

United States District Court
Northern District of California

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

USA,

Plaintiff,

v.

MARK SCHENA,

Defendant.

Case No. [5:20-cr-00425-EJD-1](#)

ORDER DENYING MOTION TO DISMISS

Re: Dkt. No. 98

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

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1 health care benefit programs, and submitted or caused the submission of claims to Medicare,
2 Medicaid, TRICARE, and other health care benefit programs. SI ¶ 2.

3 Defendant is charged with a scheme to offer and pay illegal kickbacks and a scheme to
4 commit health care fraud and securities fraud. See SI ¶ 29. The government alleges that the
5 purpose of the kickback scheme was for Defendant to enrich himself by, among other things,
6 “submitting or causing the submission of false and fraudulent claims by interstate wire to
7 Medicare, Medicaid, TRICARE, and the Commercial Insurers for services that were (i) procured
8 by the payment of kickbacks and bribes.” SI ¶ 35.

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

12 Counts 4–6 incorporate the following allegations:

13 41. SCHENA and others paid and caused the offer and payment of illegal
14 kickbacks and bribes to other individuals and purported marketing companies
15 in exchange for blood samples collected from patients and orders for allergy
16 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.

17 42. SCHENA and others distributed false and fraudulent marketing material
18 and other documents that misrepresented the medical necessity of Arrayit’s
allergy test and Arrayit’s ability to provide accurate, fast, and reliable allergy
19 test results that would be medically necessary and reasonable in the treatment
of the patient.

20

21 45. SCHENA and others obtained fraudulent orders for allergy and COVID-
19 testing by making false and fraudulent statements, directly and indirectly,
22 to health care providers, patients, and others concerning Arrayit’s ability to
provide accurate, fast, and reliable COVID-19 testing in compliance with
23 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
24 times, the Arrayit COVID-19 test had not been developed, validated,
produced, received the requisite regulatory authorization, or able to return
25 timely COVID-19 results as represented.

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27 47. SCHENA and others caused Arrayit to submit approximately \$69 million
in claims by interstate wire to Medicare, Medicaid, TRICARE, and the

1 Commercial Insurers for allergy tests that were obtained through illegal
2 kickbacks and bribes, medically unnecessary, ineligible for reimbursement,
3 and/or not provided as represented.

4 Defendant moves to dismiss three counts in the Superseding Indictment on the ground that
5 EKRA does not reach the conduct alleged in the indictment. *See* Notice of Motion and Motion to
6 Dismiss Counts Four Through Six of Superseding Indictment (“Mot.”), Dkt. No. 98. On February
7 28, 2022, the Government filed an opposition, to which Defendant filed a reply brief. *See* United
8 States’ Opposition to Defendant’s Motion to Dismiss Counts Four Through Six of the Superseding
9 Indictment (“Opp.”), Dkt. No. 103; Reply Brief in Support of Motion to Dismiss Counts Four
10 Through Six of Superseding Indictment (“Reply”), Dkt. No. 106.

11 **II. LEGAL STANDARD**

12 Rule 12(b) of the Federal Rules of Criminal Procedure permits any defense “which is
13 capable of determination without the trial of the general issue” to be raised by pretrial motion.
14 The motion must be decided before trial “unless the court, for good cause, orders that it be
15 deferred for determination at the trial of the general issue or until after verdict, but no such
16 determination shall be deferred if a party’s right to appeal is adversely affected.” Fed. R. Crim. P.
17 12(e). Under this standard, the district court must decide the issue raised in the pretrial motion
18 before trial if it is “entirely segregable” from the evidence to be presented at trial.” *United States*
19 *v. Shortt Accountancy Corp.*, 785 F.2d 1448, 1452 (9th Cir. 1986) (quotation marks and citation
20 omitted).

21 **III. DISCUSSION**

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

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

27 (1) solicits or receives any remuneration (including any kickback,
28 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,

1 clinical treatment facility, or laboratory; or
 2 (B) in exchange for an individual using the services of that
 3 recovery home, clinical treatment facility, or laboratory, shall
 4 be fined not more than \$200,000, imprisoned not more than
 5 10 years, or both, for each occurrence.

6 18 U.S.C. § 220(a).

7 For purposes of § 220, “laboratory” or “clinical laboratory” means a facility for the
 8 “biological, microbiological, serological, chemical, immune-hematological, hematological,
 9 biophysical, cytological, pathological, or other examination of materials derived from the human
 10 body for purpose of providing information for the diagnosis, prevention, or treatment of any
 11 disease or impairment of, or the assessment of the health of, human beings.” *See* 18 U.S.C.
 12 § 220(e)(4) (incorporating 42 U.S.C. § 263(a)’s definition of laboratory).

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

22 S&G employed Darren Graves, a marketer, to oversee client accounts. *S&G Labs*, 2021
 23 WL 4847430, at *2. Graves’s compensation included a base annual salary of \$50,000, plus a 35%
 24 “cut” of the monthly net profits generated by his client accounts and the client accounts handled
 25 by the S&G employees who he managed. *Id.* Clients under the contracts were not patients but
 26 were physicians or other organizations in need of having persons tested. *Id.* at 11. In early 2019,
 27 S&G’s general counsel advised the laboratory director, Dr. Puana, that EKRA prevents a medical
 28 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

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

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

16 The holding of *S&G Labs* rests on the incorporation of 42 U.S.C. § 1320a-7b(b), the Anti-
 17 Kickback statute, to define EKRA’s use of “remuneration” and “individual.” 18 U.S.C. § 202
 18 does not define either of these terms. Confusingly, EKRA specifically excludes its applicability to
 19 “conduct that is prohibited under section 1128B of the Social Security Act (42 U.S.C. § 1320a-
 20 7b).” 18 U.S.C. § 220(d)(1). Thus, the incorporation of 42 U.S.C. § 1320a-7b(b) appears
 21 misplaced.

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

23 [w]henever under this chapter or any Act of Congress, or under the
 24 law of any State, an employer is required or permitted to deduct any
 25 amount from the *remuneration* of an employee and to pay the amount
 26 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.

27 42 U.S.C. § 1301(c). The Court understands the *S&G Labs* court to use this to demonstrate that

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1 Congress did not mean to criminalize “renumerations” paid by an employer to an employee. But
2 § 1301(c) does not support this analysis. Rather, it discusses situations where renumerations are
3 permissible or required, it does not blanketly authorize any type of remuneration paid by an
4 employer to an employee. *See* 18 U.S.C. § 220(b)(2) (EKRA’s safe harbor provision provides
5 statutory exceptions for certain renumerations, but not all employer-employee renumerations).

6 Likewise, the definition of “person” is unhelpful. 42 U.S.C. § 1301(a)(3) defines “person”
7 as “an individual, a trust or estate, a partnership, or a corporation.” This definition says nothing
8 about payment needing to be made based on the “direct” recruitment of an individual patient.
9 Indeed, it does not even define “individual” as used in 18 U.S.C. § 220, let alone impose a
10 requirement of directness.

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

18 Under the rules of statutory construction, “[t]he plain meaning of the statute controls, and
19 courts will look no further, unless its application leads to unreasonable or impracticable results.”
20 *United States v. Leyva*, 282 F.3d 623, 625 (9th Cir. 2002). The plain meaning of “to induce a
21 referral of an individual” includes situations where a marketer causes an individual to obtain a
22 referral from a physician. *See Induce, Black’s Law Dictionary* (5th ed. 1979) (“To bring on or
23 about, to effect, cause, *to influence* an act or cause of conduct, lead by persuasion or reasoning,
24 incite by motives, prevail on.” (emphasis added)); *see also Hanlester Network v. Shalala*, 51 F.3d
25 1390, 1399 (9th Cir. 1995) (determining that “to induce” in the context of the Anti-Kickback
26 statute connotes “an intent to exercise influence over the reason or judgment of another in an effort
27 to cause the referral of program-related business”).

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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.

Dated: May 28, 2022



EDWARD J. DAVILA
United States District Judge

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*.