "knowledge that his conduct was unlawful," not just that he had "knowledge of the facts that constitute the offense." *Bryan v. United States*, 524 U.S. 184, 193 (1998). The lay witnesses' testimony was thus probative of an element of the offense that the government had to prove. And once again, even assuming some of the testimony crossed the line into legal opinion, it did not materially affect the verdict. *Wells*, 879 F.3d at 923–24. Nor was any cumulative error from the challenged expert and lay testimony (whether preserved or not) prejudicial. *See United States v. Wallace*, 848 F.2d 1464, 1475 (9th Cir. 1988) (noting that errors can be reversible in the aggregate even when any individual error is not).

2. We reject Schena's challenge to the jury instructions on the healthcare fraud and EKRA counts. Because Schena did not sufficiently object to the instruction in question, we review for plain error. *United States v. Rodriguez*, 971 F.3d 1005, 1012 (9th Cir. 2020). To establish plain error, Schena must show "(1) error, (2) that is plain, (3) that affected substantial

rights, and (4) that seriously affected the fairness, integrity or public reputation of the judicial proceedings." *United States v. Ferguson*, 8 F.4th 1143, 1145–46 (9th Cir. 2021) (quoting *United States v. Borowy*, 595 F.3d 1045, 1049 (9th Cir. 2010) (per curiam)).

Both the EKRA and healthcare fraud charges required the government to prove that Schena acted "knowingly and willfully." 18 U.S.C. § 220(a), 1347(a). While "willfully" in this context requires the government to show that the defendant knew his behavior was illegal, "knowingly" only requires "knowledge of the facts that constitute the offense." *Bryan*, 524 U.S. at 193. To avoid the potential for confusion, when the government is required to prove that the defendant knew his conduct was unlawful, our model jury instructions direct district courts to omit from the "knowingly" instruction certain language stating that "[t]he government is not required to prove that the defendant knew that [his] ... acts or omissions were unlawful." Ninth Cir. Model Jury Inst. 4.8 cmt.

In this case, the "knowingly" instruction included this language, apparently inadvertently, and neither the parties nor the district court caught the issue at the time. Nevertheless, we discern no plain error. The instructions did not logically conflict because they applied to different mens rea. The jury was instructed that it had to find that Schena acted both knowingly and willfully. And the jury was properly instructed that, as to the counts in question, "willfully" required the government to prove that Schena knew his conduct was unlawful. When the jury raised questions about the mens rea requirements, the district court

reminded jurors that "[t]he Government must prove each element of each offense." There was also extensive evidence showing that Schena knew his conduct was unlawful. Our decision in *United States v. Liu*, 731 F.3d 982 (9th Cir. 2013), does not require a different result because there, unlike here, the district court "never clarified what [the defendant] needed to know." *Id.* at 995.

3. Schena next challenges the sufficiency of the evidence on his securities fraud convictions. For such a challenge, we view the evidence in the light most favorable to the government. *United States v. Nevils*, 598 F.3d 1158, 1163–64 (9th Cir. 2010) (en banc). Schena concedes he did not move for acquittal on these counts below, and so we review for plain error. *United States v. Lopez*, 4 F.4th 706, 719 (9th Cir. 2021).

a. Schena's challenge to Count 7 is without merit. This charge was based on an Arrayit press release "announc[ing] an allergy testing agreement ... with Sutter Health," a large healthcare provider. In reality, Arrayit had only received interest from a few doctors at Sutter-owned Palo Alto Medical Foundation (PAMF), and the only contact Arrayit had with Sutter itself was when Sutter sent Arrayit a cease-and-desist letter. While the body of the press release does state that the machines are to be provided to the PAMF doctors, it also references to an "agreement with Sutter Health," says that the company's allergy testing now "include[s] a major healthcare provider," and states that Arrayit is "[p]artnering with healthcare leader Sutter Health." A reasonable jury could find that investors would interpret the press release to falsely imply that Arrayit had an agreement with Sutter.

b. Schena's challenge to Count 8 is similarly meritless. This charge stemmed from a tweet in which Arrayit announced it had started a $240 million "test kit manufacturing run." Schena does not appear to challenge the falsity of the statement and only argues that the statement was not material. He points to the fact that the two investors who testified at trial said the tweet did not immediately lead them to trade Arrayit stock. But the witnesses did not say the tweet did not matter to them. In fact, one said it would have affected "long term" trades. Moreover, Arrayit received a significant number of inquiries from investors asking about the tweet. Taken together, the evidence is sufficient to support a reasonable jury's determination that there was a "substantial likelihood that a reasonable shareholder would consider [the tweet] important." *Basic Inc. v. Levinson*, 485 U.S. 224, 231 (1988) (quoting *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)).

c. Schena's challenge to Count 9 also fails. This count involved a series of emails that Schena sent telling investors that Arrayit had received "more than 50,000 requests" for its COVID test. At the time, it had received fewer than 1,000 requests, and no test was ready or approved by the Food and Drug Administration. Schena argues that the 50,000 figure was not material and the emails should be read to imply that the tests were in development and not necessarily ready. But a reasonable investor at the outset of the pandemic could have found the 50,000 figure material. Nor was the jury required to credit Schena's explanation that he meant only that the test was still in development.

4. The district court ordered $24,289,540 in restitution, based on $21,562,300 in losses associated with the securities fraud violations and $2,772,240 in losses by insurers in connection with the healthcare fraud counts (the district court ordered forfeiture of this same latter amount). We address each component of the restitution order in turn.

a. We vacate the restitution order to the extent of the $21,562,300 allegedly attributable to the securities fraud violations. A restitution award "can compensate 'only for the loss caused by the specific conduct that is the basis of the offense of conviction,' so long as that offense does not involve an element of scheme, conspiracy or pattern of criminal activity." *United States v. Batson*, 608 F.3d 630, 637 (9th Cir. 2010) (quoting *Hughey v. United States*, 495 U.S. 411, 413 (1990)); *see also United States v. Reed*, 80 F.3d 1419, 1422 (9th Cir. 1996) (explaining that circuit precedent "prohibit[s] the trial court from ordering restitution for conduct that is related to the offense of conviction, but that is not an element of the offense").

In this case, a fraudulent scheme was not a necessary element of the offense, but the government maintains it was the basis of Schena's conviction, thus justifying a restitution award based on the claimed duration of the scheme, which allegedly spanned July 15, 2015, to April 14, 2020. Although the indictment contains allegations of such a scheme, Counts 7–9 were more specifically based on three false and misleading statements made on November 19, 2018, August 8, 2019, and March 19, 2020, respectively.

Between the indictment, jury instructions, verdict form, and record as a whole, the parties debate

whether the broader five-year scheme can be said to reflect "the specific conduct that is the basis of the offense of conviction" on the securities fraud counts. *Batson*, 608 F.3d at 637 (quoting *Hughey*, 495 U.S. at 413). But in assessing loss for purposes of the Sentencing Guidelines, the district court already recognized that it could not determine whether the claimed $21,562,300 loss to investors was tethered to "the three instances of securities fraud conduct charged in the Superseding Indictment." In so finding, the district court treated "Mr. Schena's conduct of conviction" as the "three instances" of false disclosures identified in Counts 7–9. Even with the different burden of proof applied to the loss calculation, the district court's characterization of Schena's conduct of conviction undermines the government's reliance on a five-year scheme as the basis for the securities fraud convictions. We accordingly vacate the restitution award as to the securities fraud violations and remand for the district court to calculate it based on the specific conduct that was the basis for these three counts of conviction. *See Batson*, 608 F.3d at 637.

Schena also points out that the district court, in rejecting the government's loss calculation for Guidelines purposes, questioned the basis for the government's assertion that Arrayit's stock became worthless upon Schena's arrest, as well as the government's reliance on a "first-in, first-out" methodology that was, in the district court's view, "devoid of any data or calculations" that would permit meaningful judicial evaluation. On remand, the district court may consider these objections in reevaluating this portion of the restitution award.

b. We affirm the district court's $2.7 million restitution award for healthcare fraud and its related forfeiture award. Schena argues that the district court erred because the allergy testing was not entirely worthless. We review this factual issue for clear error. *United States v. Dadyan*, 76 F.4th 955, 961 (9th Cir. 2023). Testimony at trial supported the government's theory that insurers would not have paid any claims had they known that Arrayit was performing more tests than medically necessary and was otherwise engaging in fraudulent conduct. Therefore, the district court did not clearly err in concluding that all the money received from insurers could be considered the result of Schena's healthcare fraud.

* * *

We affirm Schena's convictions and the $2.7 million restitution and forfeiture orders associated with the healthcare fraud counts. We vacate only the $21.5 million restitution award for the securities law violations and remand solely for a redetermination of that portion of the restitution award.

AFFIRMED IN PART, VACATED AND REMANDED IN PART.

APPENDIX C

United States District Court, N.D. California,

San Jose Division.

USA, Plaintiff,

v.

Mark SCHENA, Defendant.

Case No. 20-cr-00425-EJD-1

Signed April 29, 2023

Jacob Nathaniel Foster, Justin Weitz, Laura Connelly, Assistant U.S. Attorneys, U.S. Department of Justice, Fraud Section, Washington, DC, Christina T. Liu, Lloyd A. Farnham, Assistant U.S. Attorney, United States Attorney's Office, San Francisco, CA, for Plaintiff.

Robert Michael Carlin, Public Defender, Federal Public Defender Northern District of California, San Jose, CA, Todd Alexander Pickles, Greenberg Traurig, P.A., Sacramento, CA, Alexandra Joelle Block, Pro Hac Vice, Greenberg Traurig, LLP, San Francisco, CA, Charles Dunham, IV, Pro Hac Vice, Greenberg Traurig, P.A., Houston, TX, for Defendant.

ORDER DENYING DEFENDANT'S MOTION FOR JUDGMENT OF ACQUITTAL AND MOTION FOR NEW TRIAL

Re: ECF No. 220

EDWARD J. DAVILA, United States District Judge

Defendant Mark Schena was indicted on nine counts and found guilty by a unanimous jury of each of them. Pending before the Court is Defendant's motion for a judgment of acquittal as to Counts 1 through 6 and motion for a new trial as to Counts 7 through 9 (the "Motion"). Defendant also moves for a new trial as to Counts 1 through 6 should the Court deny his motion for a judgment of acquittal. Having reviewed the parties' written submissions and the relevant case law, and having heard oral argument on August 23, 2022 and January 30, 2023, the Court DENIES Defendant's motion for judgment of acquittal and motion for a new trial for the reasons discussed below.

I. BACKGROUND

On May 18, 2021, the government filed the Superseding Indictment, charging Defendant Mark Schena with nine counts: conspiracy to commit health care fraud and wire fraud in violation of 18 U.S.C. § 1349 (Count 1); health care fraud in violation of 18 U.S.C. § 1347 (Counts 2–3); conspiracy to pay illegal kickbacks in violation of 18 U.S.C. § 371 (Count 4); payment of illegal kickbacks in violation of 18 U.S.C. § 220 (Counts 5–6); and securities fraud in violation of 15 U.S.C. §§ 78j, 78ff and 17 C.F.R. 240.10b-5 (Counts 7–9). ECF No. 53 ("Superseding Indictment"). The Superseding Indictment alleged that between 2015 and 2020, Defendant—then the president of Arrayit Corporation, a publicly traded medical technology company that conducted various laboratory tests—and co-conspirators engaged in a scheme to deceive (1) commercial and government insurers (i.e., Medicare, Medicaid, and TRICARE) about insurance claims submitted to those insurers and (2) purchasers

and sellers of Arrayit's securities, and the market at large, about Arrayit's financial performance. *Id.* at ¶¶ 1–2, 29, 38.

Trial began on July 26, 2022. See ECF No. 189 ("7/26/22 Trial Tr."). On August 23, 2022, following the presentation of evidence but before closing arguments or jury deliberation, Defendant orally moved for a judgment of acquittal as to Counts 1 through 6 under Federal Rule of Criminal Procedure 29.[1] ECF No. 209 ("8/23/22 Trial Tr.") 2415:13–2416:8. The government opposed the motion, *id.* at 2416:11–2420:5, and the Court reserved decision on the motion, *id.* at 2420:9–11. On September 1, 2022, the jury returned a verdict finding Defendant guilty on all nine counts. ECF No. 218.

On September 15, 2022, Defendant filed the instant motion, which furthered his oral motion for a judgment of acquittal as to Counts 1 through 6, and included an additional motion for a new trial as to Counts 7 through 9 (as well as for Counts 1 through 6, should the Court deny the motion for a judgment of acquittal) under Federal Rule of Criminal Procedure 33. ECF No. 220 ("Mot."). Defendant does not advance any additional arguments in the Motion as to Count 1, noting instead that he stands on the arguments made in the initial oral motion. Id. at 3 n.1 The government opposes the Motion, asserting that the evidence presented at trial was sufficient to support the jury's verdict and that Defendant is not entitled to a new trial on any counts. ECF No. 226 ("Opp.").

[1] The motion was made outside the presence of the jury, who had been dismissed for the day. 8/23/22 Trial Tr. 2412:24, 2415:13–14.

Defendant filed a reply, ECF No. 228 ("Reply"), and the Court heard oral argument on the Motion on January 30, 2023.

II. DISCUSSION

A. Motion for Judgment of Acquittal

Federal Rule of Criminal Procedure 29 permits a court to set aside a jury's guilty verdict and enter a judgment of acquittal only if "the evidence is insufficient to sustain a conviction." Under this standard, "the relevant question is whether, after viewing the evidence in the light most favorable to the prosecution, any rational trier of fact could have found the essential elements of the crime beyond a reasonable doubt." *United States v. Riggins*, 40 F.3d 1055, 1057 (9th Cir. 1994) (quoting *Jackson v. Virginia*, 443 U.S. 307, 319 (1979)). Courts accord great deference to a jury's determination. *See Jackson*, 443 U.S. at 318–19. "The hurdle to overturn a jury's conviction based on a sufficiency of the evidence challenge is high." *United States v. Rocha*, 598 F.3d 1144, 1153 (9th Cir. 2010). The Court must find that no rational jury could have convicted Defendant of Counts 1 through 6, namely, conspiracy to commit health care fraud, the commission of health care fraud, conspiracy to pay illegal kickbacks, and the payment of illegal kickbacks. That is, the Court must conclude that, viewing the facts in the light most favorable to the government, "the government's proof was insufficient as a matter of law." *Id.*; *see also United States v. Nevils*, 598 F.3d 1158, 1164 (9th Cir. 2010) (en banc). Pursuant to this standard, the Court holds there is sufficient evidence to convict Defendant of Counts 1 through 6.

1. Count 1: Conspiracy to Commit Health Care Fraud and Wire Fraud

To prove a conspiracy to commit health care fraud and wire fraud under § 1349, the government had to prove (1) that Defendant and one or more co-conspirators agreed to commit health care fraud or wire fraud and (2) that Defendant became a member of the alleged conspiracy knowing at least one of its objects and intending to help accomplish it. Based on the evidence presented at trial, a reasonable juror could find that Defendant conspired with other individuals to commit health care fraud or wire fraud to avert Arrayit's financial collapse by submitting improper insurance claims to federal and commercial insurers related to allergy and covid-19 testing.

First, contextually, the government introduced evidence about the financial health of Arrayit and of Defendant and his wife, Renee Schena, who served as Arrayit's CEO. Arrayit was losing money in at least 2015 and 2016, and had depended on outside sources—i.e., loans—for financing. 8/10/22 Trial Tr. 1124:6–20. By early 2018, one of the lenders, TCA, was taking most of Arrayit's revenue as payback for a loan. 8/11/22 Trial Tr. 1297:15–22. In August 2018, Defendant took out a loan against his home, which was ostensibly to be secured by Arrayit's cash flow. Trial Ex. 922. The Schenas took on loans for Arrayit on atypical, unfavorable terms in order to shore up its finances. The jury could reasonably infer from these and other facts that Defendant was motivated to financially "save" Arrayit.

The government introduced evidence that Defendant did in fact agree with other co-conspirators

to commit health care fraud to benefit Arrayit. For example, Defendant hired Dr. Julie Taguchi as Arrayit's lab director, leading to Arrayit's receipt of the regulatory licenses that permitted it to perform clinical patient sample tests and bill insurance. 8/12/22 Trial Tr. 1632:17–1633:3, 1653:11–23. However, the government introduced testimony that Dr. Taguchi did not execute the duties of a lab director; she did not run or review the quality of sample testing or did not supervise anyone. 8/16/22 Trial Tr. 1795:5–22. Defendant nonetheless submitted documents to regulators stating that Dr. Taguchi was in charge of Arrayit's laboratory and carried out supervisory responsibilities, as required for Arrayit's operating licenses. 8/12/22 Trial Tr. 1650:21–1651:4.

The government also introduced the testimony of Paul Haje, the former vice president of marketing of Arrayit and cousin of Renee Schena.[2] Mr. Haje informed the jury that he had pleaded guilty to conspiring with Defendant and others, including Renee Schena, Dan Williams, Marc Jablonski, and Dr. Taguchi, to submit false and fraudulent claims to government insurers, including Medicare and TRICARE, and to private insurers. 8/11/22 Trial Tr. 1282:7–1285:7. Mr. Haje testified that Defendant led Arrayit and its employees in a scheme under which Arrayit would bill government and private insurers for unnecessary and expensive allergy tests— after deceiving regulators in order to be licensed to perform and bill for such tests—that were sourced from kickback payments. *See id.* at 1332:11–1341:24. Mr.

[2] Arrayit was a "very small company" with about seven employees, most of whom were related to each other or close friends. 8/11/22 Trial Tr. 1289:24–1290:11.

Jablonski and Dr. Taguchi testified along similar lines. *See* 8/9/22 Trial Tr. 743:4–744:25; 1758:24–1761:13. The payments to marketers who sourced tests for Arrayit were transmitted via wire by Renee Schena, in amounts decided by Defendant. 8/11/22 Trial Tr. 1291:22–1292:2. Given the evidence described above and reviewing the evidence in the light most favorable to the government, the Court cannot conclude that no rational jury would have convicted Defendant of Count 1. There is sufficient evidence to support the verdict on Count 1.

2. Counts 2–3: Health Care Fraud

To prove health care fraud, the government had to prove that Defendant (1) knowingly and willfully (2) executed or attempted to execute (3) a scheme to defraud any health care benefit program. In Counts 2 and 3, the government charged Defendant with health care fraud related to the submission of claims to, respectively, a private insurance company on behalf of Wendy Woodward and Medicare on behalf of Teresa Resendez. Superseding Indictment ¶¶ 48–49. Defendant argues that a judgment of acquittal is required because the government "never produced any evidence of (1) the claim forms submitted by Dr. Chrono on behalf of Arrayit, (2) any evidence that Mr. Schena himself was at all involved in any aspect of the submission of the claim, or (3) any evidence of mens rea by Mr. Schena in connection with those counts." Mot. 6–7. Without this evidence, Defendant asserts, "[t]here was nothing from which the jury could find, even inferentially, that Mr. Schena had anything at all to do with the submission of those claims," so that no rational jury could find Defendant guilty of health care fraud in connection with either of the claim

submissions at issue. *Id.* at 7. Defendant further contends that there was insufficient evidence for a rational jury to convict him under the *Pinkerton v. United States* theory of liability, *i.e.*, as a co-conspirator "criminally liable for reasonably foreseeable overt acts committed by others in furtherance of the conspiracy they have joined, whether they were aware of them or not." *United States v. Hernandez-Orellana*, 539 F.3d 994, 1007 (9th Cir. 2008) (citing *Pinkerton*, 328 U.S. 640, 647 (1946)). Id.

As described above, the government presented evidence that Defendant conspired to commit health care fraud. The jury heard from Dr. Catherine Tolentino of the California Department of Public Health that she would not have approved Arrayit's laboratory license—which allowed it to bill insurers for tests—but for Defendant's submission of documents stating that Dr. Taguchi was Arrayit's bona fide laboratory director, including a lab quality assurance manual that included false statements about Dr. Taguchi's role and supervision of the lab. 8/12/22 Trial Tr. 1650:25–1654:13; Trial Ex. 703. The claim submissions charged in Courts 2 and 3 could not have been charged but for these false representations by Defendant. The government also presented evidence that Defendant led a scheme to bill for medically unnecessary allergy testing, and to source such tests by making illegal kickback payments to marketers in exchange for patient referrals. 8/11/22 Trial Tr. 1332:11–1341:24; *id.* at 1361:7–21; 8/9/22 Trial Tr. 743:4–744:25; id. at 785:7–786:18.

The government also presented evidence showing that Arrayit's allergy testing revenues

declined following the beginning of the covid-19 pandemic, and that subsequently Defendant made false statements about Arrayit's covid-19 test to obtain patient blood samples to then conduct additional allergy tests that were billed to insurers. 8/9/22 Trial Tr. 802:3–808:12; 8/11/22 Trial Tr. 1382:15–1383:1. Even after doctors informed Defendant that Arrayit's requisition forms should focus on covid-19 and not allergies, Defendant continued to market a combination of covid-19 and allergy testing and to unnecessarily bundle the two types of tests. 8/9/22 Trial Tr. 807:20–23. Specifically, both Ms. Woodward and Ms. Resendez received allergy testing when they did not want or need it—Ms. Woodward solely required a covid-19 antibody test, and Ms. Resendez was required to give her blood for a covid-19 test to enter a union hall building. 8/12/22 Trial Tr. 1703:11–1710:17; 8/19/22 Trial Tr. 2092:3–2101:5. Based on this and other evidence, a rational jury could have found that Defendant "knowingly and willfully executed or attempted to execute a scheme or plan to defraud health care benefit programs," including with respect to the submission of the claims charged in Counts 2 and 3.

Defendant argues that no rational jury could convict him of health care fraud with respect to Ms. Resendez's or Ms. Woodward's claims because the government did not present evidence that he himself submitted or discussed their specific claims. Mot. 7. Defendant further contends that the jury therefore must have convicted Defendant based on Pinkerton liability, *i.e.*, based on the claim submission of a co-conspirator. *Id.* Defendant argues that the *Pinkerton* instruction was not appropriate because no other

individual was charged with the substantive offense—according to Defendant, the actual claim submission—and that there was insufficient evidence to convict him even under the theory. *Id.* at 7 & n.2. As described above, a rational jury could have convicted Defendant based on the evidence of his intent to defraud insurers by orchestrating a scheme to become licensed to perform and then bill for unnecessary and unwanted allergy tests without relying on the *Pinkerton* instruction. Further, the government's presentation of evidence was also sufficient to result in a conviction under a *Pinkerton* theory, as it was reasonably foreseeable that claims for patients, including Ms. Woodward and Ms. Resendez, would be submitted to insurers within the scheme orchestrated by Defendant. A defendant "is liable for the acts of his co-conspirators though he was not aware of the performance of those acts, nor even of the existence of the actors." *United States v. Roselli*, 432 F.2d 879, 894 (9th Cir. 1970) (quoting *Hernandez v. United States*, 300 F.2d 114, 120 (1962)). The government was not required to identify a specific co-conspirator who performed the claim submission, id. at 895, and in fact Defendant had contracted a separate billing vendor to handle the submission of Arrayit's claims. Hiring an innocent third party to conduct the final act of claim submission does not remove Ms. Woodward's and Ms. Resendez's claims from the fraudulent scheme presented to the jury as orchestrated and intended by Defendant, and the Court cannot say that no rational jury would have convicted on this evidence.

3. Count 4: Conspiracy to Pay Illegal Kickbacks

To prove a conspiracy to pay illegal kickbacks under 18 U.S.C. § 371, the government had to prove (1) that Defendant and one or more co-conspirators agreed to pay illegal health care kickbacks for referrals to testing laboratories; (2) that Defendant became a member of the alleged conspiracy knowing at least one of its objects and intending to help accomplish it; and (3) one of the members of the conspiracy performed at least one overt act after October 2018 for the purpose of carrying out the conspiracy. The Court finds that a rational jury had sufficient evidence to convict Defendant of Count 4.

The government presented evidence from Marc Jablonski, who testified that he had pleaded guilty to receiving illegal kickbacks, and that he had conspired with Defendant and others, including Renee Schena and Paul Haje, to enact the scheme. 8/9/22 Trial Tr. 743:10–744:21. Under the scheme, Arrayit's marketing representatives were to receive as kickbacks a percentage of the net reimbursement from insurers. Trial Ex. 472. Mr. Haje testified that Defendant approved and was fully aware of the pay structure, and that the pitch to marketers was that "you'll get 50 percent of the insurance reimbursement[;] you can make up to $5,000 off of a single allergy test." 8/11/22 Trial Tr. 1333:22–1334:2. Mr. Jablonski testified that he presented Arrayit's marketing plan to doctors and the government introduced the presentation that Mr. Jablonski made to doctors. Id. at 783:7–10; Trial Ex. 903. Mr. Jablonski and other marketers targeted "naïve" doctors to persuade them to order Arrayit's more expensive and unnecessarily broad blood tests, rather

than more efficient and cheaper skin allergy tests. 8/9/22 Trial Tr. 771:11–775:6. Mr. Jablonski received payments from Arrayit based on patients referred by doctors. Trial Exs. 900, 901. The government presented evidence that Defendant informed Mr. Jablonski of a new immunotherapy pitch to make to doctors, and that Mr. Jablonski subsequently induced doctors to order Arrayit tests with a pitch that doctors could make up to $1.2 million a year from immunotherapy after using Arrayit's allergy test. Trial Exs. 644, 903; 8/9/22 Trial Tr. 771:11–777:22. Further, Mr. Jablonski explained that he and other marketers made the decision as to which laboratory to send patient blood samples to following receipt from a doctor's office, and that they sent blood samples to Arrayit because of the kickbacks Arrayit paid. 8/9/22 Trial Tr. 763:7–17.

As the Court has previously noted, there is no requirement that a kickback scheme involve direct interaction between a marketer and patient; it is sufficient that Defendant arranged to pay marketers like Mr. Jablonski to induce doctors to refer patients to Arrayit, and to directly send patient blood samples to Arrayit. ECF No. 135 (Order Denying Motion to Dismiss) at 7. Based on the evidence described above, a rational jury could find that Defendant and one or more co-conspirators, including Mr. Jablonski, agreed to a scheme wherein Arrayit paid marketers illegal health care kickbacks for referrals to testing laboratories, that Defendant became a member of the conspiracy to induce referrals to Arrayit, and that one or more overt acts, including payments to marketers and marketing toward doctors, occurred in the relevant time frame.

4. Counts 5–6: Payment of Illegal Kickbacks

To prove payment of illegal kickbacks under 18 U.S.C. § 220(a), the government had to prove that Defendant (1) knowingly and willfully offered or paid renumeration, such as a kickback, bribe, or rebate (2) to induce a referral of an individual to a laboratory for services performed by the laboratory (3) that were covered in whole or part by a health care benefit program. The evidence described above is sufficient to satisfy the first two elements, and the government produced evidence—and Defendant does not contest—that the government and private insurers are health care benefit programs that covered the allergy testing services. *See* Mot. 8–9; Opp. 13–16. The jury therefore had sufficient evidence on which to convict Defendant of Counts 5 and 6.

B. Motion for New Trial

Federal Rule of Criminal Procedure 33 provides that "[u]pon the defendant's motion, the court may vacate any judgment and grant a new trial if the interest of justice so requires." Fed. R. Crim. P. 33(a). A conclusion that "despite the abstract sufficiency of the evidence to sustain the verdict, the evidence preponderates sufficiently heavily against the verdict that a serious miscarriage of justice may have occurred" may constitute grounds for a new trial. *United States v. Alston*, 974 F.2d 1206, 1211 (9th Cir. 1992) (quoting *United States v. Lincoln*, 630 F.2d 313, 319 (8th Cir. 1980)). In its evaluation, "[t]he district court need not view the evidence in the light most favorable to the verdict; it may weigh the evidence and in so doing evaluate for itself the credibility of the witnesses." *Id.* The burden of justifying a new trial

rests with the defendant. *See United States v. Shaffer*, 789 F.2d 682, 687 (9th Cir. 1986). The Ninth Circuit has emphasized that a motion for a new trial "should be granted 'only in exceptional cases in which the evidence preponderates heavily against the verdict.'" *United States v. Rush*, 749 F.2d 1369, 1371 (9th Cir. 1984) (internal quotation omitted).

1. Counts 7–9: Securities Fraud

Counts 7 through 9 charged Defendant with securities fraud, namely, deceiving Arrayit investors and the general public as to Arrayit's financial performance and contracts. See Superseding Indictment ¶¶ 59–60. To obtain a conviction on each charge, the government had to prove that (1) Defendant willfully used a device or scheme to defraud, made untrue statements of material fact, failed to disclose material facts that resulted in making his statements misleading, or engaged in any act that operated or would operate as fraud or deceit upon any person; (2) such acts or failures to act were done in connection with the purchase and sale of Arrayit securities; (3) Defendant directly or indirectly used the wires or mails in connection with the acts, statements, or failures to disclose; and (4) Defendant acted knowingly.

Defendant argues that the evidence presented did not meet any of the elements necessary to prove the securities fraud counts, and the jury relied on improper legal testimony about SEC rules and regulations from the witness Thomas Carocci to reach its verdict. Mot. 9–10. That, is, Defendant contends that the government improperly introduced opinion

evidence as to whether Defendant violated SEC rules to obtain a conviction on securities fraud. Id. at 10.

Mr. Carocci testified as a securities markets and securities law expert about the duty of publicly traded companies with respect to honesty in communications with shareholders. 8/9/22 Trial Tr. 900:18–24, 911:21–25. Mr. Carocci testified generally about industry standards and requirements under securities laws and regulations. *See id.* at 900:18–917:15. He testified that Arrayit was a publicly traded company with an obligation to be truthful to shareholders, but did not provide an opinion as to whether Arrayit had met or violated that duty. *See id.* Nor did Mr. Carocci provide any opinion regarding Defendant. See id. Under these circumstances, the Court cannot say that the government improperly introduced opinion evidence from Mr. Carocci regarding whether Defendant violated SEC rules.

Defendant argues that Jury Note No. 7 indicates that the jury looked to Mr. Carocci as a source of relevant law regarding the government's burden as to Counts 7 through 9. Mot. 9–10. Jury Note No. 7 reads: "Follow up to Note # 6 [requesting "transcript for expert witness Thomas Carocci"]. Are publicly traded companies required to be truthful on all forms of communication[s, e.g.] press release, email, tweets[?] Is the bar lower for one form of communication (e.g. tweet) vs another form (e.g. press release or email)[?]" ECF No. 230 at 14–16. In response to this note, the Court brought the jury in for a readback of Mr. Carocci's testimony regarding the duty of publicly traded companies to be honest with shareholders, which "applies to all communications ... anything that comes from a company ... [including] press releases,

emails, postings, that type of stuff." *Id.* at 17; 8/9/22 Trial Tr. 911:21–25; 912:1–8, 14–19. The jury's question, and the answer it received, did not advise the jury on law as to the government's burden as to Counts 7 through 9, i.e., that (1) Defendant willfully used a device or scheme to defraud, made untrue statements of material fact, failed to disclose material facts that resulted in making his statements misleading, or engaged in any act that operated or would operate as fraud or deceit upon any person; (2) such acts or failures to act were done in connection with the purchase and sale of Arrayit securities; (3) Defendant directly or indirectly used the wires or mails in connection with the acts, statements, or failures to disclose; and (4) Defendant acted knowingly. Therefore, Mr. Carocci's testimony in no way constituted improper opinion testimony, let alone a "serious miscarriage of justice" requiring a new trial. *Alston*, 974 F.2d at 1211.

2. Counts 1–6: Health Care Fraud and Illegal Kickbacks

Lastly, Defendant argues that the Court—should it decline to grant a judgment of acquittal as to Counts 1 through 6—should vacate the verdicts and grant a new trial as to those counts because the jury "indicated there was confusion as to the elements of knowledge and willfulness, at least as it applied to Counts [1 through 6]." Mot. 10. Jury Note No. 5 (in fact the sixth jury note) asked: "Does 'wil[l]ful' include 'knowing'? Is it possible to be 'wil[l]ful' but not 'knowing'[?]" ECF No. 230 at 12. In response, the Court referred the jury to the instructions defining "willfully" and "knowing" as to each set of counts, and stated that the government "must prove each element

of each offense as indicated in the instructions for each offense charged." Id. at 13.

"Jurors are presumed to follow the court's instructions." *United States v. Reyes*, 660 F.3d 454, 468 (9th Cir. 2011). The jury was told, both in the original instructions and the response to the note, that the government was required to prove each element of each count. As such, there is no reason to suspect that the jury reached its verdicts as to Counts 1 through 6 without having found that the government met its burden as to each element of each count. The Ninth Circuit has emphasized that jury verdict be overturned and a motion for a new trial "granted 'only in exceptional cases,'" *Rush*, 749 F.2d at 1371, and the jury's use of notes as intended— to clarify questions— does not here constitute an "exceptional case."

III. CONCLUSION

For the foregoing reasons, the Court **DENIES** Defendant's motion for a judgment of acquittal as to Counts 1 through 6, **DENIES** Defendant's motion for a new trial as to Counts 7 through 9, and **DENIES** Defendant's motion for a new trial as to Counts 1 through 6.

IT IS SO ORDERED.

APPENDIX D

United States District Court, N.D. California,

San Jose Division.

USA, Plaintiff,

v.

Mark SCHENA, Defendant.

Case No. 5:20-cr-00425-EJD-1

Signed 05/28/2022

Jacob Nathaniel Foster, Justin Weitz, Assistant US Attorneys, U.S. Department of Justice, Fraud Section, Washington, DC, Laura Connelly, Assistant US Attorney, DOJ-Crm, Criminal Division, Washington, DC, William Frentzen, Lloyd A. Farnham, Assistant US Attorneys, U.S. Attorney's Office, San Francisco, CA, for Plaintiff.

Robert Michael Carlin, Public Defender, Federal Public Defender, San Jose, CA, Todd Alexander Pickles, Greenberg Traurig LLP, Sacramento, CA, Charles Dunham, IV, Pro Hac Vice, Greenberg Traurig, P.A., Houston, TX, for Defendant.

ORDER DENYING MOTION TO DISMISS

Re: Dkt. No. 98

EDWARD J. DAVILA, United States District Judge

Defendant Mark Schena is charged by indictment with conspiracy to commit health care

fraud and wire fraud in violation of 18 U.S.C. § 1349, health care fraud in violation of 18 U.S.C. § 1347, conspiracy to pay illegal kickbacks in violation of 18 U.S.C. § 371, payment of illegal kickbacks in violation of 18 U.S.C. § 220 and securities fraud in violation of 15 U.S.C. §§ 78j & 78ff and 17 C.F.R. 240.10b-5. *See* Superseding Indictment ("SI"), Dkt. No. 53. Before the Court is Defendant's motion to dismiss Counts 4–6 of the Superseding Indictment on the grounds that the counts do not allege conduct that is prohibited by the Eliminating Kickbacks in Recovery Act ("EKRA"). Having considered the parties' arguments and submissions, and for the reasons set forth below, the Court **DENIES** the motion to dismiss.

I. BACKGROUND

Defendant served as the President of Arrayit Corporation ("Arrayit"). SI ¶ 1. Arrayit was a publicly traded medical technology company incorporated in Nevada, and based in Sunnyvale, California. SI ¶ 2. Arrayit described itself as a "world leader in microarray technology empowering researchers and doctors in the life sciences, wellness and healthcare testing markets." SI ¶ 2. Arrayit was a participating provider in the Medicare, Medicaid, TRICARE, and other health care benefit programs, and submitted or caused the submission of claims to Medicare, Medicaid, TRICARE, and other health care benefit programs. SI ¶ 2.

Defendant is charged with a scheme to offer and pay illegal kickbacks and a scheme to commit health care fraud and securities fraud. *See* SI ¶ 29. The government alleges that the purpose of the kickback scheme was for Defendant to enrich himself by, among

other things, "submitting or causing the submission of false and fraudulent claims by interstate wire to Medicare, Medicaid, TRICARE, and the Commercial Insurers for services that were (i) procured by the payment of kickbacks and bribes." SI ¶ 35.

Count 4 of the Superseding Indictment charges Defendant with conspiracy to violate 18 U.S.C. § 371, with the object of the conspiracy being to violate EKRA. SI ¶¶ 50–56. Counts 5 and 6 of the Superseding Indictment charge substantive violations of EKRA. SI ¶¶ 57–58.

Counts 4–6 incorporate the following allegations:

> 41. SCHENA and others paid and caused the offer and payment of illegal kickbacks and bribes to other individuals and purported marketing companies in exchange for blood samples collected from patients and orders for allergy testing from health care providers, all of which were used to support false and fraudulent claims that were submitted by Arrayit and others to Medicare, Medicaid, TRICARE, and Commercial Insurers.
>
> 42. SCHENA and others distributed false and fraudulent marketing material and other documents that misrepresented the medical necessity of Arrayit's allergy test and Arrayit's ability to provide accurate, fast, and reliable allergy test results that would be medically necessary and reasonable in the treatment of the patient.
>
> ....

> 45. SCHENA and others obtained fraudulent orders for allergy and COVID-19 testing by making false and fraudulent statements, directly and indirectly, to health care providers, patients, and others concerning Arrayit's ability to provide accurate, fast, and reliable COVID-19 testing in compliance with applicable state and federal regulations, and the purported need to bundle the COVID-19 test with Arrayit's allergy test, while concealing that, at various times, the Arrayit COVID-19 test had not been developed, validated, produced, received the requisite regulatory authorization, or able to return timely COVID-19 results as represented.
>
> ....
>
> 47. SCHENA and others caused Arrayit to submit approximately $69 million in claims by interstate wire to Medicare, Medicaid, TRICARE, and the Commercial Insurers for allergy tests that were obtained through illegal kickbacks and bribes, medically unnecessary, ineligible for reimbursement, and/or not provided as represented.

Defendant moves to dismiss three counts in the Superseding Indictment on the ground that EKRA does not reach the conduct alleged in the indictment. *See* Notice of Motion and Motion to Dismiss Counts Four Through Six of Superseding Indictment ("Mot."), Dkt. No. 98. On February 28, 2022, the Government filed an opposition, to which Defendant filed a reply

brief. See United States' Opposition to Defendant's Motion to Dismiss Counts Four Through Six of the Superseding Indictment ("Opp."), Dkt. No. 103; Reply Brief in Support of Motion to Dismiss Counts Four Through Six of Superseding Indictment ("Reply"), Dkt. No. 106.

II. LEGAL STANDARD

Rule 12(b) of the Federal Rules of Criminal Procedure permits any defense "which is capable of determination without the trial of the general issue" to be raised by pretrial motion. The motion must be decided before trial "unless the court, for good cause, orders that it be deferred for determination at the trial of the general issue or until after verdict, but no such determination shall be deferred if a party's right to appeal is adversely affected." Fed. R. Crim. P. 12(e). Under this standard, the district court must decide the issue raised in the pretrial motion before trial if it is "entirely segregable" from the evidence to be presented at trial." *United States v. Shortt Accountancy Corp.*, 785 F.2d 1448, 1452 (9th Cir. 1986) (quotation marks and citation omitted).

III. DISCUSSION

Defendant is charged by indictment with violation of EKRA, which provides, in relevant part:

> (a) Offense.–Except as provided in subsection (b), whoever, with respect to services covered by a health care benefit program, in or affecting interstate or foreign commerce, knowingly and willfully–

> (1) solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or
>
> (2) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind–
>
> > (A) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or
> >
> > (B) in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory, shall be fined not more than $200,000, imprisoned not more than 10 years, or both, for each occurrence.

18 U.S.C. § 220(a).

For purposes of § 220, "laboratory" or "clinical laboratory" means a facility for the "biological, microbiological, serological, chemical, immune-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the

assessment of the health of, human beings." *See* 18 U.S.C. § 220(e)(4) (incorporating 42 U.S.C. § 263(a)'s definition of laboratory).

There is no dispute that Arrayit is a medical laboratory testing facility within the meaning of § 220. Rather, the Parties dispute whether EKRA applies to situations where a marketer obtains a referral of patients by securing them indirectly from physicians, rather than working with individual patients directly. That is, whether EKRA requires the marketer to work directly with individual patients. Defendant argues that it does and contends that because the Superseding Indictment premises EKRA liability on Defendant's use of marketers to indirectly recruit patients, Counts 4–6 must be dismissed. *See* Mot. at 4. As support for this position, Defendant relies on *S&G Labs Haw., LLC v. Graves*, 2021 WL 4847430 (D. Haw. Oct. 18, 2021), a civil case. An overview of the case is helpful.

S&G employed Darren Graves, a marketer, to oversee client accounts. *S&G Labs*, 2021 WL 4847430, at *2. Graves's compensation included a base annual salary of $50,000, plus a 35% "cut" of the monthly net profits generated by his client accounts and the client accounts handled by the S&G employees who he managed. *Id.* Clients under the contracts were not patients but were physicians or other organizations in need of having persons tested. *Id.* at 11. In early 2019, S&G's general counsel advised the laboratory director, Dr. Puana, that EKRA prevents a medical testing company from compensating its employees based on the number of tests the company performed. *Id.* Dr. Puana then informed the S&G account executives, including Graves, of her intent to revise

the compensation structure. *Id.* During the revision process, Dr. Puana and Graves engaged in negotiations regarding the new employment agreement, but never entered into a new agreement. *Id.* Subsequently, Graves was terminated for cause and litigation ensued. *Id.* Graves argued that S&G breached his employment contract. In response, S&G argued that Graves's contract became illegal upon the passage of EKRA.

The court rejected S&G's argument and determined that the relevant provisions of EKRA were to be read in the context of the Anti-Kickback statute. *Id.* at *10. The court held that EKRA did not apply because Graves was not compensated in a manner that considered the referral of individual patients. While Graves's "commission-based compensation structure induced him to try to bring more business to S&G," it did not implicate EKRA because "the 'client accounts [Graves] serviced were not individuals whose samples were tested at S&G." *Id.* at *11. Because Graves was not "working with individuals, the compensation that S&G paid him was not paid to him to induce him to refer individuals to S&G." *Id.* Thus, the court determined that EKRA did not apply because there was no payment for the referral of an individual patient for laboratory services. *Id.* at *11.

The holding of *S&G Labs* rests on the incorporation of 42 U.S.C. § 1320a-7b(b), the Anti-Kickback statute, to define EKRA's use of "renumeration" and "individual." 18 U.S.C. § 202 does not define either of these terms. Confusingly, EKRA specifically excludes its applicability to "conduct that is prohibited under section 1128B of the Social

Security Act (42 U.S.C. § 1320a-7b)." 18 U.S.C. § 220(d)(1). Thus, the incorporation of 42 U.S.C. § 1320a-7b(b) appears misplaced.

Further the Anti-Kickback statute does not define renumeration. Rather, it states

> [w]henever under this chapter or any Act of Congress, or under the law of any State, an employer is required or permitted to deduct any amount from the remuneration of an employee and to pay the amount deducted to the United States, a State, or any political subdivision thereof, then for the purposes of this chapter the amount so deducted shall be considered to have been paid to the employee at the time of such deduction.

42 U.S.C. § 1301(c). The Court understands the *S&G Labs* court to use this to demonstrate that Congress did not mean to criminalize "renumerations" paid by an employer to an employee. But § 1301(c) does not support this analysis. Rather, it discusses situations where renumerations are permissible or required, it does not blanketly authorize any type of renumeration paid by an employer to an employee. *See* 18 U.S.C. § 220(b)(2) (EKRA's safe harbor provision provides statutory exceptions for certain renumerations, but not all employer-employee renumerations).

Likewise, the definition of "person" is unhelpful. 42 U.S.C. § 1301(a)(3) defines "person" as "an individual, a trust or estate, a partnership, or a corporation." This definition says nothing about payment needing to be made based on the "direct"

recruitment of an individual patient. Indeed, it does not even define "individual" as used in 18 U.S.C. § 220, let alone impose a requirement of directness.

Moreover, there is no requirement of "directness" in the text of EKRA. Rather, by its terms, it applies to situations where someone "pays or offers any remuneration," to "induce" an individual into using laboratory or clinical services. 18 U.S.C. § 220(a). Notably missing is any requirement of direct interaction between the marketer and the individual. *See Az. State Bd. of Charter Schs. v. U.S. Dep't of Educ.*, 464 F.3d 1003, 1009–1010 (9th Cir. 2006) ("This interpretation would impute meaning not apparent from a natural reading of the text and essentially rewrite the statute.").

Under the rules of statutory construction, "[t]he plain meaning of the statute controls, and courts will look no further, unless its application leads to unreasonable or impracticable results." *United States v. Leyva*, 282 F.3d 623, 625 (9th Cir. 2002). The plain meaning of "to induce a referral of an individual" includes situations where a marketer causes an individual to obtain a referral from a physician. *See Induce, Black's Law Dictionary* (5th ed. 1979) ("To bring on or about, to effect, cause, to influence an act or cause of conduct, lead by persuasion or reasoning, incite by motives, prevail on." (emphasis added*)); see also Hanlester Network v. Shalala*, 51 F.3d 1390, 1399 (9th Cir. 1995) (determining that "to induce" in the context of the Anti-Kickback statute connotes "an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business").

EKRA reaches the conduct at issue in the Superseding Indictment, namely Defendant's alleged scheme to influence marketers by paying them illegal kickbacks to induce the referral of patients to Arrayit. SI ¶¶ 41–42, 55–58. It is irrelevant that some of the marketers caused the referral of patients by conveying Defendant's allegedly false representations about Arrayit to physicians, instead of to the patients directly. The physicians referred the patients based on the misrepresentations, and the marketers received a kickback to "influence" the physician's referrals.

This conduct squarely falls within the text of EKRA. Accordingly, Defendant's motion to dismiss Counts 4–6 is **DENIED**.[1]

IV. CONCLUSION

For the foregoing reasons, Defendant's motion to dismiss is **DENIED**.

IT IS SO ORDERED.

[1] The Government suggests that it is improper to decide the issue presented at the motion to dismiss phase given that an adequate evidentiary record has not been developed. The Government requests that the Court convert the motion to a motion *in limine*. Given the Court's ability to resolve the legal issues based purely on the statutory text, the Court declines to convert the motion into a motion *in limine*.

APPENDIX E

18 U.S.C.A. § 220

Illegal remunerations for referrals to recovery homes, clinical treatment facilities, and laboratories

(a) Offense.--Except as provided in subsection (b), whoever, with respect to services covered by a health care benefit program, in or affecting interstate or foreign commerce, knowingly and willfully--

(1) solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or

(2) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--

(A) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or

(B) in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory,

shall be fined not more than $200,000, imprisoned not more than 10 years, or both, for each occurrence.

(b) Applicability.--Subsection (a) shall not apply to--

(1) a discount or other reduction in price obtained by a provider of services or other entity under a health care benefit program if the reduction in price is

properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity;

(2) a payment made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) for employment, if the employee's payment is not determined by or does not vary by--

(A) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory;

(B) the number of tests or procedures performed; or

(C) the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory;

(3) a discount in the price of an applicable drug of a manufacturer that is furnished to an applicable beneficiary under the Medicare coverage gap discount program under section 1860D-14A(g) of the Social Security Act (42 U.S.C. 1395w-114a(g));

(4) a payment made by a principal to an agent as compensation for the services of the agent under a personal services and management contract that meets the requirements of section 1001.952(d) of title 42, Code of Federal Regulations, as in effect on the date of enactment of this section;

(5) a waiver or discount (as defined in section 1001.952(h)(5) of title 42, Code of Federal

Regulations, or any successor regulation) of any coinsurance or copayment by a health care benefit program if--

(A) the waiver or discount is not routinely provided; and

(B) the waiver or discount is provided in good faith;

(6) a remuneration described in section 1128B(b)(3)(I) of the Social Security Act (42 U.S.C. 1320a-7b(b)(3)(I));

(7) a remuneration made pursuant to an alternative payment model (as defined in section 1833(z)(3)(C) of the Social Security Act) or pursuant to a payment arrangement used by a State, health insurance issuer, or group health plan if the Secretary of Health and Human Services has determined that such arrangement is necessary for care coordination or value-based care; or

(8) any other payment, remuneration, discount, or reduction as determined by the Attorney General, in consultation with the Secretary of Health and Human Services, by regulation.

(c) **Regulations.**--The Attorney General, in consultation with the Secretary of Health and Human Services, may promulgate regulations to clarify the exceptions described in subsection (b).

(d) **Preemption.**--

(1) Federal law.--This section shall not apply to conduct that is prohibited under section 1128B of the Social Security Act (42 U.S.C. 1320a-7b).

(2) State law.--Nothing in this section shall be construed to occupy the field in which any provisions of this section operate to the exclusion of State laws on the same subject matter.

(e) Definitions.--In this section--

(1) the terms "applicable beneficiary" and "applicable drug" have the meanings given those terms in section 1860D-14A(g) of the Social Security Act (42 U.S.C. 1395w-114a(g));

(2) the term "clinical treatment facility" means a medical setting, other than a hospital, that provides detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under State law;

(3) the term "health care benefit program" has the meaning given the term in section 24(b);

(4) the term "laboratory" has the meaning given the term in section 353 of the Public Health Service Act (42 U.S.C. 263a); and

(5) the term "recovery home" means a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders.

APPENDIX F

42 U.S.C.A. § 1320a-7b

Criminal penalties for acts involving Federal health care programs

(a) Making or causing to be made false statements or representations

Whoever--

(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program (as defined in subsection (f)),

(2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment,

(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized,

(4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully

converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person,

(5) presents or causes to be presented a claim for a physician's service for which payment may be made under a Federal health care program and knows that the individual who furnished the service was not licensed as a physician, or

(6) for a fee knowingly and willfully counsels or assists an individual to dispose of assets (including by any transfer in trust) in order for the individual to become eligible for medical assistance under a State plan under subchapter XIX, if disposing of the assets results in the imposition of a period of ineligibility for such assistance under section 1396p(c) of this title,

shall (i) in the case of such a statement, representation, concealment, failure, or conversion by any person in connection with the furnishing (by that person) of items or services for which payment is or may be made under the program, be guilty of a felony and upon conviction thereof fined not more than $100,000 or imprisoned for not more than 10 years or both, or (ii) in the case of such a statement, representation, concealment, failure, conversion, or provision of counsel or assistance by any other person, be guilty of a misdemeanor and upon conviction thereof fined not more than $20,000 or imprisoned for not more than one year, or both. In addition, in any case where an individual who is otherwise eligible for assistance under a Federal health care program is convicted of an offense under the preceding provisions of this subsection, the administrator of such program

may at its option (notwithstanding any other provision of such program) limit, restrict, or suspend the eligibility of that individual for such period (not exceeding one year) as it deems appropriate; but the imposition of a limitation, restriction, or suspension with respect to the eligibility of any individual under this sentence shall not affect the eligibility of any other person for assistance under the plan, regardless of the relationship between that individual and such other person.

(b) Illegal remunerations

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in

cash or in kind to any person to induce such person--

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(3) Paragraphs (1) and (2) shall not apply to--

(A) a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program;

(B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services;

(C) any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or

entities who are furnishing services reimbursed under a Federal health care program if--

(i) the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract, and

(ii) in the case of an entity that is a provider of services (as defined in section 1395x(u) of this title), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity;

(D) a waiver of any coinsurance under part B of subchapter XVIII by a Federally qualified health care center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act;

(E) any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 or in regulations under section 1395w-104(e)(6) of this title;

(F) any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1395mm of

this title or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide;

(G) the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under part D of subchapter XVIII, if the conditions described in clauses (i) through (iii) of section 1320a-7a(i)(6)(A) of this title are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1395w-114(a)(3) of this title), section 1320a-7a(i)(6)(A) of this title shall be applied without regard to clauses (ii) and (iii) of that section);

(H) any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1395w-23(a)(4) of this title;

(I) any remuneration between a health center entity described under clause (i) or (ii) of section 1396d(l)(2)(B) of this title and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or

enhance the quality, of services provided to a medically underserved population served by the health center entity;

(J) a discount in the price of an applicable drug (as defined in paragraph (2) of section 1395w-114a(g) of this title) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1395w-114a of this title;

(K) an incentive payment made to a Medicare fee-for-service beneficiary by an ACO under an ACO Beneficiary Incentive Program established under subsection (m) of section 1395jjj of this title, if the payment is made in accordance with the requirements of such subsection and meets such other conditions as the Secretary may establish; and

(L) a bona fide mental health or behavioral health improvement or maintenance program, if--

(i) such program--

(I) consists of counseling, mental health services, a suicide prevention program, or a substance use disorder prevention and treatment program;

(II) is made available to a physician or other clinician for the primary purpose of preventing suicide, improving mental health and resiliency, or providing training in appropriate strategies to promote the mental health and resiliency of such physician or other clinician;

(III) is set out in a written policy, approved in advance of the operation of the program by the governing body of the entity providing such program (and which shall be updated accordingly in advance to substantial changes to the operation of such program), that includes--

(aa) a description of the content and duration of the program;

(bb) a description of the evidence-based support for the design of the program;

(cc) the estimated cost of the program;

(dd) the personnel (including the qualifications of such personnel) implementing the program; and

(ee) the method by which such entity will evaluate the use and success of the program;

(IV) is offered by an entity described in clause (ii) with a formal medical staff to all physicians and other clinicians who practice in the geographic area served by such entity, including physicians who hold bona fide appointments to the medical staff of such entity or otherwise have clinical privileges at such entity;

(V) is offered to all such physicians and clinicians on the same terms and conditions and without regard to the volume or value of referrals or other business generated by a physician or clinician for such entity;

(VI) is evidence-based and conducted by a qualified health professional; and

(VII) meets such other requirements the Secretary may impose by regulation as needed to protect against program or patient abuse;

(ii) such entity is--

(I) a hospital;

(II) an ambulatory surgical center;

(III) a community health center;

(IV) a rural emergency hospital;

(V) a skilled nursing facility; or

(VI) any similar entity, as determined by the Secretary; and

(iii) neither the provision of such program, nor the value of such program, are contingent upon the number or value of referrals made by a physician or other clinician to such entity or the amount or value of other business generated by such physician for the entity.

(4) Whoever without lawful authority knowingly and willfully purchases, sells or distributes, or arranges for the purchase, sale, or distribution of a beneficiary identification number or unique health identifier for a health care provider under subchapter XVIII, subchapter XIX, or subchapter XXI shall be imprisoned for not more than 10 years or fined not

more than $500,000 ($1,000,000 in the case of a corporation), or both.

(c) False statements or representations with respect to condition or operation of institutions

Whoever knowingly and willfully makes or causes to be made, or induces or seeks to induce the making of, any false statement or representation of a material fact with respect to the conditions or operation of any institution, facility, or entity in order that such institution, facility, or entity may qualify (either upon initial certification or upon recertification) as a hospital, critical access hospital, skilled nursing facility, nursing facility, intermediate care facility for the mentally retarded, home health agency, or other entity (including an eligible organization under section 1395mm(b) of this title) for which certification is required under subchapter XVIII or a State health care program (as defined in section 1320a-7(h) of this title), or with respect to information required to be provided under section 1320a-3a of this title, shall be guilty of a felony and upon conviction thereof shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(d) Illegal patient admittance and retention practices

Whoever knowingly and willfully--

(1) charges, for any service provided to a patient under a State plan approved under subchapter XIX, money or other consideration at a rate in excess of the rates established by the State (or, in the case of services provided to an individual enrolled with a medicaid managed care organization under subchapter XIX under a contract under section

1396b(m) of this title or under a contractual, referral, or other arrangement under such contract, at a rate in excess of the rate permitted under such contract), or

(2) charges, solicits, accepts, or receives, in addition to any amount otherwise required to be paid under a State plan approved under subchapter XIX, any gift, money, donation, or other consideration (other than a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to the patient)--

(A) as a precondition of admitting a patient to a hospital, nursing facility, or intermediate care facility for the mentally retarded, or

(B) as a requirement for the patient's continued stay in such a facility,

when the cost of the services provided therein to the patient is paid for (in whole or in part) under the State plan,

shall be guilty of a felony and upon conviction thereof shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(e) Violation of assignment terms

Whoever accepts assignments described in section 1395u(b)(3)(B)(ii) of this title or agrees to be a participating physician or supplier under section 1395u(h)(1) of this title and knowingly, willfully, and repeatedly violates the term of such assignments or agreement, shall be guilty of a misdemeanor and upon

conviction thereof shall be fined not more than $4,000 or imprisoned for not more than six months, or both.

(f) "Federal health care program" defined

For purposes of this section, the term "Federal health care program" means--

(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of Title 5); or

(2) any State health care program, as defined in section 1320a-7(h) of this title.

(g) Liability under subchapter III of chapter 37 of Title 31

In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31.

(h) Actual knowledge or specific intent not required

With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.