UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *et al., ex rel.* MARK McGUIRE *et al.*, Plaintiffs, v. MILLENNIUM LABORATORIES, INC., and MILLENNIUM HEALTH, LLC, Defendants.	No. 12cv10132-NMG No. 12cv10631-NMG No. 13cv10825-NMG

UNITED STATES' COMPLAINT IN INTERVENTION

By notice to the Court on December 19, 2014, the United States of America partially intervened in the above-captioned cases. The United States alleges as follows:

I. INTRODUCTION

1. The United States of America ("United States") brings this action against Defendants pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA"), seeking treble damages and civil penalties, and also under common law theories of recovery.

2. Millennium Laboratories, Inc., now Millennium Health, LLC ("Millennium," the "Defendant" or the "Company"), was founded in 2007 and grew to be the largest Medicare Part B biller in the country, receiving over $630 million from Medicare for laboratory-based drug testing through 2014. Millennium performs urine drug testing ("UDT"), which, used appropriately, informs physicians of the amount of a particular substance (be it a prescription drug such as oxycodone or an illicit substance such as heroin) in a patient's system. Since its founding, Millennium has knowingly submitted many millions of dollars' worth of false claims to the Medicare program for urine drug tests that were not reasonable and necessary or that were

furnished pursuant to prohibited referrals that resulted from Millennium's improper financial relationships with physicians, in violation of the physician self-referral prohibition, 42 U.S.C. § 1395nn (commonly known as the "Stark Law"), and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

3. Millennium used a variety of schemes to cause physicians, including many of its biggest referrers, to routinely order excessive amounts of UDT for all patients (including Medicare and Medicaid patients) regardless of individual patient assessment or need. Millennium's abusive practices included the use of physician standing order forms (called "Custom Profiles") to encourage routine, excessive UDT, and the dissemination of false and misleading statements about drug abuse rates and the value of its testing. Millennium also provided many services and benefits to physician customers (including free supplies, as discussed below) contingent on referrals of certain amounts of tests to Millennium.

4. As Millennium knew, Medicare only covers tests that are reasonable and necessary for the treatment or diagnosis of an individual patient's illness or injury, based on his or her medical condition. 42 U.S.C. § 1395y(a)(1)(A). The need for ***each test*** for ***each patient*** must be individually assessed and documented in the patient's medical chart. 42 C.F.R. §§ 410.32(a), (d)(2). Many patients, including those with chronic pain, do not need extensive laboratory-based UDT. Millennium nonetheless sought to, and did, cause many physicians to routinely order extensive and expensive UDT for all of their patients in order to make more money. Millennium then billed Medicare for each drug or drug class tested—averaging more than seventeen procedure codes (many with multiple units) per urine sample—including tests for drugs that patients were not suspected of taking, and for "confirmatory" quantitative tests of expected in-office screening test results.

5. For example, Millennium billed and received from Medicare more than $15 million for laboratory UDT for phencyclidine ("PCP" or "angel dust"), abuse of which is virtually non-existent in the Medicare patient population. Millennium also billed and received from Medicare more than $55 million for laboratory drug tests for tricyclic antidepressants ("TCAs"), which also are not commonly abused. Most of Millennium's tests for PCP and TCAs were follow-up testing on in-office test results that were negative and consistent with clinical expectations ("expected negatives"), offering very little, if any, clinical value at great expense to Medicare.

6. Millennium also paid illegal kickbacks to physicians in the form of free point-of-care ("POC") drug test cups to induce physicians to make referrals to Millennium. These POC test cups cost about $5-6 each and Millennium gave physicians more than one million of them in exchange for referrals. As a condition for providing free POC test cups, Millennium explicitly required physicians to refer additional testing to Millennium or pay back the cost of the "free" test cup. Millennium's provision of the free cups was tied to its excessive testing scheme: its executives required that, to be eligible to receive free POC test cups, physicians have Custom Profiles (i.e., standing orders) with at least twelve drug tests. Millennium's provision of free POC test cups generated more than 200,000 referrals for Medicare patients, which resulted in Millennium receiving over $90 million in tainted Medicare reimbursements.

7. Millennium was warned by consultants, customers, competitors, insurers and regulators that its marketing schemes were illegal. Millennium nonetheless pressured its employees into participating in these schemes by fostering a culture of greed, intimidation, and intense sales pressure.

8. Through its practices, Millennium knowingly submitted many thousands of false and fraudulent claims to Medicare and Florida Medicaid for excessive and unnecessary testing, and for testing referred in violation of the Stark Law and the Anti-Kickback Statute, and was improperly paid many millions of dollars in reimbursement for these claims.

II. JURISDICTION, VENUE, PARTIES

9. This action arises under the FCA, as amended, 31 U.S.C. §§ 3729-33, and under common law theories of payment by mistake of fact and unjust enrichment. This Court has jurisdiction over this action under 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1345 and 1367(a).

10. Venue is proper in the District of Massachusetts pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a).

11. This Court may exercise personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) and because Defendant resides and transacts business in this District.

12. Plaintiff, the United States of America, brings this action on behalf of the Department of Health and Human Services ("HHS"), and, specifically, its operating division, the Centers for Medicare & Medicaid Services ("CMS").

13. Relator Mark McGuire is an individual who resides in Boston, Massachusetts. Mr. McGuire is the Administrative Director of Laboratory Services at MetroWest Medical Center.

14. Relator Ryan Uehling is an individual who resides in the state of California. Mr. Uehling began working with Millennium in 2007 and was the Regional Director for Millennium's Western Division until 2011.

15. Relator Omni Healthcare, Inc. ("Omni") is a professional medical company primarily based in Brevard County, Florida. Omni is a multi-specialty physician group with

physicians specializing in family practice, internal medicine, pediatrics, and surgery. Relator John Doe is Dr. Craig Deligdish, a principal of Omni and a practicing physician in the Melbourne, Florida area.

16. Defendant Millennium Health, LLC, formerly Millennium Laboratories, Inc. (also known as Millennium Laboratories of California, Inc.), is a private corporation incorporated in the State of California in 2007 with its principal place of business in San Diego, California. Millennium conducts business nationwide.

17. Defendant was founded in 2007 by James Slattery ("Slattery"), who now serves as Chairman of the Board. Slattery previously served as the Chief Executive Officer ("CEO") until 2013, when he was replaced by current CEO Brock Hardaway. Howard Appel ("Appel") is the President of Millennium, and previously served as the Chief Financial Officer ("CFO") until 2013, when he was replaced by current CFO Timothy Kennedy. Elizabeth Peacock ("Peacock") is Millennium's Executive Vice President of Emerging Opportunities, and previously held the titles of Vice President of Sales and Executive Vice President of Sales.

III. LAW

A. The Federal False Claims Act

18. The FCA provides, in pertinent part, that a person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains . . . .

31 U.S.C. § 3729(a)(1).[1] For purposes of the FCA,

> (1) the terms "knowing" and "knowingly"—
>
> (A) mean that a person, with respect to information—
> (i) has actual knowledge of the information;
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
> (iii) acts in reckless disregard of the truth or falsity of the information; and
>
> (B) require no proof of specific intent to defraud[.]

31 U.S.C. § 3729(b)(1).

B. The Medicare and Medicaid Programs

1. The Medicare Program

19. In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, known as the Medicare program. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1. CMS administers the Medicare program. At all times relevant to this complaint, CMS contracted with private contractors, referred to as "fiscal intermediaries," "carriers," and Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104. The Medicare program consists of four parts: A, B, C, and D. Millennium billed Medicare under Part B, which covers certain medical services, such as clinical laboratory test services, furnished by physicians and other providers and suppliers. 42 U.S.C. § 1395k(a)(2)(B).

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[1] The FCA was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 ("FERA"), enacted May 20, 2009. Sections 3729(a)(1) of the prior statute applies to conduct that occurred before FERA was enacted, and Section 3729(a)(1)(A) of the revised statute applies to conduct after FERA was enacted. Section 3729(a)(1)(B) is applicable to all claims in this case by virtue of Section 4(f) of FERA.

20. To participate in the Medicare program as a new enrollee, clinical laboratories, such as Millennium, must submit a Medicare Enrollment Application, CMS Form-855B. Laboratories also complete Form CMS-855B to change information or to reactivate, revalidate and/or terminate Medicare enrollment.

21. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

22. An authorized official must sign the "Certification Section" in Section 15 of Form CMS-855B, which "legally and financially binds [the] supplier to all of the laws, regulations, and program instructions of the Medicare program."

23. Authorized officials for Millennium signed the certification statement in Section 15 of Form CMS-855B, indicating that they understood that the laboratory was required to comply with Medicare laws, regulations, and program instructions, which include, but are not limited to, the Stark Law and the Anti-Kickback Statute.

24. The National Provider Identifier ("NPI") is a standard and unique health identifier for health care providers. All providers and practitioners must have an assigned NPI number prior to enrolling in Medicare.

25. To obtain Medicare and Medicaid reimbursement for certain outpatient items or services, providers and suppliers submit a claim form known as the CMS 1500 form ("CMS 1500") or its electronic equivalent known as the 837P form. Among the information the provider or supplier includes on a CMS 1500 or 837P form are certain five-digit codes, including Current Procedural Terminology Codes ("CPT codes") and Healthcare Common Procedure Coding System ("HCPCS") Level II codes, that identify the services rendered and for which

reimbursement is sought, and the unique billing identification number of the "rendering provider" and the "referring provider or other source."

26. The Medicare statute requires that each request for payment or bill submitted for an item or service payable under Medicare Part B include the name and unique physician identification number for the referring physician. 42 U.S.C. § 1395l(q)(1).

27. From 2007 to August 24, 2013, Palmetto GBA was responsible for processing Medicare Part B claims in the State of California. From August 24, 2013 to the present, Noridian Healthcare Solutions, LLC, has been responsible for processing Medicare Part B claims in the State of California. As Millennium performed all of its tests at facilities in California, it submitted all claims to these Medicare contractors.

2. The Florida Medicaid Program

28. The Florida Medicaid Program is authorized by Title XIX of the Social Security Act. 42 U.S.C. §§ 1396 *et seq*. Medicaid is a joint federal-state program that provides health care benefits, including laboratory services coverage, for certain groups including the poor and disabled. The Florida Medicaid program is required to implement a "State Plan" containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. § 1396a. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage, is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d (b). The Florida Medicaid Program is authorized by § 409.902 Fla. Stat., and Chapter 59G, Florida Administrative Code ("F.A.C."). Section 409.919, Fla. Stat., directs the Florida Agency for Health Care Administration ("AHCA") to "adopt any rules necessary to comply with or administer §§ 409.901-409.920 and all rules necessary to comply with federal requirements."

29. Medicaid handbooks (e.g., the "Florida Medicaid Provider General Handbook") are issued for the purpose of furnishing Medicaid providers with the policies and procedures needed to receive reimbursement for covered services provided to eligible Florida Medicaid recipients. The handbooks are incorporated by reference in Chapter 59G-4, F.A.C.

30. Physicians and laboratories certify in their state Medicaid provider enrollment forms that they will comply with all federal and state laws applicable to Medicaid. Florida's "Medicaid Provider Enrollment Application" must be completed by any person or entity desiring to receive payment for services provided to Medicaid recipients. Under Section VII of the Application, in order to be eligible to receive direct or indirect payments for services rendered to Florida Medicaid Program recipients, a provider must certify that the provider understands "that false claims, statements, documents, or concealment of material facts may be prosecuted under applicable federal and state laws." Florida Medicaid Provider Enrollment Application, Section VII Certification, at 9.

31. The Florida Medicaid Provider General Handbook contains the following language, in Chapter 5 at page 5-4:

> **Provider Responsibility** When presenting a claim for payment under the Medicaid program, a provider has an affirmative duty to supervise the provision of, and be responsible for, goods and services claimed to have been provided, to supervise and be responsible for preparation and submission of the claim, and to present a claim that is true and accurate and that is for goods and services that . . . [a]re provided in accord with applicable provisions of all Medicaid rules, regulations, handbooks, and policies and in accordance with federal, state and local law. . . .

Chapter 59G of the F.A.C., section 5.020, entitled Provider Requirements, requires that enrolled Medicaid providers must comply with the Florida Medicaid Provider General Handbook.

32. Under Chapter 2 of the Florida Medicaid Provider General Handbook, laboratory providers are required to fill out the Florida Medicaid Provider Enrollment Application and Non-Institutional Medicaid Provider Agreement. The applicable Medicaid Provider Agreement for Laboratory Services Providers requires that providers agree to comply with "with local, state, and federal laws, as well as rules, regulations, and statements of policy applicable to the Medicaid program, including the Medicaid Provider Handbooks issued by AHCA," and refund any moneys received in error within ninety days.

33. Every time they submit an electronic claim to the Florida Medicaid program, physicians and laboratories also certify that they are complying with state and federal laws applicable to the Medicaid program. According to the Electronic Claims Submission Agreement, all providers must abide by all Federal and State statutes, rules, regulations, and manuals governing the Florida Medicaid program. The agreement also requires providers to certify that each claim is in compliance with all federal and state laws and the conditions on the claim form, including that "the services . . . were medically indicated and necessary to the health of this patient" and that the provider understands "that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws."

3. Regulations Regarding Coverage for Laboratory Tests

34. Medicare and Florida Medicaid regulations both make clear that laboratory tests must be ordered by the physician treating the patient for the treatment of a specific illness or injury, that laboratory test orders that are not individualized to patient need (or for which the need is not documented in the patient chart) are not covered services, and that claims for such services must be denied.

a. Medicare Coverage for Laboratory Tests

35. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), as set forth at 42 C.F.R. Part 493.

36. Medicare Part B pays for covered diagnostic laboratory tests that are furnished by a laboratory. 42 C.F.R. § 410.32(d)(v). "Clinical laboratory services involve the . . . examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition." Medicare Benefit Policy Manual ("MBPM"), (Pub. 100-02), Ch. 15, § 80.1, available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf (visited March 15, 2014).

37. Medicare Part B only covers services, including diagnostic laboratory services, that are reasonable and necessary for the diagnosis or treatment of an illness. See 42 U.S.C. § 1395y(a)(1)(A) ("[N]o payment may be made under [Medicare] part A or part B . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]")

38. Pursuant to 42 C.F.R. § 410.32(a), all 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." The MPBM's "Requirements for Ordering and Following Orders for Diagnostic Tests" define an "order" as "a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary . . .

. [T]he physician must clearly document, in the medical record his or her intent that the test be performed." MPBM, Ch. 15, Section 80.6.1.

39. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary. 42 C.F.R. § 410.32(a). Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 C.F.R. § 410.32(a). MPBM, Ch. 15, § 80.1.

40. In order to assess whether those services are reasonable and necessary and whether reimbursement is appropriate, Medicare requires proper and complete documentation of the services rendered to beneficiaries. In particular, the Medicare statute provides that:

> No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

42 U.S.C. § 1395l(e); *see also* 42 U.S.C. § 1395u(c)(2)(B)(i) ("The term 'clean claim' means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) . . . .").

41. Medicare regulations expressly state that a laboratory's claim for a service will be denied if there is not sufficient documentation in the patient's medical record to establish that the service was reasonable and necessary. 42 C.F.R. § 410.32(d)(3)

42. CMS regulations further empower laboratories to request documentation from physicians regarding medical necessity:

> ***(iii) Medical necessity.*** The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary.

42 C.F.R. § 410.32(d)(3).

43. The Department of Health and Human Services, Office of Inspector General ("HHS-OIG") has published Compliance Program Guidance for Clinical Laboratories in the Federal Register. 63 Fed Reg. 45076 (Aug. 24, 1998), available at https://oig.hhs.gov/authorities/docs/cpglab.pdf (visited March 15, 2015). Among other things, the HHS-OIG guidance clarifies that laboratory order forms should emphasize the need for a justification and assessment of each test ordered and that Medicare does not pay for tests for screening purposes:

> Therefore, Medicare may deny payment for a test that the physician believes is appropriate, but which does not meet the Medicare coverage criteria (e.g., done for screening purposes) or where documentation in the entire patient record, including that maintained in the physician's records, does not support that the tests were reasonable and necessary for a given patient.
>
> . . .
>
> a. Requisition design: While HCFA [(CMS)] does not design or approve requisition forms, laboratories should construct the requisition form to capture the correct program information as required by Federal or private health care programs and to promote the conscious ordering of tests by physicians or other authorized individuals. The laboratory should construct the requisition form to ensure that the physician or other authorized individual has made an independent medical necessity decision with regard to each test the laboratory will bill. . . . **The form should contain a statement indicating that Medicare generally does not cover routine screening tests.**
>
> . . .
>
> 4. Reliance on Standing Orders
>
> Although standing orders are not prohibited in connection with an extended course of treatment, too often they have led to abusive practices. Standing orders in and of themselves are not usually acceptable documentation that tests are reasonable and necessary. . . . Medicare contractors can and may require additional documentation to support the medical necessity of the test. **As a result of the potential problems standing orders may cause, the use of standing orders is discouraged.**

Id. at 45079, 45081 (emphasis added).

44. As Millennium explained to its sales force in 2011, "the [HHS-]OIG consistently and fervently insists on the demonstration of medical necessity for all diagnostic testing." Exhibit 1.

b. Florida Medicaid Coverage for Laboratory Tests

45. Florida Medicaid also requires that testing be individualized to the medical needs of patients. As stated in 59G-1.010(166) of the Florida Administrative Code, "Medically necessary" or "medical necessity" means:

> [T]hat the medical or allied care, goods, or services furnished or ordered must: . . .
>
> > Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain; [and]
> >
> > Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs; . . .

It further clarifies:

> The fact that a provider has prescribed, recommended, or approved medical or allied care, goods, or services does not, in itself, make such care, goods or services medically necessary or a medical necessity or a covered service.

46. Florida Statute § 409.905 also states:

> 409.905 Mandatory Medicaid services. . . . Any service under this section shall be provided only when medically necessary and in accordance with state and federal law.

C. Self-Referral and Anti-Kickback Prohibitions

1. The Stark Law

47. The federal physician self-referral prohibition, 42 U.S.C. § 1395nn (commonly known as the "Stark Law") prohibits an entity from submitting claims to Medicare for twelve categories of "designated health services" ("DHS"), including clinical laboratory services, if

such services were referred to the entity by a physician with whom the entity had a financial relationship that did not fall within a statutory or regulatory exception. 42 U.S.C. §§ 1395nn; *see also* 42 C.F.R. §§ 411.351 *et seq*.

48. Compliance with the Stark Law is a condition of payment by the Medicare program. Medicare may not pay for any DHS provided in violation of the Stark Law. *See* 42 U.S.C. §§ 1395nn(a)(1), (g)(1).

49. The regulations interpreting the Stark Law require that "[a]n entity that collects payment for a designated health service that was performed pursuant to a prohibited referral must refund all collected amounts on a timely basis . . . ." 42 C.F.R. § 411.353(d).

50. A "financial relationship" includes a "compensation arrangement," which means any arrangement involving any "remuneration" paid to a referring physician "directly or indirectly, overtly or covertly, in cash or in kind" by the entity furnishing the DHS. *See* 42 U.S.C. §§ 1395nn(h)(1)(A) and (h)(1)(B).

51. Effective October 1, 2008, "a physician is deemed to 'stand in the shoes' of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if -- (A) The only intervening entity between the physician and the entity furnishing [DHS] is his or her physician organization; and (B) The physician has an ownership or investment interest in the physician organization." 42 C.F.R. § 411.354(c)(1)(ii).

52. Under the Stark Law, an "entity is considered to be furnishing DHS if it . . . [is the] entity that has presented a claim to Medicare for the [DHS] . . . ." 42 C.F.R. § 411.351.

53. A "referral" includes "the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any [DHS] for which payment may be made under Medicare Part B . . . ." 42 C.F.R. § 411.351.

54. The Stark Law and its interpretive regulations contain exceptions for certain compensation arrangements. The statute and regulations also exempt certain items from the definition of "remuneration," including items "used solely to (I) collect, transport, process, or store specimens for the entity providing the item, device, or supply, or (II) order or communicate the result of tests or procedures for such entity." 42 U.S.C. § 1395nn(h)(1)(C)(ii); 42 C.F.R. § 411.351.

2. The Anti-Kickback Statute

55. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or potentially harmful to patients. To protect the integrity of federal health care programs from these difficult-to-detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care. The statute was first enacted in 1972, and was strengthened in 1977 and 1987, to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

56. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment, in cash or in kind, to induce or reward any person for referring, recommending or arranging for federally-funded medical services, including services provided under the Medicare and Medicaid programs. In pertinent part, the statute provides:

> (b) Illegal remunerations . . .
>
> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) 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,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

57. Compliance with the Anti-Kickback Statute is a condition of payment by the Medicare program. 42 U.S.C. § 1320a-7(b)(7).

IV. BACKGROUND: TYPES OF UDT, GUIDELINES, AND REIMBURSEMENTS

A. Types of Urine Drug Tests

58. Drug testing is used to determine the presence or absence of drugs or metabolites, also known as "analytes," in a patient's system. Drug testing can be "qualitative" (to determine the presence or absence of an analyte) or "quantitative" (to provide a numerical concentration of an analyte). Different testing methodologies have different capabilities and limitations.

59. Drug testing is performed in a number of contexts. Some workplaces have mandatory drug testing requirements, in some instances required by federal regulations. In the clinical health care context, drug testing can be used to monitor whether patients are taking prescribed drugs or taking or abusing drugs not prescribed.

60. Urine is the most common medium used for drug testing, and is the predominant medium for testing used by Millennium.

61. There are different types of drug testing, generally based on the location of the test (in-office or at a laboratory), which have different associated costs.

62. "Point of care" or "POC" testing—at a physician's office or clinic—is generally performed by "immunoassay" methodologies, which generally provide a qualitative result indicating the presence or absence of a drug or drug class above pre-set "cut-off" or concentration levels. In-office testing is often performed with POC drug test cups that have a number of built-in drug test strips, each of which tests for a specific drug or drug class. In-office testing can also be performed on immunoassay analyzer machines, known as "desktop" or "benchtop" analyzers, which are more sophisticated and generally reimbursed at higher levels than POC test cups.

63. Under CLIA, CMS oversees all laboratory testing services. UDT performed using POC drug test strips and test cups is generally "CLIA-waived." CLIA-waived tests are categorized as simple laboratory examinations and procedures that have an insignificant risk of an erroneous result or pose no risk of harm to the patient if the test is performed incorrectly. 43 C.F.R. § 493.15(b). To perform CLIA-waived tests, physicians need to enroll in CLIA and obtain a waiver. 42 C.F.R. § 493.35. To operate a benchtop or desktop analyzer, physician practices are generally required to obtain CLIA certification to perform moderate- or high-complexity laboratory tests.

64. As discussed in the next section, since April 2010, Medicare generally only reimburses one unit of POC testing per patient encounter, based on the methodology used (analyzer versus POC test cup with embedded test strips). As of January 1, 2011, the Medicare

reimbursement for POC tests is determined by the complexity of the test under CLIA (HCPCS billing code "G0434" for CLIA-waived tests and "G0431" for high-complexity analyzer tests).

65. POC drug testing, including use of POC test cups, is the standard of practice for drug testing in pain management. Most patients need only limited, if any, laboratory testing, based on their POC test results, drug abuse history, and clinical presentation.

66. Testing at laboratories is generally performed by more precise methodologies, such as column chromatography in combination with mass spectrometry. Such methods include gas chromatography with mass spectrometry ("GCMS") and liquid chromatography with mass spectrometry ("LCMS"). These testing methodologies can provide quantitative results, identifying the *concentration* of a drug or metabolite in a sample. Quantitative tests are often billed for each drug or drug class tested, using CPT codes assigned for quantitative tests of each drug or class and, in some cases, multiple units of those CPT codes. Quantitative tests can be used to "confirm" POC test results, as they use a second, more accurate methodology.

67. Millennium performed UDT by liquid chromatography with tandem mass spectrometry ("LC-MS/MS").

68. Millennium's LC-MS/MS technology enabled it to test urine specimens for numerous drugs and metabolites during a single run of an aliquot of a urine sample through the LC-MS/MS machine.

B. Expected Versus Unexpected POC Test Results

69. The clinical value of Millennium's "confirmatory" or "quantitative" laboratory testing depends on a patient's medical condition. The clinical utility of a "confirmation" or "quantitation" of POC test results depends in part on whether the POC test result is expected or unexpected, and the patient's drug abuse history and clinical presentation.

70. For example, if a patient is prescribed a certain drug, such as Xanax, a positive POC test result for benzodiazepines (of which Xanax is one) would be expected. If the test result is negative for benzodiazepines, however, and the patient insists that she is taking her Xanax as prescribed, a quantitative laboratory test to "confirm" whether this unexpected negative result may be reasonable and necessary.

71. Similarly, if a patient's POC test yielded a positive result for a non-prescribed or illicit drug, then a quantitative laboratory test to evaluate (i.e., "confirm") this unexpected positive result may be reasonable and necessary.

72. In some instances, laboratory testing of an expected POC test result or for a substance not available on a POC test may also be warranted. For example, aberrant patient behavior, unexpected clinical presentation, or a history of drug abuse may justify specific laboratory tests. The clinical value of such tests, however, depends on the presentation and physician assessment of each individual patient and that patient's need for each such test. If a POC test is negative for an illicit drug or drug not prescribed, and there is nothing in the patient's presentation or drug abuse history to indicate abuse of that drug, then a quantitative laboratory test for that drug is not reasonable and necessary for the treatment and diagnosis of that patient, and therefore not covered by Medicare.

C. Guidelines on Urine Drug Testing

73. Several organizations have published guidelines regarding UDT in the clinical setting, including UDT for chronic pain patients prescribed opioids. According to the Substance Abuse and Mental Health Services Administration ("SAMSHA"), the development of UDT guidelines in the clinical setting draws on the experience of workplace drug testing, including the

Federal Drug-Free Workplace Program and its guidelines ("Federal Workplace Guidelines"). 73 Fed. Reg. 71858 (Nov. 25, 2008).

74. Under the Federal Workplace Guidelines, a "Negative Result" includes results reported by certified laboratories when a valid specimen "contains no drug or the concentration of the drug is less than the cutoff concentration for that drug or drug class." *Id.* at 71878 (Sec. 1.5). Laboratories may report a valid specimen as "negative" when "each initial drug test is negative[.]" *Id.* at 71894. Under the Federal Workplace Guidelines, a negative result on these initial immunoassay tests do not require confirmation testing by another method. *See id.*

75. Millennium is well aware that entities have published guidelines regarding the use of UDT in clinical pain management and, in fact, Millennium compiled excerpts of guidelines into a document it entitled "Urine Drug Testing Guidelines by Leading Industry Organizations." Exhibit 2. The guidelines Millennium cites include those issued by the American Pain Society, the American Society of Interventional Pain Physicians ("ASIPP"), the Department of Veterans Affairs, the State of Utah, the Federation of State Medical Boards, and the Washington State Agency Medical Directors Group.

76. As Millennium knew, none of these guidelines recommended the routine use of quantitative laboratory testing, such as the LC-MS/MS testing that Millennium performs, to "confirm" expected negative immunoassay results.

77. Instead, when these guidelines addressed the need for confirmatory/quantitative laboratory testing, they generally recommended a UDT protocol whereby an immunoassay test is administered first and then only *unexpected* results are referred for laboratory-based confirmatory testing via a quantitative method such as LC-MS/MS.

78. For example, the Washington State Agency Medical Directors Group Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain ("Washington State Guidelines") states that the purpose of the immunoassay test is to provide rapid results that should help avoid further, unnecessary laboratory confirmation testing of expected results: "The advantages of immunoassays are their ability to concurrently test for multiple drug classes, provide rapid results and guide appropriate utilization of confirmatory testing." Washington State Agency Medical Directors' Group, *Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain*, 2010 update, available at http://www.agencymeddirectors.wa.gov/Files/OpioidGdline.pdf (visited March 15, 2014).

79. The Washington State Guidelines recommend such confirmation testing only for positive results: "When the immunoassay result is unexpected and the patient does not acknowledge or credibly explain the result, a confirmatory test using either GC/MS or LC/MS/MS should be ordered." Similar recommendations are made by other authoritative entities, including the ASIPP and SAMSHA. *See* Manchikanti L, Abdi S, *et al.*, *Pain Physician 2012*; 15:S67-S116, ISSN 1533-3159, ASIPP Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain; Substance Abuse and Mental Health Services Administration, *Clinical Drug Testing in Primary Care*, Technical Assistance Publication (TAP) 32, HHS Publication No. (SMA) 12-4668.

D. Reimbursements for Laboratory Tests

80. Different types of urine drug tests have different costs.

81. Since January 2011, POC test cup tests have been billed to Medicare using HCPCS code G0434 and reimbursed at a fixed rate of approximately $20-25 per patient encounter—regardless of the number of substances tested. Also since January 2011, POC high-

complexity immunoassay tests have been billed to Medicare using HCPCS code G0431 and reimbursed at a fixed rate of approximately $100 per patient encounter—again, regardless of the number of substances tested.

82. Millennium listed the HCPCS and CPT billing codes it used in its "Annual Physician Notices." *See, e.g.*, Exhibit 3 ("2012 Physician Notice")); Millennium Health Annual Physician Notice ("2014 Physician Notice"), available at http://www.millenniumhealth.com/wp-content/uploads/2014/08/MLI-ADF11001_Annual-Physician-Notice-2014-August-D3.pdf (visited March 17, 2015). Millennium generally billed LC-MS/MS test results using individual CPT codes for each drug or drug class it tested.

83. Millennium routinely billed multiple different CPT codes for some drug classes—such as TCAs, for which Millennium billed four separate CPT codes.

84. Millennium also routinely billed multiple units of the same CPT codes—such as 83925 for opiates—suggesting that it had performed multiple procedures to test for opiates.

V. DEFENDANT'S FRAUDULENT SCHEMES

85. Millennium knowingly submitted and caused to be submitted false claims to Medicare and Florida Medicaid for non-covered drug testing that was not reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 410.32(a); MBPM, Ch. 15, Section 80.6.1.

86. Millennium increased physician testing per sample by causing physicians to order large numbers of LC-MS/MS tests on a routine basis for their patients pursuant to practice-wide standing order forms—without an individualized assessment of which drug tests were necessary for a given patient. This practice resulted in testing that was not reasonable and necessary. Millennium also made false and misleading statements about the need for and value of its drug testing services to encourage such testing, and paid physicians remuneration in the form of free

supplies—tied to physician referrals—to secure their referrals and get them to agree to high levels of testing.

87. Physicians, with Millennium's knowledge and encouragement, routinely ordered dozens of individual tests, each costing Medicare about $25, for all of their patients. In 2012 and 2013, Millennium billed Medicare for an *average* of more than twenty laboratory tests at an *average* cost of more than $450 for each urine sample. In these two years alone, Millennium billed and was paid more than $400 million by Medicare.

A. Millennium Caused Physicians to Order UDT That Was Not Reasonable and Necessary, in Violation of Medicare Requirements

88. A core element of Millennium's business model was the use of physician standing order forms. Millennium created these forms as part of its plan to direct physicians to establish protocols for laboratory testing to be performed on all of their patients—usually, at minimum, a dozen or more drug tests—regardless of each patient's individualized need and condition.

1. Millennium Required Physician Use of Standing Orders

89. Millennium enabled, required and enforced the use of physician standing orders. These forms were alternately called "Standing Order," "Test Protocol" and "Custom Profile" forms. While the name of Millennium's standing order form changed, the function remained the same.

90. These forms worked substantially as follows, with some modifications over time: a physician filled out a Custom Profile (or Standing Order or Test Protocol) form that was kept on file with Millennium and remained in effect for the physician's practice until and unless changed. When a urine sample was sent in for testing, the physician, a staff member, or even a Millennium-employed laboratory assistant or third-party specimen collector filled out an order

(or "Requisition") form for the specimen and checked a box in "Section A" of the order form labeled "Use Custom Profile." This caused Millennium to perform and bill to insurers, like Medicare, all of the tests on the Custom Profile.

91. Millennium's 2014 Annual Physician Notice explained:

> Physician Custom Profiles: Millennium offers physicians the option of establishing a Custom Profile to serve as general instructions on how they would like their patients tested. In constructing a Custom Profile, each drug the physician would like tested must be selected individually on the Custom Profile form. When ordering tests, a physician must select a testing option in Section A of the test requisition form by marking either a) USE Custom Profile, and perform additional tests if ordered, or b) DO NOT USE Custom Profile, and perform only those tests ordered on that requisition form.

92. Millennium sales representatives and executives expected and encouraged physicians to use their standing order (potentially including additional tests for a given patient—but not fewer) for all or most of the patients in their practices.

93. The importance of and emphasis on standing orders permeated Millennium's sales and marketing. For example, on September 10, 2009, Millennium's Vice President of Marketing sent an email to all sales representatives entitled "STATUS OF STANDING ORDER FORM" and stated: "As you know, the standing order is critical to our confirmation and billing process . . . ." Exhibit 4.

94. Millennium's management required physicians to have a Custom Profile on file with the Company. As stated by Millennium's customer support staff to a member of the sales force, copying Millennium's President: "STANDING ORDER MUST BE RECEIVED BEFORE SPECIMENS CAN BE SENT IN TO LAB OR PROCESSED." An April 2011 email by Mary Rouse, Millennium's Director of Sales Operation, stated: "If we do not receive updated custom

profiles, we will discontinue processing specimens for these accounts until an updated profile is received."

95. Millennium expected not only that physicians would have a Standing Order or Custom Profile, but also required certain testing thresholds, so that Millennium could make more money. Millennium refused to do business with accounts that failed to meet these thresholds.

96. Early Millennium training documents, reviewed by Millennium Chief Executive Officer James Slattery, made this clear:

> Attached is a revised and even better 'Why Confirm Every Sample' document. This information should be used on the first call and every subsequent call to establish the expectation that all samples get sent to our lab for confirmation. This also lays the groundwork for a complete Standing Order to be put in place. **If an account does not want a Standing Order in place for the 6 drugs not covered by the [POC test], we do not want to do business with them.**

Exhibit 5 (emphasis added).

97. Millennium executed this strategy by pushing for standing orders that included as many tests as possible. As stated by Elizabeth Peacock, Vice President of Sales, with respect to one customer's Custom Profile in August 2011: "I'm after a one-two punch. Layer on a couple more tests now, then push a couple of new ones as well." Exhibit 6. Or, as stated by Millennium's President regarding updated forms in September 2011: "WE DON'T WANT TESTING TO DECLINE BY UPDATING THE CP [Custom Profile] WITH LESS TESTS[.]" Exhibit 7 (capitalization in original).

98. Millennium employees routinely submitted completed Custom Profile forms to headquarters for processing, *see* Exhibit 8, and often filled out information on the Custom Profile forms themselves.

99. Millennium even processed specimens under customers' Custom Profiles in instances where the "Use Custom Profile" box in Section A of the requisition form was left blank. *See, e.g.*, Exhibit 9.

2. Millennium Set—and Enforced—Testing Thresholds for Physician Standing Orders

100. Millennium executives and sales managers set requirements for the amount of testing sales representatives had to obtain from physicians for their Custom Profiles.

101. Millennium required that physicians agree to Custom Profiles with at least twelve tests in several contexts, including approval as a Millennium customer, removal from "troubled" (unprofitable) account lists, and as a condition for receiving free POC test cups.

102. Millennium sales managers spread the message to their sales teams that Custom Profiles needed to have twelve or more tests. For example, in September 2011, the Regional Sales Manager for New England directed his sales team, while circulating new Custom Profile forms, as follows: "As we discussed on our conference call, the minimum for each account going forward is 12 test[s] + 4 Validity test[s]. . . . good selling!" Exhibit 10.[2] Similarly, the Regional Sales Manager for Florida wrote in August 2011: "Strive for at least 15 plus validity. You can take one of 2 approaches – we are losing money every month and/or the clinical necessity." Exhibit 11.

103. Millennium executives were deeply involved in monitoring and even rejecting Custom Profiles that did not meet these standards. For example, Millennium's sales support team sent an email to a sales manager in September 2011, copying Millennium's President, Mr. Appel, with the subject "cp issues – not enough tests," stating: "The attached new client

[2] Millennium offered and performed "specimen validity testing" to determine whether a urine sample had been tampered with.

paperwork . . . does not have enough tests on the [Custom Profile] to enter. Once they are updated with more tests, sales support will process the paperwork."

104. Another communication from the sales support department to a sales manager made clear that Mr. Appel himself rejected "Custom Profiles" that did not have "enough" tests: "There are not enough tests on the CP and [Mr. Appel] *will not approve*. . . . If [the sales representative] can get more tests added and send the CP back today, we can overnight the supplies." Exhibit 12. The sales manager forwarded this message to the sales representative stating, "we need more tests on this CP. Sell them on the clinical value of a more comprehensive testing menu." *Id.*

105. Millennium also made provision of resources (including millions of dollars' worth of free POC test cups) contingent on robust standing orders. To be approved for free POC test cups, Millennium required new practices to have at least twelve tests (plus four specimen validity tests) on their Custom Profiles. Exhibit 13. For existing customers, Millennium sales personnel were directed to "[v]erify profitability with VP of Business Analytics . . . . If practice falls below ML profitability guidelines, cup agreement will be denied." *Id.*

106. Millennium executives monitored the profitability of its physician customers ("accounts"), and referred to accounts that failed to meet profitability and test-per-specimen thresholds as "troubled" or "at risk."

107. If sales representatives failed to increase testing by a "troubled" account, Millennium stopped accepting samples from the account, withheld commissions for samples sent in for testing by that account, or both.

108. Millennium executives reinforced to sales representatives the need to drive up the number of tests on their customers' standing orders. For example, in a September 2011

communication to a sales manager, Millennium's President wrote: "[A]ttached are CPs we received as a follow up to the August Trouble [*sic*] Practices lists. These are still not adequate. These need to be resolved immediately." Exhibit 14.

109. Millennium executives discussed a standard for acceptable tests per specimen for "troubled accounts" in an August 2011 email chain entitled "Troubled practices." Exhibit 15. Millennium's Vice President of Analytics, Daniel Pencak, wrote that "[a]fter a few sales reps have called me, it's clear there needs to be some education to the field [on] what the minimum number of tests are required to break-even[.]" *Id.* Millennium's Vice President of Sales responded by asking "So, what's the magic number?" She suggested twelve tests per specimen. Mr. Pencak agreed that twelve was a "reasonable number." *Id.*

110. Accordingly, Millennium told sales representatives that they had to increase revenue per specimen from so-called "troubled practices" or "troubled accounts"—or it would suspend sales representatives' commissions on these accounts and/or terminate them as customers. As a Senior Financial Analyst wrote to Mr. Pencak in March 2012 regarding one such "troubled" account: "The Practice is eligible for cancelation [*sic*] as a Troubled Practice and the primary driver for its poor performance is low tests per specimen. My logic is that if they could update the custom profile to include additional tests, then it would increase tests/specimen."

111. Lists of "troubled accounts," prepared by Mr. Pencak, were circulated to sales teams with instructions to make the accounts more profitable by increasing the number of tests on their Custom Profiles. One sales manager directed her team to immediately photograph updated Custom Profiles and send the images to Millennium's Vice President of Business Analytics. Exhibit 16; Exhibit 17.

112. Millennium's employees executed these instructions successfully, repeatedly causing physicians to increase the testing on their standing orders and bragging about it. For example, in August 2011 a sales manager submitted to Ms. Peacock a "Plan of action for troubled accounts" in his region, with responses from sales representatives. Exhibit 18. One sales representative wrote: "I spoke with the office yesterday and they have modified their protocol effective immediately to include 4 additional confirmations of negative tests . . . ." *Id.* Another stated he set up a meeting to "convince [the account] to add more confirmations to their standing protocol." *Id.* Another wrote: "We will go in and get [the doctor] to increase confirm [*sic*] negatives. . . . He will make changes and add more confirm negative [*sic*] with some convincing." *Id.* Another wrote "we are meeting with these doctors to increase their testing of negatives." *Id.* The proposed marketing plans to increase testing do not reference a clinical justification for the additional tests. *Id.*

113. Millennium executives rewarded such success and agreed not to suspend sales commissions on "troubled" accounts that ordered additional testing. For example, the Regional Sales Manager for New England argued in a January 2012 email that one sales representative had made substantial progress "in increasing [an] account[']s revenue through test per specimen" and, for another account made "many strides . . . to increase profitability and protocol." Exhibit 19. For the latter account, the manager explained that the sales representative had secured a "[n]ew CP consisting of 14 test[s] per specimen," and that the practice had "[a]greed to use CP every time (Section A)." *Id.* Ms. Peacock wrote back that profitability had sufficiently increased and that commissions would not be suspended. The Sales Manager responded: "What a turn of events! Big win, I'll let [the rep] know, thanks for all the follow up!" *Id.* The email chain did not reference any clinical justification for the increased testing.

3. Millennium Promoted the Routine "Confirmation" of Negative POC Test Results and Made False and Misleading Statements to Further Encourage This Testing

114. To increase laboratory testing, Millennium trained its sales representatives to (1) "Emphasize the need to confirm every sample" and (2) "strongly suggest to our customers that negative POC results should be confirmed . . . ." Exhibit 20.

115. Millennium sales training documents emphasized that "confirmations" of POC test results were key to Millennium's revenue (and sales representatives' compensation). For example, one training presentation entitled "Sales Focus and Positioning" contained slides entitled "Make it routine" and "Emphasize the need to confirm." The "Make it routine" slide instructed sales representatives "to help practices establish a testing protocol" to prevent testing volumes from declining over time. The "Emphasize the need to confirm" slide noted that when "[p]hysicians consider point of care adequate and confirmation numbers are low" it "doesn't help our revenues—or yours!" The slide suggested a "goal" for physicians to confirm every sample. Exhibit 21.

116. Millennium paid its sales representatives commissions of $6, $8, $10, and even $12 per sample sent into Millennium for testing. These commissions were significant—some sales representatives made hundreds of thousands of dollars per year in commissions. Some Regional Managers made upwards of $1,000,000 per year in commissions. Millennium only paid commissions for samples sent in from accounts Company executives deemed sufficiently profitable.

117. Millennium trained its sales representatives to emphasize to physicians that they should not individually assess their patients, but rather extensively test all patients—with separate, expensive laboratory tests—pursuant to pre-determined Custom Profiles. Millennium

offered various reasons for this blanket approach to testing, including that "profiling" patients (i.e., taking a patient-specific approach to testing) "doesn't sit well" with the Drug Enforcement Agency. *See* Exhibit 21.

118. Millennium suggested to physicians that they could be subject to regulatory action if they did not order more tests from Millennium. In an April 2009 email, an area Sales Director wrote, "if they do not confirm every sample, they are in violation of the CLIA program. This could result in Medicare asking for all the money that they have billed for for [*sic*] the first half of the test, plus huge fines." Exhibit 22.

119. Millennium also promoted the simplicity of "confirming" all POC test results. For example, Millennium's Chief Scientific Officer wrote to a sales representative in December 2009, copying Ms. Peacock: "In fact, we recommend to practices that they confirm all POCT results (positive and negative) that way they don't fail to order the correct test for a given drug because they end up getting all the results anyways." Exhibit 23.

120. Millennium made numerous false and misleading statements regarding "false negative" rates for POC tests in order to cause physicians to increase testing for the confirmation of expected negative POC test results on their Custom Profiles.

121. Millennium falsely claimed POC tests had very high "false negative" rates. Instead of using the proper definition of "false negatives"—negative test results that should have been positive—Millennium calculated and marketed a different, misleading statistic (the percentage of positive samples missed on POC tests) and called it the "false negative" rate. Millennium did this to create an inflated sense of uncertainty surrounding POC drug tests, undermine physician confidence in POC tests, and promote the routine use of quantitative UDT for drugs that patients were not suspected of taking.

122. For example, Millennium compiled data from the second quarter of 2012 suggesting that, for every one hundred pain patients tested, approximately four were positive for cocaine on LC-MS/MS tests, and that, of these four, POC tests revealed two of them and missed two. Exhibit 24. Negative POC tests results were thus correct 98% of the time (yielding a false negative rate of approximately 2%), yet Millennium encouraged its sales representatives to say that POC tests for cocaine had a "false negative" rate of nearly 50%. *Id.* Millennium internal talking points from April of 2010 stated: "Cocaine was found to return a false negative rate in about 50% of the 2840 samples in which confirmation results vs. immunoassay were studied. Followed by 30% for propoxyphene, 28% for benzo's, etc. ***KEY TAKEAWAY: Doctors should confirm all negatives*** . . . ." Exhibit 25 (emphasis in original).

123. Millennium's own data showed that the false negative rate for POC tests was actually very low for most drugs (4% or less for methadone, amphetamines, barbiturates, TCAs, MDMA, cocaine, marijuana, and PCP). *See, e.g.*, Exhibit 26. The likelihood that a negative POC test result is "false" for a given patient is also affected by that individual patient's presentation, prescribed medications, and drug abuse history, if any.

124. Millennium nonetheless consistently directed its sales representatives to promote false and misleading "false negative" rates, including through a Company marketing document entitled "Empirical Evidence to Consider when Formulating your UDT Program" that was distributed to all sales representatives for use with physicians. Exhibit 27 at 3. As stated by a Regional Sales Manager to his team in an August 2011 email: "Use it to explain the reasons for false positive/false negatives on the POC cups. This will also be helpful in securing more test requests/specimen on the Custom Profiles." Exhibit 28. Millennium's Chief Scientific Officer wrote to another Regional Sales Manager in July 2011: "If you are looking to demonstrate the

importance of confirming negative POCT results, then I would recommend the document entitled 'Empirical data to consider when formulating your UDT program.'" Exhibit 29.

125. The Company's false statements convinced physicians to order more tests from Millennium. One Millennium sales representative wrote to Millennium's VP of Sales and other sales managers in March 2011: "I really wish we could take the Empirical data info and make it into a tri-fold presentation piece or flip chart!! It has been such a beneficial tool at sales calls." Exhibit 30.

126. Millennium also told physicians that they were risking legal liability if they relied on POC test results—despite a lack of support for routine quantitative testing in drug testing guidelines and Medicare coverage requirements that each test for each patient be reasonable and necessary.

127. For example, in June and July of 2011, Millennium's Florida sales team recycled the false statement regarding "false negative" rates into talking points for use with physicians that stated: "Our data shows huge %'s of false negatives from the POC cups . . . Cocaine-false negatives on POC occur up to 50% of the time. To risk medical license on a $6 cup is ___. You can fill in the blank :)." Exhibit 31.

128. Millennium also claimed that the alleged lack of reliability of POC tests put physicians' practices as risk: "You may not have many high risk patients, but it only takes one overdose to put your practice on the line." *Id.*

129. Millennium used unsupported threats of third-party legal actions to cause physicians to "confirm" POC drug test results.

130. In September 2011, a Millennium Regional Vice President sent an email to all sales managers describing how to respond to complaints about "HUGE BILLS." He suggested they distribute a news article entitled "Another little old lady arrested for pushing drugs":

> Hand this print out to the physician and tell them, 'don't let this patient creep up and surprise you in your practice, **set the protocol to cover most of the drugs we can test** and we will make sure your patients aren't exploited and feel over charged. Once you start cherry picking who gets tested for this and that, you miss one like this. There are hundreds of patients dying in every state every month because of overdose, drug interaction, etc. so make sure none of them come from this practice[.]'

Exhibit 32 (emphasis added). Millennium's Vice President of Sales responded "Great advice Nick."

4. Millennium's Conduct Generated Unnecessary Testing—Including "Confirmations" of Expected POC Test Results for Rarely Abused Drugs

131. Millennium's use and promotion of standing orders caused testing that was not reasonable and necessary and for which the need was not assessed or documented.

132. Routine quantitative testing under Custom Profiles led to millions of dollars in drug testing for Medicare patients that was not reasonable and necessary—including for substances that are rarely abused and diverted in the general population, much less in the Medicare population.

133. For example, Millennium billed Medicare for more than 900,000 laboratory tests for phencyclidine or PCP (CPT Code 83992), at a cost of more than $16 million. PCP is not a commonly abused drug. According to Millennium's own data, the incidence of true positives for PCP is extraordinarily low. In addition, POC tests for PCP have very low false negative rates. For example, Millennium's own data revealed that, for a quarter in 2012, Millennium identified

only 24 false negatives out of 174,960 LC-MS/MS tests following negative POC test results for PCP—or 0.01 percent. Exhibit 24.

134. Millennium also billed Medicare more than $55 million dollars for laboratory testing of four types of TCAs—approximately 660,000 drug tests each for amitriptyline (CPT Code 80152), desipramine (CPT Code 80160), imipramine (CPT Code 80174), and nortriptyline (CPT Code 80182). Millennium billed Medicare for each of these four tests nearly every time testing for TCAs was ordered.

135. TCAs have been on the market since the 1960s. TCAs present a low risk of abuse and diversion, in part because of side effects for users. TCAs are not even listed in the schedules of controlled substances under the Controlled Substances Act. 21 U.S.C. § 812.

136. While POC tests for TCAs have a somewhat higher risk of false negatives than PCP (around 3%, according to Millennium's 2012 data), the need for that testing is tempered by the low abuse potential for TCAs and lack of abuse history for the vast majority of patients.

137. Millennium knew many customers ordered TCA testing. In one email, Ms. Peacock asked Mr. Pencak, "What percent of customers order TCA confirmations?" Mr. Pencak responded: "About 49%." Exhibit 33.

138. Millennium routinely analyzed and summarized data on test ordering patterns, in "Practice Profiles" and "Regional Profiles" (summarizing tests ordered by entire states), that showed ordering patterns indicating frequent use of Custom Profiles and the ordering of unnecessary "confirmations" of expected POC test results. *See, e.g.* Exhibit 34 at 5.

5. Millennium Knowingly Submitted Claims to Medicare for Tests That Were Not Reasonable and Necessary

139. Millennium knew that, as a laboratory and Medicare supplier, it had an obligation to submit claims to Medicare only for tests that were reasonable and necessary for the diagnosis or treatment of individual patients.

140. For example, Millennium's 2012 Annual Physician notice stated:

> Medicare will only pay for tests that meet the Medicare coverage criteria and are medically necessary for the diagnosis or treatment of the individual patient. **Tests used for routine screening of patients without regard to their individual need are not usually covered by the Medicare program, and therefore are not reimbursed.** As a participating provider in the Medicare Program, the laboratory has a responsibility to make a good faith effort to ensure all tests requested are performed and billed in a manner consistent with all federal and state law regulations.

Exhibit 3 (emphasis added).

141. Millennium knew that its emphasis on Custom Profiles put it at high risk that these conditions would not be met.

142. In pursuing its practices, Millennium ignored and misled its compliance consultants. For example, its compliance consultant CodeMap repeatedly warned Millennium that all testing had to be patient-specific. In 2009 guidance provided to Millennium, CodeMap explained that Medicare does not pay for "preventative" or "screening" urine drug tests, stating:

> The original Medicare law did not cover any preventive or "screening" services. Medicare defines any test or procedure performed in the absence of signs or symptoms of illness, injury, or a malformed body part as a "screening" service. However, Congress has subsequently passed legislation that allows Medicare to cover a number of screening tests under specific conditions.

Congress has not passed legislation regarding Medicare coverage for urine drug tests in the absence of signs or symptoms of illness or injury.

143. CodeMap advised Millennium multiple times that testing had to be based on the needs and condition of an individual patient. In a July 2010 audio presentation to Millennium, CodeMap's founder, Charles Root, emphasized that confirmatory tests must be supported by an individualized determination of medical necessity. *See* Exhibit 35 ("Dr. Root did not answer an important question very favorably."). Mr. Root reiterated this principle again in September 2010, when an independent compliance consultant was upset by Millennium's marketing messages promoting confirmation testing that was not reasonable and necessary. Millennium asked Mr. Root to speak with her. Mr. Root wrote to Millennium's President: "I spoke with [her] yesterday and believe everyone is now on the same page - her issue was confirmation of ALL tests regardless of result or patient needs, I gave her the same advice that we have discussed regarding medical necessity documentation etc. and the need to tailor confirmations to patient needs." Exhibit 36. Millennium's President responded "Thanks. We agree too." *Id.* This representation was not consistent with Millennium's practices.

144. Millennium knew it was submitting claims to Medicare for UDT that failed key coverage requirements. Millennium's sales personnel knew what tests physicians were ordering, what was on their Custom Profiles, and how often they tested their patients. Millennium routinely tracked how many specimens were referred, and how many tests were ordered per sample.

145. Millennium, through its executives and employees, knowingly submitted claims to Medicare for UDT that was not reasonable and necessary.

B. Millennium Gave $5 Million Worth of Free POC Test Cups to Physicians in Exchange for Referrals in Violation of the Stark Law and Anti-Kickback Statute.

1. Millennium Distributed Free POC Test Cups in Exchange for Referrals

146. Millennium provided more than 1,000,000 POC test cups to physician-customers throughout the country for free, explicitly in exchange for laboratory UDT referrals.

147. Millennium primarily distributed these POC test cups under contractual agreements ("Free Cup Agreements"). The Free Cup Agreements required that physicians agree to refer additional testing to Millennium on the cup specimens and agree not to bill insurers for the POC test cups. *See* Exhibit 37; Exhibit 38. Under the Free Cup Agreements, physicians had to pay for any of the "free" POC test cups that did not generate referrals to Millennium. Exhibit 39. Millennium's President reviewed, approved, and signed Free Cup Agreements.

148. Millennium monitored the number of free POC test cups it shipped to customers and referrals it received back under the Free Cup Agreements, to ensure that physicians were sending the cup specimens in to Millennium for additional testing. *Id.*

149. As Millennium attested to federal regulators, over 220,000 of the "free" POC test cups were used on Medicare patients.

150. Millennium attested to federal regulators that (1) the cost of these "free" POC test cups was approximately $6.25 per cup from June 2010 through December 2012 and $4.90 per cup from January 2013 through June 2014, (2) the value of the free POC test cups used for Medicare patients exceeded $1,200,000, and (3) that Millennium received more than $90,000,000 in payments from Medicare for testing referred by physicians who received free POC test cups.

2. Millennium Knew that Free POC Test Cups Were Items of Value to Physicians

151. POC test cups are specimen collection cups with test strips embedded in them:

Standard Specimen Cup

POC Test Strips

POC Test Cup

152. Millennium knew that the test strips contained in the POC test cups made the test cups more valuable to doctors than clear collection cups—and they were significantly more expensive. Millennium knew the free POC test cups were clinical supplies that physicians normally had to purchase, as well as tools used for evaluation and management of patients.

153. CMS changed the reimbursement structure for POC test cups, effective April 2010. The new reimbursement rate applicable to POC cup tests after these changes was approximately $20-25—much less than some physicians previously had been billing. Specifically, many physicians, with Millennium's encouragement, had been billing multiple units of the applicable CPT code—one for each test strip contained within the POC test cup—obtaining reimbursements of more than $180 per test cup.

154. Once physicians could only seek approximately $20-25 in reimbursement for a POC cup test, the POC test cups were no longer a source of significant reimbursement revenue for physicians. The clinical information the POC test cups provided, however, was still valuable

in the evaluation and management of patients, and the ability to get them for free presented substantial cost savings to physicians.

155. Millennium's Free Cup program grew dramatically after CMS's rate reduction, and the number of Free Cup Agreements and the number of free POC test cups Millennium distributed increased significantly.

156. Many physicians did not want to deal with the costs and administrative burdens associated with billing and seeking reimbursement for tests performed using POC test cups. Exhibit 40. Some insurers also would not reimburse for tests performed using POC test cups. For example, under Medicare, customers that used in-office immunoassay analyzers could not bill for both a POC test cup test result and a POC analyzer test result for the same patient. Because the analyzers results were reimbursed at a higher rate, physicians chose to seek reimbursement for that test; however, practices still wanted the immediate results from POC test cups for patient management and evaluation. In addition, various state Medicaid programs also did not reimburse for tests performed using POC test cups. Some physicians in these states wanted free POC test cups in order to be able to clinically assess their Medicaid patients (and bill for the office visit)—even though the expense would have come out of pocket absent "free" POC test cups from Millennium.

157. Millennium knew that POC test cups (and the tests results they produced) had financial value. For example, Elizabeth Peacock, Millennium's VP of Sales, wrote in March 2010: "Let's really emphasize the $$ value of the instant test cups . . . . This is unique. No other labs offering. Should be very valuable for [the physician] since they have . . . no way to get that instant preliminary read. That would cost them AT LEAST $5 per patient additional if they don't go with [Millennium] for confirmations." Exhibit 41.

158. Millennium's President, Howard Appel, agreed that free POC test cups should be used by the sales force as a marketing tool. Exhibit 42.

3. Millennium Knew That Providing Free Test Strips Violated the Stark Law and Anti-Kickback Statute

159. Millennium knew that the test strips in the free POC test cups had value to physicians and that they were not used solely (or at all) to collect, transport, process, or store specimens for Millennium.

160. Millennium did not use the POC test strips or results in conducting its LC-MS/MS testing or in reporting the results of its LC-MS/MS testing. As stated by one Regional Vice President: "I could care less what cup they use. I don't care if they send it to me in a Ziploc bag. I want their urine[.]"

161. Millennium knew that providing free drug test strips—outside of cups—to physicians violated the Stark law and Anti-Kickback Statute.

162. On one occasion, Ms. Peacock circulated an internal company memo acknowledging that Millennium could not provide free test strips: "Millennium can not [sic] provide other CLIA Waived POC devices like single strips at no cost because the strips have no relationship to the specimen collection and federal regulations say that non-collection items can not [sic] be provided without charge." The same document acknowledges that the POC test cup—due to the test strips—"serves as a test vehicle for the practice."

163. Despite Millennium's knowledge that providing test strips for free was illegal, it provided millions of free test strips within the POC test cups it distributed to physicians.

164. Millennium also knew that absent an applicable statutory exception POC test cups had to be sold at "fair market value" to comply with the Stark Law and Anti-Kickback Statute.

165. Millennium's outside health care consulting firm, CodeMap LLC, advised the Company in August 2009 that point-of-care drug testing supplies provided to physicians who referred laboratory testing to Millennium must be *sold* to them at fair market value, stating: "As long as Millennium charges its customers fair market value for [point of care testing] supplies, the practice should not implicate the Anti-Kickback Law." Regarding the Stark Law, CodeMap stated that Millennium's price must meet the "Fair Market Value Compensation exception," which requires that "the compensation must be . . . consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician." Exhibit 43.

166. Millennium received concerns from customers, prior to the initiation of the Free Cup Agreement program, that it was selling POC test cups for too low a price, in violation of the Stark Law and Anti-Kickback Statute. Exhibit 44. Millennium's president, Mr. Appel, responded to these concerns stating that the pricing was legal because "the most important factor to consider" is that price is "consistent with fair market value and is not determined in a manner that takes into account the volume or value of actual or anticipated referrals." *Id.* But Millennium determined who qualified for free POC test cups based upon actual and anticipated referrals: the Cup Agreements required referrals to Millennium and the Company's "Approval Guidelines" mandated that customers must have "12 tests + validity" on a Custom Profile to be approved for a Free Cup Agreement.

167. Millennium received warnings that the provision of free POC test cups violated the Stark Law. In September 2010, Charles Root, a compliance consultant at CodeMap, wrote an email to Millennium's President advising him that the provision of free POC test cups would violate the Stark Law, in part because they provided value to physicians beyond plain specimen

collection cups: "[M]y assumption was that you provided specimen transport cups, not test cups . . . provision of a test cup rather than a simple specimen collection device *gives the physician something of value not associated with specimen collection.*" Exhibit 45 (emphasis added).

168. Despite this advice, Millennium continued to distribute free POC test cups—which contained free test strips—in exchange for referrals under the Free Cup Agreement.

169. Millennium did not disclose to sales representatives or customers CodeMap's advice that free POC test cups have value and that providing them would violate the Stark Law. In late 2010, Millennium stopped using CodeMap as a compliance auditor after Millennium refused to accept and sign the findings of CodeMap's "Annual Compliance Audit."

170. Millennium also received warnings—from customers and employees—that the provision of free POC test cups in exchange for referrals was a "blatant" and "clear" Stark Law and Anti-Kickback Statute violation.

171. In an internal January 2010 email, Millennium's Laboratory Director noted that "providing POCT test kits free as an inducement to use our lab for confirmations would be a clear Stark violation." Exhibit 46.

172. In November 2010, a customer in New England wrote to a Millennium sales representative that "After reviewing the [Free Cup Agreement] . . . I suggest we avoid receiving [POC test] cups unless we plan to pay for them. *It seems like a blatant stark/kickback concern.* The cups are $6 each. I suggest for both parties we stay clear [of] receiving this product for no charge. If we want some cups we should pay for them." Exhibit 47 (emphasis added). The sales representative forwarded this email to Millennium's President, Howard Appel. Mr. Appel responded directly to the customer, but did not mention that Millennium's own consultant, CodeMap, shared the customer's view that the provision of free POC test cups was illegal. The

customer raised a further concern in a response email that the Free Cup Agreement was inaccurate because it contained language that the POC test "supplies are used solely for collecting and transporting specimens for testing" to Millennium, and noted that "is simply not the case" for his practice. The POC test cups were not solely collection and transportation devices for Millennium; they contained drug test strips that were used by physicians as POC testing devices.

173. Millennium also knew that Florida's AHCA had specifically found that the provision of free POC test cups was illegal on July 8, 2008. Florida's AHCA issued a Declaratory Statement and Final Order that the provision of free POC test cups would violate Florida Administrative Code, Rule 59A-7.020, which mirrors the Stark Law, explaining:

> Specifically, Rule 59A-7.020(15), Florida Administrative Code, allows a laboratory to provide specimen cups to physicians free of charge *only* for the collection, transportation, processing and storing of laboratory specimens; transmitting laboratory information to the laboratory; or ordering or communicating laboratory tests or results and other patient information between the physician, surgeon, organization, agency, or person and the laboratory. Further, Rule 59A-7.020(15)(f), Florida Administrative Code, prohibits laboratories from providing free "test kits" to physicians. The Petitioner's proposal to provide physicians free specimen cups that, in addition to serving as collection devices, perform either waived tests or moderately complex tests on-site for the physicians would violate these rules. Consequently, the Agency declares that Petitioner would be subject to licensure sanctions for violating Rule 59A-7.020, Florida Administrative Code, if it were to engage in the free specimen cups arrangement proposed in the Petition.

In Re: Petition for Declaratory Statement of Dominion Diagnostics, LLC, FRAES No. 2008008228, July 8, 2008, at 5. AHCA specifically found a deficiency with respect to Millennium's provision of free POC test cups in June 2012 and sent a notice of this deficiency to Millennium. Nonetheless, Millennium continued distributing free POC test cups to physicians under its Free Cup Agreements.

174. Competitors also raised concerns that the Free Cup Agreements were illegal. For example, on October 4, 2010, a Millennium sales manager, Brandon Worley, emailed Ms. Peacock stating that potential customers "wanted documentation stating that it is legal to provide them with free cups if they don't bill for them. We think one of the other labs is telling them that it is a Stark violation." Two days later, on October 6, 2010, Ms. Peacock wrote Millennium's President, Mr. Appel, and all of Millennium's sales representatives that some "prospective and current customers have received visits from competitors who are scaring them into believing that furnishing test cups at no charge is illegal and a violation of Stark Laws."

175. A competitor of Millennium's also sued the Company in federal district court in 2011, alleging that the distribution of free POC test cups violated both the Stark Law and the Anti-Kickback Statute. *Ameritox. Ltd. v. Millennium Laboratories*, Case No. 8:11-cv-0775-T-24 (M.D. Fla) (A jury in that case ultimately found that Millennium's provision of the POC test cups violated the Stark Law and Anti-Kickback Statute, and Millennium has appealed).

4. Millennium Knowingly Submitted Claims for Tests Referred in Violation of the Stark Law and Anti-Kickback Statute

176. Millennium knew that compliance with the Stark Law and Anti-Kickback Statute was a condition of payment by Medicare. Millennium explicitly certified that, as a Medicare supplier, it would comply with all Medicare laws and regulations, including the Stark Law and Anti-Kickback Statute, on Form CMS-855B and CMS-1500 claims forms.

177. Millennium knowingly compensated physicians with millions of dollars in free POC test cups in exchange for referrals, in violation of the Stark Law and Anti-Kickback Statute. Millennium paid the kickbacks expressly to obtain referrals, to increase the number of tests referred, and to prevent customers from affiliating with competitors. In doing so, Millennium

ignored numerous, specific warnings from its employees, consultants, customers, competitors and even a government agency. Millennium submitted tens of millions of dollars of claims to Medicare for services it performed resulting from these referrals, and knew these claims were false because they were submitted in violation of the Stark Law and Anti-Kickback Statute.

178. Millennium, through its executives and employees, knowingly submitted claims to Medicare for UDT that was referred in violation of the Stark Law and Anti-Kickback Statute.

C. Millennium Fostered a Culture of Non-Compliance and Greed

179. Millennium fostered a culture of greed and intimidation in its sales force. Sales representative compensation was tied directly to the number of specimens sent in for testing—and obtaining Custom Profiles that met internal testing thresholds. Sales representatives were compensated handsomely when they successfully obtained increased testing and subjected to relentless pressure when they did not.

180. The message of sales as a means to riches came from the top of the Company. For example, at its 2012 National Sales Meeting, Millennium's CEO, Mr. James Slattery, gave a presentation to approximately 250 sales representatives where $2,000,000 worth of gold coins were brought out and placed on stage. Some of those in attendance interpreted these gold coins as a message that sales representatives should aspire to more wealth; *see* Exhibit 48, others interpreted it as a threat that Millennium was willing to use its resources against perceived threats.

181. Millennium's General Counsel gave a presentation, nominally on "compliance" entitled "Taking Over." During the presentation, Millennium's General Counsel showed an animated slide of a former employee whom Millennium had sued. The former employee's face

was shown on a target range being shot repeatedly, and another slide depicted Millennium's competitors and the former employee in body bags:

182. Speaker notes emphasized the implied threat to employees who did not toe the Company line:

> Don't be a weasel. . . . I don't want to be on the other side of litigation from any of you. I hope you don't want to be on the other side of litigation with Millennium. There is no amount of time or resources we won't spend to hold our employees accountable. . . . [W]e will protect this company . . . .

183. Millennium also made it clear it did not want any documentation of potential violations of law. In a letter to the sales team dated November 28, 2011, Millennium's President

described a violation of Millennium's "e-mail communication policies" where "a sales rep wrote an email to a client of a competitor and listed 25 separate reasons why the account should switch to Millennium, including 'free cups.'" His first proposed rule in response to this and other compliance violations identified in writing was to say "DO NOT WRITE ANY EMAILS LONGER THAN TWO SENTENCES." Exhibit 49.

184. Notes from a "Managers Meeting" in August 2011 state: "Company policy is to delete text messages 10 days or older." Exhibit 50. Similarly, notes from an October 2011 regional team meeting state: "Every two weeks delete your text messages. As we have litigation with our competitors they will want to see your phone." Exhibit 51.

185. In another instance of email deletion, Ms. Peacock, Millennium's VP of Sales, instructed sales representatives to delete all emails from a chain entitled, "4600 today," in which a Regional Vice President challenged members of the sales force to increase drug testing on Fridays and Mondays, and in which other members of Millennium's management offered cash incentives for increased testing.

186. Millennium's sales representatives responded to the Regional Vice President's "4600" email, with encouragement from management, in a manner showing a disregard for professionalism and an emphasis on sales and greed that permeated the Company's culture. For example: "GET. THAT. PEE!!"; "The Friday pee badgers [']we take what we want![']"; "Pick up the liquid GOLD before liquid goldschlager on Fridays!"; "GOLD RUSH FRIDAYS"; "Merry Pissmas!!!"; "Pick up the PISS"; "TGIP/Gold Rush Fridays"; "I LOVE everyone's emails. The common theme is the personal commitment to domination."

187. Many additional emails demonstrate an emphasis on sales without regard for medical necessity or compliance: "[G]et these doctors addicted to Millennium so [] they're

PISSED that they're 'not allowed' to send to us"; "We want MORE piss"; "Keep pushing the PISS"; "The purpose of every call is to get more PISS to the house"; "Trying to make it rain liquid gold baby!"

188. The emphasis on sales came from the top. Millennium's VP of Sales wrote an email to all Millennium sales representatives in November 2011 that stated: "**let's not forget our primary mission - to sell, sell, sell.**" Exhibit 52 (emphasis in original).

189. A Regional Sales Manager described the pressure: "they basically wanted the reps to wake up in the morning fearing their jobs. Not feeling good about themselves, thinking they were going to get fired."

190. Millennium further promoted its services to physicians with an emphasis on ways that the physicians could make money—from speaking fees, free POC test cups, reimbursements on POC test cup and analyzer test results (with Millennium assistance)—that further placed money over medical necessity.

191. For example, a Regional Vice President took credit for making Dr. Robert Windsor, Millennium's largest referrer, money in a November 2010 email: "You along with many other physicians made hundreds of thousands of dollars if not more from OUR risk."

192. Millennium emphasized profits above compliance and intimidated sales representatives to engage in marketing tactics designed to generate UDT orders that were not patient-specific and not reasonable and necessary for patient diagnosis or treatment. This caused Millennium's submission of claims to Medicare for services it performed resulting from these orders that were not reasonable, necessary, or patient-specific.

D. Examples of Physician Practices that Referred Millions of Dollars in False and Fraudulent Testing to Millennium for Medicare and Florida Medicaid Patients

1. National Pain Care – Dr. Robert E. Windsor

193. Millennium's top-referring physician provider was Dr. Robert E. Windsor, who owns pain management clinics in Georgia, Kentucky, Florida, and Ohio, all operating under the corporate umbrella of National Pain Care, Inc. ("NPC"). Medicare has paid Millennium approximately $35 million in UDT ordered by NPC clinicians. Millennium identified Dr. Windsor, who personally saw patients only infrequently, as the "referring provider" for UDT that has generated nearly $18,000,000 in Medicare payments to Millennium. A large portion of these payments to Millennium were for prohibited claims and unnecessary tests.

194. Dr. Windsor used Millennium as a test laboratory for his Georgia practice beginning in mid-2010. In August 2010, he indicated he wanted to use Millennium for his clinics in Kentucky. Elizabeth Peacock wrote to Jarrett Smith, at the time a Millennium Regional Manager, "OK, let's . . . maximize the confirmations from these accounts." Mr. Smith replied, "They have already committed to sending everything in. We will make sure they blow it out." Exhibit 53. By this, Mr. Smith meant that Dr. Windsor had told him that Dr. Windsor's practices would be ordering confirmations for all his patients for all drugs tested at the POC, plus some that were not.

195. Beginning in May and June 2011, Dr. Windsor began using Millennium for most of his clinics, including the ones in Kentucky and his newly purchased clinic in Dayton, Ohio. Dr. Windsor authorized Custom Profiles that were substantively the same across all his clinics. *See, e.g.*, Exhibit 54.

196. Beginning in approximately May 2011, Millennium provided Dr. Windsor with "Laboratory Service Assistants" ("LSAs")—Millennium employees who were hired to process urine specimens for shipment to Millennium—at no charge to the physician. These LSAs were aware of NPC's UDT protocols, and several of them did work for NPC beyond their permitted tasks—for example, operating NPC's POC analyzer machines. Millennium also gave Dr. Windsor free POC test cups to use at his Georgia clinics.

197. Dr. Windsor established uniform UDT practices throughout his pain management clinics. For example, a patient prescribed narcotics for pain relief was given a thirty-day prescription, and, to receive a refill, the patient was required to return to the clinic for a follow-up visit and undergo UDT. Thus, virtually all NPC patients prescribed narcotics (as most were) had their urine tested every thirty days. When the patient produced a specimen, NPC performed a POC test (either with a POC test cup or a chemical analyzer), so that the clinician could have immediate preliminary drug test results to help decide whether to initiate or renew a prescription. Whether NPC sent a specimen to Millennium for further testing typically depended on the patient's insurance: if an insurer would not pay, NPC discarded the specimen; otherwise NPC automatically sent the specimen to Millennium for quantitative testing.

198. Until at least March 2014, virtually all specimens NPC sent to Millennium from any given NPC clinic were subject to essentially the same quantitative UDT panel, regardless of the patient's presentation, demographic profile, medical history, or history of drug or alcohol abuse. In approximately March 2014, after learning he was a subject of government investigation, Dr. Windsor purported to modify his UDT policy to require an assessment of a patient's risk of abusing drugs.

199. Most NPC clinicians treating patients had little or no input into the UDT performed on their patients. Indeed, until approximately December 2012, the NPC clinicians did not fill out Millennium requisition forms; rather, Millennium employees—the LSAs hired by Millennium to process the specimens—carried out this task. The LSAs were instructed by their supervisors at Millennium to fill out the requisition forms and always check the "Use Custom Profile" box, contained in Section A on the form.

200. After Millennium told its LSAs in late 2012 that a NPC employee should be the one to check the "Use Custom Profile" box of the requisition forms, NPC medical assistants took over this specific task. The process varied, but one NPC medical assistant, for example, gathered 200 or so requisition forms at a time, and filled out certain information on all of the forms in advance, including checking off "Use Custom Profile." Later, when an individual patient delivered a urine specimen, the medical assistant would add the patient's name and other patient-specific information to the Requisition form.

201. Millennium sales employees knew about Dr. Windsor's UDT protocols. For example, Millennium sales representatives Joey Bilyeu and Megan Mason knew that the Georgia Pain Physician clinics (owned by NPC) always checked the box for "Use Custom Profile" on the Millennium requisition form. The Millennium Regional Director for the Mid-South Region, Jarrett Smith, believed all of the Dr. Windsor/NPC Custom Profiles—for the Georgia, Kentucky, and Ohio practices—were the same, and he understood that the clinics used the Custom Profile as the basis for quantitative UDT virtually all of the time.

202. Millennium also knew that Dr. Windsor's clinics were ordering tests for drugs that were virtually never encountered in their patient populations. For example, through about mid-2013, Dr. Windsor's Custom Profiles called for Millennium to conduct quantitative testing

for PCP, MDMA, and heroin. Yet a "Practice Profile" prepared by Millennium for Dr. Windsor, which summarized tests on 10,499 specimens from Dr. Windsor's Kentucky Pain Physicians clinic in Pikeville, Kentucky from January 1, 2013 to August 1, 2013, showed that not a single patient had tested positive for these drugs, and that Millennium's own average positive rate for these drugs (from a sample of approximately 80,000 specimens submitted by other physicians) was 0.3%, 0.0%, and 1.2%, respectively.

203. By way of example, a patient at Dr. Windsor's Georgia Pain Physicians clinic in Calhoun, Georgia, referred to herein as "Patient FA," was a Medicare patient who was seventy-eight years old at the time of his first visit to the clinic in 2011 for treatment for chronic pain. He had no history of alcohol or drug abuse. Yet, every month, NPC tested his urine with an immunoassay point-of-care screen, and then sent the urine sample to Millennium for a battery of quantitative UDT under a Custom Profile that called for testing for methadone, amphetamine, cocaine, marijuana/THC, MDMA, PCP, and specimen validity testing (creatinine, oxidant, pH, and specific gravity).

204. On October 11, 2011, Patient FA was seen at the Calhoun clinic by Dr. Adithya Reddy for a routine follow-up visit. Consistent with his past history, the POC drug test that NPC performed that day yielded negative results for amphetamine, barbiturates, benzodiazepines, cocaine, methadone, methamphetamine, PCP, TCAs, and marijuana. NPC then sent his specimen to Millennium with a Requisition form that had the boxes, "Use Custom Profile," and "Perform Specimen Validity Testing," checked off. Exhibit 55. Dr. Windsor's name was on the Requisition form as the requesting physician, even though he did not see Patient FA on that date. In accordance with the operative Custom Profile, Millennium conducted quantitative testing for Patient FA's prescribed medication, plus oxycodone, noroxycodone, oxymorphone, methadone,

EDDP (methadone metabolite), alpha-hydroxyprazolam, 7-amino-clonazepam, lorazepam, temazepam, oxazepam, amphetamine, methamphetamine, cocaine metabolite, cTHC (marijuana metabolite), MDMA, and PCP. Exhibit 56. Like all the earlier Millennium test results for this patient, the test results and specimen validity testing were consistent with the patient's prescribed medication and revealed no suggestion of abuse. Millennium submitted two claims to Medicare for this testing and was paid more than $217. Exhibit 57.

205. Many of the Millennium tests, including but not limited to the tests for methadone, EDDP (methadone metabolite), benzodiazepines (alpha-hydroxyalprazolam, 7-amino-clonazepam, lorazepam, nordiazepam, oxazepam), cocaine metabolite, amphetamines, methamphetamines, THC, MDMA, and PCP, were not reasonable and necessary and the clinicians treating the patient did not assess the medical need, if any, for these tests. Millennium's claims to Medicare were false claims. *See* Exhibit 57.

206. On or about April 24, 2012, Dr. Windsor updated his Custom Profiles, including for the Georgia Pain Physicians clinics, by adding approximately thirteen more drugs to the list of drugs for which to test. Exhibit 58. Patient FA was seen again at the NPC Calhoun Clinic for a routine follow-up visit, this time by Dr. Olalekan Ajibowo, on May 15, 2012. Although Patient FA's medical history still indicated no risk factors for drug abuse, and no reason to increase the amount of quantitative UDT, a Millennium LSA filled out the Requisition form with "Use Custom Profile" checked off (just as all the other Requisitions were filled out). This time, Millennium conducted testing on the sample for the drugs referenced in paragraph 205 above (with the exception of amphetamine, methamphetamine, and MDMA), plus propoxyphene, norporpoxyphene, tapentadol, meperidine, normeperidine, methylphedidate, ritalinic acid, ketamine, norketamine, crisoprodol, meprobamate, pehobarbital, secobarbital, butalbital,

amitriptyline, nortiptyline, imipramine, desipramine, cyclobenzaprine, ethyl glucuronide, ethyl sulfate, JWH-018(n-valeric acid)), JWH-073(N-(n-butyric acid), JWH-018(N-(n-petanol)), JWH-073(N-(n-butanol)), MDPV, methylone, mephedrone, and 6-MAM (heroin metabolite). Exhibit 59. None of the Millennium tests for these additional substances was reasonable and necessary and the clinicians who treated the patient did not assess the medical need for these tests, if any.

207. Millennium submitted claims to Medicare for this testing and was paid $678.65 for it. Exhibit 60. Millennium knew these claims for tests that were not reasonable and necessary, and not ordered by the physician treating the patient, were false. Millennium also knew that these practices occurred across NPC.

2. Tampa Pain Relief Center

208. Tampa Pain Relief Center ("Tampa Pain") is a pain management practice in Florida with clinics in Brandon, Tampa, Oldsmar, and Miami, Florida. Tampa Pain is owned by Surgery Partners, which owns a large number of medical facilities throughout the United States. Tampa Pain employs a number of physicians who work at its clinics.

209. Tampa Pain began using Millennium in 2008, and ceased using Millennium in early 2012. From 2008 through 2012, referrals from Tampa Pain to Millennium resulted in almost $5,000,000 in Medicare payments to Millennium.

210. Like NPC, Tampa Pain used common testing protocols for all patients who were prescribed narcotics, without regard to the individual circumstances of the patient. In 2008, Tampa Pain's "Standing Order" included confirmation of all POC test results (both positive and negative results), and also quantitative testing for methadone, fentanyl, and alcohol (ETOH).

211. In early 2011, Tampa Pain physicians began using Custom Profiles that covered multiple physicians and multiple locations. Exhibit 61. For patients who were prescribed

narcotics, Tampa Pain physicians almost always used the Custom Profile to order testing from Millennium, without an assessment of each patient's history, demographic information, or risk of abuse.

212. Millennium sales personnel knew that all Tampa Pain patients were receiving essentially the same extensive UDT, regardless of the individual patient's need, condition or history. *See* Exhibit 62. As one Millennium employee wrote to another in July 2011 (and as forwarded to others): "The selection in box A [of the requisition/order form] should be to use the custom profile. Any specimen coming from a Tampa pain location should all be marked to use the custom profile." Exhibit 63.

213. An example of false claims submitted by Millennium to Medicare from this conduct is the drug testing for Patient RR, a middle-aged male with a history of chronic pain who was also being treated elsewhere for depression. Patient RR's medical records show no discernible history of drug or alcohol abuse, and, throughout his treatment at Tampa Pain, he did not exhibit abberant behavior or present other indications that he was at a high risk for drug diversion or abuse. Yet, from April 12, 2011 through March 27, 2012, Tampa Pain referred eleven urine specimens of Patient RR to Millennium for testing, and each time the only instruction Tampa Pain gave to Millennium was to "Use Custom Profile."

214. On November 28, 2011, Patient RR was seen at the Tampa Pain clinic on North Habana Avenue, Tampa, Florida, for a routine follow-up visit and prescription refill. A urine drug screen was performed at the clinic, and the specimen tested positive for classes of drugs that the patient had been prescribed (methadone, opiates/morphone, and oxycodone), and negative for everything else (amphetamines, barbiturates, benzodiazepines, marijuana/THC, cocaine, alcohol, ecstacy, and PCP). Nonetheless, Tampa Pain sent the specimen to Millennium with an unsigned

Requisition form stating, "Use Custom Profile," and Millennium performed, and billed Medicare for, quantitative UDT for substances including benzodiazepines, cocaine, heroin, amphetamines, MDMA, methamphetamine, PCP, and marijuana/THC. Exhibit 64. The Millennium test results were consistent with the urine drug screen testing done by Tampa Pain and consistent with the patient's medical condition and history. Millennium billed Medicare $266.90 for these tests and Medicare paid Millennium that amount. *Id.* Millennium's claims to Medicare for these tests were not reasonable and necessary. Millennium's claims to Medicare for these tests were false claims..

215. Tampa Pain was a high profile account within Millennium. In proposed feedback to a sales representative, one manager wrote: "If you do not have an objective to get more pee to the lab and at every visit to bring value, the visit is useless. . . . Tampa Pain has a massive presence wtihin Millennium as a whole . . . ." Exhibit 65.

216. Millennium also provided free POC test cups to Tampa Pain. From April 2011 through June 2012, Millennium gave approximately 5,275 free POC test cups to Tampa Pain for use at its Habana, Fletcher, Oldsmar, and Brandon locations.

217. Millennium sales personnel also gave gifts to Tampa Pain employees, including watches, jewelry, gift cards, and electronics. These gifts were in violation of Millennium's own compliance policies.

3. Coastal Spine and Pain

218. Coastal Spine and Pain Center ("CSP") is a pain management practice with several locations in Florida, including in Jacksonville, Orange Park, Fernandina Beach, Hilliard and Middleburg. CSP has several physicians who work at its clinics, and who also own a share of the practice.

219. CSP physicians began using Millennium for UDT in June 2009. CSP physicians ordered testing from Millennium pursuant to Custom Profiles.

220. From August 2010 through May 2014, Millennium provided CSP with more than 67,000 free POC test cups—a value of more than $325,000. Millennium and CSP knew the value of the cups Millennium provided to CSP.

221. In an August 12, 2010, email, the Practice Administrator of CSP, who was partly responsible for laboratory selection for CSP, told Millennium's President that a Free Cup Agreement "is vital to our practice." Exhibit 66. In her plea for free cups, she explained that CSP physicians "are constant advocates in our area for Millennium Laboratories" and that "Every urine [sample] collected in my facilities is . . . sent for confirmation to Millennium. *Id.* Millennium agreed to provide the free POC test cups, and Millennium's President responded to a thank you note from CSP by stating "You are very welcome[.]" *Id.*

222. Millennium paid the Practice Administrator and CSP physicians who referred UDT to Millennium, tens of thousands of dollars for speaking engagements and consulting services. For example, CSP's Practice Administrator—a non-physician—had an agreement with Millennium for consulting services that paid her a $24,000 annual retainer.

223. CSP physicians almost always used Custom Profiles as standing orders for UDT for patients who were prescribed narcotics. A CSP physician testified, "we decided on what we were going to screen for . . . and put that in the [custom] profile to send to Millennium."

224. The determination of what tests Millennium performed on a particular patient's specimen was not based on the patient's history, demographic information, or risk of abuse, but rather the Custom Profile in effect at that time.

225. From 2009 through 2014, while CSP had prohibited financial relationships with Millennium under the Stark Law and the Anti-Kickback Statute as a result of its receipt of hundreds of thousands of dollars' worth of supplies in the form of POC test cups, CSP physicians referred more than $10,000,000 in UDT to Millennium for Medicare patients, the majority of which CSP referred pursuant to Custom Profiles, without assessments of individual patient needs.

226. For example, CSP ordered and Millennium performed, billed and Medicare paid for, testing that was not reasonable and necessary for Patient LE, a 70 year-old male with a history of chronic back pain. This patient had no discernible history of drug diversion, illicit drug or alcohol abuse, and throughout his treatment at CSP, he never exhibited aberrant behavior nor did he give any other indication that he presented a high risk for drug diversion or abuse. Patient LE was first seen at CSP in May 2011. From this point on UDTs were ordered for Patient LE at every visit (except for one in September 2011). Patient LE was seen on a monthly basis for the first five months he was a patient at CSP and then was stable enough to have follow-up visits every three months from October 2011 onward. From May 23, 2011 through January 17, 2014, CSP referred fourteen of LE's urine specimens to Millennium for testing, and each time Millennium performed testing pursuant to a CSP Custom Profile. Throughout this time period, Patient LE's urine test results were consistent with his medical and prescription histories.

227. By way of example, on January 23, 2012, Patient LE was seen at the CSP Fernadina Beach facility, for a routine follow-up visit and prescription refill. At the time he was taking tramadol and hydrocodone for pain management. CSP performed a urine drug screen at the clinic, and LE's specimen tested positive for opiates—as would be expected given his

prescriptions—and negative for cocaine, amphetamines, methamphetamine, phencyclidine, MDMA (ecstacy), barbiturates, benzodiazepines, methadone, tricyclic antidepressants (TCA), and oxycodone. Exhibit 67. CSP sent the specimen to Millennium with a Requisition form indicating, "Use Custom Profile," and Millennium proceeded to conduct LC-MS/MS testing for codeine, morphine, hydrocodone, norhydrocodone, hydromorphone, oxycodone, noroxycodone, oxymorphone, buprenorphine, norbuprenorphine, fentanyl, norfentanyl, methadone, EDDP (methadone metabolie), alpha-hydroxylprazolam (xanax), 7-amino-clonazepam (klonopin), lorazepam (ativan), nordiazepam (valium), temazepam, oxazepam, amphetamine, carisoprodol, meprobamate, phenobarbital, secobarbital, butalbital, methamphetamine, cocaine metabolite, and MDMA, as well as four specimen validity tests. Exhibit 68. The Millennium test results were appropriately positive for hydrocodone (which Patient LE was prescribed) and its metabolite norhydrocodone, and negative for everything else.

228. Millennium billed Medicare $387.23 for its tests, and Medicare paid Millennium $354.79, after denying two units of UDT totaling $32.44. Millennium's claims to Medicare for its testing, including but not limited to the tests it performed for codeine, morphine, oxycodone, noroxycodone, oxymorphone, buprenorphine, norbuprenorphine, fentanyl, norfentanyl, methadone, EDDP (methadone metabolite), alpha-hydroxyalprazolam, 7-amino-clonazepam, lorazepam, nordiazepam, temazepam, oxazepam, amphetamine, carisoprodol, meprobamate, phenobarbital, secobarbital, butalbital, methamphetamine, cocaine metabolite, and MDMA, were not reasonable and necessary. Millennium's claims to Medicare for these tests were false claims.

4. Frank Li

229. Dr. Frank Li is a physician in Washington state who owns Seattle Pain Center.

230. In 2012, Dr. Li ordered more than $2,100,000 in UDT to Millennium for Medicare beneficiaries at an average cost of more than $500 per beneficiary sample. In 2013, Dr. Li ordered another $1,500,000 in UDT to Millennium from Medicare. Dr. Li stopped using Millennium in 2013.

231. Dr. Li ordered his UDT from Millennium under Custom Profiles that were almost always applied to urine samples from his practice.

232. Millennium-employed LSAs, stationed at Dr. Li's offices, often filled out Dr. Li's test orders, using these blanket testing protocols. For example, an internal Millennium email from February 2012 noted, "we already have LSA's filling out the requisition forms." Exhibit 69.

233. Dr. Li agreed to the Custom Profiles in part because Millennium told him it cost Millennium the same amount to do the testing regardless of how many tests he ordered: "They said that it costs them the same amount to do the testing so why not do all of them?"

234. Dr. Li's UDT orders were inconsistent with the recommendations of the Washington State Guidelines.

235. Dr. Li's Custom Profile increased drastically in 2011 in response to sales pressure from Millennium.

236. Millennium's VP for Sales, Ms. Peacock, wrote to the Company's regional sales manager regarding Dr. Li, threatening to terminate the account: "Are you and Monet [the Millennium sales representative assigned to Dr. Li's account] able to sucessfully discuss our empirical data on the negatives and obtain additional medically necessary tests? Need to strive for 5 more to make this business viable." Exhibit 70. Although Ms. Peacock used the phrase

"medically necessary" in her email, she had no clinical basis to know that any of Dr. Li's patients actually needed more tests.

237. Dr. Li increased his testing to Millennium in exchange for resources. For example, Millennium offered to provide an electronic medical record (EMR) interface if he would increase his UDT orders. In April 2011, a Millennium sales manager wrote: "If necessary, I think Dr Li would be amenable to confirming all positives & all negatives on the POC cup in order to have the results on his EMR [Electronic Medical Record]. Then we can run all tests on all specimens regardless of the cup results." Exhibit 71.

238. Millennium sales representatives strongly promoted the confirmation of expected negative POC test results to Dr. Li, as stated in a May 2011 email: "we are making a strong case to confirm negatives on Cocaine, Opiates, Meth."

239. Shortly after that email exchange, in June 2011, Dr. Li filled out a new Custom Profile that called for automatic confirmation testing of all POC test results for certain drugs, including cocaine, opiates, and amphetamines.

240. In January 2012, Dr. Li filled out another Custom Profile for his practice with an even higher level of testing—including confirmation of all POC test drug results, including PCP and TCAs—regardless of POC test results or patient condition. Exhibit 72. This testing protocol also called for a number of other drug tests not on the POC test cup to be performed on all patients, regardless of medical condition and patient presentation or history.

241. Dr. Li also received money as a paid speaker for Millennium; but, only while he was referring UDT to Millennium.

242. Millennium executives, LSAs, and sales personnel knew that Dr. Li routinely ordered testing based on Custom Profiles regardless of patient need and without an individual

assessment of the need for each test for each patient—and that Millennium submitted claims to Medicare for this testing, in violation of Medicare claims submission rules (by submitting claims for services that were not covered) and the FCA.

5. Massachusetts Sober-Home Related Testing

243. Millennium had a strategy in Massachusetts of targeting sober homes for business. From approximately 2011 through 2013, Millennium billed Medicare more than $1,400,000 for UDT for residents of sober homes in Massachusetts, many of whom received a set of twenty or more drug tests, multiple times per week, without any documentation or justification as to what tests were actually needed.

244. Sober homes are alcohol- and drug-free living environments for persons seeking to overcome substance addiction or abuse problems. Residents of sober homes in Massachusetts for whom Millennium submitted claims to Medicare were required by the sober homes to undergo routine quantitative UDT as a condition of residency. The UDT Millennium performed on sober home residents in Massachusetts was not for the purposes of medical diagnosis or treatment and thus did not qualify for reimbursement by Medicare.

245. Millennium, through sales representative Mark Cullinan, recruited Massachusetts physicians, including Dr. Jeanne Mase, to act as "medical directors" for sober homes or ordering physicians for UDT of sober home residents.

246. Millennium performed all UDT for Massachusetts sober home residents (whether under Dr. Mase's NPI or another physician's) pursuant to test Requisition forms that had the box "Use Custom Profile" checked off.

247. The Custom Profiles put into place at these sober homes often called for quantitative testing for more than twenty separate separate tests. *See*, *e.g.*, Exhibit 73. Residents

were tested under these Custom Profiles multiple times per week, regardless of the individual resident's treatment status.

248. The Requisition forms were not filled out by Dr. Mase or her medical staff, but rather by non-medical staff at the sober homes, or by employees of "specimen collection" companies, which Millennium paid per sample.

249. Dr. Mase rarely saw the patients at the sober homes, did not provide medical treatment for the sober home residents, and did not regularly review the results of the UDT Millennium performed and billed to Medicare.

250. Millennium engaged two separate courier/"specimen collection" companies to oversee the UDT process for sober home residents. Millennium paid New England Express LLC ("NEE"), owned by Nicholas Chuckran, $31 per specimen to fill out the resident's demographic information, mark "Use Custom Profile" on the resident's Requisition form, and drop the sample off with UPS for shipping to Millennium's laboratory in San Diego, California.

251. Millennium sales representative Marc Cullinan made clear to Chuckran that NEE's specimen collectors were to check off "Use Custom Profile" on the Requisition forms and that Millennium would not pay for any sample that was accompanied by a Requisition form that did not have "Use Custom Profile" checked off.

252. Similar to NEE, Millennium also paid another courier company, Cape Test LLC ("Cape Test"), $32 per specimen to fill out sober home residents' demographic information and mark "Use Custom Profile" on their Requisition forms.

253. In early 2013, after Dr. Mase was audited by private insurer Harvard Pilgrim Healthcare ("Harvard Pilgrim") for UDT billed by Millennium to Harvard Pilgrim, Dr. Mase

informed Cullinan that she would no longer be associated with Millennium for UDT for sober home residents.

254. Medicare paid approximately $1,200,000 to Millennium for UDT of sober home residents, ordered under Dr. Mase's NPI, that was not reasonable or necessary.

255. For example, in January 2013, Millennium submitted to Medicare claims for reimbursement for UDT services ordered under Dr. Mase's NPI for a Medicare beneficiary on January 2, 4, 7, 9, 11, 14, 16, 18, 21, 23, 25, 28, and 30. For those thirteen separate dates of service in January 2013, Medicare paid approximately $12,619.88 to Millennium for tests that were not reasonable and necessary for the diagnosis or treatment of that patient's illness or injury, if any.

256. Upon learning that Dr. Mase would no longer allow her NPI to be associated with UDT for sober home residents, Cullinan informed NEE that all sober home testing should cease until a new "medical director" for sober home UDT could be located. Thereafter, Millennium attempted to work with two new physicians—Dr. Bahige Asaker (through NEE) and Dr. Joseph Sullivan—to continue Millennium's Massachusetts sober home scheme.

257. Dr. Asaker did not knowingly order UDT from Millennium for sober home residents, yet Millennium submitted tens of thousands of dollars in claims to Medicare for UDT purportedly ordered under his NPI that were not reasonable and necessary for the diangosis or treatment of patients. These tests were not properly ordered by a physician treating the beneficiary, as required by Medicare.

258. By way of example, in July 2013, Millennium submitted to Medicare claims for reimbursement for UDT services ordered under Dr. Asaker's NPI for a specific Medicare beneficiary on July 1, 3, 5, 8, 10, 12, 15, 17, and 19. For those nine dates of service in July 2013,

Medicare paid approximately $5,744.25 to Millennium for that one Medicare beneficiary. These tests were not reasonable and necessary for the treatment or diagnosis of that patient's illness or injury, if any.

259. Dr. Sullivan only ordered a very small amount of UDT from Millennium, yet Millennium submitted approximately $40,000 in claims to Medicare for drug tests allegedly ordered under his NPI that were not reasonable and necessary for the diagnosis or treatment of patients. The majority of these tests were not properly ordered by a physician treating the beneficiary, as required by Medicare.

260. By way of example, in July 2013, Millennium also submitted to Medicare claims for reimbursement for UDT services ordered under Dr. Sullivan's NPI for a specific Medicare beneficiary on July 1, 5, 8, 10, 12, 15, 19, 22, 24, 26, and 29. For those eleven dates of service in July 2013, Medicare paid approximately $7,501.23 to Millennium for that one Medicare beneficiary. These tests were not reasonable and necessary for the treatment or diagnosis of that patient's illness or injury, if any.

VI. THE UNITED STATES WAS HARMED BY MILLENNIUM'S CONDUCT

261. As a result of Defendant's conduct, the Medicare program paid Millennium many millions of dollars for many thousands of false and/or fraudulent claims for non-covered drug tests.

262. Medicare was directly affected by Millennium's fraudulent schemes. For example, in a 2011 presentation to potential lenders, Millennium represented that 23.7% of its specimens came from Medicare patients, but that Medicare represented 40.0% of revenue—likely because Millennium took advantage of Medicare's practice of promptly paying claims on the assumption that the supplier has complied with its legal obligations.

263. Medicare was particularly susceptible to Millennium's fraudulent schemes because it does not require a patient co-payment on laboratory services. Because Medicare patients were not required to pay out-of-pocket for Millennium's services, they had no reason to inquire into the charges to Medicare associated with Millennium's UDT. In addition, many Medicare beneficiaries are over sixty-five years old, and seniors are generally at lower risk of illicit drug use.

264. Exhibit 74 to the Complaint is a list of physicians and physician practices who made drug test referrals to Millennium in violation of the Stark Law and/or the Anti-Kickback Statute and the dates during which each such physician had an improper financial relationship with Millennium with respect to the free testing supplies. Exhibit 74.

265. The United States' damages arising from the Millennium's submission of claims to Medicare and Florida Medicaid referred by these physicians in violation of Stark Law and Anti-Kickback Statute exceeds $90,000,000.

266. The United States' damages arising from Millennium's submission of claims to Medicare and Florida Medicaid for UDT that was not reasonable and necessary for the diagnosis or treatment of patients, and for which the need was not assessed or documented for individual patients, including the claims referenced in Section V.E above, likely exceeds $100,000,000.

FIRST CAUSE OF ACTION
(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1) and (a)(1)(A))

267. Plaintiff incorporates by reference all paragraphs of this complaint set out above as if fully set forth.

268. Defendant knowingly presented, or caused to be presented, false and fraudulent claims for payment or approval to the United States and Florida Medicaid, including those

claims for reimbursement of laboratory drug tests that violated the Stark Law and the Anti-Kickback Statute and that were ordered by physicians for uses that were not reasonable and necessary for the diagnosis or treatment of individual patients.

269. Said claims were presented with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

SECOND CAUSE OF ACTION
(False Claims Act: False Statements Material to False Claims)
(31 U.S.C. § 3729(a)(1)(B))

270. Plaintiff incorporates by reference all paragraphs of this complaint set out above as if fully set forth.

271. Defendant knowingly made, used, and caused to be made or used, false records or statements — i.e., false statements regarding compliance and coverage for its services and false statements on forms CMS-855B, 837P and CMS-1500—to get false or fraudulent claims paid and approved by the United States.

272. Defendant's false certifications and representations were made for the purpose of inducing physicians to order its services and getting false or fraudulent claims paid, and payment of the false or fraudulent claims was a reasonable and foreseeable consequence of the Defendant's statements and actions.

273. The false certifications and representations made and caused to be made by Defendant were material to the United States' and Florida Medicaid's payment of the false claims.

274. Said false records or statements were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

THIRD CAUSE OF ACTION
(Payment by Mistake)

275. Plaintiff incorporates by reference all paragraphs of this complaint set out above as if fully set forth.

276. This is a claim for the recovery of monies paid by the United States to Millennium as a result of mistaken understandings of fact.

277. The United States paid Millennium for services that were not reasonable and necessary for the diagnosis or treatment of individual patients as required under Medicare coverage rules, and that were furnished pursuant to prohibited referrals from physicians who were in financial relationships that did not comply with the Stark Law and/or the Anti-Kickback Statute, without knowledge of material facts and under the mistaken belief that Millennium was entitled to receive payment for such claims when it was not. The United States' mistaken belief was material to its decision to pay Millennium for such claims. Accordingly, Millennium is liable to make restitution to the United States of the amounts of the payments made in error to it by the United States.

FOURTH CAUSE OF ACTION
(Unjust Enrichment)

278. Plaintiff incorporates by reference all paragraphs of this complaint set out above as if fully set forth.

279. This is a claim for the recovery of monies by which Defendant has been unjustly enriched.

280. By directly or indirectly obtaining government funds to which it was not entitled, Defendant was unjustly enriched, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the United States.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Defendant as follows:

I. On the First and Second Counts under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper.

II. On the Third and Fourth Counts for payment by mistake and unjust enrichment, for the damages sustained and/or amounts by which Defendant was unjustly enriched or was paid by mistake, or by which Defendant retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

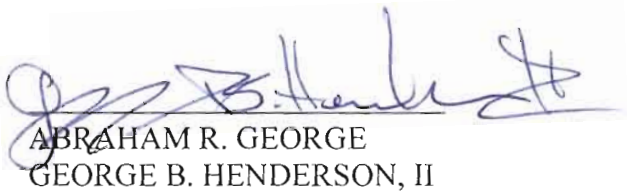
DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

Respectfully submitted,

BENJAMIN C. MIZER
Acting Assistant Attorney General

CARMEN M. ORTIZ
United States Attorney

By: 

ABRAHAM R. GEORGE
GEORGE B. HENDERSON, II
Assistant U.S. Attorneys
John J. Moakley U.S. Courthouse
Suite 9200
1 Courthouse Way
Boston, MA 02210
(617) 748-3152
(617) 748-3272
abraham.george@usdoj.gov
george.henderson2@usdoj.gov

Dated: March 19, 2015

MICHAEL D. GRANSTON
ALAN KLEINBURD
DOUGLAS J. ROSENTHAL
AUGUSTINE M. RIPA
US Department of Justice
Civil Litigation Branch
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
(202) 305-2073
(202) 305-4033

CERTIFICATE OF SERVICE

I hereby certify that on this date a true and correct copy of the foregoing document was served via electronic mail (by agreement) on:

J. Marc Vezina
Monica P. Navarro
Michelle D. Bayer
280 N. Old Woodward Ave., Suite LL20
Birmingham, MI 48009
jmv@vezinalaw.com
mnavarro@vezinalaw.com

Joel M. Androphy
Sarah M. Frazier
Noelle C. Letteri
Berg & Androphy
3704 Travis Street
Houston, TX 77002
JAndrophy@bafirm.com
SFrazier@bafirm.com
AGargour@bafirm.com

Thomas M. Greene
Michael Tabb
Greene LLP
One Liberty Square, Suite 1200
Boston MA 02109
tgreen@greenellp.com
matabb@greenellp.com

Michael E. Mone
Patricia L. Kelly
C. William Barrett
Catherine A. Ryan
Esdaile, Barrett & Esdaile
75 Federal Street
Boston MA 02110
MMone@ebelaw.com
PKelly@ebelaw.com
BBarrett@ebelaw.com
CRyan@ebelaw.com

Suzanne E. Durrell
DURRELL LAW OFFICE
180 Williams Avenue
Milton, MA 02186
Suzanne.durrell@verizon.net

Robert M. Thomas, Jr.
THOMAS & ASSOCIATES
280 Summer Street, 5th Floor
Boston, MA 02210-1131
rmt@thomasandassoc.net

Richard D. King, Jr.
Nathan A. Tilden
Jacquelyn A. McEttrick
SMITH & BRINK P.C.
350 Granite St., Suite 2303
Braintree, MA 02184
RKing@smithbrink.com
NTilden@smithbrink.com
jmcettrick@smithbrink.com

Pursuant to 31 U.S.C. § 3730(b)(2), no service was made upon the Defendant because this case is still under seal.

Dated: March 19, 2015

Abraham R. George
Assistant U.S. Attorney