BACKGROUND ON MEDICARE AND MEDICAID

1. The Medicare Program ("Medicare") was a federal "health care benefit program," as defined by 18 U.S.C. § 24(b), that provided benefits to persons who were over the age of sixty-five or disabled. Medicare was administered by the United States Department of Health and Human Services ("HHS") through its agency, the Centers for Medicare & Medicaid Services ("CMS").

2. Individuals who qualified for Medicare benefits were commonly referred to as "beneficiaries," and as beneficiaries, they were eligible to receive a variety of goods and services.

3. The Kentucky Medicaid Program ("Medicaid") was a "health care benefit program," as defined by 18 U.S.C. § 24(b), that provided benefits to Kentucky residents who met certain eligibility requirements, including income requirements. Medicaid was
jointly funded by federal and state sources and administered by CMS and by the Kentucky Cabinet for Health and Family Services, Department for Medicaid Services ("DMS"), located in Franklin County, Kentucky.

4. Individuals who qualified for Medicaid benefits were commonly referred to as “members,” and as members, they were eligible to receive a variety of goods and services.

5. Among a variety of items and services, both Medicare and Medicaid provided coverage to beneficiaries and members for outpatient physician services, such as office visits, minor surgical procedures, and laboratory services, including urine drug testing ("UDT").

6. Medical service providers, including clinics and physicians ("service providers"), meeting certain criteria, could enroll in and obtain Medicare and Medicaid provider numbers. Upon Medicare and Medicaid enrollment, service providers were permitted to provide medical services and items to beneficiaries and members, and subsequently submit claims, either electronically or in hardcopy, to Medicare and Medicaid, through fiscal intermediaries, seeking reimbursement for the cost of services and items provided.

7. When seeking reimbursement from Medicare and Medicaid, service providers certified that: (1) the contents of the claim forms were true, correct, and complete; (2) the claim forms were prepared in compliance with the laws and regulations governing Medicare and Medicaid; and (3) the services purportedly provided, as set forth in the claim forms, were medically necessary.
8. Medicare and Medicaid reimbursed claims submitted by service providers if the services and items provided were medically necessary for the diagnoses and treatment of beneficiaries and members. Conversely, Medicare and Medicaid did not cover and would not reimburse claims for services and items that were not medically necessary.

9. Medicaid, through DMS, and through its fiscal intermediaries, ultimately reimbursed claims submitted by service providers, including for laboratory services and UDT, from Franklin County, Kentucky.

RELEVANT UDT BILLING CODES

10. When seeking reimbursement from Medicare and Medicaid, service providers submitted the cost of the service or item provided together with the appropriate "procedure code," as defined by the American Medical Association, and set forth and maintained in the Current Procedural Terminology ("CPT") Manual or by the Healthcare Common Procedure Coding System ("HCPCS"). Although service providers submitted the cost of the service provided, together with other information, Medicare and Medicaid reimbursed providers designated amounts according to the CPT or HCPCS code utilized.

11. UDT was divided into two categories: presumptive (qualitative) testing and definitive (quantitative or confirmation) testing. Presumptive testing identified which substances, if any, were present in the provided specimen. Definitive testing identified how much of a particular substance was present in the provided specimen.

12. Presumptive testing was performed in a variety of ways, including utilizing devices that were capable of being read by direct optical observation, such as "cups" that reacted to the specimen and identified which drugs, if any, were present ("optical devices"),
as well as by more complex testing performed by instrument chemistry analyzers.

13. Definitive testing was necessarily performed by higher complexity instrument chemistry analyzers.

14. Medicare and Medicaid considered presumptive testing to be medically necessary, and appropriately reimbursable, in the treatment of chronic pain patients, provided the presumptive testing was used in the diagnosis and treatment of beneficiaries and members and the need for the testing was substantiated by documentation in the patient’s medical record. Conversely, Medicare and Medicaid specifically excluded from coverage, and did not consider medically necessary, “blanket orders” or routine presumptive testing of substances.

15. Medicare and Medicaid considered definitive testing to be medically necessary, and appropriately reimbursable, in the treatment of chronic pain patients in certain limited circumstances, including when beneficiaries or members had a specific and documented need for definitive testing. Conversely, Medicare and Medicaid specifically excluded from coverage, and did not consider medically necessary, “blanket orders” or routine definitive testing of substances.

16. From January 1, 2016, and continuing through December 31, 2016, presumptive drug testing was reported with HCPCS codes G0477, G0478, and G0479. As of January 1, 2017, and continuing through the return of this Indictment, presumptive drug testing was renumbered and reported with CPT codes 80305, 80306, and 80307. These codes differed based on the level of complexity of the testing methodology, and were reimbursed at different rates. For instance, HCPCS code G0479, and later CPT code
80307, indicated that a higher complexity analyzer was used to perform the presumptive testing.

17. As of January 1, 2016, definitive drug testing was reported with HCPCS codes G0480, G0481, G0482, and G0483. These codes differed based on the number of drug classes, including metabolites, tested, and were reimbursed at different rates—the more drugs tested, the greater the reimbursement.

DEFENDANT AND RELEVANT ENTITIES

18. SAI P. GUTTI, M.D. ("GUTTI") was a Kentucky-licensed physician practicing in Pikeville, Kentucky. GUTTI was enrolled as a provider with both Medicare and Medicaid, and was assigned National Provider Identifier ("NPI") xxxxxxx5410 by CMS, and provider number xxxxxx9290 by Medicaid.

19. Clinic 1 was a Kentucky Professional Services Corporation, formed in 1997, and located in Pikeville, Kentucky. Beginning in or around 2004, and continuing through the return of this Indictment, GUTTI provided physician services, including pain management services, through Clinic 1.

20. Dr. Gutti Pain Center, PLLC ("Pain Center") was a Kentucky Limited Liability Company, formed on June 5, 2013, and located in Pikeville, Kentucky. GUTTI formed, owned, and operated the Pain Center, which provided laboratory services, including UDT. The Pain Center maintained analyzers capable of performing higher-complexity presumptive testing ("presumptive analyzer") and definitive testing ("definitive analyzer") (collectively, "Pain Center analyzers").
21. Interventional Pain Consultants, PLLC ("IPC") was a Kentucky Professional Limited Liability Company, formed on June 23, 2017, principally located in Pikeville, Kentucky, with four satellite offices located in Harold, Paintsville, Whitesburg, and Belfry, Kentucky. IPC provided general physician services, including pain management services, to beneficiaries, members, and others. GUTTI, beginning in or around June 2017, and continuing through the return of this Indictment, owned and provided physician services, including pain management services, through IPC.

COUNTS 1-8
Health Care Fraud
(18 U.S.C. § 1347)

22. Paragraphs 1 through 21 of this Indictment are realleged and incorporated by reference as though fully set forth herein.

23. Beginning at least in or around August 2016, and continuing through at least on or about March 25, 2019, in Franklin and Pike Counties, in the Eastern District of Kentucky, and elsewhere,

SAI P. GUTTI, M.D.,

aided and abetted by others known and unknown to the Grand Jury, in connection with the delivery of and payment for health care benefits, items, and services, did knowingly and willfully execute, and attempt to execute, a scheme or artifice to defraud a health care benefit program affecting commerce, as defined in 18 U.S.C. § 24(b), that is, Medicare, Medicaid and other health care benefit programs, and obtain, by means of materially false and fraudulent pretenses, representations, and promises, and omission and concealment of material facts, money and property owned by, and under the custody and control of, these
health care benefit programs, in connection with the delivery of and payment for health care benefits, items, and services.

Purpose of the Scheme

24. It was a purpose of the scheme for GUTTI to unlawfully enrich himself, Clinic 1, the Pain Center, and IPC by, among other things, submitting and causing the submission of false and fraudulent claims to Medicare, Medicaid, and other health care benefit programs.

Manner and Means

25. The manner and means by which the defendant sought to accomplish the object of the scheme included, among others, the following:

a. GUTTI formed the Pain Center for the purpose of acquiring and maintaining the Pain Center analyzers so that he could provide laboratory services, specifically, UDT, to beneficiaries, members, and others;

b. In or around August 2016, GUTTI acquired and installed the definitive analyzer on the premises controlled by Clinic 1, and, later, jointly controlled by Clinic 1 and IPC, for the purpose of performing definitive testing;

c. GUTTI, through Clinic 1 and IPC, provided physician services to beneficiaries, members, and others, including purported pain management services by, among other methods, prescribing controlled substances, namely opioids ("opioid treatment");

d. During certain office visits, GUTTI directed employees of Clinic 1 and IPC to supply UDT cups to beneficiaries, members, and others for the purpose of
having these individuals provide urine specimens suitable for UDT ("provided specimens"), and further directed that these provided specimens be sent to the Pain Center for subsequent UDT;

e. **GUTTI** directed employees of Clinic 1 to perform definitive testing on every provided specimen, irrespective of any identified individualized need, and concealed the existence of this blanket order from health care benefit programs. Consequently, in performing definitive testing, the definitive analyzer generated a single report providing not only definitive results, but also presumptive results;

f. Thereafter, in or around September 2017, **GUTTI** acquired and installed the presumptive analyzer on the premises jointly controlled by Clinic 1 and IPC, for the purpose of performing unnecessary presumptive testing on provided specimens and submitting claims for reimbursement for performing separate, unnecessary presumptive testing;

g. In or around October 2017, **GUTTI** directed employees of Clinic 1 to perform both presumptive testing and definitive testing on all provided specimens, irrespective of whether prior UDT was performed and irrespective of any previously yielded results, and again concealed the existence of this blanket order from health care benefit programs;

h. **GUTTI** directed employees of Clinic 1 to sign requisition forms for the definitive testing, attesting to the definitive testing’s medical necessity, despite there being no medical necessity to perform definitive testing and even though **GUTTI** made no individualized determination that such testing was necessary for each patient;
i. With GUTTI's knowledge and consent, employees of Clinic 1, on occasion, performed definitive testing on provided specimens prior to performing presumptive testing, rendering both the definitive testing and presumptive testing medically unnecessary, but concealed this fact from health care benefit programs; and

j. At GUTTI's order and direction, employees of Clinic 1 and IPC submitted false and fraudulent claims to Medicare, Medicaid, and other health care benefit programs for presumptive and definitive testing, representing that these tests were medically necessary for the diagnosis and treatment of beneficiaries, members, and others, when, in reality, there was no medical necessity for these tests and these tests were performed for the purpose of maximizing subsequent reimbursements from Medicare, Medicaid, and other health care benefit programs.

Acts in Execution of the Scheme

26. In order to execute and attempt to execute the scheme to defraud and to obtain money and property, and to accomplish the object of the scheme, GUTTI committed, caused others to commit, and aided and abetted others in committing the following acts within the Eastern District of Kentucky, that is, on or about the dates listed below, GUTTI caused the following false and fraudulent claims to be submitted to Medicare and Medicaid, and aided and abetted the submission of such claims, which claims indicated that UDT provided was medically necessary, when, in fact, such tests were not medically necessary:
Upon conviction of Counts 1 through 8 contained in this Indictment, the defendant, SAI P. GUTTI, M.D., shall forfeit to the United States pursuant to 18 U.S.C. § 982(a)(7), all property, real and personal, that constitutes or is derived, directly or indirectly, from gross proceeds of the violations, including but not limited to a sum of money equal to the amount of gross proceeds of the offenses.

2. If any of the above-described forfeitable property, 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;

it is the intent of the United States, pursuant to 21 U.S.C. § 853(p), as incorporated by 18
U.S.C. § 982(b), to seek forfeiture of any other property of the defendant up to the value
of the forfeitable property described above.

A TRUE BILL

ROBERT M. DUNCAN, JR.
UNITED STATES ATTORNEY

JOSEPH BEEMSTERBOER
DEPUTY CHIEF, FRAUD SECTION
U.S. DEPARTMENT OF JUSTICE
PENALTIES

COUNTS 1-8: Not more than 10 years imprisonment, a fine of not more than $250,000 or the greater of twice the gross gain or twice the gross loss, and supervised release of not more than 3 years.

PLUS: Mandatory special assessment of $100 per count.

PLUS: Restitution, if applicable.

PLUS: Forfeiture as listed.