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

UNITED STATES OF AMERICA : **TO BE FILED UNDER SEAL**
 :
 v. : Hon. Leda Dunn Wettre
 :
 LEE BESEN and : Mag. No. 20-13359
 TERRI HAINES :
 : **CRIMINAL COMPLAINT**

I, Daniel Shim, being duly sworn, state the following is true and correct to the best of my knowledge and belief:

SEE ATTACHMENT A

I further state that I am a Special Agent with the Federal Bureau of Investigation, and that this Complaint is based on the following facts:

SEE ATTACHMENT B

continued on the attached pages and made a part hereof.

Daniel Shim, Special Agent
Federal Bureau of Investigation

Special Agent Daniel Shim attested to this Affidavit by Telephone Pursuant to F.R.C.P. 4.1(b)(2)(A).

July 8, 2020, at
District of New Jersey

HONORABLE LEDA DUNN WETTRE
UNITED STATES MAGISTRATE JUDGE

Signature of Judicial Officer

ATTACHMENT A

**(Conspiracy to violate the
Federal Anti-Kickback Statute)**

From in or about June 2019 to in or about October 2019, in the District of New Jersey and elsewhere, defendants

**LEE BESEN and
TERRI HAINES**

did knowingly and intentionally conspire and agree with each other and others 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 the furnishing and arranging for the furnishing of items and services, namely, the referral of genetic cancer screening tests, for which payment was made in whole or in part under a Federal health care program, contrary to Title 42, United States Code, Section 1320a-7b(b)(1)(A).

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

ATTACHMENT B

I, Daniel Shim, a Special Agent with the Federal Bureau of Investigation (“FBI”), having conducted an investigation and having discussed this matter with other law enforcement officers who have participated in this investigation, have knowledge of the following facts. Because this Complaint is being submitted for the limited purpose of establishing probable cause, I have not included each and every fact known to me concerning this investigation. Rather, I have set forth only the facts that I believe are necessary to establish probable cause. Unless specifically indicated, all dates described in this affidavit are approximate and all conversations and statements described in this affidavit are related in substance and in part.

Relevant Individuals and Background Information

1. At various times relevant to this Complaint:
 - a. Defendant DR. LEE BESEN (“BESEN”) was a physician licensed in Pennsylvania. He resided in Waverly, Pennsylvania and practiced medicine at his office in Peckville, Pennsylvania.
 - b. Defendant TERRI HAINES (“HAINES”) resided in Kennett Square, Pennsylvania and owned GenRx Testing Solutions, LLC (“GenRx”).
 - c. 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(t). People who received benefits under Medicare were commonly referred to as “beneficiaries.”
 - d. 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.
 - e. 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.
 - f. Genetic tests related to a patient’s hereditary predisposition for cancer were commonly referred to as “CGx” tests.

g. To conduct a genetic test, a laboratory had to obtain a DNA sample from the patient, typically 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 with a requisition form to the laboratory for analysis, such as CGx. The requisition form typically included information about the patient, the swab being submitted, and the referring physician. That physician or another authorized person had to confirm on the form that the genetic test was medically necessary.

h. 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 \$6,000 per test.

i. 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)(l). 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.*

j. 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).

k. "Laboratory-A," located in New Jersey, was a clinical laboratory that processed genetic tests and submitted claims to Medicare. HAINES was a Business Development Manager for Laboratory-A, and her company GenRx advertised itself as being "associated" with Laboratory-A. In that capacity, HAINES identified and solicited beneficiaries to receive CGx testing, and she sent those genetic tests to Laboratory-A. In exchange, Laboratory-A paid and agreed to pay HAINES a commission based on the volume of CGx tests that she sent to Laboratory-A.

l. "Individual-1"¹ resided in New Jersey, worked as a sales representative for clinical laboratories, and had an ongoing business relationship with

¹ Individual-1 is a cooperating witness who, in or about the spring 2019, while cooperating with the Government on federal charges, was discovered engaging in additional

BESEN. BESEN introduced HAINES to Individual-1 as a potential business partner.²

m. “Individual-2” owned and operated Laboratory-A, and previously rented office space from BESEN.

The Conspiracy

2. BESEN and HAINES never met in person, but Individual-2 introduced them virtually in or about the spring 2019. Soon after, HAINES and BESEN entered into an agreement: HAINES would solicit CGx tests for Medicare beneficiaries at “health fairs” and would pay BESEN kickbacks and bribes to use his name and medical credentials to order the genetic tests, which she would send to Laboratory-A.

3. In or about the months that followed, HAINES attended health fairs in and around Pennsylvania, collected DNA swabs for CGx tests, and submitted requisition forms for those tests to Laboratory-A in New Jersey using BESEN’s name and credentials. BESEN neither attended these health fairs, nor met with any of the beneficiaries for whom the CGx tests were ordered.

4. In or about July 2019, HAINES paid BESEN a kickback and bribe of approximately \$1,500 in exchange for using his name and credentials in the manner described above. Resulting from their scheme, from in or about June 2019, Laboratory-A billed Medicare approximately \$1,936,795 for CGx tests associated with approximately 163 Medicare beneficiaries.

5. BESEN and HAINES each separately admitted to this kickback scheme in several recorded conversations with Individual-1, as follows:

a. On or about September 12, 2019, BESEN admitted that he never met HAINES. He knew she was not a medical professional, but that she collected CGx tests at health fairs. BESEN also stated that he never attended any health fairs with her, but knew that HAINES had attended two health fairs the previous week, which, according to BESEN, generated approximately 56 CGx genetic tests.

criminal conduct during the term of Individual-1’s cooperation. Individual-1 acknowledged that additional criminal conduct and continued to cooperate with the Government.

² Distinct from this case, BESEN is charged by separate criminal complaint for conspiring with others to receive kickbacks and bribes from Individual-1 in exchange for steering genetic tests to two laboratories for which Individual-1 worked. *See* Mag. No. 20-13358 (LDW).

b. On or about September 24, 2019, BESEN admitted that HAINES was using his name and signature for the CGx tests and, as part of their agreement, in or about July 2019, HAINES sent BESEN a “\$1,500 check.” BESEN also admitted that they had no contract because HAINES “didn’t want this contractual.” He complained that his \$1,500 payment was a “fucking pittance” compared to what HAINES was likely earning off their deal.

c. On or about October 7, 2019, BESEN referenced contemporaneous news reports of criminal charges for health care fraud involving genetic testing and said he believed that HAINES’ “whole concept” was “fraud,” and that HAINES and Laboratory-A were going to be investigated. Likewise, BESEN admitted that he believed health fairs were “all fucking fraud,” genetic testing for cancer was fraudulent because there was no medical evidence it benefited patients, and the only reason Medicare kept paying for the genetic tests was “because right now they’re not catching it.” He said he was concerned about continuing to put his name of the genetic tests because “I would definitely investigate this.” BESEN again admitted that HAINES “slipped him” \$1,500 one time as part of the scheme.

d. On or about October 17, 2019, BESEN again admitted that HAINES paid him once by check.

e. On or about October 22, 2019, BESEN, acknowledging that his scheme with HAINES was illegitimate, said “I saw this as an avenue for an income stream at some point legitimately.” BESEN said he was “a little jumpy that there might be some recourse” as a result of their scheme, but he believed there was no “data that shows that I got paid anything for anything.” In that regard, BESEN said that he thought HAINES had paid him the \$1,500 kickback from a personal check, and not from her company.

f. On our about that same day, in a separate conversation, HAINES said, “between Lee [BESEN] and I you know we worked out a, like a stipend and I only paid him one month.” HAINES admitted that she was “concerned because of the anti-kickback [statute],” and she admitted believing that “if somebody’s gonna get nailed for doing something that they shouldn’t have done it’s gonna’ be me.”

g. On or about October 24, 2019, HAINES admitted that BESEN never attended any of the health fairs. She also said everybody she was talking to said “you can’t pay the doctor because that’s a kickback.”

h. On or about February 20, 2020, BESEN discussed his arrangement with HAINES and said, “There’s nothing they can get me on. There’s

no show of exchange of money.” He said, “I feel like I’m in a courtroom scene, . . . but to console myself so I don’t lose any sleep over it -- I have no interaction where, where there’s any, any show that I received any kickback.”