IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ROME DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. **CHARLES C. ADAMS, M.D.,** *and* **CHARLES C. ADAMS, M.D., P.C.** *d/b/a* **FULL CIRCLE MEDICAL CENTER,** Defendants.	Civil Action No. 4:18-CV-0191-ELR

AMENDED COMPLAINT

The United States of America, by Ryan K, Buchanan, United States Attorney, and Anthony C. DeCinque and Akash Desai, Assistant United States Attorneys for the Northern District of Georgia, brings this civil action pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733 (2009), und under common law theories of payment by mistake and unjust enrichment.

INTRODUCTION

1. The United States seeks to recover damages, civil penalties and other relief from Defendants Charles C. Adams, M.D. and from Charles C. Adams, M.D., P.C. d/b/a Full Circle Medical Center ("Defendants") for having perpetrated a scheme between November 2008 and September 2015 involving the knowing submission of false claims for medically unnecessary and "alternative" chelation

therapy that Dr. Adams administered using the drug calcium disodium versentate, or edetate calcium disodium (EDTA), which the FDA only approved for indications of lead poisoning and lead encephalopathy. In connection with this scheme, Defendants received approximately $1.5 million in Medicare reimbursements.

2. Chelation therapy is a rare treatment that is generally indicated only for patients suffering from an uncommon condition called heavy metal poisoning (HMP), of which lead poisoning is the most common subset. HMP is the accumulation of heavy metals, such as lead, mercury and cadmium, in toxic amounts, in the soft tissues of the body.[1]

3. A diagnosis of HMP generally requires a symptomatic patient who (1) has been acutely and recently exposed to lead or other heavy metals, and (2) had a blood test indicating a sufficiently high amount of heavy metal in the patient's body. (*See*, ¶¶ 77-92)

4. In the majority of cases, the only treatment for HMP is the removal of the patient from the source of exposure to heavy metal. However, in a sufficiently acute case, chelation therapy may be indicated, and it involves providing a patient with a "chelating agent" such as EDTA, which binds itself to the metals in the bloodstream and is then excreted from the body *via* urine, thereby reducing the amount of heavy metals in a patient's body.

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[1] Lead poisoning is the most commonly diagnosed form of HMP. Lead encephalopathy, which is a disease that affects the function and structure of the brain, is a condition caused by acute lead poisoning.

5. A provider bills the Medicare program for chelation by submitting two sets of procedure codes: one for the chosen chelating drug, and one or more for the procedures associated with administering that drug to a patient. For their part, Defendants utilized the procedure code J0600 to indicate the use of EDTA, as well as various additional procedure codes associated with the intravenous administrations of EDTA.[2]

6. Additionally, claims submitted to Medicare for chelation therapy are generally not payable unless a diagnosis is provided. Hence, in billing Medicare for EDTA chelation treatments, Defendants routinely utilized ICD-9 Codes that are associated with lead poisoning and/or other types of HMP, which included, but were not limited to, the following ICD-9 Codes:

- 9848 – Toxic Effect Lead Compounds NEC,
- 9840 – Toxic Effect Inorganic Lead Compound,
- 9851 – Toxic Effect Arsenic.

7. However, despite Defendants' use of diagnostic codes associated with lead poisoning, the patients chelated by Dr. Adams were not suffering from lead poisoning, as evidenced by the fact that their blood lead levels (BLLs) were generally at a *miniscule* amount (*e.g.*, less than 2 mcg/dL), far below the BLL level

[2] In intravenously administering EDTA, Dr. Adams also typically billed injection and infusion CPT codes (96365, 96366 96367, 96368), which varied based upon the length of infusion time. Normal saline and 5% dextrose water (HCPCS codes J7040, J7050 and J7060) were also used during chelation. Dr. Adams occasionally billed for Dimercaprol Injections (BAL) (HCPCS code J0470) and Dimethyl Sulfoxide, 50% 50ml (HCPCS code J1212) in conjunction with EDTA. Dr. Adams also billed for the sterile syringe and needle used during the injections (HCPCS code A4209) and routine venipuncture (CPT codes 36415).

warranting chelation, which is a serious and potentially harmful therapy.[3] (*See* ¶¶ 93-99.) Additionally, the patients chelated by Dr. Adams had generally not been recently and acutely exposed to lead or any other heavy metal, which is an essential element of lead poisoning diagnosis. Moreover, in sworn testimony given in 2017, Dr. Adams admitted that he does not actually treat lead poisoning or heavy metal toxicity (*i.e.* HMP), but an altogether different condition that he called "excess body burden of heavy metals."

8. In truth, Defendants' inclusion of HMP-related diagnosis codes on claims submitted to Medicare was false and fraudulent, and designed to secure Medicare reimbursement for Dr. Adams' use of chelation as a form of "alternative" or "experimental" therapy, which is not covered by Medicare.

9. Although EDTA chelation is indicated only for lead poisoning and lead encephalopathy, for years, Dr. Adams has advertised and administered EDTA chelation as an "alternative" treatment for a myriad of other conditions. (*See* ¶¶ 123-129.)

10. For instance, on his webpage, Dr. Adams explicitly touted chelation as an "alternative medical therapy," which can be used as an "anti-aging" treatment, to "improve circulation problems," and to "…stimulate bone growth, improve cholesterol and lower blood pressure."

11. Additionally, in or around 2001, on his webpage, and under the heading, "*Where alternative medicine is prevention[,]*" Dr. Adams publicly stated that:

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[3] Blood tests are utilized to assess the amount of heavy metals, such as lead, within a patient's body.

- Chelation Therapy with EDTA helps you feel younger by reversing the accelerated decline of your body. Chelation Therapy helps you achieve healthy aging.

- The tremendous benefits experienced by thousands and thousands of people in the areas of heart disease, cancer prevention, diabetes, and chronic fatigue make Chelation Therapy a logical and practical choice for those fortunate enough to take advantage of it.

12. Moreover, while chelation is a serious and potentially dangerous treatment, Dr. Adams represented on his webpage that, "chelation therapy is delivered while the patient relaxes in a recliner chair, perhaps watching TV, chatting, or reading."

13. As part of his pitch, Dr. Adams informed potential patients that heavy metals caused various health problems, and then utilized the results of widely discredited "provoked urine tests" to tell patients that they had "heightened" levels of heavy metal, which chelation could reduce, thereby alleviating medical problems, such as high blood pressure, poor circulation and premature aging.

14. If Dr. Adams had submitted claims to Medicare for his "alternative" and/or "experimental" EDTA chelation therapy and included diagnoses codes or descriptions of "poor circulation," "high blood pressure," "anti-aging" or "cancer prevention," such claims would not have been paid.

15. Indeed, pursuant to National Coverage Determination (NCD) No. 20.22, which was issued by the Centers for Medicare and Medicaid Services in 2003, and was in effect throughout the time period relevant to this Complaint, such "alternative" chelation therapy is not covered by Medicare. Specifically, NCD 20.22 provides that "the use of EDTA as a chelating agent to treat atherosclerosis, arteriosclerosis, calcinosis, or similar generalized conditions not listed by the FDA

as an approved use is not covered. Any such use of EDTA is considered experimental."[4]

16. As the FDA has only approved EDTA for indications of "lead poisoning" and "lead encephalopathy," Dr. Adams' use of EDTA as an elixir for "anti-aging," "bone growth," "cancer prevention" and "circulation problems" is not covered by Medicare in accordance with NCD 20.22, and is not considered reasonable and necessary.

17. Therefore, to circumvent these coverage exclusions, and obtain Medicare reimbursements for his "alternative" chelation therapy, between November 2008 and September 2015, Dr. Adams concocted and executed a scheme whereby he knowingly mischaracterized – in thousands of claims submitted to the Government – his "alternative" chelation treatment, as medically necessary treatments for patients suffering from lead poisoning and/or other types of HMP.

18. Specifically, in the approximately 4500 claims that he caused to be submitted Medicare, Dr. Adams – through the use of diagnostic codes associated with lead poisoning and/or other types of HMP (*e.g.*, 9848 – Toxic Effect Other Lead Compounds) – *falsely* represented that the claims were for medically necessary chelation to treat patients suffering from lead poisoning or other forms of HMP, but which are conditions that Dr. Adams has admitted that he does not diagnose or treat.

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[4] Additionally, CMS Medicare Program Integrity Manual, Chapter 3, Section 3.6.2.2, states that items are "reasonable and necessary" and thus covered by Medicare if, *inter alia*, they are "not experimental or investigational."

19. For four separate and independent reasons, the thousands of chelation claims that Defendants submitted to Medicare between November 2008 and September 2015 were false within the meaning of the FCA:

a. First, the chelation claims that Defendants submitted or caused to be submitted to Medicare were for chelation therapy that was not medically necessary.

b. Second, Defendants expressly stated on the chelation claims that they submitted or caused to be submitted to Medicare that their patients suffered from the "toxic effects" of lead, mercury and arsenic, even though Dr. Adams has admitted that he does not treat patients for heavy metal toxicity.

c. Third, the chelation claims that Defendants submitted or caused to be submitted to Medicare involved "alternative" and/or "experimental" chelation therapy for conditions that are excluded from Medicare coverage pursuant to NDC 20.11.

d. Finally, the chelation claims that Defendants submitted or caused to be submitted to Medicare were for indications that were not approved by the FDA, and were therefore not covered by Medicare.

20. Defendants tendered these false claims to the Government with "knowledge" – as that term is defined by the FCA – of their falsity. Specifically, in submitting the claims, Defendants either had *actual knowledge* that, or acted in *deliberate ignorance* or *reckless disregard* of the falsity of the claims.

THE PARTIES

21. Plaintiff is the United States who brings this action on behalf of the United States Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS), which administers the Medicare program.

22. Defendant Charles C. Adams, M.D. (Dr. Adams) at all times relevant to the Complaint, was a licensed physician in the State of Georgia, doing business at 4085 Cloud Springs Road, Ringgold, Georgia, 30736.

23. Defendant Charles C. Adams, M.D., P.C., d/b/a Full Circle Medical Center ("FCMC") was at all times relevant to the Complaint a corporation organized under the laws of the State of Tennessee, with its principal place of business in Ringgold, Georgia, and doing business at 4085 Cloud Springs Road, Ringgold, Georgia, 30736. FCMC is owned and operated by Dr. Charles C. Adams for the purpose of, *inter alia*, providing integrative and/or alternative therapies such as EDTA chelation, and submitting, processing and/or receiving, bills, claims, payments and reimbursements associated with such therapies.

24. According to Dr. Adams, he earned a medical degree from the University of Tennessee in 1988 and completed an internal medicine residency at Erlanger Hospital in 1992.

25. However, Dr. Adams is not board certified in internal medicine (or any other medical discipline or specialty) by the American Board of Medical Specialties (ABMS), which is the nationally recognized not-for-profit organization that – in partnership with its 24 certifying member boards – establishes professional and educational standards for medical specialty practice and certification.

26. Instead, according to Dr. Adams, in or around 2014, he obtained a "board certification" from the American Board of Integrative Medicine and Holistic

Medicine.[5] Dr. Adams testified that he is "not certain" what holistic medicine entails, but holds himself out as a practitioner of "integrative medicine," which he explains involves "looking at supplements," as well as the use of "ozone therapy, hyperbaric oxygen therapy, different IV therapies."

JURISDICTION AND VENUE

27. This Court has jurisdiction over the subject matter of this action pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331 and 1345, and supplemental jurisdiction over the United States' common law and equitable claims under 28 U.S.C. § 1367(a).

28. This Court may exercise personal jurisdiction over Dr. Adams pursuant to 31 U.S.C. § 3732(a) because Dr. Adams' office is located in the Northern District of Georgia and because he transacts business in the Northern District of Georgia. The United States' claims against Dr. Adams under Georgia law arise from the same transaction or occurrence as its claims under the 31 U.S.C. § 3729, et seq.

29. The Court may exercise personal jurisdiction over FCMC pursuant to 31 U.S.C. § 3732(a) because it maintains a physical presences and transacts business in the Northern District of Georgia. The United States' claims against FCMC under Georgia law arise from the same transaction or occurrence as its claims under 31 U.S.C. § 3729, et seq.

30. Venue is proper in the Northern District of Georgia pursuant to 28 U.S.C. §§ 1391(b) and 31 U.S.C. § 3732(a) because Defendants reside and/or transact

[5] The ABMS does not recognize either "holistic" or "integrative" medicine as either specialties or sub-specialties.

business in this district, and because they have committed acts proscribed by 31 U.S.C. 3729 in this district.

THE FALSE CLAIMS ACT

31. The False Claims Act (FCA), 31 U.S.C. §§ 3729, *et seq*. provides in pertinent part that any person who:

- knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]

- 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 . . . , plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1). *See also* 28 C.F.R. § 85.3(a)(9).

32. The FCA was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 ("FERA"), enacted May 20, 2009. Section 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.

33. For violations occurring prior to May 20, 2009, the False Claims Act provided in pertinent part that a person is liable to the United States government for each instance in which the person "knowingly presents, or causes to be

presented, to an officer or employee of the United States government . . . [a] false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1) (1986).

34. As amended in 2009, the False Claims Act extends liability, both before and after its amendments, to any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B) (2009).

35. The False Claims Act defines the terms "knowing" and "knowingly" to mean that a person, with respect to information: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b) (1986); 31 U.S.C. § 3729(b)(1)(A) (2009). The False Claims Act further provides that no proof of specific intent to defraud is required. 31 U.S.C. § 3729(b) (1986); 31 U.S.C. § 3729(b)(1)(B) (2009).

THE MEDICARE PROGRAM

36. In 1965, Congress enacted the Health Insurance for the Aged and Disabled Act, 42 U.S.C. § 1395 *et seq.*, known as the Medicare Program, to pay the costs of certain health care services. A person's entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426, 426-1.

37. The Medicare Program is administered through the U.S. Department of Health & Human Services (HHS), and HHS has delegated direct responsibility for administration of the Medicare Program to the Centers for Medicare and Medicaid Services (CMS).

38. While the Medicare program has several parts (*see*, 42 U.S.C. §§ 1395c–1395i), the allegations herein concern claims submitted by Defendants under Medicare Part B ("Supplementary Medical Insurance for the Aged and Disabled"), which generally covers, *inter alia*, those drugs that are provided incident to a physician's service and cannot usually be self-administered. *See* 42 U.S.C. § 1395k; 42 C.F.R. §§ 410.26, 414.701, 410.10.

39. To assist in the administration of Medicare Part B, CMS initially contracted with "carriers." 42 U.S.C. § 1395u. Carriers, typically private insurance companies, were responsible for processing and paying Part B claims. 42 C.F.R. §§ 421.1–421.3.

40. Beginning in November 2006, Medicare Administrative Contractors (MACs) began replacing carriers and fiscal intermediaries. *See* 42 U.S.C. § 1395kk-1; 42 C.F.R. § 421.400 *et seq.*; 71 F.R. 67960-01, at 68181 (Nov. 24, 2006). MACs generally act on behalf of CMS to process and pay Part B claims and perform administrative functions on a regional level.

41. The Part B MAC for the region that encompassed Georgia between 2009 and 2015 was Cahaba Government Benefit Administrators, LLC (Cahaba).

42. To participate in the Medicare program as a new enrollee, independent clinical laboratories, group practices, and individual providers must submit a Medicare Enrollment Application, CMS Form-855I. These entities must also complete Form CMS-855I to change information or to reactivate, revalidate, and/or terminate Medicare enrollment.[6]

[6] Presently, this form may be known as a Form CMS-855B.

43. CMS Form 855I requires, among other things, signatories to certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in Section 4(A) of this application . . . . 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 and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> * * *
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

44. Additionally, an authorized official must sign the "Certification Section" in Section 15 of Form CMS-855I, which legally and financially binds the signer to all of the laws, regulations, and program instructions of the Medicare program.

45. On November 10, 2006, Dr. Adams signed the certification statement in Section 15 of Form CMS-855I, indicating that, *inter-alia*, he understood that he and his practice were required to comply with all Medicare laws, regulations, and program instructions.

46. A Medicare provider submits a reimbursement claim for the services provided on a 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, Current Procedural Terminology Codes ("CPT Codes") and/or Healthcare Common Procedure Coding System Level II Codes ("HCPCS Codes") (collectively, "Procedure

Codes") – to indicate to CMS the specific services rendered for which the provider is seeking reimbursement.

47. In addition to Procedure Codes, providers are also required to include a diagnosis code with each claim, which describes the diagnosis or medical condition associated with a particular provider claim to Medicare. *See* 42 C.F.R. § 424.32.

48. For instance, the ICD-9 Code "9840-Toxic Effect Inorganic Lead Compound" denotes a diagnosis of lead poisoning.

49. During the relevant time period, Medicare providers were required to use the diagnostic codes ("ICD-9 Codes") set forth in *International Classification of Diseases, Ninth Revision*.[7]

50. 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 rendering and referring physicians. 42 U.S.C. § 13951(q)(1).

51. 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.

52. Dr. Adams' and/or FCMC's NPI number is 1437192465.

53. When submitting claims to Medicare, providers certify *inter alia*, that (a) the services rendered are "medically indicated and necessary for the health of the

[7] ICD-9 codes are promulgated, revised, maintained and published by the World Health Organization.

patient;" (b) the information on the claim form is "true, accurate and complete;" and (c) 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 and State laws."

54. Healthcare providers are prohibited from knowingly presenting or causing to be presented claims that represent a pattern of items or services that the person knew or should have known were not medically necessary, or knew or should have known were false or fraudulent. 42 U.S.C 1320a-7a(a)(1); 1320a-7(b)(7) (permitting exclusion of providers for the foregoing violations).

55. Medicare only covers items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." Items and services that are not reasonable and necessary are excluded from coverage under Medicare. *See* 42 U.S.C. § 1395y(a)(1)(A).

56. Additionally, CMS Medicare Program Integrity Manual, Chapter 3, Section 3.6.2.2, states that items are "reasonable and necessary" and thus covered by Medicare if, *inter alia*, they are "not experimental or investigational."

57. On November 10, 2006, Dr. Adams signed the certification statement in Section 15 of Form CMS-855I, and thereby agreed to adhere to, "…Medicare laws, regulations and program instructions[,]" which include, but are not limited to, CMS Medicare Program Integrity Manual, Chapter 3, Section 3.6.2.2.

58. Medicare provides for drug coverage only where the use of a drug has been shown to be safe and effective and is otherwise reasonable and necessary. 41 U.S.C. § 1395y(a)(1)(A).

59. Drugs approved for marketing by the FDA are considered safe and effective when used for the indications specified on the labeling.

60. Medicare may cover a drug for a use that is not included as in indication on the drug's label as approved by the FDA if the MAC determines the use to be medically accepted, taking in consideration the major drug compendia, aut]horitative medical literature and/or accepted standards of medical practice. *See* Medicare Benefit Policy Manual, Chapter 15, § 50.4.2.

61. Cahaba did not issue any local coverage determinations regarding EDTA that were in effect during the relevant time period. Moreover, Cahaba never determined that EDTA for non-indicated uses was medically accepted.

62. Because it is not feasible for Medicare personnel to review every patient's medical records for the millions of claims for payments they receive from providers, the program relies on providers to comply with Medicare requirements and trusts providers to submit truthful and accurate certifications and claims.

63. Generally, once a provider submits CMS Form 1500 or 837P Form to Medicare, the claim is paid directly to the provider without any review of supporting documentation, including medical records.

FACTUAL ALLEGATIONS

CHELATION AND HEAVY METAL POISONING

64. Chelation is a rarely administered treatment for an uncommon condition called heavy metal poisoning (HMP), which is the accumulation of heavy metals, in toxic amounts, in the soft tissues of the body.[8] The heavy metals most commonly associated with the poisoning of humans are lead, mercury and cadmium. If heavy metals accumulate in the body in concentrations sufficient to cause poisoning, serious damage may occur.

65. Lead is the heavy metal that humans are most commonly exposed to, and lead poisoning is the most commonly diagnosed form of HMP. Lead encephalopathy is a disease that affects the function and structure of the brain, and is a condition caused by acute lead poisoning.

66. Indeed, the bulk – *e.g.* approximately $1.2 million – of the approximately $1.5 million in chelation related claims that Defendants submitted or caused to be submitted to Medicare between November 2008 and September 2015 contain a diagnosis associated with lead poisoning.

67. In the majority of cases, the only treatment for HMP is the removal of the patient from the source of exposure to heavy metal. However, in a sufficiently acute case, as largely determined by the amount of a heavy metal identified in a patient's body by a reliable laboratory test, chelation therapy may be indicated.

68. Chelation therapy involves providing a patient (orally, intravenously or through injections) with a "chelating agent," which binds itself to the metals in the

[8] HMP is especially rare amongst the elderly.

bloodstream, where it is then excreted from the body *via* urine, thereby reducing levels of heavy metal.

69. There are a number of chelating agents available, such as Dimercaprol (BAL), Succimer (DMSA) and edetate calcium disodium (EDTA), which is the chelating agent most heavily utilized by Dr. Adams.

70. In terms of potential hazards and side effects, according to the American College of Medical Toxicology (ACMT), "…chelating drugs may have significant side effects, including dehydration, hypocalcemia, kidney injury, liver enzyme elevations, hypotension allergic reactions and essential mineral deficiencies. Inappropriate chelation…risk these harms, as well as neurodevelopmental toxicity, teratogenicity and death."[9]

71. Indeed, EDTA has a black box warning indicating that it "is capable of producing toxic effects which can be fatal." Moreover, the manufacturer indicates that EDTA's adverse side effects include fever, chills, malaise, fatigue, myalgia, arthralgia, hypotension, cardiac rhythm irregularities, acute necrosis of proximal tubules (which may result in fatal nephrosis), nausea, vomiting, hypercalcemia, tremors, headaches, numbness and others.

[9] The American College of Medical Toxicology is a professional, nonprofit association of physicians with recognized expertise in medical toxicology, which is a field of medicine dedicated to the evaluation and treatment of poisoned patients. This also includes adverse health effects of medications, occupational and environmental toxins, and biological agents. Medical Toxicology is an officially recognized subspecialty by the ABMS.

CHELATION IS INDICATED ONLY FOR HMP

72. The clear medical consensus is that chelation is a medical treatment that is generally only indicated for clinically confirmed cases of HMP, such as lead poisoning.

73. Indeed, in the package insert for EDTA, which is the chelating agent principally employed by Dr. Adams, the manufacturer explicitly references the FDA's determination that EDTA is only: "…indicated for the reduction of blood levels and depot stores of lead in lead poisoning (acute and chronic) and lead encephalopathy."

74. Hence, EDTA, the specific chelating agent principally utilized by Dr. Adams, is only indicated for lead poisoning and lead encephalopathy.

THE STANDARD OF CARE FOR DIAGNOSING HEAVY METAL POISONING

A Thorough Differential Diagnosis Is Necessary As There Are Few Dispositive Symptoms of HMP.

75. There are few dispositive symptoms that a patient has HMP. For instance, although encephalopathy, foot or wrist drop and severe abdominal colic are symptoms that are suggestive of severe lead poisoning, very few symptoms – in-and-of-themselves – are dispositive that a patient has lead poisoning.

76. Instead, the majority of HMP symptoms – *e.g.*, headache, nausea, joint pain, muscle pain, fatigue, persistent vomiting, diarrhea and abdominal pain – are commonly associated with a myriad of other ailments.

77. Therefore, a broad medical differential should be performed before concluding that a patient is symptomatic of, and/or actually suffering from lead poisoning, or another form of HMP.

Recent And Acute Patient Exposure To Heavy Metal Is An Essential Component Of An HMP Diagnosis.

78. In diagnosing HMP, a critical assessment is whether the patient has experienced a recent and acute exposure to heavy metal. As one article noted, "A history of exposure is the *most critical* aspect of diagnosing heavy metal toxicity."

79. As noted by the Minnesota Department of Health in 2015, "Metal toxicity is rare[,]" and "…does not typically occur in the absence of an *extraordinary* exposure."

80. "Even if a clinically significant metal exposure is suspected or possible, the differential diagnosis should remain broad until definitive proof of exposure and toxicity is obtained." *Id.*

81. Patient exposure to heavy metals is largely occupational, and typically occurs in industries such as mining, manufacturing and construction. Indeed, most acute presentations of HMP involve industrial exposure.

Laboratory Tests Are Necessary To Accurately Diagnose HMP.

82. Laboratory testing is necessary to diagnose HMP, but is generally only medically necessary where a patient has recently been acutely exposed to heavy metals *and* is symptomatic.[10]

83. In the absence of recent and acute patient exposure to heavy metals, the medical consensus is that diagnostic testing for HMP in response to vague and/or generalized symptoms is not medically necessary.

84. Indeed, the American College of Medical Toxicology (ACMT) has noted that patients should not be screened for heavy metals in the absence of excessive exposure to heavy metals:

> Individuals are constantly being exposed to metals in the environment and often have detectable levels without being poisoned. Indiscriminant testing lead to needless concern[.] Diagnosis of any metal poisoning requires an appropriate exposure history and clinical findings consistent with poisoning by that metal. A patient should only undergo specific metal testing if there is a concern for a specific poisoning based on history and physical findings.

Blood Tests Are the Most Reliable Indicator of the Amount of Heavy Metal in a Patient's Body.

85. The medical consensus is that blood tests are the most reliable indicator of whether a toxic amount of heavy metal is present in a patient's body. Hence, in diagnosing HMP, physicians utilize blood tests to assess the amount of heavy

[10] In a 2015 bulletin entitled "*Heavy Metal Detection and the Concept of Chelation*," the Minnesota Department of Health states that, "Testing in response to nonspecific symptoms, or testing in the absence of suspected exposure, is of no value."

metal in a patient's body, and this information largely drives the determination as to whether a patient is suffering from HMP.[11]

86. For example, with respect to suspected lead poisoning, blood tests are utilized to assess the amount of lead within a patient's body, and this metric is known as "BLL," which stands for "blood lead level."[12] As one medical treatise explains:

> The key clinical monitoring test for diagnosing lead toxicity is blood lead level (BLL). Measuring lead in urine, hair or other media is not as accurate or reliable and does not correlate as well with adverse health effects.

Provoked Urine Tests Are Unreliable, Potentially Dangerous And Should Not Be Utilized In Diagnosing HMP.

87. With respect to the medical consensus as to diagnosing HMP, blood tests are to be contrasted with "provoked urine tests," which are heavily utilized by practitioners such as Dr. Adams, who market and administer chelation as a so-called "alternative therapy" for a variety of ills and/or conditions.

88. A provoked urine test is given by administering a chelating agent to a patient, and then collecting a urine sample hours later. Almost invariably, the results show the presence of supposedly "heightened" levels of heavy metal, as the chelating agent dislodges heavy metal that is imbedded in the body, which is then excreted in urine.

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[11] Although the standard of care generally calls for blood test to assess levels of heavy metal in a patient's body, urine test are also sometimes utilized in conjunction with blood test with respect to certain heavy metals, such as mercury.

[12] Similarly, pursuant to the standard of care, blood tests are utilized to detect levels of other heavy metals such as mercury and cadmium.

89. Provoked urine tests have been repeatedly criticized, and the consensus is that the test is unreliable and potentially dangerous. For instance, on March 30, 2010, ACMT issued the following position statement:

> It is, therefore, the position of the American College of Medical Toxicology that post-challenge urinary metal testing has not been scientifically validated, has no demonstrated benefit, and may be harmful when applied in the assessment and treatment of patients in whom there is concern for metal poisoning.

90. Additionally, ACMT has stated that, "Scientific studies demonstrate that the administration of a chelation agent leads to increased excretion of various metals into the urine, even in healthy individuals without metal related disease. These "provoked" or "challenged" test of urine are not reliable means to diagnose metal poisoning and have been associated with harm."[13]

CHELATION IS ONLY INDICATED FOR PATIENTS WITH SIGNIFICANTLY HEIGHTENED LEVELS OF HEAVY METAL.

91. Fundamentally, and as noted by ACMT, "[m]etals are ubiquitous in the environment and all individuals are exposed to and store some quantities of metals in the body. These do not necessarily result in illness."

92. Hence, the medical consensus and standard of care provide that chelation is indicated only where a legitimate laboratory test (e.g., a blood test) – as opposed to a provoked urine test – demonstrates that lead (or another heavy metal) is present in a patient's body at a sufficiently high level.

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[13] Additionally, several private insurers have taken the position that provoked urine testing – as well any HMP diagnosis and/or HMP treatment based upon such testing – is not necessary and/or efficacious and therefore not covered.

93. For example, with respect to suspected and confirmed cases of lead poisoning, there are BLL thresholds above which chelation *may* be medically necessary, and below which chelation *is not* medically necessary.

94. While there is some variability as to the precise BLL where chelation is indicated, the consensus is that chelation is only indicated for patients with extremely heightened BLLs.

95. For instance, in a March 2007 article entitled "Recommendations for Medical Management of Adult Lead Exposure" that appeared in a peer reviewed journal published by the National Institute for Health ("NIH"), it was recommended that chelation be considered only for adult patients with BLLs greater than 50 mcg/dL and exhibiting significant symptoms or signs of lead toxicity. Absent significant symptoms or signs of lead toxicity, the article recommends chelation only for adults with BLLs equal to (or greater than) 80 mcg/dL.

96. Moreover, if a patient's BLL is less than 40 mcg/dL, any symptoms are not likely attributable to lead poisoning, and chelation is therefore neither reasonable nor necessary.[14]

97. For context, the mean BLL in adults in the United States from 2011 to 2012 was only 1.09 mcg/dL, while the medical consensus is that no action

[14] Indeed, with respect to suspected lead poisoning, the medical consensus is that there is no evidence that chelation is beneficial to patients with BLLs of less than 40 mcg/dL:

> If an adult reports clinical symptoms with BLL<40 mcg, the symptoms are not likely attributable to lead poisoning, and other explanations should be sought. There is no evidence that chelation therapy at BLL <40 mcg/dL decreases symptoms or reduces the risk of chronic disease.

whatsoever – *e.g.*, medication, counseling, reduced exposure, *ect*. – is necessary with respect to patients with BLLs less than 5 mcg/dL.

THE ADMINISTRATION OF CHELATION THERAPY

98. Once the decision to chelate a patient has been made, a number of chelating agents are available, which include, but are not limited to, Dimercaprol (BAL), Edetate calcium disodium (EDTA) and Succimer (DMSA).

99. BAL is a chelator that is effective in treating lead, arsenic and mercury poisoning, and is administered via deep intramuscular injections.

100. The most commonly prescribed chelator is DMSA, which is effective in treating lead poisoning, and is administered orally *via* tablets. According to *Goldfranks Toxicological Emergencies*, for mildly symptomatic adults with BLLs between 70 and 100 mcg/dL, DMSA is the recommended chelating agent.[15]

101. Edetate calcium disodium (EDTA) (the chelating agent utilized by Dr. Adams) is also used to treat lead poisoning, and is administered intravenously, or per the manufacturer, via intramuscular injections. According to *Goldfranks Toxicological Emergencies*, for adult patients with BLLs in excess of 100 mcg/dL, a chelation therapy consisting of BAL and EDTA is recommended.

102. Generally, an oral chelating agent (*e.g.*, DMSA) – as opposed to an intravenous chelating agent (*e.g.*, EDTA) – should be administered. Intravenous chelating agents should be reserved for an incapacitated patient.

[15] *Goldfranks Toxicological Emergencies* is an authoritative source with respect to diagnosing and treating poisoning (including, but not limited to, lead poisoning).

103. Finally, chelation therapy should be of limited duration, and should cease when laboratory tests confirm that heavy metals have been reduced to a level where they no longer present an acute health risk to the patient.

CERTAIN PRACTITIONERS MARKET CHELATION AS AN "ALTERNATIVE" OR "EXPERIMENTAL" TREATMENT FOR A HOST OF CONDITIONS

104. Although the medical consensus is that chelation is generally only indicated for HMP, certain practitioners (including Dr. Adams) of "alternative" and/or "integrative" medicine market and administer chelation as a treatment for a variety of ills and conditions, which include, but are not limited to: (1) circulation problems, (2) heart disease, (3) autism, (4) fatigue, and (5) premature aging.

105. Whereas the medical consensus is that chelation is only possibly indicated for patients with extremely high levels of heavy metal (*e.g.* BLLs in excess of 50 mcg/dL (symptomatic patient) or 80 mcg/dL (asymptomatic patient), certain practitioners of "alternative" and/or "integrative" medicine espouse the view that even low levels of heavy metals cause harm, and that therefore chelation is a medically appropriate treatment for patients with relatively low levels of heavy metals.

106. A 2013 editorial entitled "Use and Misuse of Metal Chelation Therapy" that appeared in the *Journal of Medical Toxicology* contains the following observations regarding "alternative" chelation therapy:

- Many of these treatments are performed by practitioners with a world view best described as "if it exists and has been described as harmful in some large amount, then getting rid of any amount will make you better."

- [T]he prevalence of fraudulent testing and misdiagnosis is of great concern to the American College of Medical Toxicology (ACMT) and public health entities.

- Some practitioners who provide post-provocation testing and chelation therapy for the erroneous diagnosis of chronic metal poisoning may just be ignorant[.] Others derive significant profit from the practice.

MEDICARE DOES NOT COVER "ALTERNATIVE" OR "EXPERIMENTAL" EDTA CHELATION THERAPY.

107. Medicare provides for drug coverage only where the use of a drug has been shown to be safe and effective and is otherwise reasonable and necessary. 41 U.S.C. § 1395y(a)(1)(A).

108. Drugs approved for marketing by the FDA are considered safe and effective when used for indications specified on the labeling.

109. Medicare may cover a drug for a use that is not included as an indication on the drug's label as approved by the FDA if the MAC determines the use to be medically accepted, taking in consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. *See* Medicare Benefit Policy Manual, Chapter 15, § 50.4.2.

110. Cahaba did not issue any local coverage determinations regarding EDTA that were in effect during the relevant time period. Moreover, Cahaba never determined that EDTA for non-indicated uses was medically accepted.

111. The only indicated uses on the FDA approved label for EDTA are for the reduction of blood levels and depot stores of lead in lead poisoning (acute and chronic) and lead encephalopathy, in both pediatric populations and adults.

112. Moreover, in 2003, CMS published a National Coverage Determination ("NCD") informing the public that Medicare does not cover chelation when used as an "experimental" treatment. Medicare National Coverage Determinations Manual, § 20.22.

113. Specifically, NCD 20.22 provides that, "the use of EDTA as a chelating agent to treat atherosclerosis, arteriosclerosis, calcinosis, *or similar generalized conditions not listed by the FDA as an approved use is not covered*. *Any such use of EDTA is considered experimental*. (emphasis added.)

114. Therefore, Medicare only covers the use of EDTA for lead poisoning or lead encephalopathy.

115. Between November 2008 and September 2012, Defendants knew that Medicare only covers the use of EDTA for lead poisoning or lead encephalopathy, and did not cover "experimental" uses of EDTA.[16]

PRIVATE INSURERS GENERALLY DO NOT COVER "ALTERNATIVE" OR "EXPERIMENTAL" EDTA CHELATION THERAPY.

116. Similarly, several large private insurers have found "alternative" uses of chelation therapy to be medically unnecessary and/or non-efficacious, and therefore not covered by insurance.

117. For instance, while Aetna considers chelation medically necessary to treat "heavy metal poisoning[,]" its position is that chelation with respect to other

[16] Indeed, prior to administering EDTA chelation therapy, Dr. Adams required patients to sign consents, wherein the patient had to acknowledge that, "…this therapy may be considered experimental by…Medicare[,]" and that "…if Medicare…[does] not reimburse for this therapy, the fees are my responsibility."

conditions (*e.g.*, cancer, heart disease, autism, Alzheimer's) is not covered, as "[t]he safety and effectiveness of this treatment for these indications has not been established."

118. Additionally, Blue Cross Blue Shield has also issued several policy statements regarding chelation, including one for North Carolina, which includes the following exclusions under a heading entitled "**When Chelation Therapy is not covered**":

> Chelation therapy is considered investigational, including, but not limited to, the following conditions:
>
> - Heavy metal toxicity or iron or lead poisoning where toxic levels are not documented by standard testing methods.
> - Atherosclerosis (e.g., coronary artery disease, peripheral vascular disease, secondary prevention in patients with myocardial infarction)
> - Other indications ***not*** listed under "when chelation therapy ***is*** covered"

119. Similarly, WellCare explains that "chelation therapy is considered medically necessary" for HMP when "…confirmed by appropriate laboratory results and clinical findings consistent with toxicity," but cautions that chelation "is considered experimental and investigational" – and hence not covered, with respect to a variety of conditions – *e.g.* vascular and/or artery disease, fatigue and arthritis.

120. Upon information and belief, Defendants were mailed certain of the bulletins and provider statements referenced immediately above.

FOR YEARS, DR. ADAMS MARKETED AND ADMINISTERED INTRAVENEOUS EDTA CHELATION AS AN "ALTERNATIVE" THERAPY.

121. Dr. Adams is a self-described practitioner of integrative medicine, and has actively advertised and administered chelation as an "alternative" or "integrative" treatment for a myriad of conditions.

122. In approximately 1998, Dr. Adams moved his practice from Tennessee to Georgia based upon his belief that Georgia had more liberal standards concerning what type of treatments are appropriate for patients.[17]

123. In or around 2001, on his webpage, and under the heading, "*Where alternative medicine is prevention[,]*" Dr. Adams publicly stated that:

- Chelation Therapy with EDTA helps you feel younger by reversing the accelerated decline of your body. Chelation Therapy helps you achieve healthy aging.
- The tremendous benefits experienced by thousands and thousands of people in the areas of heart disease, cancer prevention, diabetes, and chronic fatigue make Chelation Therapy a logical and practical choice for those fortunate enough to take advantage of it.

124. Additionally, on his webpage, Dr. Adams has explicitly touted chelation as an "alternative medical therapy," which can be used as an "anti-aging" treatment, to "improve circulation problems," and to "…stimulate bone growth, improve cholesterol and lower blood pressure."

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[17] As early as July 2000, Tennessee enacted laws, regulations and/or position statements that provide that, "…the advertising of EDTA's administration in any matter to prevent or cure diseases or medical conditions other than laboratory documented heavy metal poisoning/intoxication/toxicity, without support of the scientific literature contained within the National Library of Medicine or certainly much more than anecdotal evidence of its effective use in the treatment of a disease or medical condition for which a licensee advertises it may be considered to be a violation of T.C.A. 63-9-111 (b) (3), and (9) and/or the rules promulgated pursuant thereto."

125. Although NCD 20.22 explicitly provides that the use of EDTA as a treatment for atherosclerosis and/or arteriosclerosis is excluded from Medicare coverage, Dr. Adams has publicly marketed – *e.g.*, via his webpage – EDTA chelation as a treatment for these and similar heart conditions:

- Chelation therapy can be used along with most other therapies for cardiac-vascular disease.
- Common surgical bypass procedures repair only one artery at a time. Chelation therapy is comprehensive, improves circulation all over the body, and at a fraction of the cost of surgery.
- Chelation is a non-surgical treatment for heavy metal poisoning that has been found to be effective treating cases of poor circulation and hardening of the arteries.

126. Additionally, in his 2018 testimony, Dr. Adams stated that chelation is effective in "improving vision, increasing energy, reducing headaches" and promoting "an overall sense of well-being."

127. Although chelation therapy is serious and potentially dangerous, on his webpage, Dr. Adams explained that, "chelation therapy is delivered while the patient relaxes in a recliner chair, perhaps watching TV, chatting, or reading[,]" and the basic course of treatment is "thirty to forty treatments."

DR. ADAMS' PRACTICES ARE CONTRARY TO THE MEDICAL CONSENSUS AND STANDARD OF CARE APPLICABLE TO LEAD POISONING AND OTHER TYPES OF HMP.

128. The "alternative" chelation therapy marketed and administered by Dr. Adams is contrary to the medical consensus and standard of care applicable to diagnosing and treating lead poisoning, which – along with lead encephalopathy – is the *only* condition for which EDTA chelation is indicated.

Prior To Chelating Patients, Dr. Adams Failed To Perform a Differential Diagnosis.

129. Prior to chelating patients, Dr. Adams routinely failed to conduct a viable differential diagnosis.[18] Because few symptoms are strongly indicative of HMP, and most HMP symptoms are associated with other ailments, a broad differential diagnosis should be performed prior to concluding that a patient is symptomatic of, and/or actually suffering from, HMP.

130. Dr. Adams' failure to perform differential diagnoses prior to chelating patients is consistent with the fact the patients he chelated generally affirmatively sought him out seeking EDTA chelation as an "alternative" therapy for "circulation problems," as well as other conditions for which Dr. Adam's marketed EDTA chelation as an "alternative" or "integrative" treatment.

Dr. Adams Chelated Patients That Had Not Been Recently Or Acutely Exposed To Heavy Metals.

131. As noted above, testing a patient for heavy metal, rendering an HMP diagnosis and chelating a patient, are all actions that are generally unwarranted absent the patient having been recently and acutely exposed to a heavy metal, such as lead.

132. Nevertheless, Dr. Adams routinely tested patients for heavy metal, "diagnosed" such patients with HMP, and then chelated such patients (ostensibly

[18] Dr. Adams' effort to perform differentials were limited to having patients circle potential HMP symptoms listed on a document he drafted and routinely provided to patients.

to treat HMP), despite the fact that such patients – as evidenced by the medical records – had not been recently or acutely exposed to heavy metal.)

133. Instead, Dr. Adams sidestepped the essential "heavy metal exposure" aspect of a valid HMP differential diagnosis with his supposition that, because of the presence of lead in gasoline between 1930 and 1995, *anyone* that drove during this period has been "exposed to lead," and thus may be an appropriate candidate for heavy metal testing and/or chelation therapy.[19]

134. In fact, when asked how he would advise a patient that sought chelation, but had ***no*** possible exposure to lead other than the use of the roads, Dr. Adams responded that he would advise such a patient that, "Chelation therapy is a reasonable therapy to try."

Dr. Adams Chelated Patients On The Basis Of Discredited And Unreliable Provoked Urine Tests.

135. Further, whereas the medical consensus is that blood tests are the most accurate and reliable means of assessing the amount of lead and other heavy metals in a patient's body, Dr. Adams admitted that he ordered blood tests *only* to avoid problems with the medical board, and did not base his decision whether to chelate a patient on blood tests results.[20]

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[19] While lead poisoning is a rare condition, pursuant to Dr. Adams' dubious highway construct, enormous swathes of the public were "exposed" to lead by using the roads and are thus conceivable candidates for Dr. Adams' chelation therapy.

[20] Similarly, for a certain period of time, Dr. Adams also ordered traditional urine test, but did not base his treatment decisions on the basis of such test, and ordered them to avoid problems with the medical board.

136. Instead, in marketing and administering chelation to patients, Dr. Adams routinely relied upon provoked urine tests, and utilized the results of such tests to convince patients that they had "elevated" levels of heavy metal, which could be reduced by EDTA chelation, thereby alleviating a myriad of health conditions.

137. In utilizing provoked urine tests, Dr. Adams ignored the medical consensus that such tests are unreliable, potentially dangerous, and should therefore not be used to advise a patient that either heavy metal testing or chelation is warranted.

In Contravention Of The Standard Of Care, Dr. Adams Chelates Patients For As Long As They Want.

138. Whereas the standard of care associated with HMP provides that chelation therapy should be of a prescribed and limited duration, and tied to a patient's laboratory confirmed levels of heavy metal, Dr. Adams – by his own admission – chelates patients for as long the patient wants.[21]

139. For instance, Dr. Adams chelated an 83 year old Medicare beneficiary with the initials "M.D." 36 times between March 2, 2009 and December 30, 2009.

140. When asked why this patient had been chelated so many times, Dr. Adams – a licensed physician – replied that, "Her call, she feels badly."

141. Indeed, the medical records reveal that Dr. Adams chelated certain patients 108, 117 and 168 times.

[21] Additionally, Dr. Adams does not stop chelation treatments on the basis of lab results.

142. Specifically, between March 5, 2009 and February 6, 2012, Dr. Adams chelated a 71 year old Medicare beneficiary with the initials "G.P." 108 times.

143. Additionally, between March 16, 2009 and October 15, 2010, Dr. Adams chelated an 81 year old Medicare beneficiary with the initials "E.H." 117 times.

144. Finally, between March 16, 2009 and January 17, 2012, Dr. Adams chelated a 68 year old patient with the initials "W.D." 168 times.

DR. ADAMS ADMITTED THAT HE DOES NOT DIAGNOSE OR TREAT LEAD POISONING OR HMP.

145. Aware that his practices do not conform to the standard of care for diagnosing and treating lead poisoning or other types of HMP, in sworn testimony in 2017, Dr. Adams admitted that he does not diagnose or treat lead poisoning or other forms of HMP, but rather treats an *altogether different* condition that he identified as "excess body burden of heavy metals."

146. Specifically, when asked when it would be necessary to treat a patient for lead poisoning, Dr. Adams testified that, "I don't treat patients for lead poisoning[,] I treat them for excess body burden of heavy metals."[22]

147. Similarly, Dr. Adams admitted that he did not treat heavy metal toxicity, and acknowledged it would be improper for him to submit bills to the

[22] Indeed, during his 2017 testimony, Dr. Adams was unable to articulate the standard of care for treating lead poisoning. When asked to describe the difference between lead poisoning and "excess body burden of heavy metals," Dr. Adam's replied, "[t]he emergency room." Additionally, Dr. Adams admitted that different BLLs are associated with actual lead poisoning, as opposed to having an "excess body burden of lead."

Government for heavy metal toxicity: "[w]e know better than to diagnose heavy metal toxicity[,]" "[w]e know better than to use any type of toxicity."

148. However, between November 2008 and September 2015, Dr. Adams submitted, and/or caused to be submitted, thousands of claims to Medicare, wherein *he did* – in fact – seek reimbursement for chelation therapy that he indicated – through the use of ICD-9 Codes associated with lead poisoning or other forms of HMP (*e.g.* 9848-Toxic Effect Other Lead Compounds, 9840-Toxic Effect Inorganic Lead Compounds) – was provided to patients suffering from lead poisoning or another form of heavy metal toxicity, which he now concedes are conditions that he does not diagnose or treat.

DR. ADAMS VIOLATED THE FCA BY FALSELY CLAIMING $1.5 MILLION FOR "ALTERNATIVE" AND MEDICALLY UNCESSARY CHELATION THERAPY

To Secure Medicare Reimbursements For "Alterative" Or Experimental Chelation Treatments, Dr. Adams Mischaracterized Them As Treatments For Lead Poisoning And Other Forms Of HMP.

149. Between November 2008 and September 2015, Dr. Adams perpetrated a fraud against the United States by submitting claims for medically unnecessary and non-covered chelation and associated services to Medicare in order to obtain Medicare reimbursements for these services.

150. Additionally, Dr. Adams knew that EDTA chelation is only indicated for adult patients with significantly heightened BLLs (*e.g.*, in excess of 50 mcg/dL).

151. Additionally, Dr. Adams had knowledge that EDTA chelation is only indicated for adult patients with significantly heightened BLLs (*e.g.*, in excess of 50 mcg/dL or 80 mcg/dL).

152. For years, however, Defendants submitted and/or caused to be submitted claims for EDTA chelation that was marketed and administered as an "alternative medical therapy," which can be used, *inter-alia*, as an "anti-aging" treatment, to "improve circulation problems," and to "…stimulate bone growth, improve cholesterol and lower blood pressure."

153. Dr. Adams knew that such "alternative" chelation therapy is not covered under Medicare.

154. Nevertheless, between November 2008 and September 2015, Dr. Adams routinely billed Medicare for his alternative chelation therapy.

155. Pursuant to his scheme, between November 2008 and September 2015, Dr. Adams submitted approximately 4500 claims to the Government seeking reimbursement for chelation therapy that he represented was medically necessary.

156. However, although Dr. Adams caused the submission of claims to the Government that made the specific representation (using ICD-9 diagnostic codes associated with lead poisoning other forms of HMP – e.g., 9848 – Toxic Effect Other Lead Compounds), the Defendants knowingly failed to disclose that:

a. They did not actually treat lead poisoning or other forms of HMP, but an altogether different condition called "excess body burden of heavy metals."

b. They utilized EDTA chelation as an alternative or experimental treatment for conditions such as heart disease and poor circulation, which is excluded from Medicare coverage by NDC 20.22.

c. They utilized EDTA chelation as a treatment for conditions *other* than lead poisoning and lead encephalopathy, which are the *only* two conditions for which the FDA has approved EDTA as a treatment.

d. The chelation treatments were neither reasonable nor necessary as the patients chelated were not suffering from lead poisoning or any other form of HMP.

e. Defendants' omission of the aforementioned information from the chelation claims that they submitted to the Government caused them to be false.

Dr. Adams' Chelation Claims Were False As He Falsely Claimed That He Was Chelating Patients To Treat Lead Poisoning And/Or Other Types of HMP

157. Dr. Adams filed claims that falsely indicated that reimbursement was sought for chelation treatments provided to patients suffering lead poisoning or another form of HMP, when in truth, Dr. Adams – *by his own admission* – was not treating lead poisoning or another form of HMP, but a different condition that he called "excess body burden of heavy metals."

158. Specifically, through the use of ICD-9 Codes associated with lead poisoning and other forms of HMP – *e.g.* 9848-Toxic Effect Other Lead Compounds, 9840-Toxic Effect Inorganic Lead Compounds – Dr. Adams repeatedly represented in claims submitted to the Government that he was

seeking reimbursement for chelation treatments provided to patients suffering from lead poisoning or another form of HMP.

159. These statements to Medicare were false under the FCA as Dr. Adams was not treating Medicare beneficiaries for HMP or lead poisoning as the ICD-9 Codes indicated, but was chelating patients as an "alternative" or "experimental" remedy for a myriad of different conditions, such as "fatigue," "anti-aging," "excess body burden of heavy metals," and "circulation problems."

160. As an example, on July 25, 2011, Dr. Adams submitted a $376.53 claim for reimbursement to Medicare – which was paid on July 28, 2011 – for chelation therapy that the medical records reflect that he provided to a 66 year old Medicare beneficiary with the initials "C.S." (Patient C.S.) on February 23, 2010.[23] In submitting the claim, Dr. Adams utilized the HCPCS code for EDTA (J0600) (as well as various additional CPT and HCPCS codes associated the intravenous administration of the EDTA)[24] and ICD-9 Code 9948 – "Toxic Effects Lead Compounds."

a. This claim was false as, *inter-alia*, the ICD-9 Code associated with the claim was false and/or misleading.

   i. First, Dr. Adams has admitted that he does not treat lead poisoning or lead toxicity (*see*, ¶__), and the use of the ICD-9

[23] Patient C.S. was chelated a total of 45 times from 7/28/09 through 2/28/12.

[24] Specifically, Defendants also billed the Government for the following codes: J7040 and J7050 - Normal Saline Solution, 96365, 96366, and 96367 Injection/Infusion Codes, A4209- Syringe and Needle 99212 (Modifier 25)- Office/ Outpatient Visit, Est. J470- Dimercaprol Injection (BAL) 36415- Routine Venipuncture.

Code 9948 – "Toxic Effects Lead Compounds" is therefore false and misleading.

1. Indeed, Dr. Adams admitted that he treats an altogether different condition that he called "excess body burden of heavy metal."

ii. Second, Patient C.S. complained of no present symptoms and came in specifically to be chelated.

iii. Third, Dr. Adams failed to conduct a differential diagnosis to determine whether chelation was warranted with respect to Patient C.S.

iv. Fourth, the medical records do not reflect that Patient C.S. had recently been acutely exposed to lead, even though such exposure is an integral component of a lead poisoning diagnosis.

v. Fifth, a blood test administered to Patient C.S. on February 23, 2010 detected no lead in the blood. This was the only blood test administered to Patient C.S. prior to (or contemporaneously with) the February 23, 2010 chelation therapy. (Chelation is only possibly indicated for patients with BLLs greater than 50 mcg/dL (symptomatic patient) or 80 mcg/dL (asymptomatic patient). Clinical symptoms in patients with BLLs less than 40 mcg/dL are not likely attributable to lead poisoning. The medical consensus is that no action whatsoever – *e.g.*,

medication, counseling, reduced exposure, *ect*. – is necessary with respect to adult patients with BLLs less than 5 mcg/dL.)

vi. Sixth, Dr. Adams chelated Patient C.S. at least partly on the basis of the results of an inherently unreliable provoked urine test that was administered on February 23, 2010.

161. Had CMS known that, although Dr. Adams' claims sought reimbursement for chelation treatments that were affirmatively described – through the use of ICD-9 Codes associated with lead poisoning or another form of HMP – as having been rendered to treat patients suffering from lead poisoning or another form of HMP, when, in truth, the treatments were for other conditions, such as "excess body burden of heavy metals," it would not have paid the claims.

Dr. Adams Knowingly Submitted Claims To Medicare For Chelation Therapy That Was Excluded From Coverage By NCD 20.22.

162. Additionally, as Dr. Adams is a self-described practitioner of "alternative" medicine, and administers EDTA chelation as an "alternative" remedy for several conditions such as "fatigue," "excess body burden of heavy metals," and "circulation problems[,]"his chelation claims are false as they seek reimbursement for services excluded from Medicare coverage by CMS's NCD 20.22, pursuant to which "alternative" or experimental chelation therapy is *not* covered by Medicare.

163. The medical records indicate, and Dr. Adams has admitted, that Dr. Adams did not chelate patients suffering from lead poisoning or another form of HMP as his claims to Medicare indicated. Instead, the record – which includes, but is not limited to – Dr. Adams' approximately 20 year history of explicitly

marketing chelation as an "alternative" remedy for a host of diverse ailments demonstrates that Dr. Adams utilized chelation as an experimental therapy for several conditions, even though such experimental chelation therapy is specifically excluded from Medicare coverage by NCD 20.22

164. For instance, on October 21, 2011, Dr. Adams submitted a $413.86 claim for reimbursement to Medicare – which was paid October 26, 2011 – for chelation therapy that the medical records reflect that he provided to a 67 year old Medicare beneficiary with the initials "J.H." (Patient J.H.) on October 18, 2011.[25] In submitting the claim, Dr. Adams utilized the HCPCS code for EDTA (J0600) (as well as various additional CPT and HCPCS codes associated the intravenous administration of the EDTA)[26] and ICD-9 Code 9948 – "Toxic Effects Lead Compounds."

a. This claim was false as, inter-alia, Patient J.H. was not suffering from lead poisoning as indicated, but was instead seeking chelation as an "alternative" or "experimental" treatment of the type publicly espoused and marketed by Dr. Adams, but which is excluded from Medicare coverage by NDC 20.22.

    i. First, Dr. Adams has admitted that he does not treat lead poisoning or lead toxicity, and the use of the ICD-9 Code 9948

[25] Patient J.H. was chelated a total of 95 times from 11/13/08 through 3/7/12.

[26] The following codes were also billed to the Government: J7040, J7050 and J7060-Normal Saline Solution and Dextrose/Water, 96365, 96366, and 96367-Injection/Infusion Codes, J1212- Dimethyl Sulfoxide (50%) 50ml.

– "Toxic Effects Lead Compounds" is therefore false and misleading.

1. Indeed, Dr. Adams admitted that he treats an altogether different condition that he called "excess body burden of heavy metal."

ii. Second, Patient J.H. complained of only generalized symptoms - *e.g.*, visual changes, shortness of breath, urinary urgency, swelling in legs and various other symptoms – none of which were strongly suggestive of lead poisoning.

iii. Third, Dr. Adams failed to conduct a differential diagnosis to determine whether Patient J.H's symptoms were related to a condition other than ICD-9 Code 9948 – "Toxic Effects Lead Compounds" – *i.e.*, lead poisoning.

iv. Fourth, a June 22, 2011 blood test administered to Patient J.H. detected no lead in the blood. An earlier, February 22, 2010 blood test also detected no lead in Patient J.H.'s blood. These are the only two blood test that were administered to Patient J.H. prior to the October 18, 2011 chelation therapy. (Chelation is only possibly indicated for patients with BLLs greater than 50 mcg/dL (symptomatic patient) or 80 mcg/dL (asymptomatic patient). Clinical symptoms in patients with BLLs less than 40 mcg/dL are not likely attributable to lead poisoning. The medical consensus is that no action whatsoever

– *e.g.*, medication, counseling, reduced exposure, *ect*. – is necessary with respect to adult patients with BLLs less than 5 mcg/dL.)

v. Fifth, Dr. Adams chelated Patient J.H. at least partly upon the results of an inherently unreliable provoked urine test that was administered on June 29, 2011. An earlier provoked urine test was conducted on February 22, 2010.

b. As the medical records plainly demonstrate that Patient J.H was not suffering from lead poisoning or lead encephalopathy (the only two conditions for which EDTA chelation indicated), Dr. Adams' plainly chelated Patient J.H. to treat a "…generalized condition not listed by the FDA as an approved use[,]" which constitutes an "experimental" use of EDTA that is explicitly excluded from Medicare coverage by NCD 20.22.

165. In promulgating NDC 20.22, CMS expressly announced that "experimental" EDTA chelation therapy was excluded from Medicare coverage. Hence. had CMS known that Dr. Adams' claims actually sought reimbursement for "alternative" and/or "experimental" chelation therapy that is excluded from coverage under NCD 20.22, it would not have paid such claims.

Dr. Adams Knowingly Submitted Claims To Medicare For Chelation Therapy Not Indicated By The FDA Approved Label For EDTA.

166. As Dr. Adams was aware, Medicare does not reimburse providers that utilize medications for uses not indicated on the medication's FDA approved label unless specifically allowed by the MAC.

167. The FDA approved label for EDTA explicitly states that EDTA is indicated only for lead poisoning and lead encephalopathy:

- Edetate calcium disodium is indicated for the reduction of blood levels and depot stores of lead in lead poisoning (acute and chronic) and lead encephalopathy, in both pediatric populations and adults.

168. Nevertheless, Dr. Adams' extensive history of marketing chelation as an "alternative" remedy demonstrates that Dr. Adams chelated patients as "alternative" or "experimental" therapy for a host of conditions – *e.g.*, heart disease, fatigue, cancer prevention – other than lead poisoning and lead encephalopathy.

169. As an example, on August 25, 2010, Dr. Adams submitted a $349.05 claim for reimbursement to Medicare – which was paid on August 27, 2010 – for chelation therapy that the medical records reflect that he provided to a 68 year old patient with the initials "W.D." (Patient W.D.) on August 20, 2010.[27] In submitting the claim, Dr. Adams utilized the HCPCS code for EDTA (J0600) (as well as various additional CPT and HCPCS codes associated the intravenous administration of the EDTA)[28] and ICD-9 Code 9948 – "Toxic Effects Lead Compounds."

a. This claim was false as, inter-alia, Patient W.D. was not suffering from lead poisoning or another form of HMP, and received EDTA chelation for an "off-label," non-FDA approved purpose.

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[27] Patient W.D. was chelated a total of 168 times from 3/16/09 through 1/17/12.

[28] The following codes were also billed to the Government: J7040 and J7050- Normal Saline Solution, 96365, 96366, and 96367- Injection/Infusion Codes.

i. First, Dr. Adams has admitted that he does not treat lead poisoning or lead toxicity, and the use of the ICD-9 Code 9948 – "Toxic Effects Lead Compounds" is therefore false and misleading.

    1. Indeed, Dr. Adams admitted that he treats an altogether different condition that he coined "excess body burden of heavy metal."

ii. Second, Patient W.D. specifically came in to be chelated and complained of no present symptoms.

iii. Third, Dr. Adams failed to conduct a differential diagnosis to determine whether EDTA chelation was medically warranted with respect to Patient W.D.

iv. Fourth, the medical records do not reflect that Patient W.D. had recently been acutely exposed to lead or heavy metal, even though such exposure is an integral component of a lead poisoning diagnosis.

v. Fifth, a blood test administered to Patient W.D. on March 4, 2010 detected only 1 mcg/dL in the blood. This was the only blood test administered to Patient W.D. prior to his August 20, 2010 chelation therapy. (Chelation is only possibly indicated for patients with BLLs greater than 50 mcg/dL (symptomatic patient) or 80 mcg/dL (asymptomatic patient). Clinical symptoms in patients with BLLs less than 40 mcg/dL are not

likely attributable to lead poisoning. The medical consensus is that no action whatsoever – *e.g.*, medication, counseling, reduced exposure, *ect*. – is necessary with respect to adult patients with BLLs less than 5 mcg/dL.)

vi. Sixth, Dr. Adams chelated Patient W.D. at least partly on the basis of the results of an inherently unreliable provoked urine test that was administered on March 4, 2010.

b. As the medical records demonstrate that Patient W.D was not suffering from lead poisoning or lead encephalopathy (the only two conditions for which EDTA chelation indicated), Dr. Adams plainly chelated Patient W.D. in connection with an "off-label," non-FDA approved uses of EDTA, which are excluded from Medicare coverage.

170. Also, on July 25, 2011, Dr. Adams submitted a $329.70 claim for reimbursement to Medicare – which was paid on July 28, 2011 – for chelation therapy that the medical records reflect that he provided to an 83 year old patient with the initials "M.D." (Patient M.D.) on February 24, 2010.[29] In submitting the claim, Dr. Adams utilized HCPCS code J0600 for EDTA (as well as various additional CPT and HCPCS codes associated with the intravenous administration of the EDTA)[30] and ICD-9 Code 9851- "Toxic Effect Arsenic."

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[29] Patient M.D. was chelated a total of 127 times between 3/2/09 and 3/21/12.

[30] The Government was also billed for the following codes: J7040 and J7050- Normal Saline Solution, 96365, 96366, and 96367- Injection/Infusion Codes, A4209- Syringe and Needle, 99212 (Modifier 25)-Office/ Outpatient Visit, Est.

a. This claim was false as Dr. Adams has admitted that he does not treat heavy metal poisoning or toxicity, and the use of the ICD-9 Code 9851- "Toxic Effect Arsenic" is therefore false and misleading.

   i. Indeed, Dr. Adams admitted that he treats an altogether different condition that he coined "excess body burden of heavy metal."

b. Additionally, the claim is false as the FDA has not approved EDTA for use in treating arsenic poisoning, and Dr. Adam's purported use of EDTA for this purposes constitutes an "off-label," non-FDA approved use of EDTA, which is excluded from Medicare coverage.

171. Medicare does not reimburse providers for uses of a drug that go beyond their FDA specified indications, as they appear on the manufacturer's label for the drug unless specifically approved by CMS. Hence, had CMS known that Dr. Adams' claims actually sought reimbursement for "off-label" and non-FDA approved uses of EDTA, it would not have paid such claims.

Dr. Adams Knowingly Submitted Claims To Medicare For Medically Unnecessary Chelation Therapy.

172. Dr. Adams' chelation claims for chelation treatments were not medically indicated and necessary for the health of the patient.

173. In claims that Dr. Adams submitted or caused to be submitted to the Government, through the use of ICD-9 Codes associated with lead poisoning and other forms of HMP, Dr. Adams indicated that the pertinent chelation treatments were provided to patients suffering from HMP.

174. In claims that Dr. Adams submitted or caused to be submitted to the Government Dr. Adams indicated that the pertinent chelation treatments were medically necessary.

175. In truth, Dr. Adams' chelation treatments were not medically necessary, as the medical records indicate that the applicable patients were not suffering from HMP (e.g., lead poisoning).

176. Specifically, the Medicare beneficiaries Dr. Adams chelated did not present with symptoms indicative of HMP, and most sought chelation as an "alternative" treatment for conditions other than HMP, such as circulation and heart problems.

177. Moreover, Dr. Adams chelated Medicare beneficiaries with no viable history of exposure to heavy metals, which is an indispensable element of a valid HMP diagnosis.

178. Further, despite the fact that lead poisoning is exceedingly rare amongst the elderly, the overwhelming majority of the patients chelated by Dr. Adams were the age of 62 or older.

179. Finally, and fundamentally, Dr. Adams chelated patients with extremely low BLLs (e.g., 2 mcg/dL, or less), while chelation is only possibly indicated for BLLs of in excess of 50 (symptomatic patient) 80 (asymptomatic patient) mcg/dL, and the medical consensus is that, with respect to patients with BLLs less than 5mcg/dL – no action whatsoever is medically necessary.

180. For instance, on November 8, 2013, Dr. Adams submitted a $242.67 claim for reimbursement to Medicare – which was paid on November 14, 2013 –

for chelation that the medical records reflect that he provided to a 63 year old patient with the initials "J.A." (Patient J.A.) on November 6, 2013.[31] In submitting the claim, Dr. Adams utilized the HCPCS code for EDTA (J0600) (as well as various additional CPT and HCPCS codes associated with the intravenous administration of the EDTA)[32] and ICD-9 Code 9948 – "Toxic Effects Lead Compounds."

a. This claim is false as the chelation treatments were medically unnecessary as Patient J.A. was not suffering from lead poisoning.

i. First, Dr. Adams has admitted that he does not treat lead poisoning or lead toxicity, and the use of the ICD-9 Code 9948 – "Toxic Effects Lead Compounds" is therefore false and misleading.

1. Indeed, Dr. Adams admitted that he treats an altogether different condition that he called "excess body burden of heavy metal."

ii. Second, Patient J.A. complained of generalized symptoms – *e.g.*, arm and neck pain, breathing problems, constipation and change in mood – that are not strongly suggestive of lead poisoning.

iii. Third, Third, Dr. Adams failed to conduct a differential diagnosis to determine whether Patient J.A.'s symptoms were

[31] Patient J.A. was chelated a total of 67 times from 4/23/13 to 9/30/15.

[32] The Government was also billed for the following codes: J7040-Normal Saline Solution, 96365 and 96366-Injection/Infusion Codes.

related to a condition other than ICD-9 Code 9948 – "Toxic Effects Lead Compounds" – *i.e.*, lead poisoning.

iv. Fourth, the medical records do not reflect that Patient J.A. had recently been acutely exposed to lead or heavy metal, even though such exposure is an integral component of a lead poisoning diagnosis.[33]

v. Fifth, a blood test administered to Patient J.A. on April 29, 2013 detected a BLL of only 2 mcg/dL. The medical records indicate that this was the only blood test Dr. Adams ordered for Patient J.A. (Chelation is only possibly indicated for patients with BLLs greater than 50 (symptomatic patient) or 80 (asymptomatic patient) mcg/dL. Clinical symptoms in patients with BLLs less than 40 mcg/dL are not likely attributable to lead poisoning. The medical consensus is that no action whatsoever – *e.g.*, medication, counseling, reduced exposure, *ect*. – is necessary with respect to adult patients with BLLs less than 5 mcg/dL.)

vi. Sixth, Dr. Adams chelated Patient J.A. at least partly on the basis of the results of an inherently unreliable provoked urine test that was administered on August 8, 2013.

181. Similarly, on July 18, 2011, Dr. Adams submitted a $399.65 claim for reimbursement to Medicare – which was paid on July 21, 2011 – for chelation

[33] Indeed, Dr. Adams testified that his main reason for chelating this patient was the patient's 45- year exposure to lead gasoline from driving on the highway in a "cloud of lead." Dr. Adams made this determination based on Patient J.A.'s birth year of 1950.

therapy that the medical records reflect that he provided to a 62 year old patient with the initials "M.B." (Patient M.B.) on July 13, 2011.[34] In submitting the claim, Dr. Adams utilized HCPCS code J0600 for EDTA (as well as various additional CPT and HCPCS codes associated with the intravenous administration of the EDTA)[35] and ICD-9 Code 9948 – "Toxic Effects Lead Compounds."

a. This claim was false as the chelation treatments were medically unnecessary as Patient M.B. was not suffering from lead poisoning.

i. First, Dr. Adams has admitted that he does not treat lead poisoning or lead toxicity, and the use of the ICD-9 Code 9948 – "Toxic Effects Lead Compounds" is therefore false and misleading.

1. Indeed, Dr. Adams admitted that he treats an altogether different condition that he coined "excess body burden of heavy metal."

ii. Second, Patient M.B. complained of generalized symptoms - *e.g.*, arthritis pain and fatigue - that are not strongly suggestive of lead poisoning.

iii. Third, Dr. Adams failed to conduct a differential diagnosis to determine whether Patient M.B.'s symptoms were related to a

[34] Patient M.B. was chelated a total of 62 times between 1/13/09 and 4/14/12.

[35] The Government was also billed for: J7040 and J7050 - Normal Saline Solution, 96365, 96366, and 96367- Injection/Infusion Codes, J470- Dimercaprol Injection (BAL).

condition other than ICD-9 Code 9948 – "Toxic Effects Lead Compounds" – *i.e.*, lead poisoning.

iv. Fourth, the medical records do not reflect that Patient M.B. had recently been acutely exposed to lead or heavy metal, even though such exposure is an integral component of a lead poisoning diagnosis

v. Fifth, blood tests administered to Patient M.B. on March 10, 2010 and March 23, 2011 detected no lead in the blood. These were the only blood test administered to Patient M.B. prior to the July 13, 2011 chelation therapy. The medical records do not reflect that any additional blood test were administered to Patient M.B. (Chelation is only possibly indicated for patients with BLLs greater than 50 mcg/dL (symptomatic patient) or 80 mcg/dL (asymptomatic patient). Clinical symptoms in patients with BLLs less than 40 mcg/dL are not likely attributable to lead poisoning. The medical consensus is that no action whatsoever – *e.g.*, medication, counseling, reduced exposure, *ect*. – is necessary with respect to adult patients with BLLs less than 5 mcg/dL.)

vi. Sixth, Dr. Adams chelated Patient M.B. at least partly on the basis of the results of an inherently unreliable provoked urine test that was administered on March 3, 2010 and March 23, 2011.

182. Similarly, on May 29, 2012, Dr. Adams submitted a $315.37 claim for reimbursement to Medicare – which was paid on June 1, 2012 – for chelation therapy that the medical records reflect that he provided to a 66 year old patient with the initials J.B. (Patient J.B.) on May 24, 2012.[36] In submitting the claim, Dr. Adams utilized HCPCS code J0600 for EDTA (as well as various additional CPT and HCPCS codes associated with the intravenous administration of the EDTA)[37] and ICD-9 Code 9948 - "Toxic Effects Lead Compounds."

a. This claim was false as the chelation treatments were medically unnecessary as Patient J.B. was not suffering from lead poisoning.

i. First, Dr. Adams has admitted that he does not treat lead poisoning or lead toxicity, and the use of the ICD-9 Code 9948 – "Toxic Effects Lead Compounds" is therefore false and misleading.

1. Indeed, Dr. Adams admitted that he treats an altogether different condition that he coined "excess body burden of heavy metal."

ii. Second, Patient J.B. complained of generalized symptoms - *e.g.*, shortness of breath and an irregular heart beat - that are not strongly suggestive of lead poisoning.

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[36] Patient J.B. was chelated a total of 49 times from 4/20/12 to 1/2/14.

[37] Specifically, in addition to EDTA, the Government was also billed for: J7040 - Normal Saline Solution, 96365, 96366, and 96367- Injection/Infusion Codes, J470-Dimercaprol Injection (BAL), 36415- Routine Venipuncture.

iii. Third, Dr. Adams failed to conduct a differential diagnosis to determine whether Patient J.B.'s symptoms were related to a condition other than ICD-9 Code 9948 – "Toxic Effects Lead Compounds" – *i.e.*, lead poisoning.

iv. Fourth, the medical records do not reflect that Patient J.B. had recently been acutely exposed to lead or heavy metal, even though such exposure is an integral component of a lead poisoning diagnosis.

v. Fifth, a blood test administered to Patient J.B. on April 20, 2012 (in connection with Patient J.B.'s first chelation appointment with Dr. Adams) detected a BLL of only 1 mcg/dL in the blood. The medical records do not reflect that any additional blood test were administered to Patient J.B. (Chelation is only possibly indicated for patients with BLLs greater than 50 mcg/dL (symptomatic patient) or 80 mcg/dL (asymptomatic patient). Clinical symptoms in patients with BLLs less than 40 mcg/dL are not likely attributable to lead poisoning. The medical consensus is that no action whatsoever – *e.g.*, medication, counseling, reduced exposure, *ect.* – is necessary with respect to adult patients with BLLs less than 5 mcg/dL.)

vi. Sixth, Dr. Adams chelated Patient J.B. at least in part on the basis of the results of an inherently unreliable provoked urine test that was administered on April 20, 2012.

183. Pursuant to 41 U.S.C. § 1395y(a)(1)(A), Medicare only covers drugs and services that are "reasonable and necessary for the diagnosis and treatment of illness or injury." Hence, had CMS known that Dr. Adams' claims involved medically unnecessary chelation therapy, it would not have paid the claims.

THE FALSITY ASSOCIATED WITH DEFENDANTS' CLAIMS IS MATERIAL.

184. The FCA defines material as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

185. In both the common law and FCA understandings of materiality, one "look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." Absent special knowledge, if a misrepresentation is such that it would reasonably change a person's decision making process, then it is material. *See, U.S. v. Public Warehousing Company*, 2017 WL 1021745, *5-6, (N.D. Ga. March 16, 2017) (Citing to *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989 (2016), court rejected defendants' assertion that Government had not demonstrated materiality.)

186. The falsity associated with Defendants' false claims was not trivial, but material, as evidenced by the fact that the Government has actively promulgated statutes, rules and/or regulations to exclude certain items and services – *such as those reflected in Defendants claims* – from Medicare coverage, and also would refuse to pay claims for items and services that are excluded from coverage pursuant to these statutes, rules and regulations.

DEFENDANTS KNOWINGLY SUBMITTED FALSE CLAIMS TO THE GOVERNMENT.

187. Defendants submitted (or caused the submission of) the aforementioned false claims to the Government with knowledge of the falsity within the meaning of the FCA. Specifically, Defendants submitted the claims with "actual knowledge" of, or were "recklessly indifferent" or "deliberately ignorant" to, the falsity associated with such claims.

188. Defendants knowingly, within the meaning of the FCA, submitted claims to the Government that were not medically necessary and associated with "alternative," "integrative" or "experimental" treatments and/or conditions that were excluded from coverage under Medicare as they were experimental, and precluded from coverage by NCD 20.22.

189. Defendants knowingly, within the meaning of the FCA, submitted claims to the Government using ICD-9 codes indicating that the claims were associated with patients suffering from lead poisoning or other forms of HMP, when in truth, Defendants did not treat lead poisoning or other forms of HMP, but a different condition called "excess body burden of heavy metals."

COUNT I: VIOLATIONS OF THE FALSE CLAIMS ACT 31 U.S.C. § 3729(a)(1)(A)

190. The United States re-asserts all previous allegations as if set forth herein.

191. Defendants knowingly presented, or caused to be presented, to officers or employees of the United States Government, false or fraudulent claims for payment of medications and services in connection with their chelation

treatment of Medicare beneficiaries. Defendants' claims were false and/or constitute "misleading half-truths" in that they erroneously indicated that reimbursement was sought for chelation therapy that was provided as a treatment for patients suffering from lead poisoning or other forms of HMP, when in truth, Dr. Adams – by his own admission – does not treat lead poisoning or other forms of HMP. Additionally, the claims are false and/or constitute "misleading half-truths" in that they seek reimbursement for "alternative" uses outside of the indications on the FDA-approved label for EDTA, and are thus are not covered by Medicare. Finally, the claims are false and/or constitute "misleading half-truths" in the Defendants falsely certified that the chelation treatments associated with such claims were "medically indicated and necessary," when in truth, the treatments were medically unnecessary, as the patients chelated were not suffering from lead poisoning or another form of HMP. In submitting or causing the submission of these claims, the Defendants acted with actual knowledge, reckless disregard, or deliberate ignorance of the truth or falsity of the claims.

192. The Defendants made – or caused to be made – express representations that the chelation services for which he sought reimbursement were medically necessary to treat patients suffering from HMP. These representations were material to the Government's decision to pay Defendants' claims. When Defendants made these representations, they knew that these representations were false, and would continue to be false. Therefore, Defendants fraudulently induced CMS to pay claims for payment that violated the FCA.

193. By virtue of these false or fraudulent claims, the United States suffered damages in an amount to be determined at trial and is therefore entitled to treble damages under the FCA, to be determined at trial, plus civil penalties of not less than $5,500 and up to $11,000 for each violation.

COUNT II: PAYMENT BY MISTAKE OF FACT

194. The United States re-asserts all previous allegations as if set forth herein.

195. Defendants have caused the United States to make payment of certain sums of money in the mistaken belief that the Defendants' claims involved chelation therapy that was medically necessary to treat patients suffering from lead poisoning or another form of heavy metal poisoning. Indeed, Defendants' claims falsely indicated that they sought reimbursement for chelation therapy provided to patients suffering from lead poisoning or another form of HMP. In view of, *inter-alia*, the volume of claims submitted to CMS, CMS cannot check each claim for accuracy prior to paying such claim, and therefore relies upon program participants to only submit accurate claims for items and services that are reasonable and necessary. In such circumstances, payment was by mistake and was not authorized, and it would not be inequitable to full restitution of such mistaken payments, as Defendants (for the reasons outlined herein) have not acted in good faith or in good conscience in dealing the Government.

196. As a result of the unauthorized payments, the United States has sustained damages in an amount to be determined at trial.

COUNT III: UNJUST ENTRICHMENT

197. This is a claim for the recovery of monies by which the Defendants have been unjustly enriched.

198. The United States re-asserts all previous allegations as if set forth herein.

199. As described above, the Defendants received, and/or have continued to maintain control over, federal monies to which they are not entitled. Defendants were not entitled to the federal monies because Defendants, (1) in violation of 42 U.S.C. § 1395y(a)(1)(A), billed Medicare for services that were not reasonable or necessary, and/or (2) billed Medicare for "experimental" or "alternative" uses of EDTA that are outside of the indications on the FDA-approved label, and are thus are not covered by Medicare.

200. By directly or indirectly obtaining federal funds to which they were not entitled, Defendants have been unjustly enriched and are liable to account for and pay such amounts, which are to be determined at trial, to the United States.

PRAYER FOR RELIEF

WHEREFORE, the United States prays for judgment against Defendants as follows:

(1) On Counts I, under the False Claims Act, as amended, for treble the amount of the United States' damages plus interest and such civil penalties as are allowable by law, together with the costs of this action and such other and further relief as may be just and proper;

(2) On Count II, for payment by mistake of fact, for the damages sustained, plus pre-judgment and post-judgment interest, costs, and all such further relief as may be just and proper;

(3) On Count III, for unjust enrichment, for the amount of unjust enrichment, plus pre-judgment and post-judgment interest, costs, and all such further relief as may be just and proper; and

(4) That judgment be entered in favor of the United States and against the Defendants for actual damages, pre-judgment and post-judgment interest, litigation costs, investigative costs, disgorgement of all profits, and an accounting, to the fullest extent as allowed by law, and for such further relief as may be just and proper.

JURY DEMAND

The United States requests a trial by jury with respect to all issues so triable.

Respectfully submitted,

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