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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA

1:17 cv 341

UNITED STATES OF AMERICA & STATE OF NORTH CAROLINA, *ex rel.* Darryl Landis, M.D. Plaintiff, v. GENOVA DIAGNOSTICS, INC., GNVA HOLDINGS, INC., GNVA EQUITY HOLDCO., INC., LEVINE LEICHTMAN CAPITAL PARTNERS V, L.P., LAUREN LEICHTMAN, AARON PERLMUTTER, CHRIS SMITH, and JOHN DOES 1-10 Defendants.	**FIRST AMENDED COMPLAINT** **(Jury Trial Demanded)** **DO NOT PLACE IN PRESS BOX** **DO NOT ENTER IN PACER**

FILED IN CAMERA AND UNDER SEAL
Pursuant to 31 U.S.C. § 3730(b)(2) & N.C. Gen. Stat. § 1-608(b)(2)

Qui Tam Relator Dr. Darryl Landis ("**Relator**" or "**Dr. Landis**") brings this action on his own behalf and on behalf of the United States of America and the State of North Carolina to recover civil damages for violations of the Federal False Claims Act and the North Carolina False Claims Act.

I. THE PARTIES

1. Plaintiff Darryl Landis, M.D., is a North Carolina resident.

2. Defendant Genova Diagnostics, Inc. ("**Genova**" or the **"Company"**) is a Delaware corporation having its principal place of business at 63 Zillicoa Street Asheville, NC 28801-1038.

3. GNVA Holdings, Inc. ("**GNVA**") is a Delaware corporation which, upon information and belief, has a principal place of business in Asheville, North Carolina.

4. GNVA Equity Holdco., Inc. ("**GNVA Equity Holdco.**") is a Delaware corporation which, upon information and belief, has a principal place of business in Asheville, North Carolina.

5. Upon information and belief, Defendant Levine Leichtman Capital Partners V, L.P. ("**LLCP**"), is a Delaware limited partnership with its principal place of business at 335 North Maple Drive, Suite 130, Beverly Hills, California 90210.

6. Defendant Chris Smith ("**Smith**") is President and Chief Executive Officer of Genova and a member of the Board of Directors of GNVA Holdings, Inc., and Genova Diagnostics, Inc. Upon information and belief, Mr. Smith is a resident of North Carolina.

7. Defendant Lauren Leichtman ("**Leichtman**") is a member of the Board of Directors of GNVA Holdings, Inc., and Genova Diagnostics, Inc. Upon information and belief, Ms. Leichtman is a resident of California.

8. Defendant Aaron Perlmutter ("**Perlmutter**") is a member of the Board of Directors of GNVA Holdings, Inc., and Genova Diagnostics, Inc. Upon information and belief, Mr. Perlmutter is a resident of California.

9. Upon information and belief, Defendants Leichtman and Perlmutter are partners in or employees of LLCP. Defendants Leichtman and Perlmutter are collectively referred to as the "**LLCP Directors**."

10. John Does 1-10 are unidentified officers and directors of GNVA Holdings, GNVA Equity Holdco., LLCP, or Genova Diagnostics and unidentified partners in or employees of those entities who had knowledge of, the fraudulent conduct detailed herein.

II. JURISDICTION AND VENUE

11. This action arises under the FCA, as amended, 31 U.S.C. § 3729, *et seq.*, and under the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605, *et seq*. The Court has

jurisdiction over this action under 31 U.S.C. § 3730(b) and § 3732(b) and 28 U.S.C. § 1331 and 1367(a).

12. Venue is proper in the Western District of North Carolina pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a).

13. This Court may exercise personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a).

III. LEGAL FRAMEWORK

A. The Federal False Claims Act

14. The Federal False Claims Act provides, in relevant part, that any person who:

> (A) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .
>
> Is liable to the Unites States Government for a civil penalty of not less than [$10,957] and not more than [$21,916] . . . plus 3 times the amount damages which the Government sustains because of the act of that person.

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

(1) The terms "knowing" and "knowingly"—

(A) mean that a person, with respect to information—

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud[.]

31 U.S.C. § 3729(b)(1).

B. The North Carolina False Claims Act

15. Like the Federal False Claims Act, the North Carolina False Claims Act, N.C. Gen. Stat. § 1-607 also provides that any person who

(1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval [or]

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim

shall be liable for treble damages and pay a civil money penalty for each violation. The definition of "knowing" and "knowingly" is also substantially similar to the Federal False Claims Act. See N.C. Gen. Stat. § 1-606(4).

C. The Medicare Program

16. Congress enacted the Medicare program, codified at Title VII of the Social Security Act, 42 U.S.C. § 1395, et seq., in 1965. The Center for Medicare & Medicaid Services ("**CMS**") administers the Medicare program.

17. CMS contracts with private contractors, variously referred to as "fiscal intermediaries," "carriers," or Medicare Administrative Contractors ("**MACs**"), to act as agents in reviewing and paying claims submitted by health care providers. Medicare consists of four

parts: A, B, C, and D. Genova billed Medicare under Part B, which covers medical services such as clinical laboratory tests. 42 U.S.C. § 1395k(a)(2)(B).

18. To participate in the Medicare program, independent clinical laboratories such as Genova must submit a Medicare Enrollment Application, CMS Form-855B. Laboratories must also complete Form CMS-855B to change information or to reactive, revalidate and/or terminate Medicare enrollment.

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

20. An authorized official must sign the "Certification Section" in Section 15 of Form CMS-855B.

21. Authorized officials for Genova signed the certification statement in Section 15 of Form CMS-855B. In doing so, they indicated that they understood that Genova was required to comply with applicable Medicare laws, regulations, and program instructions. The authorized officials further certified that they would not "knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare" or "submit claims with deliberate ignorance or reckless disregard of their truth or falsity."

22. To obtain Medicare and Medicaid reimbursement, providers and suppliers submit a claim form known as the CMS 1500 form, or its electronic equivalent known as the 837P form.

23. The CMS 1500 or 837P requires that the provider or supplier identify each service or item provided using a five-digit code. Current Procedural Terminology codes ("**CPT codes**") are typically used to report services provided to patients, while Healthcare Common Procedure

Coding System codes ("**HCPCS codes**") are typically used to report devices, equipment or supplies provided to patients.

24. In addition, the Form 1500 or 837P requires a healthcare professional to report diagnoses that provide a basis for the selected code using International Classification of Diseases, 10th revision, Clinical Modification (**ICD-10-CM**) codes.[1]

D. Regulations Regarding Coverage for Laboratory Tests

25. Medicare only covers services that are medically necessary. Medicare.gov defines "medically necessary" as "health care services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine."

26. Medicare will only reimburse claims for diagnostic laboratory services that are reasonable and necessary for the diagnosis or treatment of an illness. See 42 U.S.C. § 1395y(a)(1)(A).

27. To be eligible for coverage, diagnostic laboratory tests "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." 42 C.F.R. § 410.32(a).

28. The Medicare Benefit Policy Manual ("**MBPM**") details CMS's policies for payment of Medicare benefits. MBPM's "Requirements for Ordering and Following Orders for Diagnostic Tests" define an "order" as "a communication from the treating physician/practitioner requesting that diagnostic test be performed for a beneficiary . . . [T]he physician must clearly

[1] Prior to October 1, 2015, healthcare providers used ICD-9 codes for diagnoses.

document, in the medical record his or her intent that the test be performed." MBPM, Ch. 15, § 80.6.1.

29. North Carolina's Medicaid program also requires that testing be individualized to the medical needs of patients. As stated in § 3.1 of the NC Division of Medical Assistance Laboratory Services Clinical Coverage Policy No: 1S-3:

> Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:
>
> a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs . . . .
>
> (available at https://files.nc.gov/ncdma/documents/files/1S-3_0.pdf)

30. In addition, 10A N.C.A.C. § 25A.0201 provides that "[a]ll medical services performed must be medically necessary and may not be experimental in nature. Medical necessity is determined by generally accepted North Carolina community practice standards as verified by independent Medicaid consultants."

31. Laboratories, like Genova, have a legal duty to ensure that they do not submit claims to Medicare or Medicaid for medically unnecessary tests.

32. In regard to that duty, the Office of the Inspector General for the Department of Health and Human Services ("**the OIG**") recommends that labs have requisition forms that "promote the conscious ordering of tests by physicians" and "ensure that the physician . . . has made an independent medical necessity decision with regard to each test the laboratory will bill." OIG Guidance, 63 Fed. Reg. 45,075, at 45,079.

IV. FACTUAL ALLEGATIONS

I. Overview of Genova Diagnostics and Its Clinical Laboratory Products.

A. Genova Diagnostics

33. Genova Diagnostics is a specialty clinical laboratory focused on the "functional" medicine market.

34. Functional medicine is a form of alternative medicine that focuses on potential interactions between the environment and the gastrointestinal, endocrine, and immune systems.

35. Founded in 1986, Genova's niche in the functional medicine market is to provide clinical laboratory tests to functional medicine practitioners that such practitioners believe will assist in developing treatment plans for their patients.

36. In 2013, Genova became a wholly-owned subsidiary of Defendant GNVA Holdings, Inc. ("**GNVA**").

37. Upon information and belief, GNVA Equity Holdco. and LLCP are the controlling and managing shareholders of GNVA.

38. Additionally, the LLCP Directors constitute a majority of the Board of Directors of both GNVA and Genova.

39. At all times relevant for purposes of this Amended Complaint, GNVA Equity Holdco. and LLCP managed and controlled both GNVA and its subsidiary, Genova.

40. As noted above, Genova offers markets a variety of unconventional laboratory tests to the functional medicine market, including test panels which relate to hormones, food allergies, nutrition, and gastro-intestinal bacterial targets ("**the Panels**").

41. Medicare and Medicaid cover services that are medically necessary to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine.

42. As explained below, there is insufficient evidence that all of the Panels' tests are medically necessary and therefore eligible for Medicare or Medicaid payment. Nonetheless, Genova, at the direction and with the knowledge of its owners and managers and in a wrongful effort to increase revenues, systematically bills Medicare and Medicaid for the Panels' tests.

43. Additionally, through Requisition Forms, Defendants knowingly force physicians to order a large number of tests on each Panel which are not individualized for patients, which results in the ordering of and Genova's billing of Medicare and Medicaid for tests that are medically unnecessary and not relevant to the diagnosis or treatment of patients.

44. From July 1, 2015 through June 30, 2017, Genova, with the knowledge or and at the direction of its owners, managers, and board of directors, has fraudulently submitted claims for payment for and received over $21 million in reimbursements from Medicare for the Panels. During that time period, it also has submitted claims for payment for and received Medicaid reimbursements from the State of North Carolina for the Panels.

B. Genova's GI Effects Panel

45. One of the above-referenced medically unnecessary test panels is the GI Effects 2200 ("**the GI Effects Panel**"),[2] which is a panel of fecal stool tests that assesses 46 different biomarkers of gastrointestinal function, including twenty-four (24) commensal bacterial targets found in the gastrointestinal system.

46. According to Genova's website, the GI Effects Panel provides "immediate, actionable clinical information for the management of gut health," and individuals with "leaky

[2] In addition to the GI Effects 2200 panel, Genova offers a variety of gastrointestinal tests that use the same methodologies and test for many of the same biomarkers as the GI Effects 2200 panel. Thus, the allegations in the Complaint as to GI Effects 2200 panel are illustrative and representative of problems endemic to all of Genova's gastrointestinal tests.

gut symptoms," "celiac disease," GI disorders, such as IBS, and cardiometabolic diseases, such as diabetes.

47. In particular, Genova recommends and markets the GI Effects Panel for use in diagnosing and/or formulating treatment plans for a wide range of clinical conditions, including irritable bowel syndrome (IBS), inflammatory bowel disease (IBD), diabetes, obesity, cardiovascular disease, celiac and other malabsorption disorders, mood disorders, autism, and autoimmune disorders.

48. Despite the fact that Genova markets the GI Effects Panel as providing "immediate, actionable clinical information" for individuals with a wide range of clinical conditions, such as GI disorders and diabetes, there is insufficient clinical evidence to establish that the GI Effects Panel is medically necessary or needed to diagnose or treat individuals with those conditions.

49. For example, there are no published, peer-reviewed studies or papers or high-quality clinical studies that assess, demonstrate, or establish the clinical validity, use, or cost-effectiveness of the GI Effects Panel in clinical practice.

50. The GI Effects Panel also utilizes proprietary testing platforms and algorithms, and those platforms and algorithms have not been published and they have not been adequately validated.

51. Significantly, Genova has been unable to internally validate the GI Effects Panel's platform or algorithms.

52. For example, when Genova undertook analyses of the performance of the GI Effects Panel's proprietary testing platform and algorithms on six healthy volunteers, results

unfortunately demonstrated substantial *variability* both within and between those individual volunteers.

53. Genova also engaged in analyses of the GI Effects Panel's proprietary testing platform and algorithms on individuals with selected self-reported chronic conditions, and results from those analyses were inexplicably *inconsistent* with existing published literature for those chronic conditions.

54. Furthermore, there is no proven medical treatment specifically directed to the twenty-four (24) commensal bacterial targets that the GI Effects Panel analyzes.

55. Although some literature shows an association between IBS and some of the twenty-four (24) commensal bacterial targets reported on the GI Effects Panel, all Defendants are aware that internal Genova data suggests that the results of the GI Effects Panel do not completely align with that described in published literature (much less establish a causal link between those bacteria and IBS).

56. In other words, there is no evidence that the GI Effects Panel is needed to prevent, diagnose, or treat a patient's illness, injury, condition, disease, or its symptoms, and the Panel does not meet the accepted standards of medicine.

57. In fact, numerous private payers, including most BlueCross BlueShield plans, UnitedHealthCare, and Cigna, have published medical policies deeming Genova's gastrointestinal Panels to be investigational and not medically necessary.

58. Genova and its owners, managers, and directors (including GNVA, GNVA Equity Holdo., LLCP, Liechtman, Perlmutter, and John Does) know that medical necessity evidence is lacking with regard to the GI Effects Panel, that the Panel is not an accepted standard of

medicine, and that the GI Effects Panel therefore is not eligible for Medicare or Medicaid payment.

59. Nonetheless, Genova, at the direction and with the knowledge of all Defendants, systematically bills Medicare/Medicaid for the GI Effects Panel and falsely certifies that the GI Effects Panel's tests are medically necessary.

60. Genova also problematically bills Medicare and Medicaid for the Panel's entire bundle of tests regardless of the relevancy of each test's use for the diagnosis or treatment of any particular individual.

61. Genova's Requisition Form has a single check box that does not differentiate between the GI Effects Panel's twenty four (24) different commensal bacteria tests. As a result, by checking the box for the GI Effects Panel, a physician automatically orders the entire panel for all twenty four (24) bacterial targets, regardless of whether tests for all twenty four (24) bacterial targets are allegedly necessary or relevant to prevent, diagnose, or treat his/her patient's illness, injury, condition, disease, or symptoms. See **Exhibit 1**.

62. Consequently, Genova's "check the box" Requisition Form interferes with providers' medical judgment by preventing them from ordering only the specific tests that the provider has deemed medically necessary for his/her particular patient. In other words, Genova's Requisition Form does not ensure that the physician is making an independent medical necessity decision with regard to each of the GI Effects Panel's tests.

63. Following the physicians' ordering of medically excessive tests, Genova, at the direction and with the encouragement of Defendants, then fraudulently submits Medicare/Medicaid claims for payment for all of those tests with knowledge that not all of them (even allegedly) are medically necessary.

64. Not only is there insufficient clinical evidence to establish the requisite medical necessity of the GI Effects Panel, but Genova, with the knowledge of and at the direction of the remaining Defendants, wrongly bills Medicare and Medicaid for that Panel with incorrect and misleading CPT codes.

65. As noted above, the GI Effects Panel assesses twenty four (24) different commensal bacterial targets.

66. Commensal bacteria are *non-infectious* bacteria present at some level in many healthy individuals and have not been shown to cause disease, do not indicate any specific treatments, and are not part of any generally accepted standard of care.

67. In particular, none of the GI Effects Panel's commensal bacterial targets have been definitively demonstrated in any published literature to cause disease or infections.

68. Despite the fact that the Panel analyzes non-infectious bacteria, Genova fraudulently bills Medicare/Medicaid for each of those tests under the CPT code 87798, which is defined as "*infectious* agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified phobe technique, each organism."

69. In other words, in submitting or causing to be submitted claims for Medicare and Medicaid payment for the GI Effects Panel that analyzes non-infectious gut bacteria, Genova and the remaining Defendants falsely represent to Medicare and Medicaid that the Panel's tests are "infectious agent" tests.

70. CPT code 87798 is not appropriate for the 24 commensal bacterial targets assessed by GI Effects panel because none of those bacterial targets have been definitively demonstrated in any published literature to cause disease or infections. Additionally, none of the

24 commensal bacterial targets in the GI Effects Panel have been shown in published literature to cause any of the associated ICD 10 conditions.

71. Thus, in submitting claims for Medicare and NC Medicaid payment of the GI Effects Panel's tests that analyze non-infectious gut bacteria, Genova, at the direction of its owners and managers, falsely represents to the governments that the 24 commensal bacteria test panels are "infectious agent" tests.

72. In addition to fraudulently using the CPT code 87798, Genova wrongly utilizes seven other CPT codes to bill for the GI Effect Panel's tests (82542; 82784; 82725; 82715; 83520; 84311; 87102).

73. The tests billed with these seven codes are not generally accepted standard of care or diagnostic for any ICD 10 conditions.

74. The remaining 11 CPT codes may have appropriate and medically necessary indications for patients with one or more of the listed ICD 10 conditions on an individual case basis. However, it is not a generally accepted standard of care to routinely order all of those tests simultaneously and without regard to the relevancy of each test's utility for the diagnosis or treatment of any particular individual.

75. Upon information and belief, Genova has submitted to Medicare claims for payment and received from Medicare substantial sums for medically unnecessary GI Effects Panel tests. For the July 1, 2015-June 30, 2017, time period, Genova received at least $8,916,899 from Medicare for GI Effects Panels.

76. Upon information and belief, Genova has submitted to North Carolina Medicaid claims for payment and received from North Carolina Medicaid funds for medically unnecessary GI Effects Panels.

C. Genova's NutrEval Panels

77. Defendants' fraudulent billing of Medicare and Medicaid also extends to two nutrition test panels: the NutrEval FMV Test and the NutrEval Plasma Test (together, the "**NutrEval Panels**").

78. The NutrEval Panels evaluate and test over 100 organic acids, amino acids, fatty acids, micronutrients, and other elements in an individual's blood and urine.

79. Genova promotes the NutrEval Test FMV (First Morning Void) test as "an advanced diagnostic tool to guide nutritional therapies, often augmenting and speeding recovery of complex chronic conditions." https://www.gdx.net/product/nutreval-fmv-nutritional-test-blood-urine (as of December 7, 2017).

80. Per Genova, the NutrEval FMV Test "identifies nutritional deficiencies that may be a *causative* factor in complex chronic conditions." Id. (emphasis added).

81. Genova markets the second NutrEval Panel, the NutrEval Plasma test, as "reveal[ing] nutritional imbalances or inadequacies," https://www.gdx.net/product/nutreval-nutritional-test-plasma (as of December 7, 2017), and it advertises the Plasma test as "a nutritional analysis that allows assessment of nutritional inadequacies or imbalances that may be playing a causative role in complex chronic conditions."

82. Genova recommends both NutrEval Panels for individuals who suffer from mood disorders, fatigue, digestive complaints, chronic pain, inflammatory conditions, cardiovascular risk, and weight issues. Id.

83. Genova's billing of Medicare and Medicaid for the NutrEval Panels is problematic and fraudulent in a number of ways.

84. First, there is no evidence that the NutrEval Panels are medically unnecessary – a fact well known to all Defendants.

85. For example, there are no published, peer-reviewed studies or papers or clinical studies that assess, establish, or demonstrate the clinical validity and utility of the NutrEval Panels for any of the identified conditions.

86. Furthermore, the NutrEval Panels utilize proprietary testing platforms and algorithms that are unpublished, not adequately validated, and have not been proven to produce clinically useful results to diagnose or treat individuals.

87. Additionally, as all Defendants are aware, the NutrEval Panels do not meet accepted standards of medical practice.

88. Because there is no evidence that the NutrEval Panels are medically necessary or meet the accepted standards of medicine, these Panels do not satisfy Medicare or Medicaid's criteria for payment.

89. Despite knowledge of that problem, Genova, at the direction of the remaining Defendants, fraudulently and systematically bills Medicare and Medicaid for those Panels and falsely certifies that the NutrEval Panels' tests are medically necessary.

90. Defendants' fraud with regard to the NutrEval Panels is also evidenced by Genova's billing of Medicare and Medicaid for the entirety of the Panels' tests, regardless of whether a medical provider deemed each test to be (allegedly) medically necessary for a patient.

91. As with the GI Effects Panel, Genova's Requisition Form for the NutrEval Panels has a single check box that does not differentiate between the 100 plus test targets or allow physicians to deselect tests that are irrelevant to and medically unnecessary for their patients. The ordering form therefore does not ensure that the physician has made an independent medical necessity decision with regard to each of the NutrEval Panel's tests.

92. As a result, by checking the box for the NutraEval Panels, a physician orders the entire panel of tests, regardless of whether the majority of the 100 plus test targets are medically unnecessary to prevent, diagnose, or treat a patient's illness, injury, condition, disease, or symptoms. As a further consequence, Genova then knowingly submits claims for Medicare and Medicaid payment for medically excessive and unnecessary tests in the NutrEval Panels.

93. Genova has submitted to Medicare claims for payment for and Medicare has reimbursed Genova substantial sums for medically unnecessary NutrEval Panels. Upon information and belief, for the July 1, 2015, through June 30, 2017 time period, Medicare paid Genova $6,275,460 for NutrEval Panels.

94. Genova also has submitted to North Carolina Medicaid claims for payment and received from North Carolina Medicaid funds for medically unnecessary NutrEval Panels.

D. Hormone Panels:

95. Defendants' false claims and fraud also stem from Genova's billing of Medicare and Medicaid for hormone panel tests, which include : (1) the Menopause Plus and Menopause Check Plus salivary hormone panel tests that evaluate sex hormones in men and women; (2) the Rhythm salivary hormone panel test, which assesses estradiol, progesterone, and testosterone over a 28 day period; and (3) the Complete Hormones urinary panel test, which "assesses parent hormones, their metabolites, and key metabolic pathways," See, e.g., https://www.gdx.net/product/complete-hormones-test-urine (as of December 8, 2017) (collectively, "**the Hormone Panel tests**").

96. Genova markets the Hormone Panel tests as assisting "in the clinical management of hormone-related conditions," and recommends the Panels to help guide hormone replacement therapy and for men and women suffering from "weight gain, anxiety, fatigue, low sex drive and performance issues, sleep disturbances, mood instability, brain fog, and hot flashes." *Id.*

97. Although Genova bills Medicare and Medicaid for the Hormone Panels, there is insufficient clinical evidence that the Panels are medically necessary.

98. Notably, as Defendants know, several of the Hormone Panels involve urine specimens, which are not standardly used in the medical community to analyze sex hormones as there is insufficient medical literature or clinical evidence that such specimens have any proven utility for the diagnosis or treatment of hormonal (or any) diseases or illnesses.

99. The Hormone Panels' salivary tests also are not clinically proven to be medically necessary to the patient population in general, and they have been determined to be unreliable by major national professional organizations, including, but not limited to, the American Association of Clinical Endocrinologists and the American College of Obstetricians and Gynecologists.

100. Although select salivary tests, such as ones for cortisol levels, may be relevant and medically necessary to a very select patient population, Genova's Hormone Panels are not limited to those salivary tests, but instead include a bundle of other medically unnecessary tests.

101. Additionally, as Genova and its owners, managers, and directors are all aware, there are no peer-reviewed clinical studies that support the medical necessity of the Hormone Panels' array of tests.

102. As with Genova's other tests, many private insurance companies deny coverage for the Hormone Panels.

103. Despite actual knowledge that there is insufficient evidence to support the medical necessity and validity of the Hormone Panels, Genova, at the direction of the other Genova Defendants and with the aim of increasing profits, systematically submits claims for payment for the Hormone Panels to Medicare and Medicaid, and, in doing so, fraudulently

certifies to Medicare and other government payers, including North Carolina Medicaid, that the Hormone Panels are in fact medically necessary.

104. Furthermore, even if some of the Hormone Panels' tests were medically necessary, Genova, through the use of Requisition Forms, denies physicians the ability to make independent medical necessity decisions for each of the Panels' tests.

105. Like the other Panels' Requisition Forms, the Hormone Panels' order form has a single check box which requires a physician to order the entire array of the Panels' tests. The form does not differentiate between the Panels' tests or allow physicians to deselect tests that they have determined are medically unnecessary and irrelevant to their particular patients.

106. With that knowledge, Genova, at the direction of and with the consent of the other Defendants, bills Medicare and Medicaid for all of the Hormone Panels' tests and fraudulently certifies each test as being medically necessary.

107. Upon information and belief, for the July 1, 2015, through June 30, 2017, time period, Genova has submitted to Medicare claims for payment and Medicare has reimbursed $1,584,351 for medically unnecessary Hormone Panels.

108. Genova also has submitted to North Carolina Medicaid claims for payment and received from North Carolina Medicaid funds for medically unnecessary Hormone Panels.

E. The IgG Food Antibody Panel:

109. Defendants' widespread fraud also encompasses Genova's billing of Medicare and Medicaid for an IgG Food Antibody Panel, which measures and tests eighty (80) plus food antibody targets.

110. Genova describes this Panel as "a food sensitivity test which helps identify those with true IgE-mediated allergies as well as IgG-mediated food intolerances."

https://www.gdx.net/product/igg-food-antibodies-food-sensitivity-test-blood (Last Checked December 13, 2017).

111. Genova claims that this Panel "is ideal for patients who may suffer from delayed reactions/sensitivities to specific foods. It may also provide insight on intolerances, or non-immune responses, to certain foods." Id.

112. Problematically, despite Genova's billing of Medicare and Medicaid for the IgG Food Antibody Panel, Genova and its owners, managers, and board members know that there is insufficient clinical evidence that the Panel is medically necessary.

113. Significantly, there is insufficient clinical evidence to and there are no peer papers that establish the clinical validity or utility of the IgG Food Antibody Panel for the diagnosis or treatment of any disease or condition. In fact:

a. There is insufficient clinical evidence that the presence of any IgG antibody in a person's body is causally related to a disease or treatment for any disease.

b. There is no evidence to support – internally from Genova or from published peer-review studies – that the patterns of IgG food antibody levels reported on Genova's IgG Food Antibody Panel actually differ between healthy and unhealthy individuals. Consequently, abnormal results for this Panel do not indicate any specific diagnosis or recommended treatment for an individual.

114. Additionally, this Panel is not part of the generally accepted standard of care.

115. A number of clinical care guidelines conclude that: "food-specific IgG4 does not indicate (imminent) food allergy or intolerance, but rather a physiological response of the immune system after exposition to food components. Therefore, testing of IgG4 to foods is

considered as irrelevant for the laboratory work-up of food allergy or intolerance and should not be performed in case of food-related complaints."

116. Medicare and Medicaid will not provide coverage for investigational services, like this Panel, that have not yet been established as medically necessary and an accepted standard of medicine.

117. Despite the overwhelming and conclusive lack of evidence that the IgG Food Antibody Panel meets Medicare's or Medicaid's requirement of medical necessity, Genova, at the direction of the remaining Defendants, systematically bills Medicare and Medicaid for the IgG Food Antibody Panel (and its entire panel of eighty [80] food antibody test targets) and falsely certifies the Panel's tests as medically necessary.

118. Defendants' fraud with regard to this Panel also encompasses Genova's use of a Requisition Form with a single check box that does not differentiate between the Panel's eighty (80) different targets or allow physicians to deselect targets that are irrelevant to their patients.

119. Wrongly, the Panel's requisition form therefore does not ensure that the physician has made an independent medical necessity decision with regard to each test for which Genova will bill Medicare/Medicaid.

120. As a result, by checking the box for the IgG Food Antibody Panel, a physician automatically orders the entire panel of tests, regardless of whether the majority of the eighty (80) test targets are "medically unnecessary" to prevent, diagnose, or treat his/her patient's illness, injury, condition, disease, or symptoms.

121. Armed with that knowledge, Genova, at the direction and with the consent of all Defendants, nonetheless then bills Medicare/Medicaid for all eighty (80) of the Panel's food

antibody targets, fraudulently certifying that the Panel (and all of its tests) was "medically necessary."

122. Upon information and belief, for the July 1, 2015, through June 30, 2017 time period, Genova has submitted to Medicare claims for payment and Medicare has reimbursed Genova $4,853,798 for medically unnecessary IgG Food Antibody Panels.

123. Genova also has submitted to North Carolina Medicaid claims for payment and received from North Carolina Medicaid funds for medically unnecessary IgG Food Antibody Panels.

F. In Summary:

124. For at least the July 1, 2015, through June 30, 2017, time period (and, in some cases, as early as 2010), Defendants systematically and fraudulently submitted or caused to be submitted claims for Medicare/Medicaid payment for the GI Effects Panel, NutraEval Panel, Hormone Panels, and IgG Food Antibody Panel, and they did so with actual knowledge that none of the Panels are medically necessary, meet accepted standards of medicine, or are eligible for Medicare or Medicaid payment.

125. Additionally, with regard to the GI Effects Panel, Defendants fraudulently and knowingly billed (or caused to be billed) Medicare and Medicaid with an incorrect and misleading CPT code.

126. During that time period, Defendants also wrongly utilized requisition forms with a single box order format that required physicians to automatically order a large number of tests without an individualized assessment of which of the many tests may be reasonable and (allegedly) medically necessary for the treatment and diagnosis of his/her individual patient's illness. As a result, the requisition forms resulted in the ordering of and Genova's performing of excessive and medically unnecessary tests.

127. In turn, Defendants then knowingly and fraudulently submitted or caused to be submitted to Medicare and Medicaid claims for payment for those medically excessive and unnecessary Panels.

II. Defendants' Knowledge of Genova's Compliance Issues and Fraudulent Billing Practices.

A. Dr. Landis's Role at and Investment in Genova

128. Genova has known since at least 2010 that its nonconventional tests lack requisite medical necessity evidence to be eligible for Medicare and Medicaid payment.

129. During the 2010-2012 time period, Genova's then CMO, Patrick Hanaway, initiated clinical development efforts in an attempt to develop such evidence.

130. In July of 2012, Genova hired Dr. Landis to be its new CMO and tasked him with developing medical necessity evidence for its tests.

131. Dr. Landis is a board-certified physician, family medicine practitioner, physician executive, and adjunct professor at a leading academic medical center.

132. Ted Hull, the former CEO of Genova, hired Dr. Landis in July 2012 because Dr. Landis was a conventionally-trained physician with deep expertise in medical policy, clinical research, and evidence-based care.

133. After he joined Genova as the CMO, Dr. Landis helped form and execute a clinical evidence development strategy so that Genova could develop reliable scientific evidence to establish the medical necessity of its various tests.

134. Dr. Landis initially secured significant budget authority from Genova to pursue his clinical evidence development strategy and the development of medical necessity evidence. Mr. Hull, and the Genova's Chief Marketing Officer, Chris Smith, expressed to Dr. Landis that

they were firmly committed to the clinical evidence development strategy. Indeed, Genova had budgeted $1 Million for a certain clinical evidence study to be conducted.

135. As detailed above, LLCP, as a controlling shareholder of GNVA, acquired Genova in 2013. As one of the four Key Managers and CMO of Genova, Dr. Landis fully participated in and contributed to all aspects of the sales process, including all management presentations to LLCP.

136. In those meetings and in diligence, there was ample discussion with LLCP and other Defendants of Genova's clinical evidence development strategy, the need to develop medical necessity evidence for Genova's test panels, and the imminent $1M clinical study, which had been approved and budgeted.

137. In reliance on LLCP's stated commitment to that clinical evidence development strategy, Dr. Landis made a significant financial investment in the Company, and was even induced to borrow money from the Company and GNVA to acquire additional equity in the Company. Dr. Landis and the limited liability company in which he is a member acquired significant equity in the form of common shares and stock options.

138. In connection with LLCP's acquisition of Genova, Dr. Landis entered into an Employment Agreement with Genova dated September 29, 2013. On November 13, 2013, Dr. Landis executed and entered into the GNVA Holdings, Inc. Stockholders Agreement, the GNVA Holdings, Inc. 2013 Stock Option Plan, and the GNVA Holdings, Inc. Non-Qualified Stock Option Agreement, as well as signing promissory notes with the Company and GNVA to secure the money loaned to him to purchase equity in the Company and GNVA.

B. Dr. Landis Warnings to Defendants About Fraudulent Billing Practices

139. As outlined below, Dr. Landis has repeatedly raised concerns about and warned all Defendants about the weak to non-existent clinical support for the medical necessity of

Genova's panel tests, including the GI Effects Panel, and the resulting impropriety of Genova's Medicare and Medicaid billing of those tests.

140. Following LLCP's acquisition, Genova's then CEO, Ted Hull, left the Company. In his place, LLCP selected Chris Smith as Genova's new CEO.

141. Under Chris Smith's tenure, Genova unfortunately focused its money and efforts on marketing and the increasing of profits, and shifted its focus away from the costly development of medical necessity evidence for Genova's panel tests. Dr. Landis attempted several other large-scale definitive clinical evidence development initiatives, but Smith, LLCP, and GNVA Equity Holdco. never approved them.

142. While it was becoming increasingly clear that LLCP, GNVA Equity Holdco., and Smith had no intention of executing on the clinical evidence development strategy, private payers and Medicare began raising questions about the medical necessity justifying the use of billing codes Genova utilized for certain of its tests.

143. Specifically, on July 16, 2015, Genova received a notification from Blue Cross Blue Shield – Federal Employee Processing regarding a negative medical policy determination related to Genova's stool testing.

144. Dr. Landis notified Genova's CEO, Smith, as well as Genova's CFO and Vice-President of Sales, about this negative policy determination.

145. A week later, on July 23, 2015, Dr. Landis voiced concern to Smith that almost none of Genova's tests met the medical necessity criteria necessary to bill Medicare, and reiterated that Genova needed to invest time and money in developing clinical evidence to support such medical necessity and Medicare eligibility.

146. Subsequently, Genova received a notice that CMS was placing Medically Unnecessary Edit ("**MUE**") on Genova's use of certain CPT codes.

147. As a result of the MUE, Dr. Landis recommended that Genova undertake a review of its coding and billing practices.

148. In connection with that effort, Dr. Landis became aware in February 2016 that Genova was billing for the GI Effects test using CPT code 87798.

149. Around that same time, Dr. Landis expressed concern to Genova's leadership team, including Smith, about the propriety of Genova's use of CPT code 87798 (a code for infectious agent detection) for the GI Effects Test, which analyzes non-infectious bacteria.

150. As a result of Dr. Landis's concerns, Genova asked Boston Healthcare Associates ("**BHA**") to review the use of CPT 87798 for the GI Effects Test.

151. In August 2016, Dr. Landis asked about the results of the BHA analysis. In response, he received a copy of a June 10, 2016 report (the "**BHA Report**").

152. Problematically, the BHA Report, which was only 1.5 pages long, did not address (i) the medical necessity of testing for commensal bacteria or (ii) the inconsistency between the code description of "infectious" compared with the "commensal" nature of the targeted bacteria. The report itself also noted that coding experts consulted by BHA "provided variable guidance on the most appropriate coding strategy."

153. As a result, the BHA Report did not establish the medical necessity or validity of Genova's billing of Medicare for the GI Effects Test or its use of CPT 87798 to do so.

154. Throughout the Fall of 2016, Dr. Landis continued to propose additional clinical evidence development initiatives for Genova's tests, none of which Genova (or its controlling entities) agreed to pursue.

155. On December 13, 2016, Dr. Landis prepared a detailed memo outlining fraud concerns with respect to: (a) Genova's use of CPT code 87798 for the GI Effects Panel, and (b) whether there was clinical evidence to support the medical necessity of, and therefore Genova's ability to bill Medicare for, the GI Effects Panel's tests. Dr. Landis submitted that memo to Genova's Compliance Hotline and to Genova's Board members, including LLCP's Aaron Perlumutter and David Burcham, David Reed, and David Zewe.

156. Genova's Board members (including John Does) did not substantively respond to Dr. Landis' allegations of Medicare fraud with regard to the GI Effects Panel. As a result, Dr. Landis continued to verbally warn and submit written warnings to Defendants about the impropriety of Genova's Medicare billing for its test panels.

157. For example, in June of 2017, Dr. Landis emailed Smith and Genova's CFO, Vice President of Sales, Compliance Officer, and Lab Director to recommend that Genova stop billing Medicare for allergy testing as there was a lack of requisite clinical evidence to establish those tests' medical necessity. However, Defendants again refused to heed that warning, and Genova, with the knowledge and consent of the remaining Defendants, continued to bill Medicare and Medicaid for those tests (and falsely certify those tests' medical necessity) in an effort to increase Genova's revenue.

158. On August 3, 2017, Dr. Landis specifically spoke about his fraud concerns with LLCP's Perlmutter and Leichtman, who were also two members of GNVA Holding's and Genova's Board of Directors. During that conversation, Dr. Landis told Perlmutter and Leictman that, in his professional assessment as Genova's CMO, Genova's tests do not meet Medicare's requirements for medical necessity, and that Genova's continued billing of Medicare for those tests could have devastating financial and legal consequences.

159. The following month, on September 7, 2017, Genova and GNVA Holdings finally responded in writing to Dr. Landis' concerns about Genova's use of the CPT code 87798 for the GI Effects Panel (which Dr. Landis had raised in writing nearly a year before).

160. According to Genova and GNVA Holdings, Genova had engaged healthcare counsel and hired an expert, Joel Brill, M.D. ("**Dr. Brill**"), to review its use of CPT Code 87798.

161. According to those parties, Dr. Brill had produced a 12-page report dated February 13, 2017.

162. Upon information and belief, that report, which was based on a literature review limited to the issue of whether commensal bacteria can be infectious and pathologic, concluded that Genova's use of CPT Code 87798 was appropriate.

163. However, Genova and GNVA Holdings have refused to provide a copy of Dr. Brill's report to Dr. Landis despite repeated requests.

164. Upon information and belief, Dr. Brill's report does not address the fundamental fraud concern raised by Dr. Landis—i.e., whether there is any clinical evidence to support the medical necessity of the GI Effects Panel.

165. On further information and belief, Genova deliberately limited the scope of Dr. Brill's assignment and provided him with limited information in order to secure a favorable conclusion that supported Genova's continued use of CPT Code 87798 for Medicare and Medicaid billing purposes.

166. Upon information and believe, Genova's activities with regard to the inadequate investigation of Dr. Landis's fraud claims were conducted with the full knowledge and approval of Genova's Board of Directors, including the LLCP Directors and John Does, and Genova's owners, managers, and controlling shareholders.

167. Furthermore, since being informed of Dr. Landis's repeated concerns regarding Genova's improper billing practices, Defendants have not taken any action to end Genova's fraudulent billing practices.

C. Defendants Retaliate Against Dr. Landis.

168. In the Spring of 2016, as Dr. Landis communicated with Smith regarding his concerns about the lack of clinical evidence to support Genova's products and billing, Smith chastised Dr. Landis both for expressing his opinions and creating a record of them.

169. Soon after, Smith, with the full knowledge and support of the LLCP Directors and John Does, met with direct reports of Dr. Landis without Dr. Landis' knowledge, and attacked and criticized Dr. Landis and his "overly conservative" point of view on the clinical evidence, and outlined his personal and professional disagreements with Dr. Landis.

170. Smith also sought to undermine Dr. Landis with Genova leadership and staff. He repeatedly initiated meetings with members of the team led by Dr. Landis, alone and without Dr. Landis' knowledge, for the purpose of fomenting discord and distrust, to fish for negative information about Dr. Landis, and to further isolate Dr. Landis.

171. Smith also repeatedly attacked and criticized Genova employees who shared Dr. Landis' views or whom Smith viewed as being aligned with Dr. Landis, ultimately forcing those employees out of Genova.

172. On June 1, 2016, Smith directed that Dr. Landis was not to utilize Medical Affairs personnel for any tasks unless specifically authorized by Smith.

173. That directive marked a substantial limitation of Dr. Landis' authority and role as Genova's Chief Medical Officer and constituted a material change in Dr. Landis' job duties.

174. That directive by Smith also significantly hampered Dr. Landis' ability to plan ahead for new product research and development.

175. On October 21, 2016, Smith prepared a negative annual performance appraisal for Dr. Landis, and questioned why Dr. Landis did not leave the Company. All of Dr. Landis' prior performance appraisals had been positive. Dr. Landis objected to the negative appraisal and disputed Smith's core negative criticisms of him.

176. On December 21, 2016, Dr. Landis complained to Ms. Earlene Clark, Genova's Compliance Officer, and sought her intercession to stop Smith's ongoing and continuous actions in retaliation.

177. In their discussion, Dr. Landis told Ms. Clark that Smith was targeting him and the Medical Affairs team; that he wanted Ms. Clark to help him have that behavior stop; and that he wanted to meet with her in person to discuss these concerns in greater depth so that they would end.

178. Ms. Clark never followed up on Dr. Landis' complaint; never interviewed Dr. Landis; and took no action of which Dr. Landis is aware, formally or informally, to investigate or address Dr. Landis' concerns.

179. Smith continued to target Dr. Landis by cutting the Medical Affairs budget and staff in FY 2016 and FY 2017, hampering Dr. Landis' ability to execute Medical Affairs components of the corporate project plan in line with industry standard clinical evidence methods.

180. Throughout 2017, Smith, with the knowledge of John Does and the LLCP Directors, repeatedly excluded Dr. Landis from the Executive Team meetings.

181. On multiple occasions, Smith held the Executive Team meetings secretly so that Dr. Landis would not know about them.

182. On one occasion, Dr. Landis discovered the entire Executive Team met about the FY 2018 budget without him.

183. On another occasion, Smith invited, and then uninvited, Dr. Landis to a meeting of the Executive Team at his personal lake home.

184. In the Spring or Summer of 2017, Smith placed further ridiculous restrictions on Medical Affairs and Dr. Landis, prohibiting Dr. Landis from engaging any medical consultant for any task, large or small.

185. Smith was well aware that due to Smith's prior staffing cuts, Dr. Landis and Medical Affairs relied upon the contributions of such consultants to deliver the team's work.

186. In June 2017, Smith convened the leadership team (including Genova's CFO, Vice President of Sales, Compliance Officer, and Lab Director) to discuss strategy and budget matters. At that meeting, Dr. Landis raised, among other concerns, the cut to the consultant budget that would delay product launches.

187. Dr. Landis suggested that, given the strategic directions and budgetary restraints, the majority investor would need to "come to Jesus" about the realities that Genova was facing. Smith agreed.

188. In or around March 2017, Smith and LLCP, the majority investor in Genova, proposed that Dr. Landis lead a Genova spinoff. During those discussions, Dr. Landis told two Board members directly that Smith was retaliating against him because of his views regarding compliance and regulatory matters.

189. On or about August 2, 2017, at a leadership team meeting, Dr. Landis was asked by Genova's CFO how he viewed the Company's challenges and what he would do about them. Only in response to that direct question did Dr. Landis again, in an entirely professional manner,

raise the fraud, regulatory, and compliance concerns he had about Genova's Medicare billing and how he thought the Company should address them.

190. Smith became visibly angry, accused Dr. Landis of being counterproductive, and sought to shut his comments down. This accusation was immediately refuted by the CFO who stated to Smith in front of the leadership team that he did not find Dr. Landis' comments counterproductive.

191. Immediately after that meeting, Perlmutter suddenly informed Dr. Landis that LLCP and Genova would not proceed with the spinoff company, after Dr. Landis had spent substantial time and his own funds for legal counsel to develop business plans, work on the legal documents, and negotiate the proposed transaction.

192. Thereafter, Dr. Landis was unexpectedly summoned to New York and interviewed by outside counsel for Genova about his fraud concerns on August 9, 2017.

193. At the conclusion of that meeting, Dr. Landis expressed his concerns (beyond CPT Code 86001 and Code 87798) about three other Company compliance issues and provided counsel with a packet of documents evidencing and supporting these concerns.

194. Dr. Landis heard nothing further from Genova about his concerns raised in the August 9, 2017 meeting.

195. Without warning, on August 14, 2017, Dr. Landis was suspended. The alleged bases for the suspension were false.

196. Genova, in direct retaliation for Dr. Landis' repeated concerns about Medicare and Medicaid fraud, falsely accused Dr. Landis of employment related misconduct and conducted an investigation of that "misconduct" as a bad faith rouse to eventually fire Dr. Landis "for cause" from Genova.

197. Genova forbade Dr. Landis from communicating with anyone about his suspension or the Company, so that he could not explain the circumstances and facts to his peers, physicians, customers, and industry contacts outside of the Company.

198. Upon information and belief, Defendants falsely, intentionally, and maliciously misled Dr. Landis' peers, physicians, customers, and industry contacts outside of the Company to believe that Dr. Landis had engaged in misconduct for which he had been suspended.

199. During his suspension, Dr. Landis was interviewed by Genova's outside counsel regarding the alleged bases of his pretextual and retaliatory suspension, but, upon information and belief, the investigator was not permitted by the Company to investigate Dr. Landis' complaints of retaliation, which Dr. Landis informed the investigator were the motivation for Genova' baseless suspension and "investigation."

200. Before firing Dr. Landis, however, with the threat of a termination for "cause" hanging over Dr. Landis' head, Genova attempted to negotiate Dr. Landis' exit from Genova. However, those negotiations were unsuccessful as Dr. Landis refused to accept terms that would require him to be silent about Defendants' ongoing Medicare and Medicaid fraud, or to accept unfair discounting of the value of his equity and forfeiture of his stock options.

201. Notably, on December 20, 2017, Perlmutter telephoned Dr. Landis and advised Dr. Landis to accept Genova's proposed exit offer. Perlmutter warned Dr. Landis that any refusal to do so would "not be pleasant" for Dr. Landis.

202. Sure enough, and shortly after that conversation, Genova fired Dr. Landis for alleged "cause" on December 22, 2017.

203. Defendants' actions to terminate Dr. Landis' allegedly for "cause" resulted in substantial reputation injury to Dr. Landis, and substantial economic damage to Dr. Landis in the

form of lost compensation and payments, loss of unvested equity, the calling in of the promissory notes that Dr. Landis had obtained to acquire equity in the Company, and redemption of his equity at an unfairly discounted value.

204. Also, on January 4, 2018, Defendants rescinded Dr. Landis' vested and unvested stock options in GNVA Holdings and removed him as a GNVA Holdings' shareholder. Notably, with the knowledge and at the direction of Smith and all Defendants, GNVA Holdings issued Dr. Landis a promissory note ("**the Note**") for his GNVA Holdings' shares at $109.11 a share (and substantially lower than the price per share Smith had previously offered to Dr. Landis).

205. As of the date of this filing, GNVA Holdings has breached the Note and failed to pay Dr. Landis quarterly interest payments.

206. The actions of Defendants described herein were taken to pressure and intimidate Dr. Landis into silence, and in retaliation for Dr. Landis repeatedly raising concerns about Medicare and Medicaid fraud

V. FIRST CLAIM FOR RELIEF
Violation of the Federal False Claims Act - § 3729(a)(1)(A)-(B)

207. Relator re-alleges and incorporates by reference the allegations contained in the above Paragraphs of the Complaint.

208. Defendants knowingly presented, or caused to be presented, and continue to present or cause to be presented, materially false and fraudulent claims for payment or approval to the United States and/or its authorized contractors in violation of 31 U.S.C. § 3729(a)(1)(A).

209. Defendants knowingly made or used, or caused to be made or used, false or fraudulent records or statements material to false or fraudulent claims for payment by the United States and/or its authorized contractors in violation of 31 U.S.C. § 3729(a)(1)(B).

210. Defendants presented these false and fraudulent claims and false or fraudulent records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

211. The United States and/or its authorized contractors relied on these false and fraudulent claims and false or fraudulent records or statements, were ignorant of the truth regarding these claims, records and statements, and would not have paid Defendant Genova for these false and fraudulent claims had they known the truth of the falsity of the said false and fraudulent claims, records and statements by these Defendants.

212. As a direct and proximate result of the false and fraudulent claims made by Defendants, the United States and/or its authorized contractors have suffered damages and therefore are entitled to recovery as provided by the FCA in an amount to be determined at trial, plus a statutorily mandated civil money penalty for each such violation of the FCA.

VI. SECOND CLAIM FOR RELIEF
Violation of the North Carolina False Claims Act

213. Relator re-alleges and incorporates by reference the allegations contained in the above Paragraphs of the Complaint.

214. Defendants knowingly presented, or caused to be presented, and continue to present or cause to be presented, materially false and fraudulent claims for payment or approval to the State of North Carolina and/or its authorized contractors in violation of N.C. Gen. Stat. §1-607(a).

215. Defendants knowingly made or used, or caused to be made or used, false or fraudulent records or statements material to false or fraudulent claims for payment by the United States and/or its authorized contractors in violation of N.C. Gen. Stat. §1-607(b).

216. Defendants presented these false and fraudulent claims and false or fraudulent records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

217. The United States and/or its authorized contractors relied on these false and fraudulent claims and false or fraudulent records or statements, were ignorant of the truth regarding these claims, records and statements, and would not have paid Defendant Genova for these false and fraudulent claims had they known the truth of the falsity of the said false and fraudulent claims, records and statements by these Defendants.

218. As a direct and proximate result of the false and fraudulent claims made by Defendants, the United States and/or its authorized contractors have suffered damages and therefore are entitled to recovery as provided by the FCA in an amount to be determined at trial, plus a statutorily mandated civil money penalty for each such violation of the FCA.

VII. THIRD CLAIM FOR RELIEF
Unlawful Retaliation - 31 U.S.C. § 3730(h)

219. Relator re-alleges and incorporates by reference the allegations contained in the above Paragraphs of the Complaint.

220. Relator has been an employee of Genova Diagnostics, Inc. since 2012.

221. As detailed above, Relator took numerous acts in furtherance of a potential claim under the Federal False Claims Act, including notifying Geneva's management of issues regarding the Company's fraudulent Medicare billing practices.

222. Defendants knew of Relator's actions.

223. Defendants willfully and intentionally retaliated against Relator by, inter alia, interfering with his ability to discharge his duties as Genova's Chief Medical Officer, undermining Relator's status with the Company, taking numerous adverse employment actions

against him, ignoring his complaints about retaliation, suspending him without basis, defaming him and damaging his reputation in the industry, firing Relator without basis or good cause, and unfairly discounting the value of Relator's equity and forfeiting his stock options.

224. As a result of Defendants unlawful retaliation, Relator has suffered damages in an amount to be determined at trial.

VIII. FOURTH CLAIM FOR RELIEF
Unlawful Retaliation - N.C. Gen. Stat. § 1-613

225. Relator re-alleges and incorporates by reference the allegations contained in the above Paragraphs of the Complaint.

226. Relator has been an employee of Genova Diagnostics, Inc. since 2012.

227. As detailed above, Relator took numerous acts in furtherance of a potential claim under the North Carolina False Claims Act, including notifying Geneva's management of issues regarding the Company's fraudulent Medicaid billing practices.

228. Defendants knew of Relator's actions.

229. Defendants retaliated against Relator by, inter alia, interfering with his ability to discharge his duties as Genova's Chief Medical Officer, undermining Relator's status with the Company, taking numerous adverse employment actions against him, ignoring his complaints about retaliation, suspending him without basis, defaming him and damaging his reputation in the industry, firing Relator without basis or good cause, and unfairly discounting the value of Relator's equity and forfeiting his stock options.

230. As a result of Defendants unlawful retaliation, Relator has suffered damages in an amount to be determined at trial.

WHEREFORE, Relator Darryl Landis requests the following relief:

1. For judgment that:

    a. Defendants have violated the Federal False Claims Act;

    b. Defendants have violated the North Carolina False Claims Act;

    c. Defendants have unlawfully retaliated against Relator in violation of 31 U.S.C. § 3730(h);

    d. Defendants have unlawfully retaliated against Relator in violation of N.C. Gen. Stat. § 1-613;

2. That the United States of America be awarded its actual damages, trebled pursuant to 31 U.S.C. § 3729 *et. seq.*; plus applicable civil money penalties;

3. That the State of North Carolina be awarded its actual damages, trebled pursuant to N.C. Gen. Stat. § 1-605 *et. seq.*, plus applicable civil money penalties;

4. That Relator be awarded a portion of any recovery by the United States of America and/or the State of North Carolina as provided by 31 U.S.C. § 3729 *et. seq.* and N.C. Gen. Stat. § 1-605 *et. seq.*;

5. That Relator be awarded its costs in this civil action, including reasonable attorneys' fees and expenses;

6. That Relator be awarded damages allowed under 31 U.S.C. § 3730(h) and N.C. Gen. Stat. § 1-63 and other applicable law and statutes;

7. That this matter be tried by jury; and

8. That Relator be awarded such other and further relief as the Court may deem just and proper.

(SIGNATURE BLOCK ON NEXT PAGE)

This 8th day of May 2018

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**Appearing pursuant to Local Civil Rule 83.1*

Attorneys for Relator Darryl Landis, M.D.

GENOVA DIAGNOSTICS

Requisition

Note: This form must be completed (including responsible party signature) and returned with specimen in order to process this test.

GDX ID# A72LK
Genova Diagnostics
Darryl Landis, MD
Individual Case Mgmnt
Research Program-GDX
Asheville, NC 28801-1074
828-210-7791

Employee Test Panel

Physician's Signature

Tests cannot be processed without Diagnosis Codes.
Individual Diagnosis Codes are required for Medicare.

Billing Options

Check only one option below

Patient, please complete information on the back if Prepayment Billing Option or Medicare Billing Option is checked below.

☐ **Bill Healthcare Practitioner Account**
If nothing is indicated, Practitioner Account will be billed. (Practitioner billing not available in NY, NJ, and RI)

☐ **Bill Medicare**
Please attach a copy of your insurance card and complete the insurance information section on reverse side.

☐ **Prepayment Enclosed** — Amount Enclosed: $
Include payment in full at schedule B price. A zero balance statement will be provided.

Please check with the ordering practitioner for payment amounts and pricing.

Potential ICD-9/ICD-10 Codes and Conditions

***IMPORTANT:** If specimen is collected prior to 9/30/2015, please select or add the appropriate ICD 9 diagnosis code(s). If specimen is collected after 9/30/2015, please select or add the appropriate ICD 10 diagnosis code(s).*

ICD-9 *(use through 9/30/2015)*		ICD-10 *(use starting 10/1/2015)*
564.1 Irritable bowel syndrome	↔	K58.0 Irritable bowel syndrome with diarrhea
564.1 Irritable bowel syndrome	↔	K58.9 Irritable bowel syndrome without diarrhea
789.00 Abdominal pain, unspecified site	↔	R10.84 Generalized abdominal pain
789.00 Abdominal pain, unspecified site	↔	R10.9 Unspecified abdominal pain
787.91 Diarrhea, NOS	↔	K52.29 Other allergic and dietetic gastroenteritis and colitis
787.91 Diarrhea, NOS	↔	K52.89 Other unspecified noninfective gastroenteritis and colitis
787.91 Diarrhea, NOS	↔	R19.7 Diarrhea, unspecified
787.3 Flatulence eruction/Gas pain	↔	R14.0 Abdominal distension (gaseous)
787.3 Flatulence eruction/Gas pain	↔	R14.1 Gas pain
787.3 Flatulence eruction/Gas pain	↔	R14.2 Eructation
787.3 Flatulence eruction/Gas pain	↔	R14.3 Flatulence
Other		Other

Please note definition of Medical Necessity on reverse side. Potential codes may not be applicable, please provide codes and conditions specific to patient.

THIS SPACE FOR LAB USE ONLY

4523463

Date Final Sample Collected: 09 Mo. 18 Day 17 Year

Sample Consistency: Day 1: hard

Sample Color: Day 1: brown

Kit K-MM-GI EFFECTS-2200-1DAY

✓ GI Effects® Comprehensive Profile #2200

EPA 139 EPB 530

Profile Components/CPT Codes

DNA NOS Amplified Probe	87798 x 24
Assay Test for Blood, Fecal	82274
Col-Chr/MS Quan 1 Stationary&Mobile Phases NES	82542
Secretory IgA	82784
Long Chain Fatty Acids	82725
Cholesterol, Phospholipids & Triglycerides	82715 x 3
Pancreatic Elastase	82656
Parasitology Identification, Concentrate	87177
Parasitology Identification, Trichrome Stain	87209
Cryptosporidium, EIA	87328
Entamoeba histolytica, EIA	87336
Giardia lamblia, EIA	87329
Calprotectin	83993
Eosinophil Protein X (EPX)	83520
Bacteriology, Aerobic	87045
Bacteriology, Aerobic	87046 x 3
B-Glucuronidase	84311
Bacteriology, Anaerobic	87075
Yeast Culture	87102

Add-on Tests for GI Effects Comprehensive Profile #2200

Additional charges apply, please see fee schedule for prices and Easypay amounts.

___Campylobacter specific antigen EIA #2130	87449
___Clostridium difficile EIA #2131	87324
___Enterohemorrhagic E. coli Shiga-like toxin #2132	87427
___Helicobacter pylori Stool Antigen EIA (HpSA) #2133	87338
___Fecal Lactoferrin #2134	83630
✓ Zonulin, Stool #2336	

The Zonulin marker is not billable to Medicare or other insurance carriers. Please include a payment method for the full cost of the Zonulin add-on marker in addition to your schedule A or schedule B amount, if applicable.

___ GI Effects® Microbial Ecology Profile #2205

EPA 114 EPB 331

Profile Components/CPT Codes

DNA NOS Amplified Probe	87798 x 24
Parasitology Identification, Concentrate	87177
Parasitology Identification, Trichrome Stain	87209
Cryptosporidium, EIA	87328
Entamoeba histolytica, EIA	87336
Giardia lamblia, EIA	87329
Bacteriology, Aerobic	87045
Bacteriology, Aerobic	87046 x 3
Bacteriology, Anaerobic	87075
Yeast Culture	87012

Add-on Tests for GI Effects Microbial Ecology Profile #2205

Additional charges apply, please see fee schedule for prices and Easypay amounts.

___Campylobacter specific antigen EIA #2130	87449
___Clostridium difficile EIA #2131	87324
___Enterohemorrhagic E. coli Shiga-like toxin #2132	87427
___Helicobacter pylori Stool Antigen EIA (HpSA) #2133	87338
___Fecal Lactoferrin #2134	83630
___Zonulin, Stool #2336	

The Zonulin marker is not billable to Medicare or other insurance carriers. Please include a payment method for the full cost of the Zonulin add-on marker in addition to your schedule A or schedule B amount, if applicable.

GI Effects is not currently available in New York State

EXHIBIT tabbies 1

Please refer to the Insurance Billing Guidelines on our fee schedule or visit www.gdx.net/patients/billing-and-payments/insurance for complete billing details. Contact our Customer Care Specialist at 1-800-522-4762 option 2 for any billing concerns.

1 Complete the Patient Information Section

Full SSN needed for insurance billing and if patient wants access to complete results online.

Patient Date of Birth mm/dd/yyyy - - **Sex:** M F **Social Security #:** - -

Patient Name (last): (first): (middle):

Mailing Address:

City: **State:** **Zip:** -

Phone: **County:** **Country:**

Alternate Phone: **Race:** Asian African-American Caucasion Other

Email: **Ethnicity:** Hispanic Non-Hispanic Other

Responsible Party Name: *(Other legal guardian or if patient is a minor child)*

Name (last): (first): (middle):

If you reside in OH or NH, the following fields are required:

Occupation: _____ Employer Address: _____

Employer: _____

2 Complete the Medicare Information Section *for us to file Medicare or Tricare on your behalf*

Medicare Patients

Genova Diagnostics is a Medicare provider and will submit to Medicare for reimbursement unless services are non – covered because 1) they are ordered by a healthcare provider not authorized to order or refer under Medicare rules (such as a Doctor of Chiropractic, Naturopathic Doctor, or Licensed Acupuncturist), or 2) as indicated by a notice of non-coverage by Medicare enclosed in your test kit. In these cases, you will be financially responsible for the charges and should utilize our pre-payment option (please contact your healthcare provider for the payment amount to submit with your kit).

List your Medicare insurance information here. Include copies of all your health insurance cards to ensure accurate claim filing.

(Print clearly)

Insurance Company: _____

Please include front/back copy of all health insurance cards

If health insurance information is provided, an insurance claim will be filed on your behalf, if applicable (unless Bill Practitioner Account is marked on the reverse of this requisition).

Claims Address: _____ Subscriber ID #/Medicare #: _____

City/State/Zip: _____ Group #: _____

Phone #: ( ) _____ Subscriber Date of Birth: ___/___/___

Subscriber Name: _____ Relation to Patient: ❑ Self ❑ Spouse ❑ Other _____

3 Complete the Payment Information Section

Traditional Medicare, Tricare, or North Carolina Medicaid patients do not need to provide a payment at this time.

If the **"Prepayment Enclosed"** option is checked on the reverse side or you have a **Non-North Carolina Medicaid plan**, please include a payment of the schedule B amount at this time.

Your practitioner will have the pricing information on their lab fee schedule

Payment from:

❑ Practitioner ❑ Patient

Payment type:

❑ Payment at Patient Resource Center: *(Patient only)* **www.gdx.net/prc** 8-Digit Confirmation Code

❑ Check #_____ *Make checks payable in US dollars to Genova Diagnostics*

❑ Credit Card Authorized Amount: $ _____

(Print clearly)

Credit Card #: _____

Background color is for security purposes

Expiration Date: ___/___ CVV: _____

Cardholder Signature: _____

Printed Name: _____

Card Holder's Billing Zip Code: _____

4 Patient/Responsible Party Acknowledgement *Please read and sign below.*

I have read the Insurance Billing Guidelines and I understand my responsibilities as described within them.

I understand that the tests requested on the front of this form may be out-of-network for my insurance plan and/or may be deemed not medically necessary, experimental, and/or investigational by my insurance carrier and I authorize the services to be performed regardless. I have been informed and agree that I will be financially responsible for amounts described in the company's fee schedule (when applicable) and for services deemed out of network, not medically necessary, experimental, and or investigational by my insurer.

Medicare patients should refer to the Advanced Beneficiary Notice (ABN) document included in the test kit for specific instructions on non-medically necessary services related to the Medicare program.

Except in the case of prepayment, I authorize payment of all medical benefits to be paid directly to Genova Diagnostics and authorize the release of any medical information required for insurance to process/pay claims resulting from my testing services. I authorize Genova Diagnostics to act as my representative in any claim appeal process. I acknowledge financial responsibility per my plan benefits and according to the applicable insurance billing program. I permit a copy of this requisition to be used in place of the original.

Patient/Responsible Party Name: _____ **Date:** _____

Signature: _____

5 Visit Your Patient Resource Center

- Access test results
- Make payments
- Complete health surveys

Log On At: **www.gdx.net/prc**

In Network Insurances

Genova will submit to in-network insurance, when appropriate, if the information is provided above.

- Payment information provided will be applied after the claim is processed.

Please contact us at 800-522-4762 option 2 or visit www.gdx.net/billing for a list of in network insurances.

CPT & ICD-10 Codes

Due to the possibility of regulatory and/or methodology changes, CPT and ICD-10 codes are subject to change without prior notification.

Definition of Medical Necessity

All claims submitted to Medicare/Medicaid for Genova Diagnostics' laboratory services must be for tests that are medically necessary. "Medically necessary" is defined as a test or procedure that is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Consequently, tests performed for screening purposes will not be reimbursed by the Medicare program. Physicians may deem it medically necessary to order a single test or a portion of a profile.

GENOVA DIAGNOSTICS

63 Zillicoa Street, Asheville, NC 28801 | 800.522.4762 | www.GDX.net