

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 17-cv-00904-KLM

MICHAEL RYAN, SHARON MOLINA, EARBY MOXON, and HEATHER MYERS on behalf of themselves, and all others similarly situated,

Plaintiffs,

v.

SUSAN E. BIRCH, in her official capacity as Executive Director of the COLORADO STATE DEPARTMENT OF HEALTH CARE POLICY AND FINANCING,

Defendant.

ANSWER TO AMENDED CLASS ACTION COMPLAINT

Defendant, Susan E. Birch, in her official capacity as Executive Director of the Colorado State Department of Health Care Policy & Financing (“Defendant”), by and through undersigned counsel of the Office of the Colorado Attorney General, hereby submits the following Answer to Plaintiffs’ Amended Class Action Complaint (“amended complaint”).

1. This paragraph contains Plaintiffs’ statement of the case to which no answer is required. Defendant denies all factual allegations.

2. Defendant denies that the United States Food and Drug Administration issued approvals in 2011 for a drug class called Direct Acting Antivirals (DAAs). Approvals by the United States Food and Drug Administration for Direct Acting Antivirals did not begin until 2013. Defendant denies all remaining allegations.

3. Denied.

4. Denied.

5. Defendant admits jurisdiction is proper under 28 U.S.C. § 1331, and denies all remaining allegations.

6. Defendant admits venue is proper under 28 U.S.C. § 1391(b), and denies all remaining allegations.

7.a Defendant denies the Department has established or is implementing a restriction on access to DAAs when the drugs are medically necessary. Defendant admits the remaining allegations.¹

7.b Defendant admits that, to the best of its knowledge, Plaintiff Michael Ryan lives in Colorado and is enrolled in Colorado Medicaid. Defendant denies for insufficient knowledge all remaining allegations.

8. Defendant admits that, to the best of its knowledge, Plaintiff Sharon Molina is a Colorado resident and is enrolled in Colorado Medicaid. Defendant denies for insufficient knowledge all remaining allegations.

9. Defendant admits that, to the best of its knowledge, Plaintiff Earby Moxon is a Colorado resident and is enrolled in Colorado Medicaid. Defendant denies for insufficient knowledge all remaining allegations.

10. Defendant admits that, to the best of its knowledge, Plaintiff Heather Myers is a Colorado resident and is enrolled in Colorado Medicaid. Defendant denies for insufficient knowledge all remaining allegations.

¹ Plaintiffs' Amended Class Action Complaint assigns "7." to two sequential paragraphs within section III describing the parties to this action. [Doc. # 14, p. 3.] For ease of reference and to differentiate between the two paragraphs, Defendant is referring to the first "7." as "7.a" and to the second as "7.b."

11. Defendant admits Plaintiffs are challenging the Department's Preferred Drug List criteria. Defendant denies all remaining allegations.

20. Defendant admits that HCV is one of the viruses that can cause Hepatitis and that there is no current vaccine for HCV. Defendant denies all remaining allegations.²

21. Defendant admits hepatitis can be self-limiting or can progress to fibrosis (scarring), and in the minority of cases, can progress to cirrhosis (liver impairment due to scarring) or liver cancer. Defendant denies all remaining allegations.

22. Defendant admits the allegations contained in the first three sentences, and denies the last sentence. Defendant denies that HCV can be transmitted without exposure to blood.

23. Denied. Defendant admits the individuals addressed in this paragraph are at risk for HCV infection, but they are not the "most at risk" population. The "most at risk" population for contracting HCV are intravenous drug users.

24. Denied.

25. Denied.

26. Denied.

27. Defendant denies for insufficient knowledge the allegation that HCV is the most deadly infectious disease in the United States. Defendant admits the remaining allegations.

28. Denied for insufficient knowledge.

29. Denied for insufficient knowledge.

² Plaintiffs' Amended Class Action Complaint assigns the number "20." to the paragraph immediately after Paragraph 11. [Doc. # 14, p. 4.]

30. Defendant admits it submitted the report cited in this paragraph, and refers to the report for its content. Defendant denies all remaining allegations.

31. Denied.

32. Defendant admits Dr. Burman sent Ms. Birch a letter attached to the amended complaint as Exhibit A, and refers to the letter for its content. Defendant admits the Centers for Disease Control has a website addressing HCV, and refers to the website for its content. Defendant denies all remaining allegations.

33. Denied.

34. Defendant admits that prior to DAAs, the standard therapy for HCV consisted of a drug regimen consisting of boceprevir, interferon, ribavirin, and telaprevir. Defendant denies all remaining allegations.

35. Defendant denies that the FDA approved a series of DAAs in 2011. Approvals by the FDA for DAAs did not begin until 2013. Defendant admits that the drugs listed are DAAs. Defendant denies all remaining allegations.

36. Denied.

37. Denied for insufficient knowledge.

38. Admitted to the extent that Paragraph 38 refers to treatment for HCV using DAAs in the United States at the time of the filing of this Answer.

39. Defendant admits the existence of the guidelines cited in this paragraph, and refers to the guidelines for their content. Defendant denies all remaining allegations.

40. Denied.

41. Defendant admits the existence of the guidelines cited in this paragraph, and refers to the guidelines for their content. Defendant denies all remaining allegations.

42. Denied.

43. Denied.

44. Denied.

45. Defendant admits that the Centers for Medicare and Medicaid Services (CMS) issued a Drug Rebate Program Notice (“Notice”) on November 5, 2015, and refers to the Notice for its content. Defendant denies all remaining allegations.

46. Defendant admits that CMS issued a Notice on November 5, 2015, and refers to the Notice for its content. Defendant denies all remaining allegations.

47. Defendant admits that CMS issued a Notice on November 5, 2015, and refers to the Notice for its content. Defendant denies all remaining allegations.

48. Denied.

49. Denied.

50. Defendant admits to the existence, but not the authority or persuasiveness, of the order cited, and refers to the order for its content. Defendant denies all remaining allegations.

51. Denied for insufficient knowledge.

52. Denied.

53. This paragraph includes no factual allegations, but instead sets forth Plaintiffs’ interpretation of certain laws. Defendant admits to the existence of the statutes referenced, and refers to them for their content. Defendant denies all remaining allegations.

54. Defendant admits that the Department administers Colorado Medicaid. Defendant denies CMS “administers” Medicaid on a federal level.

55. This paragraph includes no factual allegations, but instead sets forth Plaintiffs’ interpretation of certain laws. Defendant admits to the existence of the statutes referenced, and refers to them for their content. Defendant denies all remaining allegations.

56. Admitted.

57. This paragraph includes no factual allegations, but instead sets forth Plaintiffs’ interpretation of certain cases. Defendant admits to the existence, but not the authority or persuasiveness, of the cases referenced; and refers to them for their content. Defendant denies all remaining allegations.

58. This paragraph includes no factual allegations, but instead sets forth Plaintiffs’ interpretation of certain laws. Defendant admits to the existence of the statutes referenced, and refers to them for their content. Defendant denies all remaining allegations.

59. This paragraph includes no factual allegations, but instead sets forth Plaintiffs’ interpretation of certain laws. Defendant admits to the existence of the statutes referenced, and refers to them for their content. Defendant denies all remaining allegations.

60. This paragraph includes no factual allegations. Defendant admits to the existence of the statutes referenced and the preferred drug list, and refers to them for their content. Defendant denies all remaining allegations.

61. This paragraph includes no factual allegations, but instead sets forth Plaintiffs’ interpretation of certain statutes and cases. Defendant admits to the existence of the statutes,

regulations, and cases referenced, and refer to them for their content. Defendant denies all remaining allegations.

62. Defendant denies that DAA treatment coverage for Plaintiffs or the putative class is medically necessary. The remainder of this paragraph sets forth Plaintiffs' interpretation of certain laws. Defendant admits to the existence of the regulations referenced, and the existence, but not the authority or persuasiveness of the cases referenced, and refers to them for their content. Defendant denies all remaining allegations.

63. This paragraph includes no factual allegations, but instead sets forth Plaintiffs' interpretation of certain laws. Defendant admits to the existence of the statute referenced, and refers to it for its content. Defendant denies any remaining allegations.

64. This paragraph includes no factual allegations, but instead sets forth Plaintiffs' interpretation of certain laws. Defendant admits to the existence of the statute and regulation referenced, and refers to them for their content. Defendant denies all remaining allegations.

65. Denied.

66. Denied.

67. Denied.

68. Defendant admits that on September 1, 2016, it amended its Preferred Drug List to be effective on October 1, 2016, the Preferred Drug List is attached as Exhibit C to the amended complaint, and that the Preferred Drug List modified Prior Authorization Criteria. Defendant otherwise refers to the Preferred Drug List for its content. Defendant denies all remaining allegations.

69. Denied.

70. Denied.

71. The first sentence of this paragraph includes no factual allegations, but instead sets forth Plaintiffs' interpretation of a case. Defendant admits to the existence, but not the authority or persuasiveness, of the case referenced, and refers to it for its content. Defendant admits litigation is pending in Missouri, and states that the federal court in that case denied plaintiffs' motion for preliminary injunction. Defendant denies the third sentence for insufficient knowledge. Defendant denies all remaining allegations.

72. Defendant admits Plaintiffs were or are enrolled in Colorado's Medicaid program, which is administered by HCPF. Defendant denies all remaining allegations.

73. This paragraph includes no factual allegations, but instead sets forth Plaintiffs' conclusion of law. To the extent the paragraph contains factual allegations, denied.

74. Denied for insufficient knowledge.

75. Defendant denies for insufficient knowledge Plaintiffs' current Metavir Fibrosis Scores or other qualifying criteria. Defendant denies all remaining allegations.

76. Admitted.

77. Denied.

78. Denied for insufficient knowledge.

79. Denied.

80. Defendant admits Mr. Ryan is or was a patient of Dr. Daniel Frees and that Dr. Frees submitted a prior authorization request to Defendant. Defendant denies for insufficient knowledge the remaining allegations.

81. Defendant admits a denial issued December 8, 2016 is attached as Exhibit D to the amended complaint, and refers to the denial for its content. Defendant denies all remaining allegations.

82. Defendant admits a denial issued January 24, 2017 is attached as Exhibit E to the amended complaint, and refers to the denial for its content. Defendant denies all remaining allegations.

83. This paragraph contains Plaintiffs' characterization of the case, to which no answer is required. Defendant denies all factual allegations.

84. Denied.

85. Denied for insufficient knowledge.

86. Defendant admits it amended its Prior Authorization Criteria effective October 1, 2016; and that Ms. Molina through her physician applied for coverage of DAA treatment in February of 2017. Defendant further admits that on February 13, 2017 a denial was issued, which is attached as Exhibit F to the amended complaint. Defendant refers to Exhibit F for its content. Defendant denies all remaining allegations.

87. This paragraph contains Plaintiffs' characterization of the case, to which no answer is required. Defendant denies all factual allegations.

88. Denied.

89. Denied for insufficient knowledge.

90. Denied for insufficient knowledge. Defendant refers to Exhibits G and H for their content. Defendant denies all remaining allegations.

91. Defendant admits it amended its Prior Authorization Criteria effective October 1, 2016. Defendant further admits that Mr. Moxon through his physician applied for coverage of DAA treatment in October 2016, which is attached as Exhibit G to the amended complaint, and that on October 11, 2016 a denial was issued, which is attached as Exhibit H to the amended complaint. Defendant refers to Exhibits G and H for their content. Defendant denies all remaining allegations.

92. This paragraph contains Plaintiffs' characterization of the case, to which no answer is required. Defendant denies all factual allegations.

93. Denied.

94. Denied for insufficient knowledge.

95. Defendant admits it amended its Prior Authorization Criteria effective October 1, 2016. Defendant further admits that Ms. Myers through her physician applied for coverage of DAA treatment on November 8, 2016, and that on November 11, 2016 a denial was issued, both of which are attached as Exhibit I to the amended complaint. Defendant refers to Exhibit I for its content. Defendant denies all remaining allegations.

96. This paragraph contains Plaintiffs' characterization of the case to which no answer is required. Defendant denies all factual allegations.

97. This paragraph 97 contains Plaintiffs' description of their proposed class to which no answer is required. Defendant denies all factual allegations.

98. Defendant admits Plaintiffs seek certification of a class pursuant to FED. R. CIV. P. 23(b)(2), and refer to the rule for its content. Defendant denies all factual allegations.

99. This paragraph contains legal arguments to which an answer is not required.

Defendant denies all factual allegations.

100. This paragraph contains legal arguments to which an answer is not required.

Defendant denies all factual allegations.

101. This paragraph contains legal arguments to which an answer is not required.

Defendant denies all factual allegations.

102. This paragraph contains legal arguments to which an answer is not required.

Defendant denies all factual allegations.

103. This paragraph contains legal arguments to which an answer is not required.

Defendant denies all factual allegations.

104. Defendant incorporates the preceding paragraphs.

105. Denied.

106. Denied.

107. Denied.

108. Denied.

109. Defendant incorporates the preceding paragraphs.

110. Denied.

111. Denied.

112. Denied.

113. Defendant incorporates the preceding paragraphs.

114. Denied.

115. Denied.

116. Denied.

117. Defendant denies that Plaintiffs are entitled to any relief from Defendant, including but not limited to the relief requested in the unnumbered PRAYER FOR RELIEF paragraph on pages 27 and 28 of the amended complaint.

118. Any allegation that is not specifically admitted herein is denied.

DEFENSES AND AFFIRMATIVE DEFENSES

1. Plaintiffs have failed to state a claim upon which relief can be granted.
2. Defendant denies that it violated Plaintiffs' rights.
3. Defendant denies that it violated Title XIX of the Social Security Act or that it acted in a manner inconsistent with its duties and obligations under the Act.
4. Defendant complied with Title XIX of the Social Security Act and associated regulations, including, but not limited to, 42 C.F.R. §§ 440.230, 440.240.
5. Defendant reserves the right to assert additional defenses and affirmative defenses as they become known.

Dated: May 23, 2017.

CYNTHIA H. COFFMAN
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CERTIFICATE OF SERVICE

I certify that I served the foregoing ANSWER TO AMENDED CLASS ACTION COMPLAINT upon all parties herein by e-filing with the CM/ECF system maintained by the court this 23rd day of May, 2017 addressed as follows:

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