

INDICTMENT

The Grand Jury charges that:

ROB WILBURN (02)

General Allegations

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

Wilburn, and their co-conspirators unlawfully submitted, and caused to be submitted, false and fraudulent claims to Federal health care programs, including Medicare and Medicare Advantage, for prescriptions for cancer genetic (CGx) and pharmacogenomic (PGx) tests. Medicare and Medicare Advantage paid at least the approximate amount of \$44 million on these false and fraudulent claims. These prescriptions, as the defendants knew and intended, were, among other things, induced through the payment and receipt of unlawful kickbacks and bribes. in violation of the Federal anti-kickback statute.

Defendants John Grisham and Rob Wilburn, and their co-conspirators distributed payments from Federal health care programs among themselves to unlawfully enrich and benefit themselves and others.

The Defendants and Trinity Clinical Laboratories, LLC

- The defendant John Grisham, a resident of Denton County, Texas, was the president, chief executive officer, and an owner of Trinity Clinical Laboratories, LLC (TCL).
- 3. The defendant **Rob Wilburn**, a resident of Bexar County. Texas, was the chief financial officer and an owner of TCL.
- 4. TCL was an independent clinical laboratory (ICL) located in Lewisville, Texas, that, among other things, purportedly conducted CGx and PGx testing.
- 5. In general, ICLs operated independently from hospitals and attending or consulting physician's offices. ICLs typically performed services involving the biological, microbiological, serological, chemical, immunohematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of diagnosing, preventing, or treating a disease, or for the assessment of a medical condition. Medicare required that these ICL services be ordered and used promptly by the physician who was treating the Medicare beneficiary.
- 6. Prior to Medicare enrollment approval, ICLs were required to supply proof of certification under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). CLIA established a set of national standards for laboratories to ensure quality testing. TCL maintained active CLIA certification.

Federal Health Insurance Programs

- 7. 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. Individuals who received benefits under Medicare were commonly referred to as Medicare "beneficiaries."
- 8. Physicians, clinics, and other health care providers, including laboratories, that provided services to Medicare beneficiaries were able to apply for and obtain a "provider number." A health care provider that received a Medicare provider number was able to file claims with Medicare to obtain reimbursement for services provided to beneficiaries.
- 9. Medicare programs covering different types of benefits were separated into different program "parts." Part B of the Medicare Program 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.
- 10. The Medicare Advantage Program, formerly known as "Part C" or "Medicare+Choice," provided Medicare beneficiaries with the option to receive their Medicare benefits through a wide variety of private managed care plans, including health maintenance organizations, provider sponsored organizations, preferred provider organizations, and private fee-for-service plans, rather than through Medicare Part B.

- 11. Private health insurance companies offering Medicare Advantage plans were required to provide Medicare beneficiaries with the same services and supplies offered under Medicare Part B. To be eligible to enroll in a Medicare Advantage plan, a person had to have been entitled to benefits under Medicare Part B.
- 12. Medicare and Medicare Advantage were "health care benefit program[s]," 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).

Reference Laboratories and the Shell Lab Rule

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 "shell lab rule," as it, in essence, precluded pass-through billing arrangements where a laboratory bills Medicare for more than 30 percent of tests that were actually performed by another laboratory.

Cancer Genomic and Pharmacogenomic Testing

- 14. 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.
- 15. PGx testing detected specific genetic variations in genes that impacted the metabolism of certain medications. In other words, PGx testing helped determine, among other things, whether certain medications would be effective if used by a particular patient.
- 16. CGx and PGx testing were both generally referred to as "genetic testing."

 Genetic testing was not a method of diagnosing whether an individual had a disease, such as cancer, at the time of the test. Because CGx testing did not diagnose cancer, Medicare only covered such tests in limited circumstances, such as when a beneficiary had cancer and the beneficiary's treating physician deemed such testing necessary for the beneficiary's treatment of that cancer.
- 17. To conduct genetic testing, a laboratory needed to obtain a DNA sample (specimen) from the patient. Specimens are typically obtained from the patient's saliva by using a check swab to collect sufficient cells to provide a genetic profile. The specimen was then submitted to the laboratory to conduct a genetic test.
- 18. DNA specimens were submitted along with laboratory requisition forms that identified the patient, the patient's insurance, and the specific test to be performed (doctors' orders). In order for laboratories to submit claims to Medicare for genetic tests, the tests had to be approved by a physician or other authorized medical professional who

attested to the medical necessity of the test.

- 19. 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." Title 42, United States Code, Section 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." Title 42, Code of Federal Regulations, Section 411.15(a)(1).
- 20. 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, "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.*

Telemedicine

- 21. Telemedicine provided a means of connecting patients to a physician or other authorized medical professional by using telecommunications technology, such as the internet or telephone, to interact with a patient.
- 22. Telemedicine companies provided telemedicine services to individuals by hiring doctors and other health care providers. Telemedicine companies typically paid

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doctors a fee to conduct consultations with patients. In order to generate revenue, telemedicine companies typically either billed insurance or received payment from patients who utilized the services of the telemedicine company.

23. Medicare Part B covered expenses for specified telehealth services if certain requirements were met. These requirements included that (a) the beneficiary was located in a rural or health professional shortage area; (b) services were delivered via an interactive audio and video telecommunications system; and (c) the beneficiary was in a practitioner's office or a specified medical facility – not at a beneficiary's home – during the telehealth consultation with a remote practitioner.

Relevant Individuals and Related Entities

- 24. Defendants **John Grisham** and **Rob Wilburn**, owned, operated, and oversaw the day-to-day operations at TCL, a Medicare provider and purported genetic testing laboratory located in Lewisville, Texas.
- 25. Person 1 was a resident of Georgia and the owner and operator of a purported consulting and management company, referred to in this Indictment as Company 1, located in Atlanta, Georgia. Among other things, Person 1, through Company 1, established relationships with telemedicine and marketing companies located throughout the United States that acquired specimens from Medicare beneficiaries and doctors' orders for CGx and PGx testing, for the purpose of subsequent submission to genetic testing laboratories, including TCL.

- 26. Person 1, through Company 1 and other entities, paid the telemedicine and marketing companies in exchange for specimens from Medicare beneficiaries and doctors' orders for CGx and PGx testing.
- 27. Person 1 also established relationships with third-party billing entities that were contracted to submit CGx and PGx insurance claims, including Medicare Part B and Medicare Advantage claims, on behalf of genetic testing laboratories, including TCL.
- 28. Person 2 was a resident of Louisiana and the owner and operator of management and consulting companies based in Louisiana. that, among other things, purported to conduct management and consulting services for CGx and PGx testing to Medicare providers and genetic testing laboratories, such as TCL.
- 29. Together Person 1 and Person 2 owned and operated Company 2, a purported consulting and management services company with a principal office located in Plano, Texas.
- 30. Among other things, Person 1 and Person 2, through Company 2, established relationships with marketing companies located throughout the United States for the purpose of obtaining specimens from Medicare beneficiaries, and doctors' orders for CGx and PGx testing for subsequent submission to TCL for purported testing.
- 31. Person 1 and Person 2 paid the marketing companies through Company 1's, Company 2's, or both companies' bank accounts in exchange for specimens from Medicare beneficiaries, and doctors' orders for CGx and PGx testing mailed to TCL for purported testing.

- 32. Person 3 was a resident of South Carolina and the owner and operator of Company 3, a telemedicine corporation based in Florida, that purported to provide telemedicine services, including, among other things, doctors' orders for CGx and PGx testing of Medicare beneficiaries.
- 33. Person 4 was a resident of Florida and an owner and operator of Company 4, a marketing company located in Florida, that obtained specimens from Medicare beneficiaries for CGx and PGx testing and subsequent submission to genetic testing laboratories, including TCL, for purported CGx and PGx testing.
- 34. Person 5 was a resident of Florida and owner and operator of Company 5, a marketing company located in Florida, that obtained specimens from Medicare beneficiaries for CGx and PGx testing and subsequent submission to genetic testing laboratories, including TCL, for purported CGx and PGx testing.

Count One

Conspiracy to Defraud the United States and to Pay and Receive Health Care Kickbacks (Violation of 18 U.S.C. § 371 (42 U.S.C. §§ 1320a-7b(b)(1) and (2))

- 35. All previous paragraphs of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.
- 36. From in or around January 2018, and continuing through in or around October 2019, the exact dates being unknown to the Grand Jury, in the Dallas Division of the Northern District of Texas, and elsewhere, the defendants,

John Grisham and Rob Wilburn.

did knowingly and willfully combine, conspire, confederate and agree with each other,
Person 1, Person 2, Person 3, Person 4, Person 5, and others known and unknown to the
Grand Jury, to commit certain 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 the United States Health and Human Services in its administration and oversight of Medicare, and to commit certain offenses against the United States, that is:
- b. to violate Title 42, United States Code, Section 1320a-7b(b)(1)(A) and (B), by knowingly and willfully soliciting and receiving remuneration, including kickbacks and bribes, directly and indirectly, overtly and covertly, in cash and in kind, including by 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 by a Federal health care program, that is, Medicare and Medicare Advantage; and

c. to violate Title 42, United States Code, Section 1320a-7b(b)(2)(A) and (B). by knowingly and willfully offering and paying any remuneration, including kickbacks and bribes, directly and indirectly, overtly and covertly, in cash and in kind, including by wire transfer, to a 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 by a Federal health care program, that is, Medicare and Medicare Advantage plans; and to purchase, lease, order, and arrange for and recommend the 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 program, this is, Medicare and Medicare Advantage.

Purpose of the Conspiracy

Rob Wilburn, and their co-conspirators to unlawfully enrich themselves by: (a) soliciting, receiving, offering, and paying kickbacks and bribes in return for recruiting and referring Medicare beneficiaries to TCL; (b) soliciting, receiving, offering, and paying kickbacks and bribes in connection with the acquisition, via telehealth referrals, of doctor's orders for CGx and PGx testing for Medicare beneficiaries; (c) submitting and causing the submission of claims to Medicare and Medicare Advantage for CGx and PGx testing that TCL purported to provide to those Medicare beneficiaries but were in reality all performed by a TCL-contracted reference laboratory; (d) concealing the kickbacks

and bribes; and (e) diverting proceeds for their personal use and benefit, the use and benefit of others, and to further the conspiracy.

Manner and Means of the Conspiracy

- 38. The manner and means by which the defendants **John Grisham** and **Rob** Wilburn, and their co-conspirators sought to accomplish the objects and purpose of the conspiracy included, among other things, the following:
- 39. On or about September 24, 2018, defendant **John Grisham** on behalf of TCL submitted to Medicare a document certifying that no more than thirty (30) percent of TCL's tests would be performed by a reference laboratory. At no time relevant to this Indictment did defendant **John Grisham** on behalf of TCL submit a supplement or amended certification.
- 40. At no time relevant to this Indictment did TCL complete on its premises or on-site, properly validated and completed CGx and PGx testing for Medicare beneficiaries that were subsequently submitted, i.e., billed to Medicare or Medicare Advantage for reimbursement.
- 41. During the time relevant to this Indictment, TCL referenced out one hundred (100) percent of all CGx and PGx testing for Medicare beneficiaries to reference laboratories.
- 42. Person 4 solicited and received unlawful kickbacks and bribes, including from defendants **John Grisham** and **Rob Wilburn**, and their co-conspirators, through TCL, in exchange for recruiting and referring specimens of Medicare beneficiaries and

doctors' orders to TCL, knowing that TCL would bill Medicare for CGx and PGx testing purportedly completed by TCL.

- 43. **John Grisham** and **Rob Wilburn** offered and paid unlawful kickbacks and bribes to Person 4 in exchange for the recruitment and referral of specimens from Medicare beneficiaries and doctor's orders for CGx and PGx testing referred to TCL.
- 44. The prescribers who signed doctors' orders for CGx and PGx testing purchased by defendants **John Grisham** and **Rob Wilburn** often did so regardless of medical necessity, in the absence of a pre-existing physician-patient relationship, without a physical examination, and sometimes based solely on a short telephonic conversation.
- 45. To conceal the unlawful health care kickbacks and bribes, defendants John Grisham and Rob Wilburn, Person 4, and other co-conspirators executed sham contracts and documentation that disguised the payments from TCL to Company 4 as marketing and other services.
- 46. During the relevant time of this Indictment, TCL billed Medicare for genetic testing services purportedly provided by TCL to approximately 12,093 Medicare and Medicare Advantage beneficiaries across the United States, approximately 63 of those Medicare beneficiaries resided in Dallas County within the Northern District of Texas.
- 47. Defendants **John Grisham**, **Rob Wilburn**. Person 1, Person 2. Person 3. Person 4, Person 5 and other co-conspirators caused TCL to submit false and fraudulent claims to Medicare and Medicare Advantage, in at least the approximate amount of \$107

million, via interstate wire transfers for genetic testing that was not completed on-site at TCL and often medically unnecessary.

- 48. As the result of these false and fraudulent claims, Medicare and Medicare Advantage made payments to TCL in at least the approximate amount of \$44 million, via interstate wire transfers.
- 49. Defendants **John Grisham**, **Rob Wilburn**, Person 1. Person 2, Person 3. Person 4, Person 5, and other co-conspirators used the fraud proceeds received from TCL to benefit themselves and others, and to further the fraud scheme.

Overt Acts

- 50. In furtherance of the conspiracy, and to accomplish its objects and purpose, at least one co-conspirator committed and caused to be committed at least one of the following overt acts, among others:
- a. On or about October 9, 2018, defendant **John Grisham** on behalf of TCL executed a Business Services Agreement with Person 4 on behalf of Company 4. The Business Services Agreement was prepared in order to disguise the unlawful health care kickback and bribe payment that Company 4 would receive from TCL, through Company 1, Company 2, or both in exchange for specimens from Medicare beneficiaries and doctors' orders for CGx and PGx testing.
- b. On or about October 26, 2018, defendant **John Grisham** on behalf of TCL executed a Business Services Agreement with Person 5 on behalf of Company 5. The Business Services Agreement was prepared in order to disguise the unlawful health care kickback and bribe payment that Company 5 would receive from TCL, through Company Indictment—Page 14

- 1, Company 2, or both in exchange for specimens from Medicare beneficiaries and doctors' orders for CGx and PGx testing.
- c. On or about November 5, 2018, Person 1 sent an email to defendant **John Grisham** and a TCL employee stating that Person 1 would provide "operational funding," i.e., provide payment via wire transfer to Company 4, in exchange for specimens from Medicare beneficiaries and doctors' orders for CGx and PGx testing.
- d. On or about November 26, 2018, Person 1 sent an email to defendant Rob

 Wilburn containing a Microsoft Office Excel attachment entitled "TCL

 MonthlyCGX_PGX_Profit Performa_v3.xlsx," which was a spreadsheet detailing the cost breakdown of TCL's total monthly profit for purported CGx and PGx testing.
- e. On or about November 27, 2018, defendant Rob Wilburn received an email from Person 1's employee that discussed the monetary funding provided by Person 1's companies to TCL for the purpose of purchasing the specimens from marketing companies. including Company 4.
- f. On or about on January 26, 2019, Person 1 sent an email to several individuals including defendant **John Grisham** with the subject line "PGX Panel- Proof of Payment REDACTED" that described the reimbursement rate for PGx testing if completed on the same day as CGx testing and discussed the process the marketing companies used.
- g. On or about February 2, 2019, Person 4, through Company 4, provided TCL with a sales invoice from Company 4. The sales invoice reflected that Company 4 had shipped "47-CGX" specimens for \$1,600.00 per sample and a total of \$75,200.00 Indictment—Page 15

h. On or about March 7, 2019, Person 4, through Company 4, provided a sales invoice addressed to TCL from Company 4. The sales invoice described the service provided by Company 4 as "Operational Funding" and a quantity of 180 for a cost of \$1,600.00 per unit and a total of \$288,000.00.

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

Counts Two Through Five

Payment and Receipt of Kickbacks (Violations of 42 U.S.C. § 1320a-7b(b)(2)(A) & 18 U.S.C. § 2)

- 51. The Grand Jury re-alleges and incorporates by reference all previous paragraphs, excluding paragraphs 35 and 36, as if fully alleged herein.
- 52. On or about the dates enumerated below, in the Dallas Division of the Northern District of Texas, and elsewhere, the defendant identified in each count did knowingly and willfully offer and pay any remuneration, that is, kickbacks and bribes, directly and indirectly, overtly and covertly, in cash and in kind, including by wire transfer, as set forth below, to a 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 Medicare Advantage:

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Count	Defendants	Approximate Date	Approximate Amount	Description of the Payment Method and Entity Receiving Payment
2	John Grisham & Rob Wilburn	January 11, 2019	\$1,500,000.00	ONLINE OR MOBILE WIRE TRANSFER From TCL's Wells Fargo Account XXX6339 to Company 1's Bank of America Account XXX1133
3	John Grisham & Rob Wilburn	March 22, 2019	\$467.274.00	ONLINE OR MOBILE WIRE TRANSFER From TCL's Wells Fargo Account XXX6339 to Company 1's Bank of America Account XXX1133
4	John Grisham & Rob Wilburn	March 29, 2019	\$7,000,000.00	ONLINE OR MOBILE WIRE TRANSFER From TCL's Wells Fargo Account XXX6339 to Company 1's Bank of America Account XXX1333
5	John Grisham & Rob Wilburn	April 25, 2019	\$4,000,000.00	ONLINE OR MOBILE WIRE TRANSFER From TCL's Wells Fargo Accounts XXX6339 to Company 1's Bank of America Account XXX5424

Each in violation of Title 42, United States Code, Section 1320a-

7b(b)(2)(A) and Title 18, United States Code, Section 2.

Forfeiture Notice

(18U.S.C. §§ 981(a)(1)(C) and 982(a)(7) and 28 U.S.C. § 2461(c))

- 53. Pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c), upon conviction of Count One, the defendants, **John Grisham** and **Rob Wilburn**, shall forfeit to the United States, any property, real or personal, which constitutes or is derived from gross proceeds traceable to the violation, including but not limited to the following:
 - a. \$1,433,196.55 in funds seized from Wells Fargo account in the name of Trinity Clinical Laboratories, LLC ending in x1877:
 - b. \$45,740.76 in funds seized from Wells Fargo account in the name of Trinity Clinical Laboratories, LLC ending in x6339; and
 - c. \$12,864.11 in funds seized from Wells Fargo account in the name of Trinity Clinical Laboratories, LLC ending in x6347.
- 54. Pursuant to 18 U.S.C. § 982(a)(7), upon conviction of Counts Two through Five, the defendants, **John Grisham** and **Rob Wilburn**, shall forfeit to the United States, any property, real or personal, which constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense, including but not limited to the following:
 - a. \$1,433,196.55 in funds seized from Wells Fargo account in the name of Trinity Clinical Laboratories, LLC ending in x1877;
 - b. \$45,740.76 in funds seized from Wells Fargo account in the name of Trinity Clinical Laboratories, LLC ending in x6339; and
 - c. \$12,864.11 in funds seized from Wells Fargo account in the name of Trinity Clinical Laboratories, LLC ending in x6347.

- 55. The above-referenced property subject to forfeiture includes, but is not limited to, a "money judgment" in the amount of U.S. currency constituting the gross proceeds traceable to the offense.
- 56. Defendants **John Grisham** and **Rob Wilburn** are notified that upon conviction, a money judgment may be imposed for the gross proceeds of Counts One through Five. Pursuant to 21 U.S.C. § 853(p), as incorporated by 28 U.S.C. § 2461(c), 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, 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 intends to seek forfeiture of any other property of the defendant up to the value of the forfeitable property described above.

(Continued on the next page.)

A TRUE BILL

FOREPERSON

PRERAK SHAH
- ACTING ATTORNEY
FOR THE UNITED STATES

JOSEPH S. BEEMSTERBOER U.S. Department of Justice Criminal Division, Fraud Section Acting Chief

ALLAN J. MEDINA
U.S. Department of Justice
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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS DALLAS DIVISION

THE UNITED STATES OF AMERICA

ν.

JOHN GRISHAM (01) ROB WILBURN (02)

INDICTMENT

18 U.S.C. § 371 (42 U.S.C. §§ 1320a-7b(b)(1) and (2) Conspiracy to Defraud the United States and to Pay and Receive Health Care Kickbacks (Count 1)

42 U.S.C. § 1320a-7b(b)(1) and (2) & 18 U.S.C. § 2 Payment and Receipts of Kickbacks (Count 2-5)

18 U.S.C. §§ 981(a)(1)(C), 982(a)(7) and 28 U.S.C. § 2461(c) Forfeiture Notice

5 Counts

		/
A true bill rendered	Chro & Col	/
FORT WORTH	FOREPERSON	l
Filed in open court this 15th day of September, 2021.		

Summons to Issue

UNITED STATES MAGISTRATE JUDGE

No Criminal Matter Pending