

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA	:	Hon.
	:	
v.	:	Criminal No. 21-
	:	
NORMAN SMILEY	:	18 U.S.C. § 371

INFORMATION

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

(Conspiracy to Violate the Anti-Kickback Statute)

1. At all times relevant to this Information:

The Defendant and Sun Health Advocates LLC

a. Defendant NORMAN SMILEY (“defendant SMILEY”) was a resident of Florida, who owned and operated Sun Health Advocates LLC (“Sun Health”).

b. Sun Health was a Florida-based company founded in 2018 that was in the business of acquiring patient DNA samples and physicians’ orders for purposes of submitting those samples and orders to clinical laboratories for genetic tests and related services.

Relevant Individuals and Entities

c. Metric Lab Services, LLC (“Metric Lab”) was a clinical laboratory located in Mississippi that performed genetic tests and submitted claims to Medicare.

d. Spectrum Diagnostic Labs, LLC (“Spectrum Lab”) (together, with Metric Lab, the “Labs”) was a clinical laboratory located in Texas that performed genetic tests and submitted claims to Medicare.

e. Individual-1 was a resident of Florida who served as an intermediary between Sun Health and the Labs.

Background on the Medicare Program and Genetic Testing

f. 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.”

g. 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.

h. 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.

i. 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.

j. 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.

k. If the patient had insurance, the laboratory typically submitted 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.

2. From in or about August 2018 through in or about May 2019, in the District of New Jersey and elsewhere, defendant

NORMAN SMILEY

did knowingly and intentionally conspire and agree with others to commit an offense 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, that is, the referral of patient DNA samples to the Labs for genetic testing and related 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

3. The goal of the conspiracy was for defendant SMILEY and others to unlawfully enrich themselves by soliciting and receiving kickbacks and bribes in

exchange for referring patient DNA samples, including from beneficiaries in New Jersey, to the Labs for genetic testing and related services.

Manner and Means of the Conspiracy

4. It was part of the conspiracy that:

a. Defendant SMILEY, on behalf of Sun Health, negotiated an agreement with the Labs that determined the amount of kickbacks and bribes that the Labs would pay Sun Health and Individual-1. These kickbacks and bribes were based on the following formula (the “Sun Health Bribe Formula”): (i) calculating the amount of Medicare revenue that the Labs received as a result of genetic tests that Sun Health referred to the Labs; (ii) deducting a negotiated costs of goods sold (“COGS”) amount that the Labs incurred in connection with the tests and, in some cases, a billing fee; and (iii) paying Sun Health and Individual-1 a percentage of the remaining profit. The Sun Health Bribe Formula constituted an unlawful kickback and bribe paid to Sun Health.

b. To disguise these unlawful kickbacks and bribes, Sun Health prepared sham invoices that attempted to conceal the amount dictated under the Sun Health Bribe Formula under the guise of, among other things, purported hourly work for “marketing services” at a rate of \$750 per hour. But the amount the Labs paid Sun Health was strictly based on the Sun Health Bribe Formula and not on the number of hours or “marketing services” for which Sun Health billed.

c. In total, Sun Health received over \$1 million in kickbacks and bribes from the Labs in exchange for the referral of patient DNA samples.

Overt Acts

5. In furtherance of the conspiracy, and to effect its goal, defendant SMILEY and others committed or caused the commission of the following acts in the District of New Jersey and elsewhere:

a. In or about October 2018, Individual-1 emailed defendant SMILEY and another employee of Sun Health executed contracts between Sun Health and Spectrum Lab and Metric Lab. One of these executed agreements was entitled “Business Development Consultant Agreement” (the “Sun Health Agreement”). The Sun Health Agreement contained an Exhibit A, entitled “Compensation Plan,” which set forth the Sun Health Bribe Formula.

b. Individual-1 also included in this email a sample of a sham “medical service invoice” that defendant SMILEY was to use to disguise the kickback payments. This sham invoice purported to itemize and bill work performed on behalf of Spectrum Lab on an hourly basis (at a rate of \$250 per hour), despite the fact that Exhibit A of the Sun Health Agreement made clear that Spectrum Lab would pay Sun Health pursuant to the Sun Health Bribe Formula. Defendant SMILEY and others proceeded to submit sham invoices to the Labs based on this sample invoice in order to disguise the unlawful kickbacks and bribes.

c. On or about December 6, 2018, Individual-1 forwarded an email to defendant SMILEY and others with a spreadsheet report that Spectrum Lab prepared that itemized the genetic testing samples that Sun Health had collected from patients and submitted to Spectrum Lab for the period between November 16 and 30, 2018. The report indicated that Spectrum Lab had collected approximately

\$207,220.35 from Medicare for genetic testing samples that Sun Health had submitted. After deducting amounts for COGS and a billing fee, Spectrum Lab reported approximately \$172,787.13 in net revenue for that period.

d. Applying the Sun Health Bribe Formula to that net revenue amount resulted in a kickback of approximately \$77,754.20 (which constituted approximately 45% of the net revenue amount) for Sun Health from Spectrum Lab. In this email, Individual-1 wrote to defendant SMILEY: “Attached is your report for November 16-30th. Please prepare an invoice as we discussed.” Specifically, Individual-1 was asking defendant SMILEY to prepare a sham invoice that billed Spectrum Lab for purported hourly services totaling \$77,754—the same amount dictated by the Sun Health Bribe Formula and which Spectrum Lab had already calculated and provided in the report Individual-1 had sent to defendant SMILEY.

e. Then, on or about December 6, 2018, an employee of Sun Health emailed a corresponding sham invoice to Spectrum Lab and Individual-1 billing Spectrum Lab a total of \$77,754 in connection with 255 hours of “[m]arketing [s]ervices,” a subtotal of \$66,750, plus \$14,004.20 for “[d]ata.”

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

FORFEITURE ALLEGATION


1. Upon conviction of the offense of conspiracy to receive illegal remunerations, contrary to the federal health care program anti-kickback statute, 42 U.S.C. § 1320a-7b(b)(1)(A), in violation of 18 U.S.C. § 371, as alleged in this Information, defendant SMILEY shall forfeit to the United States, pursuant to 18 U.S.C. § 982(a)(7), all property, real and personal, obtained by the defendant that constitutes or is derived, directly and indirectly, from gross proceeds traceable to the commission of such offense.

Substitute Assets Provision

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

- (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, under 21 U.S.C. § 853(p), as incorporated by 18 U.S.C. § 982(b), to seek forfeiture of any other property of defendant SMILEY up to the value of the forfeitable property described above.


RACHAEL A. HONIG
Acting United States Attorney

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