

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA : Criminal No. 19-693
:
v. : 18 U.S.C. § 371
:
KYLE D. MCLEAN :

S U P E R S E D I N G I N F O R M A T I O N

The defendant having waived in open court prosecution by indictment, the United States Attorney for the District of New Jersey charges:

(Conspiracy to Commit Health Care Fraud)

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

The Defendant and Privy Health, Inc.

a. Defendant KYLE D. MCLEAN ("defendant MCLEAN") was a resident of Arlington Heights, Illinois. Defendant MCLEAN and co-conspirator Kacey C. Plaisance, among others, exercised control over the operations and employees of Privy Health, Inc. ("Privy"), a privately-held Illinois corporation based in Arlington Heights, Illinois. Privy partnered with Ark Laboratory Network LLC ("Ark"), a Florida limited liability company that co-conspirator Plaisance and others owned, to recruit patients and acquire their DNA samples and personal health information so that referrals for genetic testing could be submitted to laboratories.

Relevant Individuals and Entities

b. Matthew S. Ellis (“co-conspirator Ellis”) was a physician licensed in Florida who resided and practiced medicine in Gainesville, Florida. Co-conspirator Ellis also served as Privy’s Medical Director.

c. Edward B. Kostishion (“co-conspirator Kostishion”) resided in Lakeland, Florida and was a managing partner and part owner of Ark.

d. Jeremy M. Richey (“co-conspirator Richey”) resided in Mars, Pennsylvania and was a managing partner and part owner of Ark.

e. Jeffrey Tamulski (“co-conspirator Tamulski”) resided in Tampa, Florida.

f. 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. Defendant MCLEAN and others managed the Distribution Company’s operations from in and about 2017 until in and about May 2018, when defendant MCLEAN assumed the direction and control of Privy. Co-conspirator Plaisance and others managed the Distribution Company’s operations from in or about 2017 until in or about January 2019.

Background on the Medicare Program and Genetic Testing

2. 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.”

3. 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.

4. 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.

5. 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.

6. 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.

7. 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.

8. 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). In order 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.*

9. Non-physician practitioners, such as clinical nurse specialists or physician 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

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

- a. “Laboratory 1,” located in New Jersey;
- b. “Laboratory 2,” located in Mississippi;
- c. “Laboratory 3,” located in Tennessee;
- d. “Laboratory 4,” located in Georgia;
- e. “Laboratory 5,” located in Texas;
- f. “Laboratory 6,” located in Pennsylvania;
- g. “Laboratory 7,” located in Georgia; and
- h. “Laboratory 8,” located in Texas.

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

The Conspiracy

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

KYLE D. MCLEAN

did knowingly and intentionally conspire and agree with co-conspirators Kostishion, Plaisance, 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.

Object of the Conspiracy

13. The object of the conspiracy was for defendant MCLEAN, co-conspirators Kostishion, Plaisance, 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

14. The manner and means by which defendant MCLEAN, co-conspirators Kostishion, Ellis, Plaisance, and others sought to accomplish the object 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 defendant MCLEAN, co-conspirator Plaisance, 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”).

15. 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.

16. Defendant 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.

17. Specifically, these requisitions included, among other items: (a) an indication that co-conspirator Ellis was the ordering physician; (b) various patient-specific diagnosis codes which were necessary to determine the medical necessity for the genetic test; and (c) 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.

18. 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.

19. The Employees captured DNA samples through swabbing patients' cheeks.

20. 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.

21. 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.

22. 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.

23. 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: (a) provided information to the patient regarding genetic testing; (b) deemed the test medically necessary for the diagnosis or detection of a disease or illness; (c) would use the test results in the medical management and treatment decisions for the patient; and (d) was authorized by law to order the tests requested.

24. Defendant MCLEAN, co-conspirators Ellis, Kostishion, Plaisance, 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.

25. In certain cases, defendant MCLEAN, co-conspirators Ellis, Kostishion, Plaisance, 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.

26. 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.

27. 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.

28. 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

29. In turn, from in or about May 2018, through 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.

30. Co-conspirators Plaisance, Kostishion, and Richey shared in the payments that Ark received from the DNA Labs.

31. In turn, Ark paid defendant MCLEAN, Privy, 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
Defendant MCLEAN	\$87,000	November 2018 - January 2019
Distribution Company	\$32,000	July 2018 - January 2019

32. Privy paid co-conspirator Ellis approximately \$5,000 per month for his role as Privy's medical director.

Overt Acts

33. In furtherance of the conspiracy and to effect its object, defendant MCLEAN 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, co-conspirator Kostishion on behalf of Ark, and Individual-1, an employee of Laboratory 1, 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 One] . . . for all [Ark] related business."

b. On or about November 16, 2018, co-conspirator 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 defendant MCLEAN, co-conspirator Plaisance, 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, co-conspirator 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 amounted 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.

FORFEITURE ALLEGATIONS

1. Upon conviction of conspiracy to commit health care fraud, contrary to 18 U.S.C. § 1347, in violation of 18 U.S.C. § 371, as alleged in this Information, defendant MCLEAN 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 offense.

SUBSTITUTE ASSETS PROVISION

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

- (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 the defendant up to the value of the above-described forfeitable property.


CRAIG CARPENITO
United States Attorney

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SUPERSEDING INFORMATION

18 U.S.C. § 371

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