IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DISTRICT

UNITED STATES OF AMERICA

Plaintiff,

vs.

JIMMY HENRY (1); and
NICOLE GEORGES (2),

Defendants.

Case No. 2:20-cr-157

Judge Michael Watson

21 U.S.C. § 841(a)(1), (b)(1)(c)
21 U.S.C. § 846
42 U.S.C. § 1320(a) – 7b(b)(1)(B)
18 U.S.C. § 1349
18 U.S.C. § 1347
18 U.S.C. § 2

FORFEITURE ALLEGATIONS

INDICTMENT

The GRAND JURY charges:

At times material to this Indictment:

GENERAL ALLEGATIONS

The Defendants, Related Individuals, and Entities

1. Defendant JIMMY HENRY was a licensed medical doctor in Ohio, credentialed under Ohio License Number # 35.096049. HENRY was registered with federal and state authorities in Ohio to prescribe Schedule II – V controlled substances. HENRY was also enrolled with the Medicare program as a Medicare provider, and with the Ohio Medicaid program as a Medicaid provider, since at least in or around 2010.

2. Midwest Spine and Pain ("Midwest") was a purported medical practice which operated out of multiple locations, including at 5051 Forest Drive, New Albany, Ohio 43054, and at 7100 Graphics Way, #3300, Lewis Center, Ohio 43035. JIMMY HENRY owned and operated Midwest and, as part of his practice, personally prescribed controlled substances,

including highly addictive opioids, through these facilities. As the owner and operator of Midwest, HENRY also entered into agreements with Medicare and the Ohio Medicaid Program, among other insurance plans, to provide reimbursement for certain services provided at Midwest.

3. Defendant NICOLE GEORGES was employed as a representative of the pharmaceutical company Insys Therapeutics ("Insys"). GEORGES worked onsite at Midwest from at least in or around 2014 through at least in or around 2016.

4. Insys was incorporated in Delaware and headquartered in Chandler, Arizona.

5. Individual 1 was a licensed physician's assistant who worked under JIMMY HENRY's supervision at Midwest from approximately in or around November 2015 to in or around October 2019.

The Controlled Substances Act and Code of Federal Regulations

6. 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. The CSA and the CFR contained definitions relevant to this Indictment, as set forth below.

7. The term "controlled substance" meant a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV and V, as designated by Title 21, United States Code, Section 802(c)(6), and the CFR. The designation "Schedule II" meant the drug or other substance had a high potential for abuse; the drug had a currently accepted medical use with severe restrictions; and abuse of the drug or other substance may lead to severe psychological or physical dependence.

8. Fentanyl, oxycodone, and tapentadol were opioids and Schedule II controlled

substances. Fentanyl pharmaceutical products were available in multiple forms, including sublingual spray, transdermal patches, and injectable formulations. When fentanyl was prescribed for a legitimate medical purpose, it was typically for the management of breakthrough cancer pain in patients who were already receiving opioid medication for their underlying persistent pain. Transdermal patches were used in the management of chronic pain in patients who require continuous opioid analgesia. Fentanyl was a potent opioid medication and was sometimes abused for its intense euphoric effects.

9. The term "dispense" meant to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance. The term "distribute" meant to deliver (other than by administering or dispensing) a controlled substance.

10. The Drug Enforcement Administration ("DEA") issued registration numbers to qualifying doctors, who thereby became authorized to dispense Schedule II, III, IV, and V controlled substances. To issue a prescription for a controlled substance, a doctor was required to have a DEA registration number for each location in which the doctor was dispensing medicine, and for each state where the doctor was prescribing controlled substances. The term "prescription" meant an order for medication which was dispensed to or for a user but did not include an order for medication which was dispensed for immediate administration to the user.

11. Title 21, CFR, Section 1306.04, provided that "[a]ll prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner."

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

The Medicare Program

13. The Medicare program ("Medicare") was a federal health care program, affecting commerce, that provided benefits to persons who were 65 years of age or older or disabled.

14. Medicare was administered by the United States Department of Health and Human Services, through its agency, the Centers for Medicare and Medicaid Services ("CMS"). Individuals who received benefits under Medicare were referred to as Medicare "beneficiaries."

15. Individuals who qualified for Medicare benefits were commonly referred to as "beneficiaries." Each beneficiary was given a unique Medicare identification number.

16. Medicare covered different types of benefits and was separated into different program "parts."

17. Medicare Part B covered, among other things, physician services, outpatient care, and durable medical equipment.

18. Medicare Part D subsidized the cost of prescription drugs for Medicare beneficiaries. Generally, Medicare Part D covered part or all of the costs of prescription drugs dispensed to a Medicare beneficiary if, among other requirements, the prescription drugs were medically necessary and ordered by a physician.

19. In order to receive Medicare Part D benefits, a beneficiary enrolled in one of several Medicare drug plans. Medicare drug plans were operated by private health care insurance companies approved by Medicare. Those companies were often referred to as drug

plan "sponsors," each of which dictated the specific prescription drugs covered and how much would be paid for those drugs.

20. Medicare, through CMS, compensated the Medicare drug plan sponsors for providing prescription drug benefits to beneficiaries. Medicare paid the sponsors a monthly fee for each Medicare beneficiary of the sponsors' plans. Such payments were called capitation fees. The capitation fee was adjusted periodically based on various factors, including the beneficiary's medical conditions. In addition, in some cases where a sponsor's expenses for a beneficiary's prescription drugs exceeded that beneficiary's capitation fee, Medicare reimbursed the sponsor for a portion of those additional expenses.

21. Medicare and Medicare drug plan sponsors were "health care benefit program[s]," as defined by Title 18, United States Code, Section 24(b), and "federal health care program[s]," as defined by Title 42, United States Code, Section 1320a-7b(f).

22. As part of the Medicare enrollment process, health care providers, including physicians, submitted enrollment applications to Medicare. To participate in Medicare, including Medicare Part B and Part D, providers were required to certify that they would comply with all Medicare-related laws, rules, and regulations, including, among others, the federal Anti-Kickback Statute. If Medicare approved a provider's application, Medicare assigned the provider a Medicare provider number. A provider with a Medicare provider number could submit claims to Medicare to obtain reimbursement for medically necessary items and services rendered to beneficiaries. Medicare providers were given access to Medicare manuals and service bulletins describing procedures, rules, and regulations.

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