

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA : Criminal No. 19-693 (BRM)
 :
 v. : Hon. Brian R. Martinotti
 :
 EDWARD B. KOSTISHION : 18 U.S.C. § 371

SUPERSEDING INFORMATION

The defendant having waived in open court prosecution by Indictment, the Attorney for the United States, acting under authority conferred by 28 U.S.C. § 515, charges:

Count 1
(Conspiracy to Commit Health Care Fraud)

1. Unless otherwise indicated, at all times relevant to this Superseding Information:

The Defendant and Ark Laboratory Network LLC

a. Defendant EDWARD B. KOSTISHION (“KOSTISHION”) resided in Lakeland, Florida and was a managing partner and part owner of Ark Laboratory Network LLC (“Ark”). Ark was a Florida limited liability company that purported to operate a nationwide network of laboratories and laboratory partners that facilitated genetic testing. Ark’s primary business premises was KOSTISHION’s Florida residence. KOSTISHION, co-conspirator Kacey C. Plaisance (“co-conspirator Plaisance”), and co-conspirator Jeremy M. Richey (“co-conspirator Richey”) co-owned and managed Ark.

b. Through Ark, KOSTISHION, co-conspirator Plaisance, co-conspirator Richey, and others submitted or caused to be submitted referrals for genetic tests and patients' DNA samples to various clinical laboratories across the country. The laboratories paid Ark in exchange for these referrals on a per-sample basis or based on the revenue the laboratories received from insurance companies and government health care programs.

Relevant Individuals and Entities

c. Privy Health, Inc. ("Privy") was a privately-held Illinois corporation based in Arlington Heights, Illinois that partnered with Ark to recruit patients and acquire their DNA samples and personal health information so that referrals for genetic testing could be submitted to laboratories.

d. Kyle D. McLean ("co-conspirator McLean") was a resident of Arlington Heights, Illinois. Co-conspirator McLean and co-conspirator Plaisance among others, exercised control over Privy's operations and employees.

e. Matthew S. Ellis ("co-conspirator Ellis") was a physician licensed to practice medicine in Florida who resided and practiced medicine in Gainesville, Florida. Co-conspirator Ellis also served as Privy's Medical Director.

f. Jeffrey Tamulski ("co-conspirator Tamulski") resided in Tampa, Florida.

g. The "Distribution Company" was a privately-held Illinois corporation based in Arlington Heights, Illinois that partnered with Ark to recruit patients and acquire their DNA samples and personal health information so that

referrals for genetic testing could be submitted to laboratories. Co-conspirator McLean and others managed the Distribution Company's operations from in or about 2017 to in or about May 2018, when co-conspirator McLean assumed direction and control of Privy. Co-conspirator Plaisance and others managed the Distribution Company's operations from in or about 2017 to in or about January 2019.

Background on the Medicare Program and Genetic Testing

h. Medicare was a federal program that provided free or below-cost health care benefits to certain individuals, primarily the elderly, blind, and disabled. Medicare was a "health care program" as defined in 18 U.S.C. § 24(b) and a "Federal health care program" as defined in 42 U.S.C. § 1320a-7b(f). Individuals who received benefits under Medicare were commonly referred to as "beneficiaries."

i. The Medicare Part B program was a federally funded supplemental insurance program that provided Medicare insurance benefits for individuals aged 65 or older, and for certain individuals who were disabled. The Medicare Part B program paid for various medical services for beneficiaries, including diagnostic genetic tests.

j. Genetic tests were laboratory tests designed to identify specific inherited mutations in a patient's genes. These genetic variations affected a patient's risk of developing certain diseases or how the patient responded to medications.

k. Genetic tests related to a patient's hereditary predisposition for cancer were commonly referred to as "CGx" tests. Pharmacogenomic genetic tests related to identifying how a patient's genes affect the patient's response to drugs were commonly referred to as "PGx" tests.

l. To conduct a genetic test, a laboratory must obtain a DNA sample from the patient. Such samples were typically obtained from the patient's saliva by using a cheek (buccal) swab to collect sufficient cells to provide a genetic profile. The DNA sample was then submitted to the laboratory for analysis, such as CGx or PGx.

m. If the patient had insurance, the laboratory would typically submit a claim for reimbursement for the test to the patient's insurance carrier. Reimbursement rates for CGx tests may have exceeded \$10,000 per test, while reimbursement rates for PGx may have exceeded \$6,500 per test.

n. Medicare excluded from coverage diagnostic genetic tests "that are not reasonable and necessary . . . [f]or the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 C.F.R. § 411.15(k)(1). To be considered "reasonable and necessary," Medicare rules required that genetic testing "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." 42 C.F.R. § 410.32(a).

“Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.” Id.

o. Non-physician practitioners, such as clinical nurse specialists or physicians assistants, may also order genetic tests but were subject to the same requirement as physicians: they must consult or treat the beneficiary for a specific medical problem and use the test results to manage the beneficiary’s specific medical problem. 42 C.F.R. § 410.32(a)(2).

The Clinical Laboratories

p. The following clinical laboratories (collectively, the “DNA Labs”) performed genetic testing and submitted claims to Medicare:

1. “Laboratory 1,” located in New Jersey;
2. “Laboratory 2,” located in Mississippi;
3. “Laboratory 3,” located in Tennessee;
4. “Laboratory 4” located in Georgia;
5. “Laboratory 5” located in Texas;
6. “Laboratory 6” located in Pennsylvania;
7. “Laboratory 7” located in Georgia; and
8. “Laboratory 8” located in Texas.

q. “Individual-1” was an employee of Laboratory 1.

The Conspiracy

2. From at least as early as in or about 2017 through on or about January 16, 2019, in the District of New Jersey, and elsewhere, defendant

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did knowingly and intentionally conspire and agree with co-conspirators Plaisance, McLean, Ellis, and others to commit an offense against the United States, that is, to knowingly and willfully execute, and attempt to execute, a scheme and artifice to defraud any health care benefit program, as that term is defined in Title 18, United States Code, Section 24(b), and to obtain, by means of false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of, any health care benefit program in connection with the delivery of and payment for health care benefits, items, and services, contrary to Title 18, United States Code, Section 1347.

Goal of the Conspiracy

3. The goal of the conspiracy was for KOSTISHION, co-conspirators Plaisance, McLean, Ellis, and others to unlawfully enrich themselves by submitting and causing the submission of false and fraudulent claims to Medicare, among other health care benefit programs, for genetic tests that co-conspirator Ellis ordered and by receiving a portion of the money that Medicare paid to clinical laboratories for those genetic tests.

Manner and Means of the Conspiracy

4. The manner and means by which KOSTISHION, co-conspirators Plaisance, Ellis, McLean, and others sought to accomplish the goal of the conspiracy, included, among other things, the following:

a. Ark partnered with Privy and the Distribution Company (together, the “Patient Acquisition Groups”) to recruit patients from across the country for genetic testing without the involvement of a health care professional who was treating the patients.

b. At the direction of co-conspirator Plaisance, co-conspirator McLean, and others, employees from Privy and the Distribution Company (together, the “Employees”) marketed genetic tests directly to patients by, among other methods: (i) offering gift cards under the guise of a “market research study” to induce patients to submit to testing; (ii) promoting genetic tests to patients at public and corporate health and wellness fairs, on social media, and at expositions; and (iii) in certain cases, directing the Employees to mail DNA testing kits directly to beneficiaries so that they could self-administer a DNA swab and return the DNA sample to Privy, all without the involvement of a health care professional who was treating the patients (the “DNA Acquisition Methods”).

c. Through the DNA Acquisition Methods, the Employees and others acting on behalf of the Patient Acquisition Groups acquired the personal health information, Medicare numbers, and DNA samples belonging to hundreds of patients.

d. Co-conspirator McLean and others devised and oversaw a system through which the Patient Acquisition Groups used the patient information they obtained via the DNA Acquisition Methods, including the purported “study,” to complete laboratory requisitions for genetic tests, which were the forms provided to laboratories that identified the tests to be performed.

e. Specifically, these requisitions included, among other items: (i) an indication that co-conspirator Ellis was the ordering physician; (ii) various patient-specific diagnosis codes which were necessary to determine the medical necessity for the genetic test; and (iii) for CGx tests, information pertaining to a patient’s personal or family history of cancer and the specific form of cancer, such as breast, ovarian, or pancreatic cancer.

f. The Patient Acquisition Groups obtained patients’ electronic signatures and copied those signatures onto requisition forms that were not presented to or reviewed with the patient.

g. The Employees captured DNA samples through swabbing patients’ cheeks.

h. Through the DNA Acquisition Methods, the Patient Acquisition Groups obtained patients’ DNA samples before co-conspirator Ellis, as the ordering physician, signed the patient’s requisition that ordered the genetic test.

i. The Patient Acquisition Groups inserted certain patient-specific information on the requisitions and co-conspirator Ellis signed or

authorized the use of his signature on requisitions ordering genetic tests for patients he never met, treated, or evaluated.

j. The Patient Acquisition Groups met and captured DNA samples from patients in various states, including New Jersey, in which co-conspirator Ellis was not licensed to practice medicine.

k. Co-conspirator Ellis signed or authorized the use of his signature on requisitions submitted to certain of the DNA Labs that included false certifications from co-conspirator Ellis that, as the ordering physician, he: (i) provided information to the patient regarding genetic testing; (ii) deemed the test medically necessary for the diagnosis or detection of a disease or illness; (iii) would use the test results in the medical management and treatment decisions for the patient; and (iv) was authorized by law to order the tests requested.

l. KOSTISHION, co-conspirators Ellis, Plaisance, McLean, and others, submitted or caused to be submitted requisitions and other patient-specific documents to the DNA Labs that falsely stated that co-conspirator Ellis was the treating provider for the patient, when, in fact, co-conspirator Ellis never interacted with the patient.

m. In certain cases, KOSTISHION, co-conspirators Ellis, Plaisance, McLean, and others, submitted or caused to be submitted CGx requisitions and other patient-specific information to certain DNA Labs that falsely indicated that a patient had a personal or family history of cancer.

n. Each of the DNA Labs entered into separate agreements with Ark under which the DNA Labs paid Ark in exchange for genetic test referrals and DNA samples that Ark submitted or caused to be submitted to the DNA Labs.

o. From in or about January 2018 to in or about January 2019, the DNA Labs billed Medicare over approximately \$13 million in connection with genetic tests that Ark referred or caused to be referred to the DNA Labs.

p. From in or about January 2018 to in or about January 2019, Medicare paid the DNA Labs at least approximately \$4.6 million for genetic tests that Ark referred or caused to be referred to the DNA Labs.

q. In turn, from in or about May 2018 to in or about January 2019, the DNA Labs paid Ark at least \$1.8 million in exchange for the genetic test referrals that Ark delivered to the DNA Labs.

r. KOSTISHION and co-conspirators Plaisance and Richey shared in the payments that Ark received from the DNA Labs.

s. In turn, Ark paid Privy, co-conspirator McLean, and the Distribution Company in connection with their respective patient and DNA sample acquisition services related to the referrals submitted to the DNA Labs, as reflected in the table below:

Entity/Individual Receiving Payments from Ark	Approximate Amount	Approximate Period
Privy	\$789,000	July 2018 - January 2019
Co-conspirator McLean	\$87,000	November 2018 – January 2019
Distribution Company	\$32,000	July 2018 - January 2019

t. Privy paid co-conspirator Ellis approximately \$5,000 per month for his role as Privy's medical director.

Overt Acts

5. In furtherance of the conspiracy and to effect its goal, KOSTISHION and his co-conspirators committed or caused the commission of the following overt acts in the District of New Jersey and elsewhere:

a. On or about October 26, 2018, KOSTISHION, on behalf of Ark, and Individual-1, an employee of Laboratory 1 in New Jersey, executed an agreement relating to genetic testing of ten proposed DNA swabs. Under the agreement, Laboratory 1 would pay Ark "50% . . . of the total gross reimbursement by on [sic] all paid adjudicated specimens tested by [Laboratory 1] . . . for all [Ark] related business."

b. On or about November 16, 2018, KOSTISHION sent via email to Individual-1 ten requisitions for CGx tests (the "Requisitions"), with the intent that Laboratory 1 would bill such tests to Medicare.

c. At the direction of co-conspirator Plaisance, co-conspirator McLean, and others, Privy acquired the Requisitions through, among other methods, the use of gift cards to induce patients to provide their DNA samples.

d. The Requisitions contained false information regarding the patients' medical histories and conditions, and falsely represented that co-conspirator Ellis, the physician who purportedly ordered the tests, provided the

patients with information regarding genetic testing and determined that the genetic tests were medically necessary.

e. On or about January 2, 2019, KOSTISHION sent to Laboratory 1 a sham invoice for work that Ark purportedly performed in connection with the Requisitions that contained an hourly fee and hourly breakdown that added up to the same amount of the percentage owed to Ark under its agreement with Laboratory 1.

f. On or about January 7, 2019, Ark received payment of approximately \$36,860.52, which reflected Ark's share of the total Medicare billings relating to the Requisitions.

In violation of Title 18, United States Code, Section 371.

COUNT 2
(Conspiracy to Violate the Anti-Kickback Statute)

6. Paragraphs 1 and 3 through 5 of Count 1 are realleged here.

7. From in or about 2017 through on or about September 2019, in the District of New Jersey and elsewhere, defendant

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did knowingly and intentionally conspire and agree with co-conspirators Plaisance, Richey, Tamulski, and others to commit certain offenses against the United States, that is, to knowingly and willfully solicit and receive remuneration, directly and indirectly, overtly and covertly, in cash and in kind, that is, kickbacks and bribes, in exchange for referring an individual to a person for the furnishing and arranging for the furnishing of items and services for which payment was made in whole or in part under a Federal health care program, namely, Medicare, contrary to Title 42, United States Code, Section 1320a-7b(b)(1)(A).

Goal of the Conspiracy

8. The goal of the conspiracy was to unlawfully solicit and receive kickbacks and bribes for KOSTISHION, co-conspirators Plaisance, Richey, Tamulski, and others.

Manner and Means of the Conspiracy

9. The manner and means by which KOSTISHION, co-conspirators Plaisance, Richey, Tamulski and others sought to accomplish the goal of the conspiracy, included, among other things, the following:

a. Ark entered into sham agreements with clinical laboratories, including Laboratories 1, 2, and 3 (the “Three DNA Labs”) under which Ark offered to provide various consulting, marketing, and other services (the “Sham Agreements”) in exchange for charging the Three DNA Labs an hourly basis and rate for Ark’s services.

b. In reality, the Three DNA Labs paid Ark and co-conspirator Tamulski in exchange for referrals based on the revenue that the Three DNA Labs received from federal health care programs.

c. Specifically, KOSTISHION, co-conspirators Plaisance, Richey, and Tamulski generally agreed with each of the Three DNA Labs that each laboratory would determine the amount of kickbacks and bribes paid to Ark and co-conspirator Tamulski based on the following formula (the “Kickback and Bribe Formula”): (i) calculating the amount of Medicare revenue that the laboratory received as a result of genetic tests that Ark referred to the laboratory; (ii) deducting a negotiated costs of goods sold (“COGS”) amount that the laboratory incurred in connection with the tests and, in some cases, a billing fee; and (iii) paying Ark and co-conspirator Tamulski a percentage of the remaining profit.

d. The Three DNA Labs and KOSTISHION, co-conspirators Plaisance, Richey, and Tamulski made efforts to track: (i) the amounts paid as kickbacks and bribes to KOSTISHION, co-conspirators Plaisance, Richey, and Tamulski; (ii) the genetic tests that KOSTISHION, co-conspirators Plaisance,

Richey, and Tamulski referred or caused to be referred; and (iii) the revenue that these genetic tests generated for each of the Three DNA Labs.

e. To conceal the solicitation and receipt of kickbacks and bribes from the Three DNA Labs, KOSTISHION, co-conspirators Plaisance, Richey, and Tamulski drafted, submitted, and facilitated the submission of sham Ark invoices to the Three DNA Labs based on hourly services and rates.

f. Specifically, Ark submitted invoices for hourly services to conceal the fact that the Three DNA Labs, KOSTISHION, co-conspirators Plaisance, Richey, Tamulski, and others, had already determined and agreed upon the amount that each of the Three DNA Labs would pay Ark based on the Kickback and Bribe Formula in exchange for referring and arranging for referrals of genetic tests for Medicare beneficiaries to the Three DNA Labs.

g. KOSTISHION and co-conspirators Plaisance and Richey shared in the payments that Ark received from the Three DNA Labs.

h. From in or about January 2018 to in or about January 2019, Medicare paid the Three DNA Labs over \$480,000 for genetic tests that Ark referred or caused to be referred to the Three DNA Labs.

i. In turn, from in or about May 2018 to in or about January 2019, the three DNA Labs paid Ark over \$250,000 in exchange for the genetic test referrals that Ark delivered to the DNA Labs.

Overt Acts

10. In furtherance of the conspiracy, and to effect its goal, KOSTISHION, co-conspirators Plaisance, Richey, Tamulski, and others committed or caused the commission of the following acts in the District of New Jersey and elsewhere:

a. On or about October 26, 2018, KOSTISHION, on behalf of Ark, executed an agreement with Individual-1 at Laboratory 1, in which Ark would be paid “50% . . . of the total gross reimbursement by on [sic] all paid adjudicated specimens tested by [Laboratory 1] . . . for all [Ark] related business.”

b. In or about November 2018, KOSTISHION and co-conspirator Plaisance submitted to Individual-1 ten DNA samples and corresponding patient requisitions, all from Medicare beneficiaries.

c. On or about December 20, 2018, KOSTISHION explained to Individual-1 that, although Laboratory 1 would pay Ark based on the Kickback and Bribe Formula, Ark would invoice Laboratory 1 on an hourly basis and that “other labs like [for Ark] to bill at \$500 an hour increments” and Ark would “back into the number” of the bribe by billing for “services, like . . . all the quote ‘marketing’ services: sales, meetings, ah, accounting, and then we bill you by the hour, which basically totals whatever that amount of money is you owe us.” KOSTISHION further informed Individual-1 that the “benefit” of using this fake invoice method was that “it looks more compliant.”

d. On or about January 2, 2019, KOSTISHION explained to Individual-1 that Ark would invoice Laboratory 1 “at an hourly rate . . . we kind of leave off the cents, and either round it up or round it down.” KOSTISHION further informed Individual-1 that the benefit of the bogus invoice method was that it “protects us, it protects you” and that: “What this will look like my friend, it will be an invoice, . . . remember there’s three partners [in Ark] so it could say 24 hours slash three at \$500 an hour equals . . . I don’t know, \$52,000 for general marketing services, blah, blah, blah, OK?”

e. On or about January 7, 2019, Ark received payment of approximately \$36,860.52 pursuant to the Kickback and Bribe Formula.

In violation of Title 18, United States Code, Section 371.

FORFEITURE ALLEGATIONS

Count 1

1. Upon conviction of the conspiracy offense alleged in Count 1, KOSTISHION shall forfeit to the United States, pursuant to 18 U.S.C. § 982(a)(7), all property, real and personal, he obtained that constitutes or is derived, directly and indirectly, from gross proceeds traceable to the commission of the conspiracy to commit health care fraud, contrary to 18 U.S.C. § 1347, in violation of 18 U.S.C. § 371.

Count 2

2. Upon conviction of the conspiracy offense alleged in Count 2, KOSTISHION shall forfeit to the United States, pursuant to 18 U.S.C. § 982(a)(7), all property, real and personal, he obtained that constitutes or is derived, directly and indirectly, from gross proceeds traceable to the commission of the conspiracy to solicit and receive kickbacks and bribes, contrary to 42 U.S.C. § 1320a-7b(b)(1)(A), in violation of 18 U.S.C. § 371.


SUBSTITUTE ASSETS PROVISION **(Applicable to All Forfeiture Allegations)**

3. If any of the above-described forfeitable property, as a result of any act or omission of KOSTISHION:

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third person;
- 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 subdivided without difficulty;

it is the intent of the United States, pursuant to 21 U.S.C. § 853(p), as incorporated by 28 U.S.C. § 2461(c) and 18 U.S.C. § 982(b)), to forfeiture of any other property of KOSTISHION up to the value of the above-described forfeitable property.


RACHAEL A. HONIG
Attorney for the United States,
Acting Under Authority Conferred
By 28 U.S.C. § 515

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