

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA : Hon.
: :
: Crim. No.
v. : :
: 18 U.S.C. §§ 371, 1347 and 2;
: 21 U.S.C. § 846; and
MUKARAM GAZI : 42 U.S.C. § 1320a-7b(1)(B)

INDICTMENT

The Grand Jury in and for the District of New Jersey, sitting at Newark,
charges:

COUNT ONE
(Conspiracy to Violate the Anti-Kickback Statute)

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

The Defendant and Others

a. Defendant MUKARAM GAZI was a urologist who was licensed to practice medicine in New Jersey. GAZI owned and maintained a urology practice with locations in Freehold, Hamilton, Howell, and Toms River, New Jersey.

b. GAZI maintained a Drug Enforcement Administration ("DEA") registration number in New Jersey. GAZI was authorized to issue prescriptions for Schedule II through Schedule V controlled substances in the usual course of professional practice and for a legitimate medical purpose.

c. Insys Therapeutics was a pharmaceutical company incorporated in Delaware and headquartered in Arizona.

d. Co-Conspirator 1 and Co-Conspirator 2, co-conspirators not charged in this Indictment, were sales representatives employed by Insys.

e. Co-Conspirator 3, a co-conspirator not charged in this Indictment, was the owner of a specialty pharmacy that operated in New Jersey and elsewhere.

f. Patient-1 was a patient of GAZI.

The Medicare Program

g. The Medicare Program ("Medicare") was a federal health care program that provided benefits to certain individuals, primarily people who were 65 years of age or older or disabled. Medicare was administered by the Centers for Medicare and Medicaid Services ("CMS"), a federal agency within the U.S. Department of Health and Human Services ("HHS"). Individuals who received Medicare benefits were referred to as Medicare "beneficiaries." Medicare was a "Federal health care program" as defined in Title 42, United States Code, Section 1320a-7b(f) and a "health care benefit program" as defined in Title 18, United States Code, Section 24(b).

h. Prescription drug benefits were covered by the Medicare Part D program. In order for Medicare to pay for medications, they had to be prescribed by a physician. Medicare paid for claims only if the services were medically reasonable and necessary. Medicare would not pay for medications if the prescriptions were written in exchange for a bribe or kickback.

i. Physicians could enroll as Medicare providers. To enroll in Medicare, providers had to agree to abide by all provisions of the Social Security Act, the regulations promulgated under the Act, and applicable policies,

procedures, rules, and regulations issued by CMS and its authorized agents and contractors.

j. GAZI was enrolled as a Medicare provider. As such, he certified to Medicare on multiple occasions that he would comply with all Medicare rules and regulations, including that he would not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare and that he would refrain from violating the federal Anti-Kickback Statute.

The Medicaid Program

k. Medicaid was a jointly funded, federal-state health insurance program that provided health benefits to the disabled, as well as to individuals and families who met financial and other eligibility requirements. CMS was responsible for overseeing the Medicaid program in participating states, including New Jersey. Individuals who received benefits under Medicaid were referred to as Medicaid “beneficiaries.”

l. The New Jersey Department of Human Services, Division of Medical Assistance and Health Services (“NJ DHS”) administered the Medicaid program in New Jersey (“NJ Medicaid”). NJ DHS received, reviewed, and paid NJ Medicaid claims submitted by health care providers, including claims for professional services, such as office visits and medical procedures, as well as claims for prescription drugs. NJ Medicaid was a “Federal health care program” as defined in Title 42, United States Code, Section 1320a-7b(f) and a “health care benefit program” as defined in Title 18, United States Code, Section 24(b).

m. Pursuant to the rules and regulations issued by NJ DHS, NJ Medicaid covered the costs of certain medical services, products, and benefits,

including prescription drug benefits, for beneficiaries. For NJ Medicaid to cover part or all of the costs of prescription drugs dispensed to an NJ Medicaid beneficiary, the prescription drugs had to be medically necessary and ordered by a physician.

Insys and Subsys

n. In or around January 2012, the U.S. Food and Drug Administration (“FDA”) approved Insys’s application to sell and market Subsys.

o. Subsys was a potent opioid designed to rapidly enter a patient’s bloodstream upon being sprayed under the tongue. Subsys contained fentanyl, a synthetic opioid pain reliever that was classified as a Schedule II controlled substance under the Controlled Substances Act, meaning that it had a high potential for abuse.

p. The FDA approved Subsys solely for the “management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”

q. Subsys was in a category of drugs known as Transmucosal Immediate Release Fentanyl (“TIRF”). Because of the risk of misuse, abuse, addiction, and overdose associated with TIRF drugs, including Subsys, only practitioners enrolled in the FDA-mandated TIRF Risk Evaluation and Mitigation Strategy program (the “TIRF REMS Program”) were allowed to prescribe TIRF drugs. Practitioners were required to complete training and testing to enroll in the TIRF REMS Program.

The Conspiracy

2. From in or about March 2014 through at least in or about November 2015, in the District of New Jersey and elsewhere,

MUKARAM GAZI

knowingly and intentionally conspired and agreed with others to commit certain offenses against the United States, namely:

a. knowingly and willfully soliciting and receiving remuneration, including kickbacks and bribes, directly and indirectly, overtly and covertly, in cash and in kind, in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, namely Medicare and NJ Medicaid, contrary to Title 42, United States Code, Section 1320a-7b(b)(1)(B); and

b. knowingly and willfully offering and paying remuneration, including kickbacks and bribes, directly and indirectly, overtly and covertly, in cash and in kind, to any person to induce such person to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, namely Medicare and NJ Medicaid, contrary to Title 42, United States Code, Section 1320a-7b(b)(2)(B).

Goal of the Conspiracy

3. It was the goal of the conspiracy for GAZI and his co-conspirators to unlawfully enrich themselves by offering, paying, soliciting, and receiving kickbacks and bribes in exchange for prescribing and dispensing Subsys.

Manner and Means of the Conspiracy

4. It was part of the conspiracy that:

a. GAZI received kickbacks from Insys under the guise of payments for educating medical providers about Subsys through the Insys “Speaker Program,” when in fact, and as GAZI well knew, such payments were made in return for GAZI prescribing Subsys to his patients, and despite his lack of experience prescribing TIRF drugs or treating breakthrough cancer pain.

b. In or about March 2014, GAZI entered into a sham “Speaker Agreement” with Insys whereby he agreed to accept payments to provide Speaker Programs and falsely represented that the Speaker Programs would be “of a professional quality conforming to generally accepted industry standards and practices.” GAZI further falsely represented that the Speaker Program payments that he received from Insys would be consistent with “fair market value” and would not affect his decisions about prescribing Subsys.

c. On or about May 20, 2014 and January 8, 2015, GAZI falsely certified to Medicare that he would comply with all Medicare rules and regulations, including that he would not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare and that he would refrain from violating the federal Anti-Kickback Statute.

d. Between in or about April 2014 and in or about November 2015, GAZI received between approximately \$3,000 and \$5,100 plus expenses from Insys for each Speaker Program he purportedly conducted. These programs often functioned as social events with non-prescribers at upscale

restaurants paid for by Insys, and not substantive presentations for an appropriate audience.

e. To give the false appearance that GAZI's Speaker Programs were legitimate presentations to appropriate audiences of licensed practitioners seeking educational information about Subsys, GAZI, Co-Conspirator 1, Co-Conspirator 2, and others fabricated, falsified, altered, and caused the fabrication, falsification, and alteration of sign-in sheets at certain Speaker Programs, including by forging the signatures of medical practitioners who did not attend the programs.

f. In exchange for these kickbacks and bribes, GAZI prescribed Subsys to his patients, including patients for whom Subsys was medically unnecessary.

g. During the course of the conspiracy, GAZI demanded increased kickbacks from Co-Conspirator 2 in the form of additional Speaker Programs in order to continue prescribing Subsys. In response, Co-Conspirator 2, in consultation with others at Insys, secured additional Speaker Programs for GAZI so that he would continue prescribing Subsys.

h. In total, GAZI solicited and received approximately \$132,000 in bribes and kickbacks in connection with his Speaker Programs in return for prescribing Subsys.

i. GAZI submitted and caused to be submitted a significant number of the Subsys prescriptions that he wrote to Co-Conspirator 3's pharmacy. In return for Co-Conspirator 3 filling GAZI's Subsys prescriptions, and to induce Co-Conspirator 3 to continue to fill GAZI's Subsys prescriptions

so that GAZI could continue to receive bribes and kickbacks from Insys, GAZI prescribed Co-Conspirator 3 and Co-Conspirator 3's significant other medically unnecessary high-dosage dextroamphetamine-amphetamine (commonly known by the brand name "Adderall"), a Schedule II stimulant commonly used to treat attention-deficit hyperactivity disorder and narcolepsy.

j. GAZI submitted and caused to be submitted for payment by Medicare and NJ Medicaid prescriptions that were procured by the payment of kickbacks and bribes, medically unnecessary, or not eligible for reimbursement.

Overt Acts

5. In furtherance of the conspiracy and to effect its object, the following overt acts were committed in the District of New Jersey and elsewhere:

a. In or about March 2014, GAZI entered into a sham "Speaker Agreement" with Insys in which he agreed to accept payments, purportedly to provide Speaker Programs.

b. On or about April 22, 2014, GAZI prescribed dextroamphetamine-amphetamine to Co-Conspirator 3, which prescription was outside the usual course of professional practice and not for a legitimate medical purpose.

c. On or about October 2, 2014, GAZI prescribed Subsys to Patient-1, despite the fact that Patient-1 had not been diagnosed with cancer or suffering from breakthrough cancer pain.

d. On or about November 12, 2014, GAZI and his co-conspirators at Insys purported to provide a Speaker Program at a restaurant in New Jersey. In exchange, GAZI received approximately \$3,000 from Insys.

e. On or about March 10, 2015, GAZI and his co-conspirators at Insys purported to provide a Speaker Program at a restaurant in New Jersey. In exchange, GAZI received approximately \$3,000 from Insys.

f. On or about March 31, 2015, GAZI and his co-conspirators at Insys purported to provide a Speaker Program at a restaurant in New Jersey. In exchange, GAZI received approximately \$5,100 from Insys.

g. On or about April 20, 2015, GAZI prescribed dextroamphetamine-amphetamine to Co-Conspirator 3's significant other, which prescription was outside the usual course of professional practice and not for a legitimate medical purpose.

h. On or about October 25, 2015, GAZI entered into another sham "Speaker Agreement" with Insys to conduct a virtual Speaker Program in or about October or November 2015.

i. On or about November 10, 2015, GAZI received a check for approximately \$1,055 as payment for a purported Speaker Program.

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

COUNT TWO
(Violation of the Anti-Kickback Statute)

1. The allegations in paragraphs 1 and 3 to 5 of Count 1 of this Indictment are realleged here.

2. On or about November 10, 2015, in the District of New Jersey and elsewhere, defendant

MUKARAM GAZI

did knowingly and willfully solicit and receive remuneration, including kickbacks and bribes, directly and indirectly, overtly and covertly, in cash and in kind, in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, namely Medicare and NJ Medicaid, in violation of Title 42, United States Code, Section 1320a-7b(b)(1)(B) and Title 18, United States Code, Section 2.

COUNT THREE
(Scheme to Commit Health Care Fraud)

1. The allegations in paragraphs 1 and 3 to 5 of Count 1 of this Indictment are realleged here.

2. From in or about December 2013 to in or about November 2015, in the District of New Jersey and elsewhere, defendant

MUKARAM GAZI

did knowingly and willfully execute and attempt to execute a scheme and artifice to defraud health care benefit programs, namely Medicare, NJ Medicaid, and other health insurance providers that are “health care benefit programs” within the meaning of Title 18, United States Code, Section 24(b), and to obtain, by means of false and fraudulent pretenses, representations, and promises, money owned by, and under the custody and control of, said health care benefit programs, in connection with the delivery of or payment for health care benefits, items and services.

Goal of the Scheme

3. It was the goal of the scheme for GAZI and others to unlawfully enrich themselves by submitting and causing the submission of false and fraudulent claims to Medicare, NJ Medicaid, and other health insurance providers for prescriptions for Subsys and dextroamphetamine-amphetamine, which were induced through kickbacks, were medically unnecessary, and were not eligible for reimbursement.

4. It was part of the scheme and artifice to defraud that GAZI:

a. Provided prescriptions for controlled substances, including Subsys and dextroamphetamine-amphetamine, knowing that such prescriptions were issued outside the usual course of professional practice, not for a legitimate medical purpose, and procured by the payment of kickbacks and bribes; and

b. Caused the submission of claims to pay for such prescriptions to NJ Medicaid, Medicare, and other health insurance providers.

In violation of Title 18, United States Code, Section 1347 and Section 2.

COUNT FOUR
(Conspiracy to Unlawfully Distribute Controlled Substances)

1. Paragraphs 1 and 3 to 5 of Count 1 of this Indictment are realleged here.

2. At all times relevant to Count 4 of this Indictment:

The Controlled Substances Act and Code of Federal Regulations

a. The Controlled Substances Act (“CSA”), Title 21, United States Code, Section 841(a), *et. seq.*, and Title 21, Code of Federal Regulations (“CFR”), Section 1306.04, governed the manufacture, distribution, and dispensation of controlled substances in the United States.

b. The CSA authorized Schedule II controlled substances to be dispensed to individuals by a valid prescription. 21 U.S.C. § 829.

c. Chapter 21, Code of Federal Regulations, Section 1306.04 governed the issuance of prescriptions and provided, among other things, that a prescription for a controlled substance “must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”

d. Chapter 21, Code of Federal Regulations, Section 1306.04 further provided that “[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [the CSA] and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.”

e. Under the CSA and CFR, a prescription for a controlled substance was unlawful unless issued for a legitimate purpose by a practitioner acting in the usual course of professional practice.

3. From in or around December 2013 through in or around November 2015, in the District of New Jersey and elsewhere, defendant

MUKARAM GAZI

a licensed physician, did knowingly and intentionally conspire and agree with others, known and unknown, to distribute and dispense, outside the usual course of professional practice and not for a legitimate medical purpose, mixtures and substances containing detectable amounts of Schedule II controlled substances, including fentanyl and dextroamphetamine-amphetamine, contrary to Title 21, United States Code, Sections 841(a)(1) and (b)(1)(C).

In violation of Title 21, United States Code, Section 846.

FORFEITURE ALLEGATIONS

1. The allegations contained in this Indictment are re-alleged and incorporated by reference as though fully set forth herein for the purpose of alleging forfeiture pursuant to the provisions of Title 21, United States Code, Section 853 and Title 18, United States Code, Section 982.

2. Upon conviction of the federal health care offenses (as defined in 18 U.S.C. § 24) alleged in Counts 1 to 3 of this Indictment, defendant MUKARAM GAZI shall forfeit to the United States, pursuant to 18 U.S.C. § 982(a)(7), all property, real or personal, that constitutes or is derived, directly and indirectly, from gross proceeds traceable to the commission of the offenses (as defined in 18 U.S.C. § 24) alleged in Counts 1 to 3 of this Indictment.

3. Upon conviction of the controlled substance offense charged in Count 4 of this Indictment, defendant MUKARAM GAZI shall forfeit to the United States, pursuant to 21 U.S.C. § 853, any property constituting, or derived from, any proceeds obtained, directly or indirectly, as the result of such violation, and any and all property used or intended to be used in any manner or part to commit and to facilitate the commission of the violations alleged in this Indictment.

4. If any of the property described above, as a result of any act or omission of the defendant:

- 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 pursuant to Title 21, United States Code, Section 853(p) and 18 U.S.C. § 982(b).

A TRUE BILL

FOREPERSON


RACHAEL A. HONIG
Acting United States Attorney