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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE CENTRAL DISTRICT OF CALIFORNIA**
**WESTERN DIVISION**

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| **UNITED STATES OF AMERICA** and the **STATE OF CALIFORNIA** *ex rel.* Yvonne Huemoeller, and **YVONNE HUEMOELLER**, individually,<br><br>Plaintiffs,<br><br>v.<br><br>**PACIFIC TOXICOLOGY LABORATORIES,**<br><br>Defendant. | No. CV 19-02900-MWF (MRWx)<br><br>**FIRST AMENDED *QUI TAM* COMPLAINT AND DEMAND FOR JURY TRIAL FOR VIOLATION OF:**<br><br>1. 31 U.S.C. §§ 3729(A), (B), and (C);<br><br>2. Cal. Gov't Code §§ 12651(a)(1), (2), and (3); and<br><br>3. Cal. Ins. Code § 1871.7(b). |

**FIRST AMENDED *QUI TAM* COMPLAINT**
**AND DEMAND FOR JURY TRIAL**

Plaintiff and *qui tam* Relator Yvonne Huemoeller ("Relator"), by and through her undersigned counsel, Brown, LLC and the Law Office of Mann & Elias, alleges of personal knowledge as to her own observations and actions, and on information and belief as to all else, as follows:

## I.
## PRELIMINARY STATEMENT

1. Defendant Pacific Toxicology Laboratories ("PacTox") orchestrated and engaged in a long-running kickback scheme whereby both PacTox and certain referring physicians fraudulently obtained remuneration for laboratory tests, many of which were medically unnecessary.

2. PacTox induced physicians to refer testing for *government-insured* patients by offering remuneration in the form of a reduced per-specimen testing rate for the physicians' *commercially insured* patients, and then allowed and instructed the providers to bill the commercial carriers directly as if the tests had been performed in the providers' offices, even though the providers did not have the equipment needed to conduct those tests. This enabled the physicians to make handsome profits over the laboratory's "loss leader" per-specimen rates. This was the "pass-through" billing scheme.

3. PacTox further induced providers to participate in the scheme by providing free point-of-care ("POC") urine test cups ("POCT cups"), with the

agreement that all specimens collected in those cups would be returned to PacTox laboratory for additional expensive testing, regardless of the POCT result – and with the agreement that the providers could bill for the POC tests.

4. These free POCT cups enabled the physicians to perform and bill commercial insurers for preliminary urine drug screens in their offices at a considerable savings, further enhancing the physicians' bottom lines.

5. PacTox also induced provider to participate in the scheme by providing personnel to act as specimen "collectors" in high-volume offices, thereby relieving those physicians of the need to dedicate their own employees to those duties.

6. This scheme violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS") and the Medi-Cal Anti-Kickback Statute, Cal. Welf. & Inst. Code § 14107.2 (the "Medi-Cal AKS"). Both the claims submitted by the physicians for the test results they "bought" from PacTox at a discount, and the claims that PacTox itself submitted directly to the government plans, were tainted by these AKS violations. Thus, all such claims were fraudulent under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the "FCA") and the California False Claims Act, Cal Gov't Code §§ 12650 *et seq.* (the "California FCA").

7. The scheme also violated the Stark Law, Pub. L. No. 101-239, § 6204, 130 Stat. 2106 (1989) and accompanying regulations, which prohibit an entity such as PacTox from submitting a Medicare claim for any "designated health services" – including laboratory diagnostic testing – rendered pursuant to a referral from a

provider who has a "financial relationship" with the entity. 42 U.S.C. § 1395nn(a)(1)(B); *see also* 42 C.F.R. § 411.353(b).

8. In addition, PacTox explicitly encouraged participating physicians to order unnecessary tests by creating "standing orders" for "custom panels" on file at Pactox. For the physicians' commercially insured patients, the standing order was for full qualitative and quantitative testing on every substance and analyte available to test, and to quantitate or confirm all "negative results" on every patient, every visit.

9. Standing orders for government payers would include the maximum amounts of qualitative and quantitative tests allowed; however, because government payers expressly prohibit confirmation of negative results, such confirmations were not part of the custom panel for which PacTox billed government payers.

10. These standing orders were not based on medical necessity or a patient's individual needs, but were created to maximum reimbursement These panels were intended to encourage physicians to take the easy route and order the same extensive panel of tests on every urine specimen, including those of government-insured patients, regardless of medical necessity.

11. Often, when PacTox received such a panel order, the laboratory would adjust it so that they would perform only tests for which the particular carrier would reimburse – again, without regard to medical necessity – to avoid declinations that might invite unwanted scrutiny.

12. Claims on government insurance programs for tests that are not medically necessary are also false and fraudulent under the FCA and the California FCA (for state insurance programs such as Medi-Cal).

13. Moreover, some tests were improperly "unbundled" – billed to insurances individually when they should have been billed (less expensively) collectively.

14. Beginning in approximately early 2014, PacTox included genetic testing in its pass-through billing scheme.

15. Relator worked as a PacTox Sales Representative from 2010 until 2015. It was her job to service the physician accounts assigned to her, and to market PacTox services to new prospects.

16. Relator worked as an independent contractor, as further explained *infra*.

17. For almost all of her five-year tenure, Relator was paid entirely on commission, calculated as a percentage of PacTox's expected revenues from her accounts' referrals, less certain costs and other deductions.

18. Her compensation thus took into account the volume and value of referrals to PacTox, including referrals of government-insured business.

19. Because she was an independent contractor and not paid a base salary, the commissions paid to Relator for the procurement of government-insured business did *not* fall within the safe harbors for "bona fide employ[ees]," found in both the federal AKS, *see* 42 U.S.C. § 1320a-7b(b)(3)(B), and the Medi-Cal AKS, *see* Cal.

Welf. & Inst. Code § 14107.2(c)(1). All claims upon government insurance programs procured by independent contractors are tainted by this violation and therefore false and fraudulent under the FCA and the California FCA.

20. When Relator began working for PacTox in 2010, she was one of only three Sales Representatives working for the company.

21. On information and belief, as of 2016 PacTox had approximately 350 sales representatives nationwide, all of whom worked (or still work) as independent contractors and were (or are still) paid on a straight-commission basis similar to Relator.

22. Therefore, all claims upon government insurance programs procured by any of these other Sales Representatives were tainted by AKS violations and therefore also false and fraudulent under the FCA and the California FCA.

23. Relator brings this *qui tam* action on behalf of the United States under the FCA to recover treble the damages actually sustained by, and civil penalties and restitution owed to, the United States as a result of Defendant's fraud.

24. Relator also brings this action on behalf of the State of California under the California FCA, and the California Insurance Frauds Prevention Act, Cal. Ins. Code §§ 1871 *et seq*. (the "CIFPA"), to recover treble the damages actually sustained by, and civil penalties and restitution owed to, California and various commercial insurers as a result of Defendant's fraud.

## II.
## JURISDICTION AND VENUE

25. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331, because this action is brought for violations of the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, a federal statute. The Court has jurisdiction of the state-law claims pursuant to 28 U.S.C. § 1367.

26. The Court has personal jurisdiction over Defendant because Defendant (a) is a resident of, or transacts business in, this District; and (b) has carried out its fraudulent scheme in this District.

27. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)(2), because Defendant can be found in, and transacts or has transacted business in, this District, and the events and omissions that give rise to these claims have occurred in this District.

28. The original Complaint was filed within the period prescribed by 31 U.S.C. §§ 3731(b). This First Amended Complaint is filed under seal.

## III.
## NO PUBLIC DISCLOSURE; DIRECT AND INDEPENDENT KNOWLEDGE OF VIOLATIONS OF THE FALSE CLAIMS ACT

29. There has been no public disclosure, relevant under 31 U.S.C. § 3730(e), of the "allegations or transactions" in the original Complaint or this First Amended Complaint. Alternatively, to the extent that any such public disclosure has

been made, Relator possesses information that is independent of and materially adds to any allegations that may have been publicly disclosed.

30. Relator makes the allegations in this First Amended Complaint based on her own knowledge, experience and observations. Relator is the original source of the information on which the allegations herein are based, has direct and independent knowledge of such information, and voluntarily disclosed such information to the United States and California before filing this action.

## IV.
## THE PARTIES

### A. The United States

31. Relator brings this action on behalf of Plaintiff the United States. At all times relevant to this Complaint, the United States, acting through the Centers for Medicare & Medicaid Services ("CMS"), has reimbursed Defendant for the provision of laboratory tests through the Medicare and Medicaid programs. Furthermore, the United States, acting through the Department of Defense, has reimbursed Defendant through the TRICARE program; and acting through the Department of Veterans has reimbursed Defendant through the CHAMPVA program.

### B. The State of California

32. Relator brings this action on behalf of Plaintiff the State of California. California, through its Medicaid program ("Medi-Cal"), has reimbursed Defendant

for the provision of laboratory tests. In addition, private insurers in California have reimbursed Defendant's physician co-conspirators for the provision of laboratory tests, and Relator brings a claim on behalf of California under the CIFPA for fraud upon those private insurers.

**C. Relator**

33. Relator Yvonne Huemoeller is a citizen of the United States and a resident of Maricopa County, Arizona. Relator worked as a Sales Representative for Defendant from approximately December 20, 2010 until September 15, 2015; her territory was the state of Arizona. Prior to that, Relator practiced as an independent licensed psychotherapist.

34. Relator worked for Defendant as an independent contractor.

35. Relator was not a "bona fide employee," for purposes of the AKS and the Medi-Cal AKS.

36. Relator worked as a PacTox Sales Representative from 2010 until 2015. When she entered into her contract with PacTox, Relator had no reason to question the legality of the compensation structure provided to her by PacTox, and had no intent to violate any healthcare or other regulations.

37. During her engagement with PacTox, Relator developed many concerns about the obscure methods by which PacTox determined commission compensation for sales representatives, and about PacTox policy of assigning a percentage of all laboratory expenses to their independent sales representatives.

38. Relator was outspoken about her concerns, and raised them to CEO Jeff Lanzolatta, CFO Neil Patel, and Rana Ostridami on numerous occasions. However, her concerns were dismissed or explained away, and PacTox management assured her that everything about her compensation arrangement and duties was proper. Management's only objective for sales representatives was that they produce new sales.

**D. Defendant**

39. Defendant Pacific Toxicology Laboratories ("PacTox") is a domestic corporation with its principal business address at 9348 De Soto Avenue, Chatsworth, California 91311.[1] PacTox describes itself on its website as "one of the country's leading specialty laboratories."[2]

## V.
## THE LEGAL FRAMEWORK

**A. The Medicare and Medicaid Programs**

40. In 1965 Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for certain healthcare services provided to certain

[1] PacTox has allegedly been involved in previous schemes similar to the one alleged here. In 2017, the California Insurance Commissioner charged 26 physicians and pharmacists in a kickback scheme. Although PacTox was not charged, it was alleged that some of the defendant physicians in that case paid PacTox "a flat rate of $60 per test and [billed] the insurance carriers hundreds of dollars per patient." *See* "$40M Workers' Comp Medical Kickback Operation in California Shut Down," Insurance Journal (Apr. 20, 2017), https://www.insurancejournal.com/news/west/2017/04/20/448555.htm (last accessed Jan. 5, 2022).

[2] https://www.pactox.com/ (last accessed Jan. 5, 2022).

segments of the population. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 1395 *et seq*.

41. The federal Department of Health and Human Services, through CMS, administers the Medicare program. Certain commercial insurers also administer Medicare managed-care or "Advantage" plans.

42. Part B of the Medicare program authorizes payment for outpatient services, including diagnostic testing of the sort at issue here.

43. CMS enters into agreements with healthcare providers such as Defendant to establish their eligibility to participate in the Medicare program. Entities that are participating providers in Medicare may seek reimbursement from CMS for services rendered to patients who are Medicare beneficiaries.

44. To enroll as an authorized participant in Medicare, a laboratory like Defendant is required to make the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply …. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Statute …).

Medicare Enrollment Application: Clinics/Group Practices and Other Suppliers, CMS-855B, at 30.[3]

[3] *Available* at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855b.pdf (last accessed Jan. 5, 2022).

45. On information and belief, at all times relevant herein, PacTox has been an enrolled Medicare provider.

46. In order to be reimbursable by Medicare, services must, *inter alia*, be medically necessary, and must be documented in a manner that allows CMS to determine if the services are properly payable. *See* 42 U.S.C. § 1395y(a)(1)(A). Each patient's need for each test must be individually assessed and documented in the patient's medical record. 42 C.F.R. §§ 410.32(a), (d)(2).

47. Compliance with applicable Medicare program rules and regulations is material to the government's decision to pay and its subsequent payment of claims.

The Medicare Claims Process

48. In order to receive reimbursement from Medicare, providers must submit a claim form. *See* Form CMS-1500.[4] That claim form requires the provider to make the following certification:

> In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete ... 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) **this claim ... complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment [and] … 5) the services on this form were medically necessary ….**

[4] *Available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1500.pdf (last accessed Jan. 5, 2022).

*Id.*, at 2 (emphasis added).

49. A provider may also submit the electronic equivalent of this claim form, which contains a substantially similar certification.

50. CMS guidance as to electronic claims submission is found in Chapter 24 of the Medicare Claims Processing Manual, CMS Publication No. 100-04 (the "Claims Manual").[5] Among other things, the guidance specifies the minimum content of the enrollment form that a local Medicare Administrative Contractor or "MAC"[6] may use to sign up providers to submit claims electronically. Per the Claims Manual, such an enrollment form must contain, and the enrolling provider must acknowledge, at least the following statements:

> The provider agrees to the following provisions for submitting Medicare claims electronically to CMS or to CMS' A/B MACs or CEDI:
>
> * * *
>
> 7. That it will submit claims that are accurate, complete, and truthful;
>
> * * *
>
> 12. That it will acknowledge that all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare program, and that anyone who misrepresents or falsified

[5] *Available at* https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c24.pdf (last accessed Jan. 5, 2022).

[6] A MAC is a private insurer awarded a geographic jurisdiction to process medical claims for Medicare beneficiaries. MAC jurisdictions can be found at https://www.cms.gov/files/document/macs-state-jun-2021.pdf (last accessed Jan. 5, 2022). The current MAC for Defendant's jurisdiction is Noridian Healthcare Solutions, LLC.

> or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law; [and]
>
> * * *
>
> 14. That it will research and correct claim discrepancies[.]
>
> * * *

Claims Manual, Chapter 24 § 30.2.

51. The submission of such a certification, if false, renders all subsequent claims false and fraudulent under the FCA. 31 U.S.C. § 3729(a).

52. Each such claim is a separate violation of the FCA.

The Medicaid Program

53. Congress enacted Medicaid under Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq*. The program is jointly funded by the federal and state governments to provide health care to certain groups, primarily the poor and the disabled. *See* 42 C.F.R. §§ 430.0 *et seq*.[7]

[7] Because Medicaid is partly funded by the federal government, the United States has a cause of action under the federal FCA for false claims made to state Medicaid programs. *See, e.g., Hays v. Hoffman*, 325 F.3d 982, 988 (8th Cir. 2003) ("When Congress amended the FCA in 1986, it defined 'claim' to include requests for money made to grantees of the federal government. The legislative history explained this was done to clarify that false claims for FCA purposes include claims submitted to state agencies under the Medicaid program and other State, local, or private programs funded in part by the United States where there is significant Federal regulation and involvement.") (internal citation and quotation marks omitted; citing S. Rep. No. 99-345 at 22, 1986 U.S.C.C.A.N. at 5287); *Kane ex rel. United States v. Healthfirst, Inc*., 120 F. Supp. 3d 370, 396 (S.D.N.Y. 2015) ("Congress has repeatedly and specifically provided that claims submitted to Medicaid constitute false claims for the purposes of the FCA.") (citing, *inter alia*, S. Rep. No. 111-10, at 11, 2009 U.S.C.C.A.N. at 438, explaining that the 2009 Fraud Enforcement and Recovery Act clarified that "the FCA reaches all false claims submitted to State administered Medicaid programs.").

54. Under the Medicaid program, the federal government pays a specified percentage of each state's Medicaid program expenditures (the federal medical assistance percentage, or "FMAP"). *See* 42 U.S.C. § 1396d(b). In FY 2021, Arizona's FMAP was 76.21%, and California's was 56.20%. In FY 2012, the two states had FMAPs of 67.30% and 50.00%, respectively.

55. The Medicaid program in Arizona is administered by the Arizona Health Care Cost Containment System ("AHCCCS").[8] California's Medicaid program is administered by Medi-Cal. In both states, various private insurers provide and administer different Medicaid plans, including Medicaid Managed Care Organizations ("MCOs").

56. Each state's Medicaid agency sets its own specific requirements for provider enrollment, but all states – including Arizona and California – require providers to certify on enrollment and upon the submission of claims that they will comply with all applicable federal and state laws and regulations.

57. On information and belief, at all times relevant herein, PacTox has been an enrolled provider for the Medicaid programs of Arizona and California.

[8] Pronounced "access."

**B. TRICARE, CHAMPVA, and the FEHB Program**

58. The federal government pays for healthcare provided to U.S. military personnel (both active and former) and their dependents through the TRICARE and CHAMPVA programs.

59. TRICARE is a program of the Department of Defense, covering active-duty and most retired military personnel and their dependents or survivors. It was established to provide "a comprehensive managed health care program for the delivery and financing of health care services in the Military Health System." 32 C.F.R. § 199.17.

60. The TRICARE program includes "TRICARE for Life," which provides "Medicare-wraparound coverage for TRICARE-eligible beneficiaries who have Medicare Part A and B." TRICARE for Life is secondary to Medicare coverage.

61. The Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA") covers the civilian dependents or survivors of disabled veterans.

62. Urine drug testing, when ordered by a doctor, is covered by both TRICARE and CHAMPVA.

63. TRICARE network providers must be enrolled Medicare providers, 32 C.F.R. § 199.17(p)(4)(iv), and therefore must make the certifications and acknowledgments set out in paragraphs 48-52, *supra*.

64. On information and belief, during all times relevant herein, PacTox has been a network provider for TRICARE and/or TRICARE for Life.

65. TRICARE considers billing practices to be fraudulent in cases including (a) unbundling services to increase reimbursement, (b) misrepresenting the identity of the person who rendered the service, and (c) overutilization of services. *See* 32 C.F.R. § 199.9(c).

66. The CMS-1500 is acceptable for submitting claims to CHAMPVA.

67. On information and belief, at all times relevant herein, Defendant has been an enrolled CHAMPVA provider and has submitted claims to that program using the CMS-1500 or its electronic equivalent.

68. The Federal Employees Health Benefits ("FEHB") Program, which is administered by the federal Office of Personnel Management, provides healthcare benefits for qualified federal employees and their dependents. FEHB plans are provided by private insurers but are subsidized in part by the federal government. *See* 5 U.S.C. §§ 8901 *et seq*.

69. Like the other programs discussed herein, the FEHB Program does not cover medically unnecessary services or devices. *See id*., § 8902a(c)(4) (billing for medically unnecessary services or supplies a basis for provider debarment).

70. The Medicare, Medicaid, TRICARE, CHAMPVA, and FEHB Programs described *supra* are referred to herein collectively as "Government Insurance Programs."

**C. The Federal False Claims Act**

71. As pertinent here, the federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the "FCA"), establishes treble damages liability for any "person" (natural or corporate) that:

> (A) knowingly presents, or causes to be presented [to an officer, employee, agent, contractor, or grantee of the United States], a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to [such] a false or fraudulent claim; [or]
>
> (C) conspires to commit a violation of subparagraph (A) [or] (B)[.]

31 U.S.C. § 3729(a)(1).

72. A claim upon a Government Insurance Program is a "claim" for purposes of the FCA.

73. "Knowing" is defined in the FCA to include "deliberate ignorance of the truth" or "reckless disregard of the truth." *Id.* § 3729(b)(1).

74. For each false claim or other FCA violation, the FCA provides for the assessment of treble damages, plus a civil penalty.[9]

[9] 31 U.S.C. § 3729(a)(1) provides 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.

75. The FCA also provides for payment of a percentage of the United States' recovery to a private individual who brings suit on behalf of the United States (the "relator") under the FCA. *See* 31 U.S.C. § 3730(d).

**D. The Federal Anti-Kickback Statute**

76. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), (the "AKS") prohibits, *inter alia*, the offering or paying of anything of value to induce the referral of business for which payment may be made by a Government Insurance Program.

77. A violation of the AKS is, in turn, a violation of the FCA. *See* 42 U.S.C. § 1320a-7b(g) ("[A] claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]").

78. The AKS includes a safe harbor for payments to "bona fide employ[ees]" for procuring referrals of business that may be reimbursed by a Government Insurance Program. *See* 42 U.S.C. § 1320a-7b(3)(b) (exempting from the reach of the AKS any payments "by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services").

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§ 2461 note; Public Law 104-410). The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, 28 U.S.C. § 2461 note, substituted a different statutory formula for calculating inflation adjustments on an annual basis. For violations committed after November 2, 2015, the minimum penalty is currently $11,803 and the maximum is $ 23,607 (both per claim), for penalties assessed after December 13, 2021.

79. A "bona fide employment relationship" is generally characterized by a high degree of control by the employer over the employee's activity, and by an hourly or salaried wage. In contrast, an independent contractor is paid per job or on commission; has substantial control over and responsibility for her own schedule and activities; pays any other workers she might supervise; and may concurrently perform work for others.

80. "[P]ayment on straight commission suggests the worker is an independent contractor." *U.S. v. Porter*, 569 F. Supp. 2d 862, 874 (S.D. Iowa 2008); *see also Murray v. Principal Fin. Grp., Inc.*, 613 F.3d 943, 946 (9th Cir. 2010) (finding "strong factors" indicating independent contractor status where, among other things, worker was "paid on commission only").

81. Kickbacks, in turn, raise four major concerns for federal healthcare programs: (a) corruption of medical judgment, (b) overutilization, (c) increased costs to the federal healthcare programs and beneficiaries, and (d) unfair competition. Dep't of Health and Human Services, Office of Inspector General, "Special Fraud Alert: Laboratory Payments to Referring Physicians," June 25, 2016, at 2.

82. Because it is paying for healthcare services free of these concerns, the "government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback." *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011). AKS compliance is thus a fundamental aspect of what

the government purchases when it pays for medical care for federally insured beneficiaries.

83. "[T]he Standard Medicaid Provider Application, the Standard Medicare Provider Agreement, and the Claim Form 1500 used for submission of Medicare, Medicaid, and TRICARE/CHAMPUS claims … require compliance with 'applicable Federal or State laws,' a universe that plainly encompasses the AKS. ... Indeed, the conclusion that [AKS] compliance is a precondition of payment is rendered inescapable when the purpose of the [AKS] is considered within the context of these healthcare statutes." *U.S. ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 817 (S.D.N.Y. 2017), *rev'd on other grounds*, 899 F.3d 163 (2d Cir. 2018) (internal quotation marks omitted).

84. "[T]he only reasonable inference is that AKS violations are *per se* material." *U.S. ex rel. Lutz v. Berkeley Heartlab, Inc.*, No. 9:14-230-RMG, 2017 U.S. Dist. LEXIS 198727, at *5-6 (D.S.C. Dec. 4, 2017).

**E. The Stark Law**

85. The Stark Law, Pub. L. No. 101-239, § 6204, 130 Stat. 2106 (1989), and accompanying regulations prohibit an entity such as PacTox from submitting a Medicare claim for any "designated health services"[10] rendered by the entity

[10] "Clinical laboratory services" are a designated health service under the Stark Law and its regulations. 42 CFR § 411.351

pursuant to a referral from a provider who has a "financial relationship" with the entity. 42 U.S.C. § 1395nn(a)(1)(B); 42 C.F.R. § 411.353(b).

86. The statute and regulations also prohibit Medicare from paying such claims, 42 U.S.C. § 1395nn(g)(1); 42 C.F.R. § 411.353(c), and require an entity that receives payment for such a claim to reimburse such funds to the United States, 42 C.F.R. § 411.353(d).

87. For Stark Law purposes, a "financial relationship" includes "any arrangement involving any remuneration between a physician … and an entity," 42 U.S.C. § 1395nn(h)(1)(A), where "remuneration" includes "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. § 1395nn(h)(1)(B); *see also* 42 C.F.R. § 411.351.

88. Courts have construed "remuneration" under the Stark Law to include the opportunity to earn a fee. *See, e.g.*, *U.S. v. Bay State Ambulance and Hospital Rental Co.*, 874 F.2d 20, 26 (1st Cir. 1989).

89. Courts have also held that Point-of-Care ("POC") testing cups ("POCT cups") can be remuneration for purposes of the Stark Law, when provided for free or at a discount by a laboratory to providers who refer government business to the laboratory. *See, e.g.*, *Ameritox, Ltd. v. Millennium Labs., Inc.*, No. 8:11-cv-775-T-24-TBM, 2014 U.S. Dist. LEXIS 127983, at *6-7 (M.D. Fla. Sep. 12, 2014) ("Ameritox showed, and the jury accepted, that Millennium's provision of free POCT cups was

simply an improper way to induce referrals, [and as such] it was a violation of the AKS and Stark Law.").[11]

90. Providers are required by Medicare and Medicaid to certify their compliance with the Stark Law when enrolling and when submitting claims.

**F. The California False Claims Act**

91. The California FCA is substantially similar to the federal FCA, and provides liability for any person who:

> (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.
>
> (2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim.
>
> (3) Conspires to commit a violation of this subdivision.

Cal. Gov't Code § 12651(a).

92. The California FCA defines "knowing" to include deliberate ignorance and reckless disregard of the truth or falsity of information. *Id*. § 12650(b)(3).

93. The California FCA defines a "claim" to include any request for money, property, or service that:

> (B) Is made to a contractor, grantee, or other recipient, if the money, property, or service is to be spent or used on a state or any political subdivision's behalf or to advance a state or

[11] *See also* OIG Special Fraud Alert: Laboratory Payments to Referring Physicians, at 2 (Jun. 25, 2014) ("[W]henever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business.") (quoting OIG Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services (Oct. 1994), *reprinted at* 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994)).

> political subdivision's program or interest, and if the state or political subdivision meets either of the following conditions—
>
> > (i) Provides or has provided any portion of the money, property, or service requested or demanded.
> >
> > (ii) Will reimburse such contractor, grantee, or other recipient for any portion of the money, property, or service which is requested or demanded.

*Id*. § 12650(b)(1). A claim upon Medi-Cal is a "claim" for purposes of the California FCA.

94. Any person violating any of these provisions is liable for a civil penalty of not less than $11,665 and not more than $ 23,331 for each violation, plus treble damages. *Id* § 12651(a).[12]

**G. The California Insurance Fraud Prevention Act**

95. The CIFPA prohibits the knowing employment of persons to procure clients or patients to perform or obtain services or benefits under a contract of insurance. *See* Cal. Ins. Code § 1871.7(a).

96. Furthermore, the CIFPA establishes civil liability for violations of Cal. Pen. Code §§ 549, 550, or 551, which criminalize various forms of insurance fraud.

97. Cal Pen. Code § 549 makes it illegal to solicit, accept, or refer any business to or from any entity with the knowledge that, or with reckless disregard for whether, the entity intends to violate Cal Pen. Code § 550.

[12] As adjusted by the Federal Civil Penalties Inflation Adjustment Act; *see id*.; *see also* n.9, *supra*.

98. Cal. Pen. Code § 550 provides, in pertinent part, that:

> (a) It is unlawful to do any of the following, or to aid, abet, solicit, or conspire with any person to do any of the following:
>
> * * *
>
> (5) Knowingly prepare, make, or subscribe any writing, with the intent to present or use it, or to allow it to be presented, in support of any false or fraudulent claim.
>
> (6) Knowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit.
>
> * * *
>
> (b) It is unlawful to do, or to knowingly assist or conspire with any person to do, any of the following:
>
> (1) Present or cause to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.
>
> (2) Prepare or make any written or oral statement that is intended to be presented to any insurer or any insurance claimant in connection with, or in support of or opposition to, any claim or payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.

99. For each violation of the CIFPA, California assesses a civil penalty of not less than $5,000 and not more than $10,000, plus an assessment of not more than three times the amount of each claim. *See* Cal. Ins. Code § 1871.7(b).

100. The CIFPA also provides for payment of a percentage of California's recovery to a relator who brings suit on behalf of California. *See id.* § 1871.7(g).

## H. The Medi-Cal Anti-Kickback Statute

101. The Medi-Cal Anti-Kickback Statute (the "Medi-Cal AKS") is substantially similar to the federal AKS. In relevant part, the Medi-Cal AKS establishes criminal liability for "[a]ny person who offers or pays … any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in valuable consideration of any kind" either in return for the referral of, or to refer, "any individual to a person for the furnishing … of any service … for which payment made be made, in whole or in part, under [Medi-Cal] …." Cal. Welf. & Inst. Code § 14107.2.

102. The Medi-Cal AKS contains a safe harbor similar to that in the federal AKS. *See id.*, subsection (c)(1) (stating that the Act does not create liability for payments "by an employer to an employee, who has a bona fide employment relationship with that employer").

103. To participate in Medi-Cal, a provider must sign an agreement to comply with applicable state and federal laws, including the Medi-Cal AKS. The agreement is a representation of compliance. By violating the Medi-Cal AKS, a provider renders such representation false and thereby violates the CFCA.

## VI.
## DEFENDANT'S FRAUD

104. Defendant's fraud begins with its agreements – with Relator and her fellow Sales Representatives on the one hand, and with the physicians who participated (and participate) in the scheme on the other.

105. Relator and her fellow Sales Representatives were independent contractors for PacTox.

106. Their work procuring government business for PacTox – tests on specimens provided by beneficiaries of Medicare, Medicaid, TRICARE, and other Government Insurance Programs, including those programs administered by private commercial insurers – was therefore in violation of the AKS and the Medi-Cal AKS, and any claims submitted to these Government Insurance Programs by PacTox were therefore tainted by those violations, and false and fraudulent for purposes of the FCA and the California FCA.

107. PacTox obtained its government business from participating providers by offering them inducements, including: (a) the right to obtain a fee on non-government-insured tests, after buying them back from PacTox at "loss leader" prices (the "pass through" scheme); (b) free POCT cups; (c) the free services of collectors (whose wages were paid by PacTox, in part from deductions from Sales Representatives' commissions); and (d) in some cases, debt forgiveness. These inducements also violated the AKS and the Medi-Cal AKS, tainting all claims that

PacTox submitted to the government and rendering them false and fraudulent for purposes of the FCA and the Med-Cal AKS.

**A. Relator and Other PacTox Sales Representatives Were Commission-Paid Independent Contractors and Not Bona Fide Employees**

108. In 2010, PacTox recruited Relator as the sales representative for the Arizona region.

109. She worked for PacTox in that position, as an independent contractor, until she separated from the company in 2015.

110. **Exhibit A** is a copy of PacTox's "Sales Executive Incentive Compensation Program," signed by Relator on December 20, 2010. The document explicitly states that it is intended to "define the entire compensation amount that may be earned by a PACTOX Sales Executive participating in the Program." *See id.*, § 1.0.

111. The "Sales Executive Incentive Compensation Program" defined Relator's compensation as a percentage of PacTox's net revenues from her accounts, discounted for "Bad Debt experienced by PACTOX" and certain disallowances, less certain costs. *Id.*, at §§ 3.0, 4.0.

112. Although PacTox changed her actual percentage from time to time, Relator was paid *only* by commission during her entire tenure at PacTox, except during the last three months of 2012. *See* **Exhibit B**, which states that for those months, Relator's "compensation plan … would be a combination of $3200

guarantee per month plus commission amount calculated based on your current Sales Employment Agreement." Conspicuously absent is any mention of a base salary *other than* this special, short-term guarantee.

113. Nowhere else does the "Program" reference any base salary or other compensation that Relator would receive in addition to the "incentive compensation payments" set out therein.

114. In other words, Relator's pay throughout her tenure with PacTox was determined in a manner that took into account the volume or value of referrals generated between the Physicians and PacTox, because the net revenues on which her commission was based rose and fell depending on referrals, including referrals of government business, that PacTox received from her accounts.

115. Other sales representatives were paid similarly. *See*, *e.g.*, **Exhibit C**, the employment agreement for a different PacTox sales representative, dated October 10, 2014, showing she was to be paid a 15% commission on her accounts' "client bill revenues" – that is, revenues from the tests her accounts "bought back" from PacTox – with a "$5000.00 bonus after 1st 500" specimen cups were sent by each account to PacTox for testing.

116. "[P]ayment on straight commission suggests the worker is an independent contractor." *U.S. v. Porter*, 569 F. Supp. 2d 862, 874 (S.D. Iowa 2008); *see also*, *e.g.*, *Murray v. Principal Fin. Grp., Inc.*, 613 F.3d 943, 946 (9th Cir. 2010).

117. Numerous other aspects of Relator's work for PacTox make clear that she was an independent contractor and not a bona fide employee. For instance, Relator:

a. was given only minimal training by Defendant;

b. had to develop her own leads, and was not provided any by Defendant;

c. had complete control over her territory;

d. had complete control over her work schedule;

e. was required to pay (in the form of deductions from her commissions) part of the wages of PacTox employees who worked at some of her higher-volume accounts as "collectors"; and

f. received no employee benefits (paid time off, 401-K, insurance, etc.).

118. Importantly, Relator worked concurrently for several compounding pharmacies as an independent contractor sales representative at the same time she worked for PacTox. Relator engaged in this other work with the full knowledge and acquiescence of PacTox management, including Lanzolatta.[13]

119. **Exhibit D** is a February 2014 email exchange in which Relator wrote to confirm with Lanzolatta that continuing such work would not be a breach of her contract with PacTox. In his reply, Lanzolatta ensured her that such other work would not breach her contract, and commented that "*If you were a full time salaried* employee it might be a different situation." *Id.* (emphasis added).

[13] Relator was in fact introduced to some of these compounding pharmacies by Lincoln Maxwell, who was at the time National Sales Director for PacTox.

120. Such concurrent work is an indicator that a worker is an independent contractor, even if certain formal aspects of the relationship indicate otherwise.

121. Relator was not a "bona fide employee" as that term is defined in 26 U.S.C. § 3121(d)(2); by applicable precedent; or under the 20-factor test used by the Internal Revenue Service. *See* Rev. Rul. 87-41 (1987 IRB LEXIS 254, at *11).

122. When Relator began working for PacTox in 2010, the laboratory had only three sales representatives nationwide.

123. On information and belief, as of 2016 PacTox had approximately 350 sales representatives nationwide.

124. On information and belief, these sales representatives were and are also independent contractors, paid in a similar manner as Relator was paid.

125. Thus, all claims submitted by PacTox for government business procured by any and all of its Sales Representatives nationwide were and are tainted by the AKS and Medi-Cal AKS violations caused by their employment status and pay arrangement. Any and all such claims are therefore false and fraudulent for purposes of the FCA and, as applicable, the California FCA.

**B. The Pass-Through Billing Scheme**

126. Part of Relator's job was to "educate" physicians about PacTox's toxicology and genetic testing services, including the purported benefits of the pass-through billing model, and to sign them up for the plan.

127. Relator was encouraged and incentivized by PacTox upper management, including CEO Jeff Lanzolatta, who did not direct her but who did monitor her progress carefully.

The agreements with physicians

128. Once a doctor or a practice was interested in using PacTox for urine screening and testing, that provider would be offered a "Laboratory Services Agreement."

129. PacTox contracted with at least the following physicians and practices to participate in the pass-through billing scheme: Advanced Medical Center; Dependency Relief Specialists; Gregory Ellison, M.D.; twelve locations of Pain Stop Clinics LLC; Quality of Life Medical & Research Center; Rehab Arizona, LLC; and Scottsdale Treatment Institute (collectively herein, the "Physicians").

130. **Exhibit E** is a contract, signed by CEO Lanzolatta on behalf of PacTox and offered by PacTox to Rehab Arizona in 2013.

131. **Exhibit E** is typical of the PacTox agreements. Under the contract, PacTox agrees to "provide SERVICES for the benefit of the patients" of Rehab Arizona; to provide to the practice "the supplies needed for the collection and submission of specimens" to PacTox; and to assign to the practice "certain Claims," namely commercial insurance claims, for Rehab Arizona to bill for its own profit. *Id.*, § 1.

132. In return, Rehab Arizona agrees to pay PacTox $100 per specimen tested, *see id.*, § 4,[14] regardless of how many tests are run. This gives the practice an obvious incentive to order unnecessary tests on those "certain Claims" it is assigned (the commercial insurance claims) in order to make as much profit as possible over and above their fixed costs of $100 per specimen.

133. The contract is careful to state that the laboratory's per-specimen fees are "fixed and set in advance for one year and are not tied to referral volume of ANY [*sic*] in any manner." *Id.* But the contract takes equal care to elide the fact that PacTox is also being paid by receiving Rehab Arizona's referrals of government business – the claims that remain after PacTox assigns the commercial claims. *See* **Exhibit F** (instructions to collectors on how to document referrals to PacTox, in effect in 2014, noting that the collector is to choose "Client" on the form "when the Doctor's office will be submitting the lab bill to the patient's ins company," and that "*PacTox bills all Medicare or Medicaid specimens*") (emphasis added).

134. **Exhibit G** is a contract provided by PacTox to Ameyer Medical Practice in 2014. This is substantially similar to the Rehab Arizona contract described *supra*, except that PacTox was to charge this practice $130 per specimen *if*

[14] The contract refers to "Qualitative/Quantitative Group." *Id.*, last page. Urine drug tests fall into two categories: qualitative (or presumptive) and quantitative (or confirmatory). Qualitative testing indicates only the presence or absence of a tested substance and is relatively inexpensive. Quantitative testing, in contrast, is able to discern the amount that is present of a tested substance and is generally ordered only when the qualitative test returns an unexpected positive result.

the practice were to cover the cost of a collector for the processing of up to 200 specimens per month, or would charge $150 per specimen but "provide a collector to process the specimens." *Id.*, at last page (noting that the collector's wages "can only be paid … through the staffing agency designated by PacTox").

135. **Exhibit H** is a contract substantially similar to the two just described, entered into by PacTox and Scottsdale Treatment Institute on or about April 6, 2015. By then – two years after the Rehab Arizona agreement – the laboratory's per-specimen charge had risen to $130. *See id.*, last page.

The pass-through scheme

136. In their Laboratory Services Agreements, the Physicians agreed to refer urine specimens to PacTox for drug testing.

137. After PacTox completed the testing on the referred specimens, the Physicians "bought" the test results back from PacTox for patients enrolled in commercial insurance plans, paying PacTox a flat "loss leader" amount per specimen.

138. The Physicians then billed the commercial insurers for those tests. With the knowing collaboration of PacTox, the Physicians submitted claims and documentation falsely stating that the tests had been performed at their own offices,

even though at least some of their offices did not have the equipment needed to perform the tests.[15]

139. PacTox generally charged the Physicians between $50 and $150 per patient specimen for the tests the laboratory ran.

140. This was substantially lower than the reimbursement the Physicians received from the insurance plans.

141. The Physicians thus made handsome profits by means of the pass-through scheme. *See* **Exhibit I**[16] (PacTox invoice to Scottsdale Treatment Institute, dated June 30, 2015, showing $75 per-specimen charges, with handwritten notes[17] indicating insurance payments; also showing profits on some specimens of more than 300%). These substantial and unearned profits induced the Physicians to refer tests to PacTox rather than to other laboratories, and to order unnecessary testing.

142. In return, PacTox was able to bill for and collect reimbursements for tests on patients enrolled in Government Insurance Plans like Medicare, Medicaid, TRICARE, and CHAMPVA; and in managed-care plans administered for the government by commercial insurers.

[15] In fact, clients were instructed by PacTox CFO Neil Patel and others to fill out their claim forms as if the testing had been performed at the practice. Claims that were denied were forwarded to PacTox to bill. PacTox entered its own address on these re-bills, indicating that the tests had been performed at PacTox, and submitted the claims to commercial insurers for reimbursement. PacTox then paid any reimbursements it received on these re-bills to the originating clients.

[16] Identifying information redacted; highlighting added.

[17] The notes were written by Scottsdale Treatment Institute personnel.

Exemplar claims

143. **Exhibit J** is a non-exhaustive compilation of data from claims for tests performed by PacTox on specimens referred by Relator's accounts, and submitted by PacTox to Government Insurance Plans, including government plans administered by commercial insurers, during the period 2013-2015. The data are taken from spreadsheets provided by PacTox to Relator to help keep track of commissions.

144. Similarly, **Exhibit K** is a non-exhaustive compilation of data from claims for tests performed by PacTox on specimens referred by Relator's accounts, and submitted by PacTox to Medi-Cal carriers in California, during the period 2014-2015.

145. As described *supra*, all of the claims represented in **Exhibits J** and **K** were submitted by PacTox in violation of the AKS – and, where applicable, the Medi-Cal AKS – and are therefore false and fraudulent for purposes of the FCA and the California FCA.

146. Many of the claims are also false and fraudulent in that the testing was medically unnecessary.

147. For instance, a very large number of these exemplar claims include separate qualitative screens for five different tricyclic anti-depressants ("TCAs"): amitriptyline (CPT code 80152), desipramine (80160), doxepin (80166), imipramine (80174), and nortriptyline (80182). *See*, *e.g.*, **Exhibit J** at n.1 (claim submitted by PacTox to Noridian Healthcare Solutions for $367.07, referred to PacTox by

Advanced Medical Center, for account number 35 ****688, with a date of service of January 6, 2014). Each TCA screen was billed at between $20.72 and $23.93.

148. Such screens were not medically necessary since the compounds present a low risk of abuse or diversion because (a) the drugs do not produce the "high" that most drug abusers seek[18] (making it unproductive to test for unexpected positive results), and (b), conversely, because it is very unlikely that any one patient would be prescribed all five TCAs at one time (making it pointless to test for unexpected negatives *on all five*). And yet, Defendant's own records show that PacTox frequently tested government-insured patients for all five of these TCAs at once. *See* **Exhibit J**, *passim*.

PacTox's knowledge

149. PacTox's upper management were the architects of the pass-through billing scheme, and knowingly promoted and maintained it.

150. PacTox CEO Jeff Lanzolatta signed all contracts with providers. *See* **Exhibits E**, **G** and **H**.

151. Lanzolatta actively participated in the recruitment of new providers into the pass-through billing scheme. For example, in February 2014 Lanzolatta wrote to Rehab Arizona, a then-new account, with "talking points" about how to get the

[18] *See, e.g.*, www.addictioncenter.com/stimulants/antidepressants/ (last accessed Jan. 6, 2022).

practice senior management "all on the same page" regarding transitioning to PacTox, including:

a. "This is a good business decision for Rehab Arizona, your staff will feel your enthusiasm, *they don't need to know the details of the arrangement*, but they will feel your excitement"; and

b. "PacTox will provide onsite employees/collectors during and after the transition as needed to assure superior service levels."

152. Lanzolatta also took steps to make sure that, once onboarded, a client physician or practice remained happy and would continue to use PacTox. For example, he was part of an email discussion in June 2014 about a client who had compared their "returns" on "the testing they are buying and re-billing" from PacTox to the returns of other PacTox clients in Arizona, and was complaining because their returns were somehow lower.

153. As another example, Lanzolatta personally wrote on June 8, 2015, to try to mollify a doctor who had left PacTox when the laboratory stopped providing POCT cups for free.[19] Lanzolatta wrote that PacTox should "have been in better communication with you to lower the client bill fee for the tests you buy from us to absorb the change," and promised to "work personally with you on this to eliminate

[19] This change was apparently prompted by PacTox becoming aware of the 2014 verdict in *Ameritox, Ltd. v. Millennium Labs.*, in which a jury in the Middle District of Florida agreed with Ameritox "that Millennium's provision of free POCT cups was simply an improper way to induce referrals, as it was a violation of the AKS and Stark Law." *Id.*, No. No. 8:11-cv-775-T-24-TBM, 2014 U.S. Dist. LEXIS 127983, at *6-7 (M.D. Fla. Sep. 12, 2014), *rev'd on other grounds by Ameritox, Ltd. v. Millennium Labs., Inc.*, 803 F.3d 518 (holding district court's exercise of supplemental jurisdiction to be an abuse of discretion).

the impact of the change on your practice if the new lab does not live up to your expectations."

154. When he wrote that email, Lanzolatta had in fact already been aware for some time of at least one legal opinion raising serious concerns about a similar free-cup program and pass-through billing scheme. In approximately late 2011 or early 2012, Lanzolatta forwarded to Relator and others a 2010 legal opinion obtained by an unrelated company with a similar billing scheme.[20] The document is attached here as **Exhibit L**.

155. The opinion notes that "government enforcement officials have long taken the position that the 'swapping' of client bill discounts for Medicare or Medicaid referrals" – a succinct description of the PacTox pass-through scheme – "implicates the [A]nti-[K]ickback [S]tatute," *id.*, at 1.[21] The writer concludes by opining that "federal enforcement officials likely would consider these arrangements to violate the [A]nti-[K]ickback [S]tatute, thus providing a basis for criminal prosecution of both the laboratory and the physicians as well." *Id.*, at 2.

156. Despite Lanzolatta having this damning legal opinion, PacTox continued to actively engage in and promote the pass-through billing scheme.

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[20] *See id.* ("[W]e understand that in an attempt to acquire new business, certain [Urine Drug Testing] laboratories recently have begun offering physicians the opportunity to contractually purchase testing from the laboratory at a discount for their commercially insured patients under a written or oral agreement that then permits the physicians to re-bill that testing to insurers at a substantial profit.").

PacTox cannot rely on the Physicians' "determinations" of medical necessity

157. PacTox also knew that many of the tests for which it was billing were medically unnecessary.

158. "[A] laboratory … is permitted to rely on the ordering physician's determination that the laboratory tests billed to Medicare are medically necessary"; however, FCA liability may lie where a laboratory "engage[s] in a scheme to encourage … physicians to order medically unnecessary tests through[, *inter alia*,] preprinted test requisition forms."[22]

159. PacTox provided the Physicians with preprinted requisition forms, *see, e.g.*, **Exhibit M**. And, as detailed *infra*,[23] PacTox actively encouraged the Physicians to order as many different tests as possible, both qualitative and quantitative, and to code them for billing in such a way as to maximize profit for both the practices and PacTox – without any particular regard for medical necessity. PacTox cannot therefore "rely on the ordering physician's determination that the laboratory tests billed to Medicare are medically necessary," because that "determination" was itself usually fraudulent, which PacTox knew and in fact encouraged.

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[22] *U.S. v. Boston Heart Diagnostics Corp.*, 296 F. Supp. 3d 155, 165 (D.D.C. 2017); *see also U.S. ex rel. Lutz v. Lab. Corp. of Am. Holdings*, No. 9:14-cv-3699-RMG, 2019 U.S. Dist. LEXIS 7486, at *7 (D.S.C. Jan. 15, 2019) (FCA liability may lie "where a laboratory engages in a scheme to encourage physicians to order medically unnecessary tests") (quoting *Boston Heart*, at 165 (cleaned up))*; and see* HHS OIG Guidance, 63 Fed Reg. 45,076, 45,079-080 (stating that laboratories should, *inter alia*, "construct requisition forms to promote conscious ordering of tests by physicians, and review coding").

[23] *See* discussion of "custom panels," ¶¶ 164-170.

160. As David Gee of the law firm Davis Wright Tremaine, LLP publicly observed in a PowerPoint presentation for the 2017 California Clinical Laboratory Association's Annual Conference, "Labs must be prepared to support the medical necessity of their testing."[24]

161. And in fact, Medicare regulations expressly state that a laboratory's claim 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).

162. Yet PacTox did nothing to ensure that the testing it performed for the Physicians was medically necessary. PacTox knew that, or deliberately ignored or recklessly disregarded whether, "medical necessity" was lacking when Physicians used the laboratory's pre-printed requisitions and "custom panels" to order qualitative and quantitative tests.

## C. Medically Unnecessary Testing

163. To maximize reimbursements, PacTox and its co-conspirator Physicians (a) tested for substances unlikely to be present; (b) needlessly performed confirmation testing following "expected negative" qualitative results; and (c) initiated "standing orders" for urine drug screens on every patient, regardless of medical necessity.

[24] David Gee, Esq., "Lions and tigers and bears! Oh my! A Fraud and Abuse Update," *available at* www.ccla.info/uploads/1/2/3/0/12309172/david_gee.pptx, at slide 30 (last accessed Jan 4, 2022).

164. PacTox provided the Physicians with a customized drug panel form to help them create standing orders for qualitative and quantitative testing for all their patients. *See* **Exhibit N**, PacTox Request for Qualitative/Quantitative Custom Group form, signed by Dr. Gregory Ellison and dated March 15, 2015.

165. Using this form, the provider set up a "custom" panel for ordering from PacTox – but note that the "custom" panel included *all* of the quantitative tests then offered by PacTox, including tests for such substances as acetaminophen, nicotine, and NSAIDs (non-steroidal anti-inflammatory drugs), a group that includes aspirin and ibuprofen.

166. The form discouraged, and was intended to discourage, the Physicians from tailoring drug tests to fit each patient's needs. Instead, by filling out the form, a Physician gave broad authority to PacTox "to screen/quantify patient specimens from [his or her] practice for each of the prescription drug classes ... selected from the list below ...." **Exhibit N**, at 1. In effect, the form was a standing order for every patient referred by that Physician's office.

167. PacTox encouraged each of the Physicians to have this standing order form on file.

168. Medicare considers routine standing orders for drug tests to be "not reasonable and necessary," and will not knowingly reimburse for their use.[25]

[25] "Local Coverage Determination (LCD): Urine Drug Testing (L36037)", *available at* https://tinyurl.com/2cp9tuxr (last accessed Jan. 4, 2022).

169. In their standing orders to PacTox, the Physicians also commonly ordered quantitative (confirmatory) testing for all specimens, even those with negative qualitative results. That is, the Physicians would order tests to confirm the *amounts* of substances that they knew were not even present.

170. PacTox also performed and billed for unnecessary multi-substance panels for the beneficiaries of Government Insurance Programs referred to them by the Physicians. As the scheme progressed and the billing methods became more sophisticated, the testing panels grew from 12 drug classes to over 40 drug classes.

**D. Unbundled tests**

171. When a medical provider conducts a drug test using a multi-panel urine cup, Medicare requires all the tests to be bundled and billed under one billing code. *See* CMS Provider Inquiry Assistance Bulletin JA6852 (announcing rule effective for dates of service on or after April 1, 2010).[26] Some commercial insurers also follow this practice.

172. Both PacTox and the Physicians frequently unbundled the tests they performed, billing each drug class separately to fraudulently obtain higher levels of reimbursement.

[26] *Available at* www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/JA6852.pdf (last accessed Dec. 27, 2021). The guidance notes Medicare's replacement of CPT code 80101 (drug screen, qualitative; single drug class) with code G0431 (drug screen, qualitative; multiple drug classes by high complexity test method) ("New test code G0431 is a direct replacement for CPT code 80101. … Effective April 1, 2010, CPT code 80101 will no longer be covered by Medicare.").

173. For instance, PacTox records show that the laboratory billed Bridgeway Health Medicare for 23 separate instances of CPT code 80101 (drug screen, qualitative; single drug class) for patient "A.P." (account no. 35 ****706) on the single date of service of June 4, 2014 – even though the use of that code had been discontinued by Medicare *four years* previously.

174. The patient was referred to PacTox by Dependency Relief Specialists, a practice participating in the pass-through billing scheme described herein. PacTox billed each instance of code 80101 at $23, for a total of $529 for just those tests.[27]

175. Similarly, PacTox billed Care1st Arizona Medicare for 23 separate instances of CPT code 80101 for patient "M.F." (account no. 35 ****237) on the single date of service of June 6, 2014.

176. The tests were billed at $23 each, again for a total of $529 for just those tests.

177. The total bill for "M.F." for that date of service was a whopping $732.87. This patient was also referred to PacTox by Dependency Relief Specialists.

178. In contrast to these two examples, during 2014 PacTox normally billed one instance of code G0431 – the Medicare-approved bundled code for multiple screens – at only $124.94.

[27] In total, PacTox billed Bridgeway Health Medicare $652.30 related to services for "A.P." on that date.

**E. Free POCT cups**

179. Point-of-care test cups ("POCT" cups) feature paper testing strips for multiple different substances, glued inside the cup. A strip will change color, much like a litmus strip, if the corresponding substance is present in the specimen.

180. In early 2015, POCT cups cost between $5 and $15 each.[28]

181. Yet up until approximately 2015, PacTox was giving these cups for free to its higher-volume client practices. *See* **Exhibits E**, **G** and **H**, in which PacTox agrees to provide "the supplies needed for the collection and submission of specimens," with no mention of any payment for those supplies by the practices; *see also* **Exhibit O** (June 8, 2015 email from Lanzolatta discussing then-recently imposed "change" to charging for POCT cups).

182. These free cups were a substantial financial benefit to the practices, which were after all expected to use 200 or more cups per month to send referrals to PacTox. **Exhibit G**, last page.

183. Importantly, not only did the provision by PacTox of free POCT cups allow the Physicians to avoid costs they might otherwise have had to bear; the cups also conferred the valuable benefit of instant, qualitative results which the Physicians

[28] Amicus brief of the United States in *Ameritox v. Millennium* (14-14281, 11th Cir) (filed Feb. 2, 2015) at 10 (citing brief of Plaintiff Ameritox, at 7-9); *see also* Complaint in Intervention in *U.S., et al., ex rel. McGuire v. Millennium Laboratories, Inc., et al.*, 1:12-cv-10132-NMG (D. Mass.), ¶ 6 (filed Mar. 19, 2015) (citing a cost of $5 - $6).

could use in determining the need (if any) for further testing, and in making treatment decisions.

184. The instant results made possible by the test strips were beneficial to the Physicians only, and not to PacTox. Therefore, the free POCT cups were an illegal inducement by PacTox under the AKS and the Medi-Cal AKS, and were also "remuneration" that created a "financial relationship," rendering the Physician's referrals to PacTox illegal under the Stark Law. *See* 42 U.S.C. § 1395nn(h)(1), subsections (B) and (C)(ii); 42 C.F.R. § 411.351.[29]

**F. Collectors**

185. PacTox supplied collector personnel to its higher-volume clients.

186. Collectors were individuals, whose wages were usually paid by PacTox, who were stationed at the practices to collect and process specimens and to send them to PacTox for testing. *See*, *e.g.*, **Exhibit F**; *see also* **Exhibit G**, last page (assuming that collectors would be provided, offering two different arrangements for paying their wages).

[29] *See also* OIG Special Fraud Alert: Laboratory Payments to Referring Physicians, at 2 (Jun. 25, 2014) ("[W]henever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business.") (quoting OIG Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services (Oct. 1994), *reprinted at* 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994).

187. PacTox would then recoup some of the expense of providing these collectors by deducting from the commissions of Relator and other Sales Representatives a percentage of the wages of the collectors at their accounts.

188. Not only did the provision by PacTox of these collectors allow the Physicians to avoid having to pay their own staff to process and ship specimens; the collectors also performed work for the Physicians unrelated to their collection duties.

189. For instance, a September 2015 email thread discussed a collector having faxed some prescriptions to a compounding pharmacy for a medical practice, office chores which had nothing to do with PacTox.

190. The provision of such "free" services was an illegal inducement by PacTox under the AKS and the Medi-Cal AKS, and was also "remuneration" that created a "financial relationship," rendering the Physician's referrals to PacTox illegal under the Stark Law. *See* 42 U.S.C. § 1395nn(h)(1), subsections (B) and (C)(ii); 42 C.F.R. § 411.351.

**G. Debt forgiveness**

191. The Laboratory Services Agreements required the Physicians to pay on a certain schedule for the tests they "bought back" from PacTox. *See* **Exhibits E**, **G** and **H**., **§ 4** (requiring 60-day payment).

192. But PacTox did not always collect the payments it was owed, to avoid losing future business.

193. For instance, during 2013 and 2014, Rehab Arizona accumulated a debt of approximately $300,000 with PacTox for its test purchases.

194. PacTox forgave the full debt to induce Rehab Arizona to continue participating in the pass-through billing scheme and referring business, including government business.

**COUNT I**
**FEDERAL FALSE CLAIMS ACT:**
**PRESENTATION OF FALSE CLAIMS**

195. As alleged above, Defendant presented claims to federal health plans for urine drug tests and genetic tests procured and/or furnished in violation of the AKS. Each such claim is a false claim under the FCA.

196. Many of the claims that PacTox submitted were also false in that they were for tests that were medically unnecessary, and/or for tests that were inappropriately unbundled.

197. Accordingly, Defendant knowingly presented to the United States false or fraudulent claims for payment, in violation of 31 U.S.C. § 3729(a)(l)(A).

198. The submission of these false claims caused the United States to pay out monies that it would not have paid if it had known of the falsity of the claims.

199. Each false or fraudulent claim submitted to the United States is a separate violation of the FCA.

200. By reason of the false or fraudulent claims that Defendant knowingly presented and caused to be presented, the United States has been damaged in an amount to be proven at trial.

**COUNT II**
**FEDERAL FALSE CLAIMS ACT: MAKING OR USING FALSE RECORD OR STATEMENT TO CAUSE FALSE CLAIM TO BE PAID**

201. As alleged above, Defendant knowingly made, used, or caused to be made or used, false records and statements material to false claims. These records include false documentation of who performed urine drug tests and where they were performed, false documentation that the tests were medically necessary, and false certifications that the claims were compliant with all applicable laws and regulations.

202. Accordingly, Defendant violated 31 U.S.C. § 3729(a)(l)(B).

203. These false records and statements caused the United States to pay out monies that it would not have paid if it had known of the falsity of these claims.

204. Each false or fraudulent claim submitted to the United States is a separate violation of the FCA.

205. By reason of the false records and statements that Defendant knowingly made, used, and/or caused to be made or used, the United States has been damaged in an amount to be proven at trial.

**COUNT III**
**FEDERAL FALSE CLAIMS ACT:**
**CONSPIRACY TO GET A FALSE CLAIM PAID**

206. As alleged above, Defendant conspired with multiple physicians to submit claims to federal health programs for urine drug tests and genetic tests that were false and fraudulent because they were (a) procured and/or furnished in violation of the AKS, (b) medically unnecessary, and/or (c) inappropriately unbundled.

207. Defendant also conspired with multiple physicians to make or use false records and statements material to those false claims.

208. Accordingly, Defendant conspired to submit false claims in violation of 31 U.S.C. § 3729(a)(l)(C).

209. As a result of this conspiracy, the United States has been damaged in an amount to be proven at trial.

**COUNT IV**
**CALIFORNIA FALSE CLAIMS ACT:**
**PRESENTATION OF FALSE CLAIMS**

210. As alleged above, Defendant presented claims to Medi-Cal for urine drug tests and genetic tests procured and/or furnished in violation of the Medi-Cal AKS. Each such claim is a false claim under the California FCA.

211. Defendant also caused the Physicians to present claims to California commercial insurers for urine drug tests and genetic tests that Defendant provided in

violation of the Medi-Cal AKS. Each such claim is also a false claim under the California FCA.

212. Many of the claims that both PacTox and the Physicians submitted were also false in that they were for tests that were medically unnecessary, and/or for tests that were inappropriately unbundled.

213. Accordingly, Defendant knowingly presented or caused to be presented false or fraudulent claims to Medi-Cal for payment, in violation of Cal. Gov't Code § 12651(a)(1).

214. The submission of these false claims caused California to pay out monies that it would not have paid if it had known of the falsity of these claims.

215. Each false or fraudulent claim submitted to California is a separate violation of the California FCA.

216. By reason of the false or fraudulent claims that Defendant knowingly presented, California has been damaged in an amount to be proven at trial.

**COUNT V**
**CALIFORNIA FALSE CLAIMS ACT: MAKING OR USING FALSE RECORD OR STATEMENT TO CAUSE FALSE CLAIM TO BE PAID**

217. As alleged above, Defendant knowingly made, used, or caused to be made or used, false records and statements material to false claims presented to Medi-Cal and to Medicaid managed-care plans. These records include false documentation of who performed urine drug tests and where they were performed,

false documentation that the tests were medically necessary, and false certifications that the claims were submitted in compliance with applicable laws and regulations.

218. Accordingly, Defendant knowingly used false records or statements material to false or fraudulent claims for payment, in violation of Cal. Gov't Code § 12651(a)(2).

219. The submission of these false claims caused California to pay out monies that it would not have paid if it had known of the falsity of these claims.

220. Each false or fraudulent claim submitted to California is a separate violation of the California FCA.

221. By reason of the false records and statements that Defendant knowingly made, used, and/or caused to be made or used, California has been damaged in an amount to be proven at trial.

**COUNT VI**
**CALIFORNIA FALSE CLAIMS ACT:**
**CONSPIRACY TO GET FALSE CLAIMS PAID**

222. As alleged above, Defendant conspired with multiple physicians to submit to Medi-Cal claims for urine drug tests and genetic tests that were false and fraudulent because they were (a) procured and/or furnished in violation of the Medi-Cal AKS, (b) medically unnecessary, and/or (c) improperly unbundled.

223. Defendant also conspired with multiple physicians to make or use false records and statements material to those false claims.

224. Accordingly, Defendant conspired to submit false claims in violation of Cal. Gov't Code § 12651(a)(3).

225. As a result of this conspiracy, California has been damaged in an amount to be proven at trial.

**COUNT VII**
**CALIFORNIA INSURANCE FRAUD PREVENTION ACT:**
**INSURANCE FRAUD**

226. As alleged above, Defendant engaged in the following conduct:

(a) Did, aided, abetted, solicited, or conspired to:

i. Knowingly prepare, make, or subscribe any writing with the intent to present or use it, or allow it to be presented, in support of false or fraudulent claims; and

ii. Knowingly make or cause to be made false or fraudulent claims for payment of a health care benefit.

(b) Did, or knowingly assisted or conspired to:

i. Present or caused to be presented any oral or written statement as part of or in support of a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contained any false or misleading information concerning any material fact; and

ii. Prepare or make any written oral statement that is intended to be presented to any insurer or any insurance claimant in connection with, or in support of, any claim or payment or other benefit pursuant to an insurance policy, knowing that the statement contained false or misleading information concerning any material fact.

(c) Solicited, accepted, or referred any business to or from any entity with the knowledge that, or with the reckless disregard for whether, the entity intends to violate the foregoing paragraph (a) or (b).

227. Accordingly, Defendant violated Cal. Pen. Code §§ 549, 550. These violations give rise to civil liability under Cal. Ins. Code § 1871.7(b).

228. As a result, California has been damaged in an amount to be proven at trial.

## PRAYER FOR RELIEF

**WHEREFORE**, Relator respectfully requests that this Court enter judgment in her favor and that of the United States and California and against Defendant, granting the following on all Counts:

A. an award to the United States for treble its damages, a statutory penalty for each violation of the FCA, and for its costs pursuant to 31 U.S.C. § 3729(a)(3);

B. an award to California for treble its damages and a statutory penalty for each violation of the CIFPA pursuant to Cal Ins. Code § 1871.7(b), and for its costs pursuant to Cal Ins. Code § 1871.7(g)(1)(A)(ii);

C. an award to Relator in the maximum amount permitted under 31 U.S.C. § 3730(d) and Cal. Ins. Code § 1871.7(g)(1)(A)(i), and for the reasonable attorneys' fees and costs she incurred in prosecuting this action;

D. awards to the United States, California, and Relator for pre- and post-judgment interest at the rates permitted by law; and

E. such other and further relief as this Court may deem to be just and proper.

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## DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Relator demands trial by jury on all questions of fact raised by the Complaint.

Dated: January 7, 2022

Respectfully submitted,

**BROWN, LLC**
**(Lead Counsel)**

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**CERTIFICATE OF SERVICE**

I hereby certify that on January 7, 2022, or as soon thereafter as feasible, I caused a true copy of the First Amended Complaint in the matter captioned *United States of America ex rel. Yvonne Huemoeller v. Pacific Toxicology Laboratories.*, No. CV 19-02900-MWF (MRWx), to be served upon the following by email and by USPS Priority Mail:

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