

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. **23- 80109-CR-SINGHAL/MCCABE**

18 U.S.C. § 1349

18 U.S.C. § 982(a)(7)

UNITED STATES OF AMERICA

vs.

MICHAEL LEWIN,
JASON SANTINI, and
STEVEN BURACK,

Defendants.

FILED BY <u>SAL</u> D.C.
<i>Jun 27, 2023</i>
ANGELA E. NOBLE CLERK U.S. DIST. CT. S. D. OF FLA. - Miami Magistrate

INFORMATION

The United States Attorney charges that:

GENERAL ALLEGATIONS

At all times material to this Information:

Medicare Program

1. The Medicare Program ("Medicare") was a federally funded program that provided free or below-cost health care benefits to certain individuals, primarily the elderly, blind, and disabled. The benefits available under Medicare were governed by federal statutes and regulations. The United States Department of Health and Human Services ("HHS"), through its agency, the Centers for Medicare and Medicaid Services ("CMS"), oversaw and administered Medicare. Individuals who received benefits under Medicare were commonly referred to as Medicare "beneficiaries."

2. Medicare was a "health care benefit program," as defined by Title 18, United States Code, Section 24(b), and a "Federal health care program," as defined by Title 42, United States Code, Section 1320a-7b(f).

3. Medicare covered different types of benefits and was separated into different program "parts." Medicare "Part A" covered health services provided by hospitals, skilled nursing facilities, hospices, and home health agencies. Medicare "Part B" was a medical insurance program that covered, among other things, medical services provided by physicians, medical clinics, laboratories, and other qualified health care providers, such as office visits, minor surgical procedures, and laboratory testing, that were medically necessary and ordered by licensed medical doctors or other qualified health care providers.

4. Physicians, clinics, laboratories, and other health care providers (collectively, "providers") that provided services to beneficiaries were able to apply for and obtain a "provider number." A provider that received a Medicare provider number was able to file claims with Medicare to obtain reimbursement for services provided to beneficiaries.

5. A Medicare claim was required to contain certain important information, including: (a) the beneficiary's name and Health Insurance Claim Number ("HICN"); (b) a description of the health care benefit, item, or service that was provided or supplied to the beneficiary; (c) the billing codes for the benefit, item, or service; (d) the date upon which the benefit, item, or service was provided or supplied to the beneficiary; and (e) the name of the referring physician or other health care provider, as well as a unique identifying number, known either as the Unique Physician Identification Number ("UPIN") or National Provider Identifier ("NPI"). The claim form could be submitted in hard copy or electronically via interstate wire.

6. When submitting claims to Medicare for reimbursement, providers were required to certify that: (a) the contents of the forms were true, correct, and complete; (b) the forms were prepared in compliance with the laws and regulations governing Medicare; and (c) the items and services that were purportedly provided, as set forth in the claims, were medically necessary.

7. Medicare claims were required to be properly documented in accordance with Medicare rules and regulations. Medicare would not reimburse providers for claims that were procured through the payment of kickbacks and bribes.

Part B Coverage and Regulations

8. CMS acted through fiscal agents called Medicare administrative contractors ("MACs"), which were statutory agents for CMS for Medicare Part B. The MACs were private entities that reviewed claims and made payments to providers for services rendered to beneficiaries. The MACs were responsible for processing Medicare claims arising within their assigned geographical area, including determining whether the claim was for a covered service.

9. Novitas Solutions Inc. was the MAC for consolidated Medicare jurisdictions that included Louisiana, Mississippi, Oklahoma, Texas, and Pennsylvania. Palmetto GBA was the MAC for consolidated Medicare jurisdictions that included Georgia, Alabama, Tennessee, South Carolina, North Carolina, Virginia, and West Virginia.

10. To receive Medicare reimbursement, providers had to make appropriate applications to the MAC and execute a written provider agreement. The Medicare provider enrollment application for laboratories, CMS Form 855B, was required to be signed by an authorized representative of the provider. CMS Form 855B contained a certification that stated:

I agree to abide by the Medicare laws, regulations, and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by

Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

11. CMS Form 855B contained additional certifications that the provider "will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity."

12. Payments under Medicare Part B were often made directly to the provider rather than to the patient or beneficiary. For this to occur, the beneficiary would assign the right of payment to the provider. Once such an assignment took place, the provider would assume the responsibility for submitting claims to, and receiving payments from, Medicare.

Genetic Tests

13. Various forms of genetic testing existed using DNA sequencing to detect mutations in genes that could indicate a higher risk of developing certain diseases or health conditions in the future. For example, cancer genomic ("CGx") testing used DNA sequencing to detect mutations in genes that could indicate a higher risk of developing certain types of cancers in the future. CGx testing was not a method of diagnosing whether an individual presently had cancer. Pharmacogenetic ("PGx") testing used DNA sequencing to assess how the body's genetic makeup would affect the response to certain medications.

14. Medicare did not cover laboratory 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." 42 U.S.C. § 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." 42 C.F.R. § 411.15(a)(1). Among the statutory

exceptions covered by Medicare were cancer screening tests such as “screening mammography, colorectal cancer screening tests, screening pelvic exams, [and] prostate cancer screening tests.”

Id.

15. 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. 42 C.F.R. § 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.” “Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.” *Id.*

The Defendants, Related Entities, and Relevant Persons

16. Palm Sales LLC (“Palm”) was a limited liability company formed under the laws of Florida and whose principal place of business was located in Delray Beach, Florida.

17. Defendant **MICHAEL LEWIN** was a resident of Delray Beach, Florida, and was the owner, manager, and operator of Palm.

18. Defendant **JASON SANTINI** was a resident of Delray Beach, Florida.

19. Defendant **STEVEN BURACK** was a resident of Boca Raton, Florida.

20. Company 1 was a limited liability company formed under the laws of Florida and whose principal place of business was located in Aventura, Florida.

21. Individual 1 was a resident of San Antonio, Texas, and was the owner, manager, and operator of Company 1.

22. Clio Laboratories, LLC (“Clio”) was a limited liability company formed under the

laws of Florida and later Georgia, and whose principal place of business was located in Lawrenceville, Georgia. Clio purported to serve as a diagnostic testing laboratory.

23. Performance Laboratories, LLC ("Performance") was a limited liability company formed under the laws of Oklahoma and whose principal place of business was located in Oklahoma City, Oklahoma. Performance purported to serve as a diagnostic testing laboratory.

24. Khalid Satary was a resident of Lawrenceville, Georgia, and was an owner, manager, and operator of Clio and Performance.

25. Brett Hirsch was a resident of Delray Beach, Florida.

COUNT 1
Conspiracy to Commit Health Care Fraud
(18 U.S.C. § 1349)

1. The General Allegations section of this Information is re-alleged and incorporated by reference as though fully set forth herein.

2. From in or around November 2017, and continuing through in or around July 2019, in Palm Beach County, in the Southern District of Florida, and elsewhere, the defendants,

**MICHAEL LEWIN,
JASON SANTINI, and
STEVEN BURACK,**

did knowingly and willfully, that is, with the intent to further the object of the conspiracy, combine, conspire, confederate, and agree with each other, Khalid Satary, Individual 1, Brett Hirsch, and others known and unknown to the United States Attorney, to commit an offense against the United States, that is to knowingly and willfully execute a scheme and artifice to defraud a health care benefit program affecting commerce, as defined in Title 18, United States Code, Section 24(b), that is, Medicare, 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 program, 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

3. It was a purpose of the conspiracy for the defendants and their co-conspirators to unlawfully enrich themselves by, among other things: (a) paying and receiving kickbacks and bribes in exchange for the referral of Medicare beneficiaries, so that laboratories, including Clio and Performance, could bill Medicare for genetic tests, without regard to whether the beneficiaries needed the tests; (b) paying kickbacks and bribes to doctors, including **STEVEN BURACK**, in exchange for ordering and arranging for the ordering of genetic tests for Medicare beneficiaries, without regard to whether the beneficiaries needed the tests; (c) submitting and causing the submission of false and fraudulent claims to Medicare for genetic tests that were medically unnecessary, ineligible for reimbursement, and procured through the payment of kickbacks and bribes; (d) concealing the submission of false and fraudulent claims to Medicare, the payment and receipt of illegal kickbacks and bribes, and the transfer of the proceeds of the fraud; and (e) diverting fraud proceeds for their personal use and benefit, the use and benefit of others, and to further the fraud.

Manner and Means

The manner and means by which the defendants and their co-conspirators sought to accomplish the object and purpose of the conspiracy included, among other things:

4. **MICHAEL LEWIN, JASON SANTINI, Brett Hirsch, Individual 1, and other co-conspirators** recruited Medicare beneficiaries by targeting them at purported health fairs and other direct solicitations with deceptive marketing to induce them to accept genetic tests regardless of medical necessity.

5. **MICHAEL LEWIN, JASON SANTINI, Brett Hirsch, Individual 1, and other co-conspirators** offered and paid illegal kickbacks and bribes to doctors, including **STEVEN BURACK**, to sign laboratory requisition forms—also known as “prescriptions”—for genetic tests that were medically unnecessary or ineligible for reimbursement, as the doctors did not meet with or examine the beneficiaries, were not treating the beneficiaries for cancer or symptoms of cancer or other diseases, and did not use the test results in the treatment of the beneficiaries.

6. **MICHAEL LEWIN, JASON SANTINI, Brett Hirsch, Individual 1 and other co-conspirators** provided the doctors, including **STEVEN BURACK**, with pre-filled prescriptions that pre-selected which genes the doctors would order to be tested for the beneficiaries.

7. **MICHAEL LEWIN, JASON SANTINI, Brett Hirsch, Individual 1 and other co-conspirators** selected the genes to be tested based on how much Medicare reimbursed for the tests, irrespective of the medical history, physical findings, or medical needs of each specific beneficiary.

8. **MICHAEL LEWIN, JASON SANTINI, and other co-conspirators** solicited and received kickbacks and bribes from Brett Hirsch, Individual 1, and others in exchange for the genetic test samples and Medicare-required documents, including signed prescriptions for the genetic tests (collectively referred to as “doctor’s orders”).

9. Brett Hirsch, Individual 1, and other co-conspirators solicited and received kickbacks and bribes from Khalid Satary and other laboratory owners in exchange for the doctor’s orders.

10. **MICHAEL LEWIN, JASON SANTINI, Brett Hirsch, Individual 1, and other co-conspirators** disguised the scheme by creating sham invoices and documents, including those that disguised the kickbacks and bribes as payments for purported marketing services, when, in truth

and fact, Brett Hirsch and Individual 1 were paying **MICHAEL LEWIN, JASON SANTINI**, and other co-conspirators an illegal kickback and bribe in the form of a portion of the gross revenues paid by Medicare to the laboratories for the genetic tests.

11. **MICHAEL LEWIN, JASON SANTINI, STEVEN BURACK**, Brett Hirsch, Khalid Satary, Individual 1, and other co-conspirators caused laboratories, including Clio and Performance, to submit false and fraudulent claims for the genetic tests to Medicare, in at least the approximate amount of \$3,299,573.

12. As the result of these false and fraudulent claims, Medicare made payments to laboratories, including Clio and Performance, in at least the approximate amount of \$1,045,349.

13. **MICHAEL LEWIN, JASON SANTINI, STEVEN BURACK**, Brett Hirsch, Individual 1, and other co-conspirators used the fraud proceeds received from laboratories to benefit themselves and others, and to further the fraud.

All in violation of Title 18, United States Code, Section 1349.

FORFEITURE ALLEGATIONS

1. The allegations of this Information are re-alleged and by this reference fully incorporated herein for the purpose of alleging forfeiture to the United States of certain property in which the defendants, **MICHAEL LEWIN, JASON SANTINI**, and **STEVEN BURACK**, have an interest.

2. Upon conviction of a violation of Title 18, United States Code, Section 1349, as alleged in this Information, the defendants shall forfeit to the United States any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense, pursuant to Title 18, United States Code, Section 982(a)(7).

3. If any of the property subject to forfeiture, 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 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,

the United States shall be entitled to forfeiture of substitute property under the provisions of Title 21, United States Code, Section 853(p).

All pursuant to Title 18, United States Code, Section 982(a)(7), and the procedures set forth in Title 21, United States Code, Section 853, as incorporated by Title 18, United States Code, Section 982(b)(1).


MARKENZY LAPOINTE
UNITED STATES ATTORNEY

GLENN S. LEON, CHIEF
CRIMINAL DIVISION, FRAUD SECTION
U.S. DEPARTMENT OF JUSTICE


REGINALD CUYLER JR.
TRIAL ATTORNEY
CRIMINAL DIVISION, FRAUD SECTION
U.S. DEPARTMENT OF JUSTICE

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

UNITED STATES OF AMERICA

CASE NO.: _____

v.

CERTIFICATE OF TRIAL ATTORNEY

MICHAEL LEWIN, et al.,

Defendants.

Court Division (select one)

- ☐ Miami ☐ Key West ☐ FTP
☐ FTL ☒ WPB

Superseding Case Information:

New Defendant(s) (Yes or No) _____

Number of New Defendants _____

Total number of counts _____

I do hereby certify that:

1. I have carefully considered the allegations of the indictment, the number of defendants, the number of probable witnesses and the legal complexities of the Indictment/Information attached hereto.
2. I am aware that the information supplied on this statement will be relied upon by the Judges of this Court in setting their calendars and scheduling criminal trials under the mandate of the Speedy Trial Act, Title 28 U.S.C. §3161.
3. Interpreter: (Yes or No) No
List language and/or dialect: _____
4. This case will take 0 days for the parties to try.
5. Please check appropriate category and type of offense listed below:
(Check only one) (Check only one)
I ☒ 0 to 5 days ☐ Petty
II ☐ 6 to 10 days ☐ Minor
III ☐ 11 to 20 days ☐ Misdemeanor
IV ☐ 21 to 60 days ☒ Felony
V ☐ 61 days and over
6. Has this case been previously filed in this District Court? (Yes or No) No
If yes, Judge _____ Case No. _____
7. Has a complaint been filed in this matter? (Yes or No) No
If yes, Magistrate Case No. _____
8. Does this case relate to a previously filed matter in this District Court? (Yes or No) Yes
If yes, Judge Ruiz Case No. 19-CR-80197
9. Defendant(s) in federal custody as of _____
10. Defendant(s) in state custody as of _____
11. Rule 20 from the _____ District of _____
12. Is this a potential death penalty case? (Yes or No) No
13. Does this case originate from a matter pending in the Northern Region of the U.S. Attorney's Office prior to August 8, 2014 (Mag. Judge Shaniek Maynard? (Yes or No) No
14. Does this case originate from a matter pending in the Central Region of the U.S. Attorney's Office prior to October 3, 2019 (Mag. Judge Jared Strauss? (Yes or No) No
15. Did this matter involve the participation of or consultation with now Magistrate Judge Eduardo I. Sanchez during his tenure at the U.S. Attorney's Office, which concluded on January 22, 2023? No

By: _____

REGINALD CUYLER, JR.

DOJ Trial Attorney

FL Bar No. 0114062

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

PENALTY SHEET

Defendant's Name: MICHAEL LEWIN

Case No: _____

Count #: 1

Title 18, United States Code, Section 1349

Conspiracy to Commit Health Care Fraud

* Max. Term of Imprisonment: 10 years

* Mandatory Min. Term of Imprisonment (if applicable): N/A

* Max. Supervised Release: 3 years

* Max. Fine: \$250,000 or twice the gross gain or loss from the offense

***Refers only to possible term of incarceration, supervised release and fines. It does not include restitution, special assessments, parole terms, or forfeitures that may be applicable.**

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

PENALTY SHEET

Defendant's Name: JASON SANTINI

Case No: _____

Count #: 1

Title 18, United States Code, Section 1349

Conspiracy to Commit Health Care Fraud

* Max. Term of Imprisonment: 10 years

* Mandatory Min. Term of Imprisonment (if applicable): N/A

* Max. Supervised Release: 3 years

* Max. Fine: \$250,000 or twice the gross gain or loss from the offense

*Refers only to possible term of incarceration, supervised release and fines. It does not include restitution, special assessments, parole terms, or forfeitures that may be applicable.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

PENALTY SHEET

Defendant's Name: STEVEN BURACK

Case No: _____

Count #: 1

Title 18, United States Code, Section 1349

Conspiracy to Commit Health Care Fraud

* Max. Term of Imprisonment: 10 years

* Mandatory Min. Term of Imprisonment (if applicable): N/A

* Max. Supervised Release: 3 years

* Max. Fine: \$250,000 or twice the gross gain or loss from the offense

*Refers only to possible term of incarceration, supervised release and fines. It does not include restitution, special assessments, parole terms, or forfeitures that may be applicable.

UNITED STATES DISTRICT COURT
for the
Southern District of Florida

United States of America

v.

Michael Lewin,

Defendant

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)

Case No.

WAIVER OF AN INDICTMENT

I understand that I have been accused of one or more offenses punishable by imprisonment for more than one year. I was advised in open court of my rights and the nature of the proposed charges against me.

After receiving this advice, I waive my right to prosecution by indictment and consent to prosecution by information.

Date: _____

Defendant's signature

Signature of defendant's attorney

Printed name of defendant's attorney

Judge's signature

Judge's printed name and title

UNITED STATES DISTRICT COURT
for the
Southern District of Florida

United States of America

v.

Jason Santini,

Defendant

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)

Case No. _____

WAIVER OF AN INDICTMENT

I understand that I have been accused of one or more offenses punishable by imprisonment for more than one year. I was advised in open court of my rights and the nature of the proposed charges against me.

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Date: _____

Defendant's signature

Signature of defendant's attorney

Printed name of defendant's attorney

Judge's signature

Judge's printed name and title

UNITED STATES DISTRICT COURT

for the
Southern District of Florida

United States of America

v.

Steven Burack,

Defendant

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Case No.

WAIVER OF AN INDICTMENT

I understand that I have been accused of one or more offenses punishable by imprisonment for more than one year. I was advised in open court of my rights and the nature of the proposed charges against me.

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Date: _____

Defendant's signature

Signature of defendant's attorney

Printed name of defendant's attorney

Judge's signature

Judge's printed name and title