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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, **v.** **PAUL HAJE, Defendant.**	)	**CASE NO.** CR 21 00214 **VIOLATION(S):** **18 U.S.C. § 371 (Conspiracy to Defraud the United States and Pay and Receive Kickbacks– 1 count)** **18 U.S.C. § 1349 (Conspiracy to Commit Health Care Fraud – 1 count)** **Notice of forfeiture** 2 cts **SAN JOSE VENUE**

INFORMATION

COUNT ONE
(Conspiracy to Defraud the United States and Pay and Receive Kickbacks)

THE ACTING UNITED STATES ATTORNEY CHARGES THAT:

At all times material to this Information:

The Medicare, Medicaid, and TRICARE Programs

1. The Medicare program ("Medicare") was a federally-funded health care program that provided benefits to persons who were at least 65 years old or disabled. Medicare was administered by

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the Centers for Medicare and Medicaid Services ("CMS"), a federal agency under the United States Department of Health and Human Services ("HHS").

2. The Medicaid program ("Medicaid") was jointly funded by the federal and state governments and was a program that provided health care benefits to certain low-income individuals and families in states. Medicaid was administered by CMS and various state agencies.

3. The United States Department of Defense ("DoD"), through the Defense Health Agency ("DHA"), administered the TRICARE program ("TRICARE"), which was a comprehensive health care insurance program that provided health care benefits to United States military personnel, retirees, and their families.

4. Medicare, Medicaid, and TRICARE were each a "Federal health care program" as defined in Title 42, United States Code, Section 1320a-7b(f), and a "health care benefit program" as defined in Title 18, United States Code, Section 24(b).

5. Individuals who received benefits under Medicare, Medicaid, and TRICARE were referred to as "beneficiaries."

6. Diagnostic testing laboratories, physicians, clinics, and other health care providers (collectively, "providers"), all of which provided services to beneficiaries, were able to apply for and obtain a "provider number." A health care provider that received a provider number was able to file claims with Medicare, Medicaid, and TRICARE to obtain reimbursement for services provided to beneficiaries.

7. To participate in Medicare, Medicaid, and TRICARE, providers were required to submit an application in which the providers agreed to abide by the policies and procedures, rules, and regulations governing reimbursement. To receive funds, enrolled providers, together with their authorized agents, employees, and contractors, were required to abide by all provisions of the Social Security Act, the regulations promulgated under the Act, and applicable policies, procedures, rules, and regulations issued by CMS, relevant state and federal agencies, and authorized agents and contractors. Health care providers were given and provided with access to manuals and services bulletins that described proper billing procedures and billing rules and regulations.

8. A health care provider who was assigned a PIN and provided services to beneficiaries was able to submit claims for reimbursement that included the PIN assigned to that medical provider. The claim form required certain important information, including: the beneficiary's name and identification number; a description of the health care benefit, item, or service that was provided or supplied to the beneficiary; the billing codes for the benefit, item, or service; the date upon which the benefit, item, or service was provided or supplied to the beneficiary; and the name of the referring physician or other provider, as well as the applicable identification number for the referring physician or provider. Payments were often made directly to a provider of the goods or services, rather than to a beneficiary. This payment occurred when the provider submitted the claim for payment, either directly or through a billing company.

9. Medicare, Medicaid, and TRICARE regulations required health care providers to maintain complete and accurate patient medical records reflecting the medical assessment and diagnoses of their patients, as well as records that documented actual treatment of the patients to whom services were provided and for whom claims for payment were submitted by the physician. Medicare, Medicaid, and TRICARE required complete and accurate patient medical records so that Medicare, Medicaid, and TRICARE would be able to verify that the services were provided as described on the claim form. These records were required to be sufficient to permit Medicare, Medicaid, or TRICARE, or their contractors, to review the appropriateness of payments made to the health care provider.

10. Medicare, Medicaid, and TRICARE paid for claims only if the items or services were medically reasonable, medically necessary for the treatment or diagnosis of the patient's illness or injury, documented, and actually provided as represented to Medicare, Medicaid, and TRICARE. Medicare, Medicaid, and TRICARE would not pay for items or services that were procured through kickbacks and bribes.

Commercial Insurance Plans

11. Commercial insurance plans were provided by private health insurance companies ("Commercial Insurers") that offered individual and group health benefit plans under which individuals

could obtain coverage for health care items and services. Individuals who received benefits from Commercial Insurers were referred to as "members."

12. Each of the Commercial Insurers was a "health care benefit program" as defined in Title 18, United States Code, Section 24(b) and Title 18, United States Code, Section 220(e)(3).

13. Commercial Insurers often made payments directly to laboratories and other providers, rather than to members who received the health care benefits, items, and services.

14. To obtain payment for treatment or services provided to a member, laboratories and other providers were required to submit itemized claim forms to the member's commercial insurance plan. The claim forms were typically submitted electronically. The claim form required certain important information, including: the member's name and identification number; a description of the health care benefit, item, or service that was provided or supplied to the member; the billing codes for the benefit, item, or service; the date upon which the benefit, item, or service was provided or supplied to the member; and the name of the referring physician or other provider, as well as the applicable identification number for the referring physician or provider.

15. When a provider submitted a claim to Commercial Insurers, the provider certified that the contents of the form were true, correct, complete, and that the form was prepared in compliance with applicable laws and regulations. The provider also certified that the items or services being billed were medically necessary and were in fact provided as billed.

Rules and Regulations Regarding Diagnostic Testing

16. CMS regulated all laboratory testing (except research) performed on humans in the United States through the Clinical Laboratory Improvement Amendments (CLIA). All clinical laboratories seeking reimbursement were required to be properly certified by CLIA and state regulatory agencies.

17. Examples of clinical laboratory testing included the following:

a. Allergy testing: Allergy referred to conditions in which immune responses to environmental antigens caused tissue inflammation and organ dysfunction. Allergy testing was performed to determine immunologic sensitivity or reaction to antigens for the purpose of identifying

the cause of the allergic state.

b. COVID-19 antibody testing: COVID-19 antibody testing was a test for antibodies in the blood to determine whether an individual was previously infected with the novel coronavirus disease 2019, commonly referred to as "COVID-19." COVID-19 antibody testing would not reliably diagnose a current COVID-19 infection.

18. Medicare did not cover diagnostic testing, including allergy and COVID-19 antibody testing, that was "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Title 42, United States Code, Section 1395y(a)(1)(A). Except for certain statutory exceptions, Medicare did not cover "examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint or injury." Title 42, Code of Federal Regulations, Section 411.15(a)(1).

19. If diagnostic testing was necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, Medicare imposed additional requirements before covering the testing. Title 42, Code of Federal Regulations, Section 410.32(a) provided, "All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem[,]" and "[t]ests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." Title 42, United States Code, Section 1395l(h)(5) provided that payments from Medicare for covered clinical diagnostic laboratory tests may be made only to "the person or entity which performed or supervised the performance of such test."

20. Medicare, through its contractors, and Commercial Insurers set forth rules and regulations regarding the circumstances in which allergy testing was reasonable and necessary. One type of allergy testing was "in vivo," which correlated the performance and evaluation of selective cutaneous and mucous membrane tests (commonly referred to as "skin tests") with the patient's history, physical examination, and other observations. Another type of allergy testing was a test for allergy hypersensitivity "in vitro" (commonly referred to as "blood tests"), which measured allergen-specific

serum IgE. Percutaneous skin testing was the test of choice in most clinical situations where immediate hypersensitivity reactions were suspected. Overall, skin testing was quick, safe, and cost-effective.

21. Under certain limited conditions, in vitro testing was medically necessary. Quantitative (measuring the amount of sensitivity) in vitro allergen specific IgE testing was medically necessary under conditions where skin testing was not possible or was not reliable. Examples of indications for in vitro testing would include patients with severe dermatographism, ichthyosis, or generalized eczema. In vitro testing is significantly more expensive than skin testing.

22. It would not be medically necessary to test all patients for the same number of allergens. The number of allergens that are tested for was required to be judicious and related to the history, physical findings, and clinical judgment specific to each individual.

The Defendant and Related Individuals and Entities

23. Arrayit was a Nevada corporation based in the Northern District of California. Arrayit described itself as "a world leader in microarray technology empowering researchers and doctors in the life sciences, wellness and healthcare testing markets." Arrayit was a participating provider in the Medicare, Medicaid, TRICARE, and Commercial Insurers programs and submitted claims to Medicare, Medicaid, TRICARE, and Commercial Insurers.

24. Defendant PAUL HAJE was the Vice President of Marketing of Arrayit and a consultant for Arrayit.

25. Mark Schena was a 56-year-old scientist who described himself as the "Father of Microarray Technology," and served as Arrayit's President.

26. CEO 1 was the Chief Executive Officer of Arrayit.

27. Marketer 1 was the CEO of an Arizona Marketing Organization.

COUNT ONE: (18 U.S.C. § 371 – Conspiracy to Defraud the United States and Pay and Receive Kickbacks)

28. From in or around September 2018, and continuing through in or around May 2020, in the Northern District of California and elsewhere, the defendant,

PAUL HAJE,

did willfully, that is, with the intent to further the objects of the conspiracy, and knowingly combine, conspire, confederate, and agree with Mark Schena, CEO-1, Vice President of Marketing-1, and others, known and unknown to the Acting United States Attorney, to commit certain offenses against the United States, that is:

a. to defraud the United States by cheating the United States government or any of its departments or agencies out of money and property, and by impairing, impeding, obstructing, and defeating through deceitful and dishonest means, the lawful government functions of the United States or any of its departments or agencies, namely, HHS, CMS, and DHA in its administration and oversight of Medicare and Medicaid; and

b. to violate Title 42, United States Code, Section 1320a-7b(b) by soliciting and receiving, and offering and paying, remuneration (including any kickback, bribe, or rebate), directly and indirectly, overtly and covertly, in cash and in kind, in return for purchasing, leasing, ordering, and arranging for and recommending purchasing, leasing, or ordering any good, facility, service, and item for which payment may be made in whole and in part under a Federal health care program; and

c. to violate Title 18, United States Code, Section 220(a), by (1) soliciting and receiving 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 laboratory and (2) paying and offering 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 laboratory, with respect to services covered by a health care benefit program in and affecting interstate commerce.

Goal of the Conspiracy

29. It was the goal of the conspiracy for defendant PAUL HAJE, Mark Schena, CEO 1, and their co-conspirators to unlawfully enrich themselves and others by, among other things, (a) soliciting, receiving, offering, and paying kickbacks and bribes in return for ordering and arranging for the ordering of allergy testing for beneficiaries and inducing the referral of members; (b) submitting and causing the submission of claims to Medicare, Medicaid, TRICARE, and the Commercial Insurers for allergy testing that was procured through kickbacks and bribes; (c) concealing the submission of false

claims to Medicare, Medicaid, TRICARE, and Commercial Insurers; and (e) diverting proceeds of the illegal kickback scheme for his personal use and benefit, the use and benefit of others, and to further the illegal kickback conspiracy.

Manner and Means

30. Defendant PAUL HAJE and his co-conspirators used the following manner and means, among others, to accomplish the object and purpose of the conspiracy:

31. Defendant PAUL HAJE, Mark Schena, CEO 1 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 providers.

32. Defendant PAUL HAJE, Mark Schena, CEO 1, and others entered into sham contracts and agreements in order to conceal and disguise the illegal kickbacks and bribes.

33. As the effects of the COVID-19 pandemic began to be felt in the United States and many beneficiaries and members faced difficulty obtaining access to COVID-19 testing, defendant PAUL HAJE, Mark Schena, CEO 1, and others used the pandemic as an opportunity to expand the pre-existing allergy test scheme and to capitalize on a national emergency for their own financial gain by offering COVID-19 testing and bundling the COVID-19 test with, i.e. requiring combination with, Arrayit's more expensive allergy testing, which did not identify or treat COVID-19.

34. In furtherance of the conspiracy, defendant PAUL HAJE, together with others, caused the submission of more than approximately $70 million in false and fraudulent claims to Medicare, Medicaid, TRICARE and Commercial Insurers that were procured through the payment of kickbacks and bribes. Medicare, Medicaid, TRICARE and Commercial Insurers paid more than approximately $2.4 million to Arrayit.

Overt Acts

35. In furtherance of the conspiracy, and to accomplish its objects and purpose, at least one of the co-conspirators committed and caused to be committed, in the Northern District of California and elsewhere, at least one of the following overt acts, among others:

36. On or about December 16, 2019, defendant PAUL HAJE, Mark Schena, CEO 1 and

others caused an illegal kickback and bribe, in the approximate amount of $19,289.74, to be paid to Marketer 1 in exchange for the referral of individuals to Arrayit.

37. On or about April 17, 2020, defendant PAUL HAJE, Mark Schena, CEO 1 and others caused an illegal kickback and bribe, in the approximate amount of $6,650.58, to be paid to Marketer 1 in exchange for the referral of individuals to Arrayit.

All in violation of Title 18, United States Code, Section 371.

COUNT TWO: (18 U.S.C. § 1349 – Conspiracy to Commit Health Care Fraud)

38. The factual allegations in Paragraphs 1 through 27 of this Information are re-alleged and incorporated by reference as if fully set forth herein.

39. Beginning in or around January 2020, and continuing through in or around May 2020, in the Northern District of California and elsewhere, the defendant,

PAUL HAJE,

did willfully, that is, with the intent to further the objects of the conspiracy, and knowingly combine, conspire, confederate, and agree with others known and unknown to the Grand Jury to commit certain offenses against the United States, to wit: to execute a scheme and artifice to defraud health care benefit programs affecting commerce, as defined in Title 18, United States Code, Section 24(b), that is, Medicare, Medicaid, TRICARE, and the Commercial Insurers, and to obtain by means of materially false and fraudulent pretenses, representations and promises, money and property owned by, and under the custody and control of, said health care benefit programs, in connection with the delivery of and payment for health care benefits, items, and services, in violation of Title 18, United States Code, Section 1347.

Purpose of the Conspiracy

40. It was a purpose of the conspiracy for defendant PAUL HAJE, Mark Schena, CEO 1, and other co-conspirators to unlawfully enrich themselves by: (a) submitting or causing the submission of false and fraudulent claims to Medicare, Medicaid, TRICARE, and the Commercial Insurers for services that were (i) procured by the payment of kickbacks and bribes; (ii) medically unnecessary; (iii) not eligible for reimbursement; and/or (iv) not provided as represented; (b) concealing the submission of false and fraudulent claims to Medicare, Medicaid, TRICARE, and the Commercial Insurers, and the

receipt and transfer of the proceeds from the fraud; and (c) diverting proceeds of the fraud for their personal use and benefit, and to further the conspiracy.

Manner and Means

41. Defendant PAUL HAJE and his co-conspirators used the following manner and means, among others, to accomplish the object and purpose of the conspiracy.

42. PAUL HAJE, Mark Schena, CEO 1, 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 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.

43. PAUL HAJE, Mark Schena, CEO 1, 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.

44. PAUL HAJE, Mark Schena, CEO 1, and others caused Arrayit to test for 120 allergens regardless of the medical necessity, availability of the less expensive skin tests, reasonableness, rules against ordering the same test for each beneficiary or member, or use of such testing in the treatment of each beneficiary or member, in order to maximize the amount billed to Medicare, Medicaid, TRICARE, and the Commercial Insurers.

45. As the effects of the COVID-19 pandemic began to be felt in the United States and many beneficiaries and members faced difficulty obtaining access to COVID-19 testing, PAUL HAJE, Mark Schena, CEO 1, and others used the COVID-19 pandemic as an opportunity to expand the pre-existing allergy test scheme and to capitalize on a national emergency for their own financial gain by offering COVID-19 testing and bundling the COVID-19 test with, i.e., requiring combination with, Arrayit's more expensive allergy testing, which did not identify or treat COVID-19.

46. PAUL HAJE, Mark Schena, CEO 1, and others obtained fraudulent orders for allergy and COVID-19 testing by making false and fraudulent statements, directly and indirectly, to providers,

beneficiaries, members, 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. PAUL HAJE, Mark Schena, CEO 1, and others entered into sham contracts and agreements, and created and maintained false and fraudulent invoices and other documents, in order to conceal and disguise the illegal kickbacks and bribes, as well as that the testing was not provided as billed to Medicare, Medicaid, TRICARE, and the Commercial Insurers, including concealing the ordering physician, medical clinic, and/or laboratory that actually conducted the testing.

48. During the COVID-19 public health emergency, PAUL HAJE, Mark Schena, CEO 1, and others caused Arrayit to submit more than approximately $15 million in claims 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.

In violation of Title 18, United States Code, Section 1349.

NOTICE OF FORFEITURE

THE ACTING UNITED STATES ATTORNEY FURTHER CHARGES THAT:

1. As a result of the violations of Title 18, United States Code, Sections 371 and 1349, set forth in this Information, the defendant,

PAUL HAJE,

shall forfeit to the United States of America any property, real or personal, that constitutes, or is derived, directly or indirectly, from the gross proceeds traceable to the commission of the offense, including, but not limited to, the sum of $602,504.

2. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

(a) cannot be located upon the exercise of due diligence;

(b) has been transferred or sold to, or deposited with, a third party;

(c) has been placed beyond the jurisdiction of the Court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 18, United States Code, Section 982(b), incorporating Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture.

All pursuant to Title 18, United States Code, Section 982(a)(7).

STEPHANIE HINDS
Acting United States Attorney
Northern District of California

DANIEL KAHN
Acting Chief, Fraud Section
U.S. Department of Justice

/s/

JUSTIN WEITZ
Acting Principal Assistant Chief
JACOB FOSTER
Assistant Chief
Criminal Division, Fraud Section
U.S. Department of Justice

/s/

WILLIAM FRENTZEN
Chief, Corporate Fraud Strike Force
U.S. Attorney's Office for the
Northern District of California

AO 257 (Rev. 6/78)

DEFENDANT INFORMATION RELATIVE TO A CRIMINAL ACTION - IN U.S. DISTRICT COURT

BY: ☐ COMPLAINT ☒ INFORMATION ☐ INDICTMENT ☐ SUPERSEDING

Name of District Court, and/or Judge/Magistrate Location

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

FILED
MAY 25 2021
SUSAN Y. SOONG
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE

OFFENSE CHARGED

COUNT ONE : 18 U.S.C. § 371 – Conspiracy

COUNT TWO: 18 U.S.C. § 1349 Conspiracy to Commit Health Care Fraud

☐ Petty ☐ Minor ☐ Misde-meanor ☒ Felony

PENALTY: COUNT ONE: Not more than 5 years imprisonment, not more than $250,000 fine, not more than 3 years supervised release, $100 assessment; COUNT TWO: Not more than 10 years imprisonment, not more than $250,000 fine, not more than 3 years supervised release and $100 assessment.

DEFENDANT - U.S

▶ PAUL HAJE

DISTRICT COURT NUMBER

CR 21 00214 LHK

DEFENDANT

VKD

IS *NOT* IN CUSTODY

1) ☒ Has not been arrested, pending outcome this proceeding. If not detained give date any prior summons was served on above charges ▶ _____

2) ☐ Is a Fugitive

3) ☐ Is on Bail or Release from (show District)

_____

IS IN CUSTODY

4) ☐ On this charge

5) ☐ On another conviction } ☐ Federal ☐ State

6) ☐ Awaiting trial on other charges

If answer to (6) is "Yes", show name of institution

_____

Has detainer been filed? ☐ Yes ☐ No } If "Yes" give date filed _____

DATE OF ARREST ▶ Month/Day/Year _____

Or... if Arresting Agency & Warrant were not

DATE TRANSFERRED TO U.S. CUSTODY ▶ Month/Day/Year _____

PROCEEDING

Name of Complaintant Agency, or Person (& Title, if any)

_____

☐ person is awaiting trial in another Federal or State Court, give name of court

_____

☐ this person/proceeding is transferred from another district per (circle one) FRCrp 20, 21, or 40. Show District

_____

☐ this is a reprosecution of charges previously dismissed which were dismissed on motion of: ☐ U.S. ATTORNEY ☐ DEFENSE } SHOW DOCKET NO. _____

☐ this prosecution relates to a pending case involving this same defendant

☐ prior proceedings or appearance(s) before U.S. Magistrate regarding this defendant were recorded under } MAGISTRATE CASE NO. _____

Name and Office of Person Furnishing Information on this form STEPHANIE HINDS

☒ U.S. Attorney ☐ Other U.S. Agency

Name of Assistant U.S. Attorney (if assigned) WILLIAM FRENTZEN

☐ This report amends AO 257 previously submitted

ADDITIONAL INFORMATION OR COMMENTS

PROCESS:

☐ SUMMONS ☒ NO PROCESS* ☐ WARRANT Bail Amount: _____

If Summons, complete following:

☐ Arraignment ☐ Initial Appearance

** Where defendant previously apprehended on complaint, no new summons or warrant needed, since Magistrate has scheduled arraignment*

Defendant Address:

_____

Date/Time: _____ Before Judge: _____

Comments: