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United States Courts Southern District of Texas FILED

June 25, 2024

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF TEXAS HOUSTON DIVISION

Nathan Ochsner, Clerk of Court

UNITED STATES OF AMERICA	§
	§
V.	§
	§
HAROLD ALBERT "AL" KNOWLES (1)	§
and	§
CHANTAL SWART (2),	Š
	§
Defendants.	§

Criminal No.	<u>4:24-cr-0</u> 0340
UNDER SEA	L

INDICTMENT

The Grand Jury charges:

General Allegations

At all times material to this Indictment, unless otherwise specified:

The Medicare Program

1. The Medicare Program ("Medicare") was a federally funded program that provided free and below-cost health care benefits to 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 & 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 B" covered, among other things, medical services provided by

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physicians, medical clinics, laboratories, and other qualified health care providers, such as office visits and laboratory testing, that were medically necessary and ordered by licensed medical doctors or other qualified health care providers.

4. Medicare "providers" included independent clinical laboratories, physicians, and other health care providers who provided items or services to beneficiaries. To bill Medicare, a provider was required to submit a Medicare Enrollment Application Form ("Provider Enrollment Application") to Medicare. The Provider Enrollment Application contained certifications that the provider was required to make before the provider could enroll with Medicare. Specifically, the Provider Enrollment Application required the provider to certify, among other things, that the provider would abide by the Medicare laws, regulations, and program instructions, including the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and that the provider would not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare.

5. A Medicare "provider number" was assigned to a provider upon approval of the Provider Enrollment Application. A health care provider that received a Medicare provider number was able to file claims with Medicare to obtain reimbursement for reasonable and necessary services provided to beneficiaries.

6. A Medicare claim was required to contain certain information, including: (a) the beneficiary's name and Health Insurance Claim Number; (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; (e) the name of the referring physician or other health care provider; and (f) the referring provider's unique identifying number, known either as the Unique Physician Identification Number or National Provider Identifier. The claim form could be submitted in hard

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copy or electronically.

7. When submitting claims to Medicare for reimbursement, providers were required to certify that: (1) the contents of the forms were true, correct, and complete; (2) the forms were prepared in compliance with the laws and regulations governing Medicare; and (3) the services that were purportedly provided, as set forth in the claims, were medically necessary.

8. 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 illegal kickbacks and bribes.

Medicare Coverage for Genetic Testing

9. Cancer genetic ("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.

10. Genetic testing for cardiovascular disease used DNA sequencing to detect mutations in genes that could indicate an increased risk of developing serious cardiovascular conditions in the future and could assist in the treatment or management of a patient who presently had signs or symptoms of a cardiovascular disease or condition. Genetic testing for cardiovascular disease was not a method of diagnosing whether an individual presently had a cardiac condition.

11. Laboratories purported to offer other kinds of genetic testing that used DNA sequencing to detect mutations in genes that could indicate an increased risk of developing diseases such as Parkinson's disease, Alzheimer's disease, dementia, diabetes, obesity, pulmonary diseases, and hearing loss (collectively, with CGx and genetic testing for cardiovascular disease, "genetic testing"). All genetic testing was a form of diagnostic testing.

12. For genetic testing, a beneficiary provided a saliva sample or cheek or nasal swab

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containing DNA material. The DNA sample was then submitted to a laboratory to conduct genetic testing. Tests were then run on different "panels" of genes. Genetic testing typically involved performing lab procedures that resulted in billing Medicare using certain billing codes, each with its own reimbursement rate.

13. DNA samples were submitted along with requisitions (or the physician's order) that identified the beneficiary, the beneficiary's insurance, and indicated the specific type of genetic testing to be performed. For laboratories to submit claims to Medicare for genetic testing, the requisitions had to be signed by a physician or other authorized medical professional, who attested to the medical necessity of the genetic testing.

14. Medicare did not cover diagnostic 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 "[e]xaminations 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).

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. Title 42, Code of Federal Regulations, Section 410.32(a) provided, "[A]II... diagnostic laboratory 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[.]"

Shell Lab Rule

16. Title 42, United States Code, Section 1395I (h)(5) provided that payment from Medicare for covered clinical diagnostic laboratory tests "may only be made to the person or entity which performed or supervised the performance of such test[.]" If a test was "performed at the request of a laboratory by another laboratory," the referring laboratory could only be paid by Medicare for that test if "not more than 30 percent of the clinical diagnostic laboratory tests for which such referring laboratory ... receives requests for testing during the year in which the test is performed, are performed by another laboratory[.]" *Id.* This was commonly called the "70/30 rule" or the "shell lab rule," as it precluded pass-through billing arrangements in which a lab billed Medicare for more than 30 percent of the tests that another lab performed.

The Relevant Entities

17. Bio Choice Laboratory, Inc. ("Bio Choice"), doing business as US Genomix, was a Texas corporation with a principal place of business in Harris County, Texas. Bio Choice was an independent clinical laboratory enrolled with Medicare that purportedly provided laboratory services and diagnostic testing, including genetic testing, to individuals, including Medicare beneficiaries.

18. Bios Scientific LLC ("Bios Scientific") was a Delaware limited liability company with a principal place of business in Montgomery County, Texas. Bios Scientific was an independent clinical laboratory enrolled with Medicare that purportedly provided laboratory services and diagnostic testing, including genetic testing, to individuals, including Medicare beneficiaries.

19. KAB Health, LLC ("KAB") was a Nevada limited liability company with a principal place of business in Hall County, Georgia. KAB purportedly provided management

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services on behalf of other health care businesses, including Bio Choice.

20. US Genomix Management LLC ("USG Management") was a Texas limited liability company with its principal place of business in Hall County, Georgia. USG Management was a successor entity to KAB.

21. CLHS Consulting LLC ("CLHS") was a Florida limited liability company, with its principal place of business in Palm Beach County, Florida.

The Defendants and Relevant Individuals

22. Defendant **HAROLD ALBERT "AL" KNOWLES** ("**KNOWLES**") was a resident of Coweta County, Georgia, and Broward County, Florida, and was an owner of Bio Choice, Bios Scientific, KAB, and USG Management. **KNOWLES** signed the Provider Enrollment Application on behalf of Bios Scientific.

23. Defendant CHANTAL SWART ("SWART") was a resident of Palm Beach County, Florida, and an owner of CLHS. SWART referred DNA samples and signed doctors' orders for genetic testing to Bio Choice and Bios Scientific. SWART also referred other marketers to Bio Choice.

24. Employee 1 was a resident of Hall County, Georgia, and the Chief Operating Officer of Bio Choice, Bios Scientific, KAB, and USG Management.

25. Employee 2 was a resident of Coweta County, Georgia, and KNOWLES's personal assistant.

26. Employee 3 was a resident of Fulton County, Georgia, and an employee involved in sales for Bio Choice and Bios Scientific.

<u>COUNT ONE</u> Conspiracy to Commit Health Care Fraud (18 U.S.C. § 1349)

27. Paragraphs 1 through 26 of this Indictment are realleged and incorporated by reference as though fully set forth herein.

28. Beginning in or around September 2019, and continuing through in or around January 2022, the exact dates being unknown to the Grand Jury, in the Houston Division of the Southern District of Texas, and elsewhere, the Defendant,

HAROLD ALBERT "AL" KNOWLES,

did knowingly and willfully combine, conspire, confederate, and agree with others known and unknown to the Grand Jury to execute and attempt to 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

29. It was a purpose of the conspiracy for **KNOWLES** and his co-conspirators, known and unknown, to unlawfully enrich themselves by, among other things: (a) paying and receiving illegal kickbacks and bribes in exchange for the referral of Medicare beneficiaries' DNA samples and signed doctors' orders for genetic testing, and other documentation necessary to submit claims to Medicare, without regard to the medical necessity for the genetic testing; (b) submitting and causing the submission, via interstate wire, of false and fraudulent claims to Medicare for genetic

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testing that were predicated on kickbacks and bribes, medically unnecessary, and ineligible for Medicare reimbursement; (c) concealing and causing the concealment of the submission of false and fraudulent claims to Medicare; and (d) 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 **KNOWLES** and his co-conspirators, known and unknown, sought to accomplish the objects and purpose of the conspiracy included, among other things:

30. **KNOWLES**, **SWART**, and others obtained access to tens of thousands of beneficiaries across the United States by targeting them with deceptive telemarketing campaigns. Call center representatives—who were almost never medical professionals—often prompted beneficiaries to disclose their medical conditions and induced them to agree to genetic testing regardless of medical necessity.

31. **KNOWLES** negotiated illegal kickback and bribe arrangements with marketers, including **SWART**, and knowingly and intentionally disguised the nature and source of these illegal kickbacks and bribes through sham contracts and agreements that purported to pay marketers on a "flat fee" or hourly basis for legitimate marketing services.

32. **KNOWLES**, through Bio Choice, offered to pay, and paid or caused the payment of, illegal kickbacks and bribes to marketers, including **SWART**, in exchange for the referral of DNA samples and for the ordering and arranging for the ordering of genetic testing for Medicare beneficiaries by Bio Choice and Bios Scientific. **SWART** and other marketers, receiving illegal kickbacks and bribes from **KNOWLES**, knew that Bio Choice and Bios Scientific billed Medicare for genetic testing that was purportedly provided on behalf of these beneficiaries and that was

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predicated on these illegal kickbacks and bribes.

33. **KNOWLES**, **SWART**, and others agreed that **SWART** and others would pay illegal kickbacks and bribes to purported telemedicine companies to obtain signed doctors' orders for genetic testing after only a brief telemedicine visit. **KNOWLES** and his co-conspirators knew that the purported telemedicine companies' physicians were rarely, if ever, the beneficiaries' treating physicians and rarely, if ever, used the genetic testing results in the beneficiaries' treatment.

34. **KNOWLES** and others caused Bio Choice and Bios Scientific to bill Medicare over \$10,000 per genetic test by submitting billing codes that inaccurately described the testing performed. Medicare reimbursed Bio Choice over \$7,000 for these tests.

35. **KNOWLES** and others intentionally violated the 70/30 rule that applied to claims Bio Choice and Bios Scientific submitted to Medicare. **KNOWLES** and others submitted and caused Bio Choice and Bios Scientific to submit claims for genetic testing to Medicare despite knowing that these labs did not have the capability to perform their own genetic testing and paid another lab to perform virtually all their genetic testing, making these labs ineligible for reimbursements on the tests referred to other labs.

36. From in or around October 2019, and continuing through in or around January 2022, **KNOWLES** and others submitted and caused Bio Choice to submit approximately \$355 million in false and fraudulent claims to Medicare for genetic testing that was often: (a) induced through kickbacks and bribes; (b) medically unnecessary; and (c) ineligible for reimbursement. In reliance on these representations, Medicare paid approximately \$227 million on those claims.

37. From in or around September 2021, and continuing through in or around January2022, KNOWLES and others submitted and caused Bios Scientific to submit approximately \$4

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million in false and fraudulent claims to Medicare for genetic testing that was often: (a) induced through kickbacks and bribes; (b) medically unnecessary; and (c) ineligible for reimbursement. In reliance on these representations, Medicare paid approximately \$2.4 million on those claims.

38. After Medicare reimbursed Bio Choice and Bios Scientific, **KNOWLES** transferred proceeds of the fraud to himself, marketers, and other co-conspirators.

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

COUNT TWO

Conspiracy to Defraud the United States and Pay and Receive Health Care Kickbacks (18 U.S.C. § 371)

39. Paragraphs 1 through 26 and 30 through 38 of this Indictment are realleged and incorporated by reference as though fully set forth herein.

40. Beginning in or around April 2021, and continuing through in or around January 2022, the exact dates being unknown to the Grand Jury, in the Houston Division of the Southern District of Texas, and elsewhere, the Defendants,

HAROLD ALBERT "AL" KNOWLES and CHANTAL SWART,

did knowingly and willfully combine, conspire, confederate, and agree with each other, and with others known and unknown to the Grand Jury, to commit offenses against the United States, that is:

- a. to defraud the United States by impairing, impeding, obstructing, and defeating through deceitful and dishonest means, the lawful government functions of HHS and CMS in their administration and oversight of Medicare;
- b. to violate Title 42, United States Code, Section 1320a-7b(b)(1), by soliciting and receiving any remuneration, including kickbacks and bribes, directly and indirectly, overtly and covertly, in cash and in kind, including by check and interstate wire transfer, in return for

referring an individual to a person for the furnishing and arranging for the furnishing of any item and service for which payment may be made in whole and in part under a Federal health care program, that is, Medicare; and in return for purchasing, leasing, ordering, and arranging for, and recommending purchasing, leasing, and ordering of any good, service, and item for which payment may be made in whole and in part under a Federal health care program, that is, Medicare; and

c. to violate Title 42, United States Code, Section 1320a-7b(b)(2), by offering and paying any remuneration, including kickbacks and bribes, directly and indirectly, overtly and covertly, in cash and in kind, including by check and interstate wire transfer, to any person to induce such person to refer an individual to a person for the furnishing and arranging for the furnishing of any item and service for which payment may be made in whole and in part under a Federal health care program, that is, Medicare; and to purchase, lease, order, and arrange for and recommend purchasing, leasing, and ordering any good, facility, service, and item for which payment may be made in whole and in part under a Federal health care.

Purpose of the Conspiracy

41. It was a purpose of the conspiracy for **KNOWLES**, **SWART**, and their coconspirators, known and unknown, to unlawfully enrich themselves by, among other things: (a) soliciting, receiving, offering, and paying illegal kickbacks and bribes in exchange for the referral of Medicare beneficiaries' DNA samples and arranging for doctors' orders for genetic testing to Bio Choice and Bios Scientific; (b) submitting and causing the submission of false and fraudulent claims to Medicare for genetic testing that were procured through illegal kickbacks and bribes, were medically unnecessary, were ineligible for reimbursement, and were not provided as represented; (c) concealing and causing the concealment of the payment and receipt of illegal kickbacks and bribes; and (d) diverting the proceeds for their personal use and benefit, the use and benefit of others, and to further the conspiracy.

Manner and Means

The manner and means by which **KNOWLES**, **SWART**, and their co-conspirators, known and unknown, sought to accomplish the objects and purpose of the conspiracy included, among other things, the following:

42. **SWART** and others targeted and recruited beneficiaries through telemarketing campaigns to induce them to submit DNA samples for genetic testing.

43. **SWART** and others solicited and received illegal kickbacks and bribes from **KNOWLES** in exchange for DNA samples and signed doctors' orders for genetic testing, knowing that Bio Choice would bill Medicare for genetic testing purportedly provided on behalf of those beneficiaries. **SWART** and others submitted these DNA samples and signed doctors' orders for genetic testing to Bio Choice in Houston, Texas.

44. **KNOWLES** offered, paid, and caused the payment of illegal kickbacks and bribes to be transmitted to **SWART** and others, by check and interstate wire, from bank accounts held by Bio Choice and KAB to bank accounts held in the names of companies **SWARTS** controlled.

45. **KNOWLES** and **SWART** caused Bio Choice to submit false and fraudulent claims by interstate wire to Medicare for genetic testing knowing that they were procured through the payment of illegal kickbacks and bribes, medically unnecessary, and ineligible for reimbursement.

46. From in or around April 2021, and continuing through in or around October 2021, **KNOWLES** paid and caused the payment of approximately \$7.6 million from bank accounts held by Bio Choice and KAB, or other bank accounts **KNOWLES** or his co-conspirators controlled, to

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bank accounts held in the names of companies **SWART** controlled, which constituted illegal kickbacks and bribes paid in exchange for DNA samples and signed doctors' orders for genetic testing that **SWART** referred or caused to be referred to Bio Choice. **SWART**'s referrals supported claims to Medicare for which Medicare reimbursed Bio Choice.

47. **KNOWLES**, **SWART**, and their co-conspirators used the Medicare proceeds to benefit themselves and others, and to further the conspiracy.

Overt Acts

In furtherance of the conspiracy, and to accomplish its objects and purpose, at least one coconspirator committed and caused to be committed, in the Houston Division of the Southern District of Texas, and elsewhere, at least one of the following overt acts, among others:

48. On or about June 18, 2021, **SWART**, acting on behalf of CLHS, exchanged a marketing agreement with **KNOWLES** providing that **SWART** was to receive an annual fee of approximately \$7.2 million payable in 24 bimonthly installments of approximately \$300,000 in exchange for purported marketing services.

49. On or about July 2, 2021, **KNOWLES** caused a payment of an illegal kickback and bribe of approximately \$300,000 from bank accounts held by Bio Choice to CLHS for the benefit of **SWART**.

50. On or about July 20, 2021, **KNOWLES** texted Employee 1 that the volume of beneficiary DNA samples and signed doctors' orders for genetic testing he expected **SWART** to refer to Bio Choice and Bios Scientific increased from approximately 300 each month to approximately 1,000 each month.

51. On or about July 21, 2021, **SWART** texted **KNOWLES** and Employee 2 to create a contract that purported to be a flat-fee contract for legitimate marketing services for a new

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marketer but was, in reality, a contract for approximately \$400,000 per month based on an expected volume of approximately 200 samples each month.

52. On or about July 27, 2021, Employee 2 prepared a new contract for CLHS on behalf of **KNOWLES** providing that **SWART** was to receive an annual fee of approximately \$27.6 million payable in 24 bimonthly installments of approximately \$1.15 million.

53. On or about August 2, 2021, **KNOWLES** caused a payment of an illegal kickback and bribe of approximately \$1.15 million from bank accounts held by Bio Choice and KAB to CLHS for the benefit of **SWART**.

All in violation of Title 18, United States Code, Section 371.

COUNT THREE

Receipt of Health Care Kickbacks in Connection with a Federal Health Care Program (42 U.S.C. § 1320a-7b(b)(1) and 18 U.S.C. § 2)

54. Paragraphs 1 through 26, 30 through 38, and 42 through 53 of this Indictment are realleged and incorporated by reference as though fully set forth herein.

55. On or about the date set forth below, in the Houston Division of the Southern District of Texas, and elsewhere, the Defendant,

CHANTAL SWART,

aiding and abetting, and aided and abetted by, others known and unknown to the Grand Jury, did knowingly and willfully solicit and receive remuneration, that is, kickbacks and bribes, directly and indirectly, overtly and covertly, in cash and in kind, including by check and interstate wire transfer, in return for referring an individual to a person for the furnishing and arranging for the furnishing of any item and service for which payment may be made in whole and in part under a Federal health care program, that is, Medicare; and in return for purchasing, leasing, ordering, and arranging for and recommending purchasing, leasing, and ordering any good, facility, service, and

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item for which payment may be made in whole and in part under a Federal health care program, that is, Medicare as set forth below:

Approx. Date of Payment	Approx. Amount	Description
August 2, 2021	\$1.15 million	Wire Transfer from Bio Choice's account at Bank of America to CLHS's account at Bank of America

In violation of Title 42, United States Code, Section 1320a-7b(b)(1) and Title 18, United States Code, Section 2.

<u>NOTICE OF CRIMINAL FORFEITURE</u> (18 U.S.C. §§ 981(a)(1)(C), 982(a)(7), and 28 U.S.C. § 2461(c))

56. The allegations contained in Counts One through Three of this Indictment are hereby realleged and incorporated by reference for the purpose of alleging forfeitures pursuant to Title 18, United States Code, Sections 981(a)(1)(C) and 982(a)(7); and Title 28, United States Code, Section 2461(c).

57. Upon conviction of the offenses set forth in Counts One and Two of this Indictment, the Defendant **HAROLD ALBERT "AL" KNOWLES** shall forfeit to the United States of America, pursuant to Title 18, United States Code, Section 982(a)(7) and Title 28, United States Code, Section 2461(c), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offenses.

58. Upon conviction of the offenses set forth in Counts Two and Three of this Indictment, the Defendant **CHANTAL SWART** shall forfeit to the United States of America, pursuant to Title 18, United States Code, Section 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offenses.

59. Defendants HAROLD ALBERT "AL" KNOWLES and CHANTAL SWART

are notified that upon conviction, a money judgment may be imposed against them. If any of the property described above, 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 of America shall be entitled to forfeiture of substitute property up to the amount of the money judgment pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b)(1) and Title 28, United States Code, Section 2461(c).

(continued on next page)

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A TRUE BILL

Original Signature on File

FOREPERSON

ALAMDAR S. HAMDANI UNITED STATES ATTORNEY

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

Andrew Tamayo

ANDREW TAMAYO MONICA COOPER TRIAL ATTORNEYS FRAUD SECTION, CRIMINAL DIVISION U.S. DEPARTMENT OF JUSTICE