

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION**

EXACT SCIENCES CORPORATION; and
EXACT SCIENCES LABORATORIES,
LLC,

Plaintiffs,

v.

HUMANA, INC.,

Defendant.

Civil Action No. 3 : 16CV - 58 - JHM

COMPLAINT AND JURY DEMAND

Plaintiffs, Exact Sciences Corporation (“Exact Sciences”) and Exact Sciences Laboratories, LLC (“Exact Labs”) (collectively, “Exact” or “Plaintiffs”), file this Complaint against Defendant Humana, Inc. (“Humana” or “Defendant”) and state as follows:

INTRODUCTION

1. Exact files this Complaint against Humana, because Humana has improperly and illegally adopted an official policy of denying benefits and refusing to pay Exact for the costs of performing Exact’s proprietary colorectal cancer screening test, Cologuard®. Since at least October 2014, and continuing through the present, Humana has improperly and illegally refused to pay Exact for claims, under commercial plans, Medicare Advantage plans, and otherwise, totaling in excess of \$800,000.

2. Humana provides healthcare insurance, administration, and/or benefits to policyholders or plan participants pursuant to a variety of healthcare benefit plans and policies of insurance, including employer-sponsored benefit plans, government-sponsored benefit plans, and individual health benefit plans (the “Plans”).

3. As shown further below, Humana has violated its duties under the Employee Retirement Income Security Act (“ERISA”), 29 U.S.C. § 1001, *et seq.*, and state law. In particular, the laws of many states in which Humana writes plans, detailed further below, specifically require insurers such as Humana to cover costs for colorectal cancer screening tests recommended by the American Cancer Society (“ACS”) or otherwise in accordance with accepted medical practice guidelines for colorectal screening, like Cologuard® (“Coverage Mandates”). Humana has violated these laws, *inter alia*, by failing and refusing to pay Exact promptly and in full for the tests that Exact has performed for patients covered by the Plans provided or administered by Humana (“Humana Subscribers”).

4. Specifically, since October 2014, Exact has performed 4,664 Cologuard® tests for at least 4,664 Humana Subscribers in 45 different states, plus Washington D.C., and, accordingly, billed Humana for the medical services provided. Exact’s total billed charges to Humana for these claims are in excess of \$800,000.

5. Humana has denied these claims for various reasons including, but not limited to its contention that Cologuard® is excluded as “Experimental or Investigational.”

6. Moreover, Humana has adopted the official policy of excluding Cologuard® under its commercial plans as ineffective and, according to Humana, “Experimental or Investigational” as it defines those terms under its Plans, and thus refused to reimburse Exact as required under applicable law and terms of the Plans.

7. Humana distributed a flier falsely informing medical providers that Cologuard® is ineffective and further stating that “Cologuard™ is not covered under Humana’s commercial plans” (emphasis in original). Humana distributed this notice to physicians located in Kentucky and, potentially, other states including Georgia, Missouri, North Carolina, Texas, Illinois,

Indiana, Nevada, and Oklahoma (together with Kentucky, the “Mandate States”), as well as medical providers nationwide.

8. Humana’s contention in its physician flier is false. In Kentucky and the other Mandate States, Humana is required by law to cover Cologuard® and, therefore, Cologuard® must be covered under the commercial plans in those states. Moreover, and contrary to Humana’s contention, Cologuard® is effective, has been approved by the U.S. Food and Drug Administration (“FDA”) and the Centers for Medicare and Medicaid Services (“CMS”) following an extensive clinical trial, and has been endorsed by the American Cancer Society (“ACS”) and other organizations as a safe and non-invasive colorectal cancer stool DNA (“sDNA”) screening examination.

9. Humana’s wholesale refusal to provide coverage for Cologuard® is in clear violation of state and federal law, as well as Humana’s Plans, and has caused Exact to sustain substantial damages. If Humana’s conduct is allowed to continue, it threatens irreparable harm to Exact as well as the patients who depend upon the test that Exact provides.

PARTIES, JURISDICTION AND VENUE

10. Plaintiff Exact Sciences is a corporation organized under the laws of the State of Delaware, with its principal place of business located at 441 Charmany Drive, Madison, Wisconsin 53719.

11. Plaintiff Exact Labs is a limited liability company organized under the laws of the State of Delaware, with its principal place of business located at 145 East Badger Road, Madison, Wisconsin 53713. Exact Labs is a wholly owned subsidiary of Exact Sciences.

12. Defendant Humana is a corporation organized under the laws of the State of Delaware, with its principal place of business in this District located at 500 West Main Street, Louisville, Kentucky 40202.

13. This Court has personal jurisdiction over Humana in this action as Humana operates, conducts, engages in, does business in, and has committed tortious acts within the State of Kentucky; and Humana engages in substantial and not isolated activities within Kentucky.

14. This Court also has personal jurisdiction over Humana because, at all times material hereto, Humana purposefully carried on one or more businesses or business ventures in this judicial District, operating as a licensed health insurer; the requisite nexus exists between the business(es) and this action; and Humana engaged in substantial and not isolated activity within this District.

15. This Court also has jurisdiction over the subject matter of this action pursuant to (i) 28 U.S.C. § 1331 and 29 U.S.C. § 1132(e)(1), as this is a civil action, the claims asserted include ERISA claims and, therefore, this suit arises under the Constitution, laws, or treaties of the United States; and (ii) 28 U.S.C. § 1367, as Exact's non-ERISA state law claims are supplemental to its Federal claims.

16. Venue is proper in this District pursuant to (i) 28 U.S.C. § 1391(b)(2), because a substantial portion of the violations alleged herein either occurred here or were directed towards Exact in this District, and events giving rise to the Complaint occurred in this District; and (ii) 29 U.S.C. § 1132(e)(2) because a substantial portion of the insurance and/or benefits plans at issue in this case are administered in this District.

BACKGROUND AND RELEVANT FACTS

A. Cologuard® is Tested and Proven Effective; Cologuard® is Not “Experimental or Investigational”

17. Cologuard® is a non-invasive colorectal cancer sDNA screening examination.

18. Every day the lining of the colon naturally sheds cells. If a patient has cancer or precancer in his or her colon, abnormal cells are shed into the colon, along with normal cells, where they are picked up by stool as it passes through the colon.

19. Cologuard® uses advanced sDNA technology to find elevated levels of altered DNA in these abnormal cells, as well as a fecal immunochemical test to find elevated levels of hemoglobin in these abnormal cells, which could be associated with cancer or precancer.

20. Exact Sciences developed Cologuard® along with researchers at the Mayo Clinic.

21. In its pivotal clinical study, the over 10,000 subject Multi-Target Colorectal Cancer Screening Test for the Detection of Colorectal Advanced Adenomatous Polyps and Cancer (“DeeP-C”) Study, Cologuard® demonstrated sensitivity at 92% of that seen with colonoscopy in detecting colorectal cancer, and it demonstrated sensitivity significantly greater than that seen for the fecal immunochemical test (FIT) in detecting colorectal cancer and advanced adenomas (AAs).

22. The Deep-C study results were published in the *New England Journal of Medicine* in April, 2014.

23. Cologuard’s sensitivity and specificity results, as demonstrated by the Deep-C study, have been corroborated in a subsequent study involving over 600 Alaska natives.

24. Cologuard received premarket approval (“PMA”) from the FDA on August 11, 2014.

25. Cologuard® is the first and only DNA screening test for colorectal cancer approved by the U.S. Food and Drug Administration (“FDA”).

26. Effective October 9, 2014, CMS extended coverage to Cologuard across the Medicare Program (Traditional Medicare (Part B) and Medicare Advantage (MA) health plans) by the National Coverage Determination for Colorectal Cancer Screening Tests (210.3).

27. Cologuard is the first medical product successfully to complete the joint FDA-CMS parallel review process.

28. Cologuard is also the only multi-target sDNA screening test for colorectal cancer.

29. Cologuard® is a proprietary test provided by Exact Labs, exclusively processed at Exact Labs, and not available through any other laboratory.

30. Cologuard® is a sole-sourced test; there are no other labs that offer a comparable sDNA test for colorectal cancer screening.

31. Because of the compelling DeeP-C Study and Alaska Native study results and the well-known rigor of the PMA process, the analytical validity, clinical validity and clinical utility of Cologuard® have been well documented.

32. Numerous commercial health plans have extended coverage to Cologuard® as the data describing its performance compares well with technology assessment criteria and conditions for coverage under commercial health plans.

33. As a result, at seventeen months following FDA approval, Cologuard® has achieved a broad coverage footprint of 110 million or more Americans in the Medicare program and commercial health plans.

34. Moreover, the American Cancer Society (“ACS”) specifies sDNA tests and Cologuard® in its current guidelines for colorectal screening.¹

35. Specifically, the ACS guidelines state that “[b]eginning at age 50, people at average risk with no symptoms should follow one of the testing options below: ...Stool DNA test (sDNA), every 3 years.”

36. As to sDNA tests, the ACS endorses Cologuard®™ as “the test currently available” in its recommendations.

37. Thus, Cologuard® is not “Experimental or Investigational” as those terms are defined in any Plan.

B. Humana Subscribers Assign their Insurance Benefits to Exact

38. As noted above, Exact has provided medically necessary tests to numerous Humana Subscribers who obtained medical insurance from Humana under various Plans in Coverage Mandate States and nationwide.

39. In Coverage Mandate States, regardless of Plan language, Humana must provide coverage for colorectal cancer screening to all Humana Subscribers in Coverage Mandate States.

40. In addition, upon information and belief, Cologuard® specifically meets the requirements for coverage under the terms of the applicable Plans.

¹ See

<http://www.cancer.org/healthy/informationforhealthcareprofessionals/colonmdcliniciansinformation/colorectalcancerscreeningandsurveillanceguidelines/index>;
<http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancerearlydetection/colorectal-cancer-early-detection-acs-recommendations>; and
<http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancerearlydetection/colorectal-cancer-early-detection-screening-tests-used>.

41. Upon information and belief, all Humana Plans provide coverage for colorectal screening tests or examinations, unless the test or examination fits within the definition of “Experimental or Investigational” under the terms of the applicable Plan.

42. As detailed above, Cologuard® is not and cannot be deemed “Experimental or Investigational” as those terms are defined in any Plan.

43. Each patient prescribed Cologuard®, including each Humana Subscriber, provides Exact with a “Patient Assignment of Benefits Notice (AOB)” (the “AoB”).

44. In the AoB, Humana Subscribers agree to be financially responsible for the costs of the Cologuard® test that Exact provides, and they further assign to Exact their right to benefits under the applicable Plans for the test Exact provides.

45. Specifically, the AoB provides:

Authorization to assign benefits, accept financial responsibility, and disclose health records: I authorize Exact Sciences Laboratories to bill my insurance/health plan and furnish them with my Cologuard® order information, my test results, or other information requested for reimbursement, to appeal any reimbursement denial, and authorize all reimbursements to be paid directly to the laboratory in consideration for services performed. I understand that I am responsible for any amount not paid, including amounts for non-covered services.

46. For every claim at issue in this case, the beneficiary provided an AoB in a form identical to or substantially the same as those referenced in the preceding paragraph.

47. As set forth below, Humana has failed and refused to provide insurance coverage for Cologuard® tests provided to Humana Subscribers.

C. Coverage Mandates

48. Kentucky Revised Statutes §304.17A-257 (the “Kentucky Mandate”) is titled “Coverage under health benefit plan for colorectal cancer examinations and laboratory tests.”

49. The Kentucky Legislative Record Online describes the Kentucky Mandate as “AN ACT relating to removing barriers to colorectal cancer screening.”²

50. The Kentucky Mandate provides as follows:

- (1) A health benefit plan issued or renewed on or after January 1, 2016,³ shall provide coverage for all colorectal cancer examinations and laboratory tests specified in current American Cancer Society guidelines for complete colorectal cancer screening of asymptomatic individuals as follows:
 - (a) Coverage or benefits shall be provided for all colorectal screening examinations and tests that are administered at a frequency identified in the most recent version of the American Cancer Society guidelines for complete colorectal cancer screening; and
 - (b) The covered individual shall be:
 1. Fifty (50) years of age or older; or
 2. Less than fifty (50) years of age and at high risk for colorectal cancer according to current colorectal cancer screening guidelines of the American Cancer Society.
- (2) Coverage under this section shall not be subject to a deductible or coinsurance for services received from participating providers under the health benefit plan.

51. As set forth above, the ACS specifies Cologuard® in its current guidelines as a recommended colorectal cancer screening examination and thus the Kentucky Mandate applies.

52. Despite the clear application of Kentucky Mandate to Cologuard®, Humana has adopted a policy of non-coverage for Cologuard® and, to date, wrongfully denied 120 Cologuard® claims totaling \$69,701 in Kentucky.

² See <http://www.lrc.ky.gov/record/15rs/HB69.htm>.

³ The Kentucky Legislature revised the Kentucky Mandate in December of 2015, effective January 1, 2016. However, with the exception of allowing for a carrier to require deductibles or coinsurance in some situations, the predecessor mandate was substantially the same, was effective from January 1, 2009 through January 1, 2016, and applies to Plans issued or renewed as of January 1, 2009.

53. In addition to Kentucky, many other states have enacted Coverage Mandates (“Coverage Mandate States”) including: Georgia;⁴ Missouri;⁵ North Carolina;⁶ Texas;⁷ Illinois;⁸ Indiana;⁹ Nevada;¹⁰ and Oklahoma.¹¹ Attached as an “Appendix” hereto are true and correct copies of these Coverage Mandate statutes, along with the Kentucky Mandate.

54. Despite these Coverage Mandates, Humana has, upon information and belief, adopted a policy of non-coverage for Cologuard® in the Coverage Mandate States.

55. To date, Humana has denied 293 Cologuard® claims totaling \$168,965 in Coverage Mandate States other than Kentucky.

D. Humana’s Illegal Policy and Its Misinforming of Medical Providers

56. Humana has issued a notification flier titled “Colorectal Cancer Screening Cologuard®™ Quality-Compliance Issue” (the “Flier”).

57. In the Flier, Humana sets forth its policy that Cologuard® is ineffective and that “Cologuard®™ is not covered under Humana’s commercial plans.” (emphasis in original).

58. This could be Humana’s policy nationwide since the Flier is not state-specific.

59. The statements in the Flier are false, misleading, and contrary to applicable law in Coverage Mandate States where Humana is legally required to cover Cologuard®.

⁴ See GA Code §33-24-56.3.

⁵ See Mo. Rev. Stat. §376.1250.

⁶ See N.C. Gen. Stat. §58-3-179.

⁷ See Tex. Ins. Code §1363.003 and Texas Department of Insurance Commissioner’s Bulletin # B000609.

⁸ See 215 ILCS 5/356x.

⁹ See Ind. Code §27-8-14.8-3.

¹⁰ See Nev. Rev. Stat. §689A-04042; 689B-0367; 695B-1907; 695C-1731; and 695G-168.

¹¹ See 36 Okla. Stat. §6060.8a.

60. Humana has sent the Flier directly to its in-network healthcare providers in Kentucky.

61. Upon information and belief, Humana has sent the Flier directly to other healthcare providers nationwide.

62. Upon information and belief, medical providers who received Humana's false information, by way of the Flier or otherwise, have ceased to prescribe Cologuard®.

63. By letter dated January 21, 2016, counsel for Exact sent a "Cease and Desist Notice" to Humana demanding that Humana (i) immediately cease and desist distributing the Flier, (ii) immediately notify any provider to whom it sent the Flier that Humana is required to cover Cologuard® under applicable law and that it retracts the Flier; and (iii) certify to Exact that Humana has complied with this demand.

64. By letter dated January 29, 2016, counsel for Humana replied to the Cease and Desist letter stating that (i) Humana believes it did not distribute the Flier beyond Kentucky; (ii) any miscommunication in the Flier was unintentional; (iii) Humana has ceased using the "version" of the Flier described herein; (iv) Humana will "reprocess" Cologuard® claims it has denied since January 1, 2016; and (v) Humana "will attempt to determine which Kentucky physicians received the flier and contact them if any clarification is needed."

65. Humana also states that it will investigate and "evaluate whether any modification of [its policies] is warranted."

66. However, Humana failed to address the many claims it wrongfully denied prior to January 1, 2016 in Kentucky and the other Mandate States.

67. Likewise, Humana offered no assurances that it would rectify the situation and comply with the Coverage Mandates in the future.

E. The Claims at Issue, the Wrongful Denials, and the Preauthorization Pretext

68. Since October 2014, Exact performed Cologuard® tests for 4,664 Humana Subscribers and accordingly billed Humana for these medical tests. Exact's total billed charges to Humana for these claims were over \$800,000, reflecting the usual, customary, and reasonable rates for the medical testing provided at Exact.

69. Humana has denied coverage for these claims on various grounds including that Cologuard® is "Experimental or Investigational" and that Exact failed to secure preauthorization before performing its tests.

70. Pursuant to the settlement of a large provider class action, Humana agreed to publish all procedure codes requiring preauthorization. Specifically, the settlement agreement provides that:

[Humana] shall post to its Provider Website not later than three (3) months after the Final Order Date those services or supplies for which Precertification is routinely required for its products, and [Humana] shall update such posting to the extent the services or supplies for which Precertification is routinely required changes.

71. Despite the fact that the procedure code for Cologuard® is not on Humana's published preauthorization list, Humana nonetheless is denying claims for lack of preauthorization for Cologuard® because the test was not pre-authorized with Humana by the provider or patient.

72. Moreover, preauthorization is irrelevant under the Coverage Mandates.

E. Exact has Exhausted all Known Internal Appeals Procedures

73. Although Humana has never supplied to Exact the terms of the actual Plans covering the Humana Subscribers, upon information and belief, Exact has repeatedly and in good faith exhausted all known available appeals avenues under those Plans in an effort to convince Humana to reimburse Exact properly on its claims for Cologuard® tests that Exact provided to the Humana Subscribers.

74. Exact has submitted 1,053 internal appeals and Humana has denied 528, including 305 in Mandate States. Humana has also underpaid approximately 350 claims and still owes Exact at least \$64,700 for those claims.

75. In its “Cease and Desist” letter, Exact also demanded that Humana reverse its previous benefit denials, promptly pay all previously submitted Cologuard® claims, and conform its medical policies and claims systems programming so that Humana’s entire organization recognizes its obligation to pay for Cologuard® as a covered service.

76. As of the date of this Complaint, Humana has failed to comply in full with these demands or provide sufficient assurances that Humana would not repeat its conduct.

F. Further Exhaustion Efforts would be Futile

77. Upon information and belief, Humana’s national policy for its commercial plans, as set forth in the Flier, is to exclude all Cologuard® claims.

78. Humana has not responded to Exact’s demands or otherwise given any indication that it is willing to reconsider its wrongful policy.

79. It is clear that Humana has adopted a pattern or practice of wrongfully denying Exact’s claims, such that further exhaustion efforts would be futile.

* * * * *

80. Humana's conduct has caused Exact to incur substantial damages and, if allowed to continue, threatens irreparable harm to Exact as well as the patients it tests, thus necessitating the filing of this action.

81. This action is timely commenced well within five (5) years after Exact was notified by Humana that it was rejecting or dramatically underpaying Exact's claims for reimbursement for the services that Exact provided to Humana Subscribers, and otherwise within five (5) years after each of Exact's claims against Humana accrued.

CAUSES OF ACTION

COUNT ONE (Claim for ERISA Benefits)

82. Plaintiff incorporates by reference all of the foregoing allegations as if set forth at length herein.

83. Exact files this action pursuant to ERISA §502(a)(1)(B), 28 U.S.C. §1132, to recover benefits assigned to it by the participants or Humana Subscribers of an ERISA plan.

84. Exact has provided Cologuard® tests to at least 4,664 Humana Subscribers since October, 2014.

85. These Humana Subscribers have assigned Exact the right to seek reimbursement from payors, "to appeal any reimbursement denial," and have "authorized all reimbursements to be paid directly to [Exact] in consideration for services performed."

86. As assignee of the Humana Subscribers of the Humana Plans, Exact is entitled to recover benefits due to the Humana Subscribers and enforce the rights of the Humana Subscribers under the terms of the Humana Plans. In particular, as assignee of the Plans, Exact is entitled to reimbursement under the ERISA-governed Plans for the Cologuard® tests provided to the Humana Subscribers.

87. Upon information and belief, the Plans did not prohibit the Humana Subscribers from assigning their rights to benefits under the Plans to Exact, including the right of direct payment of benefits under the Plans to Exact. To the contrary, upon information and belief, the Plans expressly authorize the Humana Subscribers to assign their rights to benefits and their rights of direct payment of benefits under the Plans to providers like Exact.

88. Moreover, to the extent that any of the Plans prohibited the assignment of benefits to Exact, Humana waived any purported anti-assignment provisions, ratified the assignment of benefits to Exact, and/or is estopped from using any purported anti-assignment provisions against Exact due to its course of dealing with Exact.

89. And to the extent that the Plans prohibited the assignment of benefits to Exact, any such purported anti-assignment prohibitions are unenforceable as, among other things, contrary to public policy, as adhesion contracts, and/or due to a lack of privity with Exact.

90. Upon information and belief, the Humana Plans require reimbursement of medical expenses incurred by Humana Subscribers at usual, customary, and reasonable rates.

91. Humana is obligated to pay for medically necessary services, covered services, or covered benefits as defined under its Plans.

92. Humana has breached the terms of the Plans by refusing to make reimbursements for charges covered by the Plans, in violation of ERISA 502(a)(1)(B), 29 U.S.C. § 1132(a)(1)(B).

93. As a result of, among other acts, Humana's numerous procedural and substantive violations of ERISA, any appeals are deemed exhausted or excused, and Exact is entitled to have this Court undertake a *de novo* review of the issues raised herein.

94. Moreover, pursuant to 29 U.S.C. § 1132(a)(1)(B), Exact is entitled to recover unpaid benefits from Humana. Exact is also entitled to declaratory and injunctive relief to enforce the terms of the Plans and to clarify its right to future benefits under such plans, as well as attorneys' fees.

COUNT TWO
(Violation of Fiduciary Duties of Loyalty and Due Care in Violation of ERISA)

95. Plaintiff incorporates by reference all of the foregoing allegations as if set forth at length herein.

96. 29 U.S.C. § 1132(a)(3) states that a civil action may be brought by “a participant, beneficiary, or fiduciary to (A) enjoin any act or practice which violates any provision of this subchapter or the terms of the plan, or (B) to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of this subchapter or the terms of the plan.”

97. Humana is a fiduciary under ERISA, to the extent that the Plans are issued pursuant to an employee benefit plan and Humana:

- a. exercises discretionary authority or discretionary control respecting the management of an employment benefit plan and the disposition of its assets; and
- b. has discretionary authority in the administration of the Plan.

98. As an ERISA fiduciary, Humana owed Exact a duty of care, defined as an obligation to act prudently, with the care, skill, prudence and diligence that a prudent fiduciary would use in the conduct of an enterprise of like character. Further, as a fiduciary, Humana was required to ensure that it was acting in accordance with the documents and instruments governing the Plans, and in accordance with ERISA § 404(a)(1)(B) and (D), 29 U.S.C. §

1104(a)(1)(B) and (D). In failing to act prudently, and in failing to act in accordance with the documents governing the Plans, Humana has violated their fiduciary duty of care.

99. As a fiduciary, Humana also owed Exact a duty of loyalty, defined as an obligation to make decisions in the interest of its beneficiaries, and to avoid self-dealing or financial arrangements that benefit the fiduciary at the expense of members, in accordance with ERISA § 404(a)(1)(A), 29 U.S.C. § 1104(a)(1)(A) and ERISA § 406, 29 U.S.C. § 1106. Thus, Humana could not make benefit determinations for the purpose of saving Humana money at the expense of the Humana Subscribers.

100. Humana has violated its fiduciary duty of loyalty to Exact by, among other things, refusing to make reimbursements for Cologuard® tests, to its own advantage, at the expense of Humana Subscribers. In addition, Humana violated its fiduciary duty of loyalty by failing to inform Exact, as assignees of the Humana Subscribers, of material information, by misrepresenting requirements for reimbursement under the Plans.

101. The Humana Subscribers described herein have assigned their rights under the Plans to Exact.

102. As assignees of the Humana Subscribers, Exact is entitled to recover benefits due to the Humana Subscribers and enforce the rights of Humana Subscribers under the terms of the Plans and policies.

103. Humana has violated their fiduciary duty of loyalty to Exact by, among other things: refusing to cover Cologuard® tests; refusing to allow Exact any opportunity to negotiate coverage beyond the unduly burdensome terms it has wrongfully required in contravention of applicable law and Plan terms; and failing to inform Exact, as assignees of the Humana Subscribers, of material information.

104. Exact has standing to pursue claims under ERISA as an assignee and authorized representative of the Humana Subscribers' claims.

105. Exact is entitled to relief to remedy Humana's violation of its fiduciary duties under ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), including declaratory and injunctive relief.

COUNT THREE
(Denial of Full and Fair Review in Violation of ERISA § 503)

106. Exact incorporates by reference all of the foregoing allegations as if set forth at length herein.

107. As an assignee and authorized representative of the Humana Subscribers' claims, Exact is entitled to receive protection under ERISA, including (a) a "full and fair review" of all claims denied by Humana; and (b) compliance by Humana with applicable claims procedure regulations.

108. Although Humana is obligated to provide a "full and fair review" of denied claims pursuant to ERISA § 503, 29 U.S.C. § 1133 and applicable regulations, including 29 C.F.R. § 2560.503-1 and 29 C.F.R. § 2590.715-2719, Humana has failed to do so by, among other actions: refusing to provide the specific reason or reasons for the denial of each of the claims; refusing to provide the specific plan provisions relied upon to support its denial; refusing to provide the specific rule, guideline or protocol relied upon in making the decision to deny claims; refusing to describe any additional material or information necessary to perfect a claim, such as the appropriate diagnosis/treatment code; refusing to notify the relevant parties that they are entitled to have, free of charge, all documents, records and other information relevant to the claims for benefits; refusing to provide a statement describing any voluntary appeals procedure available, or a description of all required information to be given in connection with that procedure; and denying coverage based on a lack of preauthorization when

the Plans require no such preauthorization as a condition to coverage. By failing to comply with the ERISA claims procedures regulations, Humana failed to provide a reasonable claims procedure.

109. Because Humana has failed to comply with the substantive and procedural requirements of ERISA, any administrative remedies are deemed exhausted pursuant to 29 C.F.R. § 2560.503-1(l) and 29 C.F.R. § 2590.715-2719(b)(2)(ii)(F)(1). Exhaustion is also excused because it would be futile to pursue administrative remedies, as Humana does not acknowledge any basis for its denials and thus offers no meaningful administrative process for challenging denials. Finally, exhaustion would be futile since Humana has adopted a clear policy of excluding coverage for Cologuard®.

110. Exact has been harmed by Humana's failure to provide a full and fair review of appeals submitted under ERISA § 503, 29 U.S.C. § 1133, and by Humana's failures to disclose information relevant to appeals and to comply with applicable claims procedure regulations.

111. Exact is entitled to relief under ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), including declaratory and injunctive relief, to remedy Humana's failures to provide a full and fair review, to disclose information relevant to appeals, and to comply with applicable claims procedure regulations.

COUNT FOUR
(Violation of the Kentucky Mandate)

112. Exact incorporates by reference all of the foregoing allegations as if set forth at length herein.

113. Pursuant to the Kentucky Mandate, KRS §304.17A-257,

- (1) A health benefit plan issued or renewed on or after January 1, 2016, shall provide coverage for all colorectal cancer examinations and laboratory

tests specified in current American Cancer Society guidelines for complete colorectal cancer screening of asymptomatic individuals as follows:

- (a) Coverage or benefits shall be provided for all colorectal screening examinations and tests that are administered at a frequency identified in the most recent version of the American Cancer Society guidelines for complete colorectal cancer screening; and
- (b) The covered individual shall be:
 1. Fifty (50) years of age or older; or
 2. Less than fifty (50) years of age and at high risk for colorectal cancer according to current colorectal cancer screening guidelines of the American Cancer Society.
- (2) Coverage under this section shall not be subject to a deductible or coinsurance for services received from participating providers under the health benefit plan.

114. Humana has violated the Kentucky Mandate by adopting a policy of non-coverage for Cologuard® and by denying, to date, at least 120 Cologuard® claims totaling at least \$69,701 in Kentucky.

115. Pursuant to KRS §446.070 (Penalty no bar to civil recovery), “A person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation.”

116. As a direct and proximate result of Humana’s violation of the Kentucky Mandate, Exact has sustained and will continue to sustain in the future damages, and has been deprived and will continue to be deprived in the future of the compensation to which it is entitled to receive for providing covered tests discussed in this Complaint.

**COUNT FIVE
(Declaratory Judgment)**

117. Plaintiff incorporates by reference all of the foregoing allegations as if set forth at length herein.

118. This is a count for declaratory relief pursuant to 28 U.S.C. § 2201.

119. Pursuant to the Kentucky Mandate, KRS §304.17A-257, as well as the Coverage Mandates enacted by many other states including: Georgia;¹² Missouri;¹³ North Carolina;¹⁴ Texas;¹⁵ Illinois;¹⁶ Indiana;¹⁷ Nevada;¹⁸ and Oklahoma,¹⁹ Humana must cover Cologuard® tests.

120. Despite the Coverage Mandates, Humana has adopted, as set forth in the Flier, a policy of non-coverage for Cologuard® and, to date, denied at least 293 Cologuard® claims totaling at least \$168,965 in Coverage Mandate States other than Kentucky.

121. In light of the Coverage Mandates, Humana should not be denying coverage for Cologuard® tests under any Humana Plan issued in the Coverage Mandate States.

122. As a direct and proximate result of Humana's acts and omissions, including but not limited to Humana's failures to comply with the terms of the Plans, the Coverage Mandates, and other state and federal law, Exact has sustained and will continue to sustain in the future damages and has been deprived and will continue to be deprived in the future of the compensation to which it is entitled to receive for providing Cologuard®.

123. The existence of another potentially adequate remedy does not preclude a judgment for declaratory relief. Federal Rules of Civil Procedure Rule 57.

124. Exact is entitled to declaratory relief pursuant to 28 U.S.C. §2201, including the payment of all money that was not paid to Exact by Humana for the providing Cologuard®.

¹² See GA Code §33-24-56.3.

¹³ See Mo. Rev. Stat. §376.1250.

¹⁴ See N.C. Gen. Stat. §58-3-179.

¹⁵ See Tex. Ins. Code §1363.003 and Texas Department of Insurance Commissioner's Bulletin # B000609.

¹⁶ See 215 ILCS 5/356x.

¹⁷ See Ind. Code §27-8-14.8-3.

¹⁸ See Nev. Rev. Stat. §689A-04042; 689B-0367; 695B-1907; 695C-1731; and 695G-168.

¹⁹ See 36 Okla. Stat. §6060.8a.

COUNT SIX
(Breach of Contract - as Assignees)

125. Plaintiff incorporates by reference all of the foregoing allegations as if set forth at length herein.

126. To the extent that some of the Plans are not employee welfare benefit plans governed by ERISA, they are nonetheless valid and enforceable insurance contracts.

127. As set forth more fully above, upon information and belief, all of the Plans require reimbursement of medically necessary medical expenses incurred by Humana Subscribers at usual, customary, and reasonable rates. Further, under the terms of the Plans, Humana Subscribers are entitled to coverage for the services that they received from Exact.

128. By virtue of the AoBs provided by Humana Subscribers, Exact was assigned the right to receive reimbursement under the Plans for the services that it rendered to the Humana Subscribers. Pursuant to said AoBs, Humana is, expressly or impliedly, contractually obligated to reimburse Exact for these services.

129. Claiming various purported reasons for denying coverage, Humana failed to make payment of benefits to Exact in the manner and amounts required under the terms of the Plans, the Coverage mandates, and other applicable state and federal laws.

130. Upon information and belief, the Plans did not prohibit the Humana Subscribers from assigning their rights to benefits under the Plans to Exact, including the right of direct payment of benefits under the Plans to Exact.

131. Moreover, as set forth more fully above, to the extent that the Plans prohibited the assignment of benefits to Exact, Humana waived any purported anti-assignment provisions, have ratified the assignment of benefits to Exact, and/or is estopped from using any purported anti-

assignment provisions against Exact due to its course of dealing with and statements to Exact, discussed more fully above.

132. As set forth more fully above, to the extent that the Plans prohibited the assignment of benefits to Exact, any such purported anti-assignment prohibitions are unenforceable as, among other things, contrary to public policy, as adhesion contracts, and/or due to a lack of privity with Exact.

133. As the result of Humana's failures to comply with the terms of the Plans, and/or any other applicable state common law, statutes, or regulations requiring timely payment of claims, Exact, as assignee, has suffered damages and lost benefits, for which it is entitled to damages from Humana, including unpaid benefits, restitution, interest, and other contractual damages sustained by Exact.

COUNT SEVEN
(Breach of Contract - As Third-Party Beneficiary)

134. Plaintiff incorporates by reference all of the foregoing allegations as if set forth at length herein.

135. To the extent the Humana Plans are not issued pursuant to an employee benefit plan, Humana's failure to pay for the medically necessary services provided by the Exact to Humana Subscribers described in this Complaint constitutes a breach of contract under applicable law.

136. Exact is a third-party beneficiary under the Plans, as Humana intended to reimburse providers under the Plans for services provided to Humana Subscribers.

137. Exact is a third-party beneficiary of the Humana Plans and is entitled to recover benefits due to the Humana Subscribers and enforce their rights under the Plans and policies.

138. As the result of Humana's failures to comply with the terms of the Plans, and/or any other applicable state common law, statutes, or regulations requiring timely payment of claims, Exact, as a third-party beneficiary, has suffered damages and lost benefits, for which it is entitled to damages from Humana, including unpaid benefits, restitution, interest, and other contractual damages sustained by Exact.

COUNT EIGHT
(Breach of Fiduciary Duty – non-ERISA)

139. Plaintiff incorporates by reference all of the foregoing allegations as if set forth at length herein.

140. Under the Humana Plans, Humana is a fiduciary entrusted with the obligation to pay for medically necessary services, covered services, or covered benefits as defined by the Plans. Humana further owes its Humana Subscribers a fiduciary duty and a duty to act in good faith and deal fairly.

141. Humana breached and abused its fiduciary duties to its Humana Subscribers by denying payment of the claims for services provided to its insured arbitrarily and capriciously, in bad faith, and under false pretenses in order to maximize its profits.

142. The Humana Subscribers described in this Complaint have assigned their rights to coverage under Humana Plans to Exact.

143. As assignees of the Humana Subscribers of the Plans, Exact is entitled to recover benefits due to the Humana Subscribers and enforce the rights of Humana Subscribers under the terms of the Plans and policies.

144. Humana violated its fiduciary duty of loyalty to Exact by, among other things, wrongfully denying claims for costs associated with Cologuard® tests in violation of the Plans, state and federal law, and under false pretenses; denying coverage based on a lack of

preauthorization when the Plans require no such preauthorization as a condition to coverage; refusing to allow Exact any opportunity to negotiate coverage beyond the unduly burdensome terms it has wrongfully required in contravention of applicable law and Plan terms; and failing to inform Exact, as assignees of the Humana Subscribers, of material information.

145. As the result of Humana's violations of its fiduciary duties to Exact, including, but not limited to, Humana's failures to comply with applicable state and federal common law, statutes, or regulations requiring timely payment of claims, Exact has suffered, and continues to suffer, substantial damages.

COUNT NINE
(Breach of the Duty of Good Faith and Fair Dealing – non-ERISA)

146. Exact incorporates by reference all of the foregoing allegations as if set forth at length herein.

147. As set forth more fully above, if any of the Plans are not employee welfare benefit plans governed by ERISA, they are nonetheless valid and enforceable insurance contracts. As such, the Plans contain an implied duty of good faith and fair dealing.

148. Humana, as the obligor under the Plans, owed the Humana Subscribers a duty of good faith and fair dealing with respect to said Plans.

149. As set forth more fully above, the Humana Subscribers received healthcare services from Exact and provided AoBs in which they assigned to Exact their right to benefits under the Plans for the services that Exact provided to the Humana Subscribers.

150. By virtue of these assignments, Humana also owe this duty of good faith and fair dealing to Exact.

151. As set forth more fully above, upon information and belief, the Plans did not prohibit the Humana Subscribers from assigning their rights to benefits under the Plans to Exact, including the right of direct payment of benefits under the Plans to Exact.

152. Moreover, to the extent that the Plans prohibited the assignment of benefits to Exact, Humana waived any purported anti-assignment provisions, have ratified the assignment of benefits to Exact, and/or is estopped from using any purported anti-assignment provisions against Exact due to its course of dealing with and statements to Exact.

153. And to the extent that the Plans prohibited the assignment of benefits to Exact, any such purported anti-assignment prohibitions are unenforceable as, among other things, contrary to public policy, as adhesion contracts, and/or due to a lack of privity with Exact.

154. Humana breached its duty of good faith and fair dealing owed to Exact, as assignee of rights and benefits under the Plans, in a number of ways, described more fully above, including wrongfully denying claims for costs associated with Cologuard® tests in violation of the Plans, state and federal law, and under false pretenses; denying coverage based on a lack of preauthorization when the Plans require no such preauthorization as a condition to coverage; refusing to allow Exact any opportunity to negotiate coverage beyond the unduly burdensome terms it has wrongfully required in contravention of applicable law and Plan terms; and failing to inform Exact, as assignees of the Humana Subscribers, of material information.

155. Humana's conduct in derogation of its duty of good faith and fair dealing under the Plans has deprived Exact of its reasonable expectations and benefits as assignee of benefits under the Plans.

COUNT TEN
(Insurance Bad Faith – non-ERISA)

156. Exact incorporates by reference all of the foregoing allegations as if set forth at length herein.

157. As set forth more fully above, if any of the Plans are not employee welfare benefit plans governed by ERISA, they are nonetheless valid and enforceable insurance contracts. As such, the Plans contain an implied duty of good faith and fair dealing.

158. Humana, as the obligor under the Plans, owed the Humana Subscribers a duty of good faith and fair dealing with respect to said Plans.

159. As set forth more fully above, the Humana Subscribers received healthcare services from Exact and provided AoBs in which they assigned to Exact their right to benefits under the Plans for the services that Exact provided to the Humana Subscribers.

160. By virtue of these assignments, Humana is precluded from engaging in unfair claims settlement practices pursuant to Kentucky Revised Statutes (“KRS”) §304.12-230 and similar statutes and/or common law in other states.

161. Without limitation, Humana has engaged in insurance bad faith under KRS §304.12-230 and other laws by: (1) Misrepresenting pertinent facts or insurance policy provisions relating to coverages at issue; (2) Failing to acknowledge and act reasonably promptly upon communications with respect to claims arising under insurance policies; (3) Failing to adopt and implement reasonable standards for the prompt investigation of claims arising under insurance policies; (4) Refusing to pay claims without conducting a reasonable investigation based upon all available information; (5) Not attempting in good faith to effectuate prompt, fair and equitable settlements of claims in which liability has become reasonably clear; and (6)

Failing to promptly provide a reasonable explanation of the basis in the insurance policy in relation to the facts or applicable law for denial of a claim or for the offer of a compromise settlement.

162. As set forth more fully above, upon information and belief, the Plans did not prohibit the Humana Subscribers from assigning their rights to benefits under the Plans to Exact, including the right of direct payment of benefits under the Plans to Exact.

163. Moreover, to the extent that the Plans prohibited the assignment of benefits to Exact, Humana waived any purported anti-assignment provisions, ratified the assignment of benefits to Exact, and/or is estopped from using any purported anti-assignment provisions against Exact due to its course of dealing with and statements to Exact as an out-of-network provider.

164. And to the extent that the Plans prohibited the assignment of benefits to Exact, any such purported anti-assignment prohibitions are unenforceable as, among other things, contrary to public policy, as adhesion contracts, and/or due to a lack of privity with Exact.

165. Humana has acted in bad faith in a number of ways, described more fully above, including wrongfully denying claims for costs associated with Cologuard® tests in violation of the Plans, state and federal law, and under false pretenses; denying coverage based on a lack of preauthorization when the Plans require no such preauthorization as a condition to coverage; refusing to allow Exact any opportunity to negotiate coverage beyond the unduly burdensome terms it has wrongfully required in contravention of applicable law and Plan terms; and failing to inform Exact, as assignees of the Humana Subscribers, of material information.

166. Humana's bad faith conduct under the Plans has deprived Exact of its reasonable expectations and benefits as assignee of benefits under the Plans.

COUNT ELEVEN
(Tortious Interference with Prospective Economic Advantage)

167. Exact incorporates by reference all of the foregoing allegations as if set forth at length herein.

168. As set forth more fully above, upon information and belief, Humana has sent the Flier directly to healthcare providers and/or otherwise misrepresented to such healthcare providers that Cologuard® is ineffective and not covered under Humana commercial plans.

169. Upon information and belief, medical providers who received Humana's false information, by way of the Flier or otherwise, have ceased to prescribe Cologuard®.

170. Exact had and has an economic relationship with these medical providers and Humana Subscribers.

171. Humana has knowledge of the probability of future economic benefit to Exact by virtue of this economic relationship.

172. Humana's misrepresentations were designed intentionally to disrupt Exact's relationship with Humana Subscribers.

173. Exact's relationship with Humana Subscribers has been disrupted.

174. Exact has suffered damages as a proximate cause of this disruption.

COUNT TWELVE
(Quantum Meruit)

175. Exact incorporates by reference all of the foregoing allegations as if set forth at length herein.

176. Exact has conferred upon Humana the benefit of providing treatment to Humana Subscribers.

177. At the times Exact treated the Humana Subscribers, Exact reasonably expected remuneration from Humana in the form of its full billed charges minus any applicable patient responsibilities.

178. By refusing to pay Exact for the treatment that Exact provided to Humana Subscribers, Humana has been unjustly enriched.

179. As the result of Humana's unlawful, unjust, and wrongful acts, Exact suffered and continues to suffer damages, and it is owed restitution from Humana.

PRAYER FOR RELIEF

WHEREFORE, Exact demands judgment in its favor against Humana as follows:

A. Declaring that Humana has breached the terms of the Plans and awarding damages for unpaid benefits, as well as awarding injunctive and declaratory relief to prevent Humana's continuing actions detailed herein that are unauthorized by the Plans;

B. Declaring that Humana failed to provide a "full and fair review" under § 503 of ERISA, 29 U.S.C. § 1133, and applicable claims procedure regulations, and that "deemed exhaustion" under such regulations is in effect as a result of Humana's actions, as well as awarding injunctive, declaratory and other equitable relief to ensure compliance with ERISA and its claims procedure regulations;

C. Declaring that Humana violated its fiduciary duties under § 404 of ERISA, 29 U.S.C. § 1106, and awarding injunctive, declaratory and other equitable relief to ensure compliance with ERISA;

D. Declaring that Humana violated and continues to violate the Coverage Mandates, and awarding injunctive, declaratory and other equitable relief to ensure compliance with ERISA;

E. Temporarily and permanently enjoining Humana from continuing to pursue their actions detailed herein, and ordering Humana to pay benefits in accordance with the terms of the Plans and applicable law;

F. Awarding lost profits, contractual damages, and compensatory damages in such amounts as the proofs at trial shall show;

G. Awarding exemplary damages for Humana's intentional and tortious conduct in such amounts as the proofs at trial will show;

H. Awarding restitution for reimbursements improperly withheld by Humana;

I. Declaring that Humana has violated the terms of the relevant Plans and/or policies of insurance covering the Humana Subscribers;

J. Requiring Humana to make full payment on all previously denied charges relating to the Humana Subscribers;

K. Requiring Humana to pay Exact the benefit amounts as required under the Plans;

L. Awarding reasonable attorneys' fees, as provided by common law, federal or state statute, or equity, including Section 502(g) of ERISA, 29 U.S.C. § 1132(g);

M. Awarding costs of suit;

N. Awarding pre-judgment and post-judgment interest as provided by common law, federal or state statute or rule, or equity; and

O. Awarding all other relief to which Plaintiffs are entitled.

JURY DEMAND

Plaintiff hereby requests a trial by jury on all issues so triable.

Dated: February 1, 2016

Respectfully submitted,

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