

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**

ELI LILLY AND COMPANY,
Lilly Corporate Center
893 Delaware Street
Indianapolis IN 46225, *et al.*,

Plaintiffs,

–v–

NORRIS COCHRAN
200 Independence Avenue, SW
Washington, DC 20201, *et al.*,

Defendants.

Case No. 1:21-cv-81-SEB-MJD

**THE AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AMERICA’S
ESSENTIAL HOSPITALS, THE ASSOCIATION OF AMERICAN MEDICAL
COLLEGES, THE CHILDREN’S HOSPITAL ASSOCIATION, AND THE AMERICAN
SOCIETY OF HEALTH-SYSTEM PHARMACIST’S MOTION TO INTERVENE**

The American Hospital Association, 340B Health, America’s Essential Hospitals, the Association of American Medical Colleges, National Association of Children’s Hospitals d/b/a the Children’s Hospital Association, and American Society of Health-System Pharmacists (collectively the Proposed Intervenors) move this Court, pursuant to Federal Rule of Civil Procedure 24(a), or in the alternative pursuant to Federal Rule of Civil Procedure 24(b), to Intervene as Defendants in this lawsuit.

In support of this motion, Proposed Intervenors submit a Memorandum in Support of the Motion to Intervene. Proposed Intervenors also submit a Proposed Order. Exhibit A (the Declaration of Maureen Testoni) and Exhibit B (Intervenors Proposed Answer) are attached to this Motion.

Proposed Intervenors consulted with counsel for Plaintiffs and Defendants. Plaintiffs have deferred taking a position on the Motion to Intervene until they have had an opportunity to review the Motion and supporting Memorandum. Defendants oppose the Motion to Intervene.

For the reasons set forth in the Memorandum in Support of the Motion to Intervene, Proposed Intervenors request the Court to grant their motion to intervene as right under Rule 24(a) or, in the alternative, to allow Proposed Intervenors to intervene under Rule 24(b).

Dated: February 19, 2021

Respectfully submitted,

/s/ Alice M. Morical

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Exhibit A

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,
Lilly Corporate Center
893 Delaware Street
Indianapolis IN 46225, *et al.*,

Plaintiffs,

—v—

NORRIS COCHRAN
200 Independence Avenue, SW
Washington, DC 20201, *et al.*,

Defendants.

Case No. 1:21-cv-81-SEB-MJD

**DECLARATION OF MAUREEN TESTONI IN SUPPORT OF THE AMERICAN
HOSPITAL ASSOCIATION, 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS,
THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES, THE CHILDREN'S
HOSPITAL ASSOCIATION, AND THE AMERICAN SOCIETY OF HEALTH-SYSTEM
PHARMACIST'S MOTION TO INTERVENE**

I, Maureen Testoni, state as follows under the penalty of perjury:

1. I am the President and Chief Executive Officer of 340B Health, a national, not-for-profit organization headquartered in Washington, D.C. Our vision and mission is to be the leading 340B advocate and resource in helping hospitals serve their patients, so that 340B hospitals and health systems fulfill their mission to provide care for patients with low income and those living in rural communities.

2. The information set forth in this affidavit is based upon my personal knowledge.

3. Following Eli Lilly's June 2020 announcement that it would cease offering Cialis® at 340B pricing to 340B entities if dispensed by a contract pharmacy, 340B Health conducted a "Contract Pharmacy Survey." The survey was administered to all 340B Health hospital members

(about 1500). Responses were received between July 14 and August 8, 2020. 435 hospitals responded. The respondent mix was 64% disproportionate share hospitals (DSH) hospitals, 24% critical access hospitals (CAH), and 12% other hospital types. Data were cleaned to remove duplicates.

4. A second survey, the 340B Health Annual Survey, was launched on November 3, 2020. Responses were received between November 3, 2020 and January 7, 2021. 489 hospitals responded. The respondent mix included 61% DSH hospitals, 28% CAH hospitals, and 11% other hospital types. Data were cleaned to remove duplicates.

5. The following information is derived from those two 340B Health surveys.

6. Respondents to the Annual Survey reported that discounts for drugs dispensed through a contract pharmacy provided over half of the total 340B benefit from the 340B discounts for CAHs (51%) and about a quarter of the total such benefit for all 340B hospital types (27%).

7. Respondents to the Contract Pharmacy Survey reported that the reduction or elimination of the discounts for drugs dispensed through contract pharmacies would lead to cuts in programs and services for people with low income and/or living in rural areas.

8. Respondents to the Contract Pharmacy Survey reported using the discount benefit from 340B drugs dispensed through contract pharmacies to support programs and services offered by 340B hospitals. For example, respondents reported that the discount benefit from 340B drugs dispensed through contract pharmacies allows them to:

- Maintain/provide more patient care services (97%)
- Maintain/provide more uncompensated and unreimbursed care (93%)
- Maintain/provide more services in underserved areas (83%)
- Develop/maintain targeted programs to serve vulnerable patients (73%)
- Keep the doors open (70%)

9. Respondents to the Contract Pharmacy Survey reported that a reduction or elimination of discounts for drugs dispensed through a contract pharmacy would harm the ability of 340B hospitals to maintain programs and services. Specific services that would be harmed include:

- Patient care services (94%)
- Uncompensated and unreimbursed care (86%)
- Services in underserved areas (81%)
- Programs to serve vulnerable patients (73%)

10. Sixty percent of Respondents to the Contract Pharmacy Survey reported that a reduction in the discounts from 340B drugs dispensed through contract pharmacies could lead the hospital to close.

On this 19th day of February, 2021, I declare under penalty of perjury that the foregoing is true and correct.



Maureen Testoni
President and
Chief Executive Officer
340B Health

Exhibit B

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**

ELI LILLY AND COMPANY,
Lilly Corporate Center
893 Delaware Street
Indianapolis, IN 46225, et al.,

Plaintiffs,

v.

NORRIS COCHRAN, in his official capacity as
Acting Secretary of Health & Human Services,
Office of the Secretary
200 Independence Avenue, S.W.
Washington, D.C. 20201, et al.,

Defendants.

No. 1:21-cv-81-SEB-MJD

**[PROPOSED] ANSWER IN INTERVENTION TO PLAINTIFFS' FIRST
AMENDED COMPLAINT**

Intervenors American Hospital Association, 340B Health, the Association of American Medical Colleges, America's Essential Hospitals, National Association of Children's Hospitals d/b/a the Children's Hospital Association, and American Society of Health-System Pharmacists (collectively the Intervenors) hereby answer the First Amended Complaint filed by Plaintiffs Eli Lilly and Company and Lilly USA, LLC (collectively "Plaintiffs") as follows.

The preliminary section of the First Amended Complaint contains Plaintiffs' characterization of this Action to which no response is required.

THE PARTIES

1. Intervenor lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 1 and therefore deny the same.

2. Intervenor lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 2 and therefore deny the same.

3. Intervenor admit the first sentence of Paragraph 3, but lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the second sentence of Paragraph 3 and therefore deny the same.

4. Intervenor admit the allegations contained in Paragraph 4.

5. Intervenor admit the first sentence, except Daniel J. Barry, currently Acting General Counsel, is automatically substituted for Robert P. Charrow as a defendant. As to the second sentence, Intervenor admit that the Office of General Counsel is responsible for issuing legal opinions on behalf of the agency.

6. Intervenor admit the allegations contained in Paragraph 6.

7. Intervenor admit the allegations contained in Paragraph 7, except that they lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the third sentence of Paragraph 7 and therefore deny the same.

JURISDICTION AND VENUE

8. The allegations in Paragraph 8 are conclusions of law to which no response is required.

9. The allegations in Paragraph 9 are conclusions of law to which no response is required.

10. The allegations in Paragraph 10 are conclusions of law to which no response is required.

11. The allegations in Paragraph 11 are conclusions of law to which no response is required.

FACTS

12. The allegations in Paragraph 12 address legal rather than factual matters and characterize section 340B of the Public Health Service Act, 42 U.S.C. § 256b, which is the best evidence of its content. To the extent that Paragraph 12 makes any material allegations that are inconsistent with the statute, they are denied.

13. The allegations in Paragraph 13 address legal rather than factual matters and characterize 42 U.S.C. § 1396r-8(a)(1), (5), which is the best evidence of its content. To the extent that Paragraph 13 makes any material allegations that are inconsistent with the statute, they are denied.

14. Intervenor admits the allegations in Paragraph 14.

15. Intervenor lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 15 and therefore denies the same.

16. The allegations in Paragraph 16 address legal rather than factual matters and characterize 42 U.S.C. § 1396r-8(b)(4)(B)(v), and its implementing regulations, which are the best evidence of their content. To the extent that Paragraph 16 makes any material allegations that are inconsistent with the statute and the regulations, they are denied.

17. The allegations in Paragraph 17 address legal rather than factual matters and characterize 42 U.S.C. § 256b(a)(1), which is the best evidence of its content. To the extent that Paragraph 17 makes any material allegations that are inconsistent with the statute, they are denied.

18. The allegations in Paragraph 18 address legal rather than factual matters and characterize 42 U.S.C. § 256b(a)(4), which is the best evidence of its content. To the extent that Paragraph 18 makes any material allegations that are inconsistent with the statute, they are denied.

19. The allegations in Paragraph 19 address legal rather than factual matters and characterize 42 U.S.C. § 256b(a)(4), which is the best evidence of its content. To the extent that Paragraph 19 makes any material allegations that are inconsistent with the statute, they are denied.

20. The allegations in Paragraph 20 address legal rather than factual matters and characterize 42 U.S.C. § 256b(a)(4), which is the best evidence of its content. To the extent that Paragraph 20 makes any material allegations that are inconsistent with the statute, they are denied.

21. The allegations in Paragraph 21 address legal rather than factual matters and characterize 42 U.S.C. § 256b(a)(9), and its implementing regulation, which are the best evidence of their content. To the extent that Paragraph 21 makes any material allegations that are inconsistent with the statute and the regulation, they are denied.

22. The allegations in the first and second sentences of Paragraph 22 address legal rather than factual matters and characterize 42 U.S.C. §§ 256b(a)(1), (a)(4), (b)(1), which are the best evidence of their content. To the extent that Paragraph 22 makes any material allegations that are inconsistent with the statute, they are denied. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the third and fourth sentences of Paragraph 22 and therefore deny the same.

23. The allegations in Paragraph 23 address legal rather than factual matters and characterize 42 U.S.C. § 256b(a)(9), and § 256b(d)(1)(B)(vi), which are the best evidence of their content. To the extent that Paragraph 23 makes any material allegations that are inconsistent with the statutes, they are denied. Intervenors admit the allegations in the last sentence.

24. The allegations in Paragraph 24 address legal rather than factual matters and characterize 42 U.S.C. § 256b(d)(1)(B)(vi), and its implementing regulations, which are the best evidence of their content. To the extent that Paragraph 24 makes any material allegations that are inconsistent with the statute and the regulations, they are denied.

25. The allegations in Paragraph 25 address legal rather than factual matters and characterize 42 U.S.C. § 256b(a)(5)(A), which is the best evidence of its content. To the extent that Paragraph 25 makes any material allegations that are inconsistent with the statute, they are denied.

26. The allegations in Paragraph 26 address legal rather than factual matters and characterize 42 U.S.C. § 256b(a)(5)(B), which is the best evidence of its content. To the extent that Paragraph 26 makes any material allegations that are inconsistent with the statute, they are denied.

27. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 27 and therefore deny the same.

28. The allegations in Paragraph 28 address legal rather than factual matters and characterize 42 U.S.C. § 256b which is the best evidence of its content. To the extent that Paragraph 28 makes any material allegations that are inconsistent with the statute, they are denied.

29. The allegations in Paragraph 29 address legal rather than factual matters and characterize 42 U.S.C. § 256b which is the best evidence of its content. To the extent that Paragraph 29 makes any material allegations that are inconsistent with the statute, they are denied.

30. The allegations in Paragraph 30 address legal rather than factual matters and characterize 42 U.S.C. § 256b(1) which is the best evidence of its content. To the extent that Paragraph 30 makes any material allegations that are inconsistent with the statute, they are denied.

31. The allegation in Paragraph 31 is a conclusion of law to which no response is required.

32. The allegations in Paragraph 32 address legal rather than factual matters and characterize 42 U.S.C. § 256b(a)(4) which is the best evidence of its content. To the extent that Paragraph 32 makes any material allegations that are inconsistent with the statute, they are denied.

33. The allegations in Paragraph 33 address legal rather than factual matters and characterize 42 U.S.C. § 256b which is the best evidence of its content. To the extent that Paragraph 33 makes any material allegations that are inconsistent with the statute, they are denied.

34. The allegations in Paragraph 34 address legal rather than factual matters and characterize 42 U.S.C. § 256b which is the best evidence of its content. To the extent that Paragraph 33 makes any material allegations that are inconsistent with the statute, they are denied.

35. The allegations in Paragraph 35 address legal rather than factual matters and characterize 42 U.S.C. § 256b which is the best evidence of its content. To the extent that Paragraph 35 makes any material allegations that are inconsistent with the statute, they are denied.

36. The allegations in Paragraph 36 address legal rather than factual matters and characterize 42 U.S.C. § 256b which is the best evidence of its content. To the extent that Paragraph 36 makes any material allegations that are inconsistent with the statute, they are denied.

37. The allegations in Paragraph 37 are conclusions of law to which no response is required.

38. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 38 and therefore deny the same.

39. The allegations in Paragraph 39 address legal rather than factual matters and characterize the HRSA guidelines issued in 1996 which is the best evidence of its content. To the

extent that Paragraph 39 makes any material allegations that are inconsistent with the HRSA guidelines, they are denied.

40. The allegations in Paragraph 40 address legal rather than factual matters and characterize the HRSA guidelines issued in 1996 which is the best evidence of its content. To the extent that Paragraph 40 makes any material allegations that are inconsistent with the HRSA guidelines, they are denied.

41. The allegations in Paragraph 41 address legal rather than factual matters and characterize the HRSA guidelines issued in 1996 which is the best evidence of its content. To the extent that Paragraph 41 makes any material allegations that are inconsistent with the HRSA guidelines, they are denied.

42. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 42 and therefore deny the same.

43. The allegations in Paragraph 43 address legal rather than factual matters and characterize the HRSA guidelines issued in 1996 which is the best evidence of its content. To the extent that Paragraph 43 makes any material allegations that are inconsistent with the HRSA guidelines, they are denied.

44. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 44 and therefore deny the same.

45. The allegations in Paragraph 45 address legal rather than factual matters and characterize the HRSA guidelines issued in 2010 which is the best evidence of its content. To the extent that Paragraph 45 makes any material allegations that are inconsistent with the HRSA guidelines, they are denied.

46. The allegations in Paragraph 46 address legal rather than factual matters and characterize the HRSA guidelines issued in 2010 which is the best evidence of its content. To the extent that Paragraph 46 makes any material allegations that are inconsistent with the HRSA guidelines, they are denied.

47. The allegations in Paragraph 47 address legal rather than factual matters and characterize the HRSA guidelines issued in 2010 which is the best evidence of its content. To the extent that Paragraph 47 makes any material allegations that are inconsistent with the HRSA guidelines, they are denied.

48. Intervenors deny the allegations in Paragraph 48.

49. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 49.

50. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 50.

51. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 51.

52. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 52.

53. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 53.

54. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 54.

55. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 55.

56. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 56.

57. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 57.

58. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 58.

59. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 59.

60. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 60.

61. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 61.

62. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 62.

63. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 63.

64. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 64.

65. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 65.

66. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 66.

67. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 67.

68. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 68.

69. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 69.

70. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 70.

71. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 71.

72. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 72.

73. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 73.

74. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 74.

75. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 75.

76. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 76.

77. Intervenor admits that Lilly introduced a new distribution program but deny the remaining allegations in Paragraph 77.

78. Intervenor admits the allegations contained in Paragraph 78.

79. Intervenor admits the allegations contained in Paragraph 79.

80. Intervenor admits that Lilly implemented an exception process for covered entities that do not have their own in-house pharmacy. Intervenor lacks knowledge or information sufficient to form a belief about the truth of the allegations in the second sentence of Paragraph 80 and deny the remaining allegations in Paragraph 80.

81. Intervenor denies the allegations contained in Paragraph 81.

82. Intervenor lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 82 and therefore deny the same.

83. The allegations in Paragraph 83 address legal rather than factual matters and characterize Executive Order No. 13,937 which is the best evidence of its content. To the extent that Paragraph 83 makes any material allegations that are inconsistent with the Executive Order, they are denied.

84. Intervenor lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 84 and therefore deny the same.

85. Intervenor lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 85 and therefore deny the same.

86. Intervenor lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 86 and therefore deny the same.

87. Intervenor lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 87 and therefore deny the same.

88. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 88 to the extent that they are not quoting from Exhibit B.

89. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 89 to the extent they are not quoting from Exhibit B.

90. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 90 to the extent they are not quoting from Exhibit C.

91. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 91 to the extent they are not quoting from Exhibit D.

92. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 92 and to the extent they are not quoting from Exhibit D.

93. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 93 to the extent they are not quoting from Exhibit D.

94. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 94 to the extent they are not quoting from the *340B Report* article discussing HRSA's reaction to Lilly's distribution program.

95. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 95, which reference a letter that was not attached to the Amended Complaint, and therefore deny the same.

96. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 96 to the extent they are not quoting from Exhibit E.

97. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 97 to the extent they are not quoting from Exhibits F or G.

98. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 98 to the extent they are not quoting from Exhibits A or B.

99. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 99 to the extent they are not quoting from Exhibit H.

100. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 100 to the extent they are not quoting from Exhibit I.

101. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 101 to the extent they are not quoting from the *340B Report* article cited.

102. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 102 to the extent they are not quoting from Exhibit J.

103. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 103 to the extent they are not quoting from Exhibit K.

104. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 104 and therefore deny the same.

105. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 105 to the extent they are not quoting from Exhibit L.

106. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 106 to the extent they are not quoting from the 2020 GAO Report or Defs.' Mot. to Dismiss for Lack of Jurisdiction 19–20, *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906 (D.D.C. Dec. 14, 2020), ECF No. 41.

107. Intervenors admit that HHH's General Counsel issued an advisory opinion on December 30, 2020 stating that 340B discounts apply when a contract pharmacy acts as an agent for a covered entity but deny the characterization of this advisory opinion as incorrect.

108. The allegation in Paragraph 108 addresses legal rather than factual matters and characterizes the Advisory Opinion issued on December 30, 2020, which is the best evidence of its content. To the extent that Paragraph 108 makes any material allegations that are inconsistent with the Advisory Opinion, they are denied.

109. The allegations in Paragraph 109 address legal rather than factual matters and characterize the Advisory Opinion issued on December 30, 2020, which is the best evidence of its content. To the extent that Paragraph 109 makes any material allegations that are inconsistent with the Advisory Opinion or the underlying statute, they are denied.

110. The allegations in Paragraph 110 address legal rather than factual matters and characterize the Advisory Opinion issued on December 30, 2020, which is the best evidence of its content. To the extent that Paragraph 110 makes any material allegations that are inconsistent with the Advisory Opinion or the underlying statute, they are denied.

111. The allegations in Paragraph 111 address legal rather than factual matters and characterize the Advisory Opinion issued on December 30, 2020, which is the best evidence of its content. To the extent that Paragraph 111 makes any material allegations that are inconsistent with the Advisory Opinion or the underlying statute, they are denied.

112. The allegations in Paragraph 112 address legal rather than factual matters and characterize the Advisory Opinion issued on December 30, 2020, which is the best evidence of its content. To the extent that Paragraph 112 makes any material allegations that are inconsistent with the Advisory Opinion or the underlying statute, they are denied.

113. The allegations in Paragraph 113 address legal rather than factual matters and characterize the Advisory Opinion issued on December 30, 2020, which is the best evidence of its content. To the extent that Paragraph 113 makes any material allegations that are inconsistent with the Advisory Opinion or the underlying statute, they are denied.

114. The allegations in Paragraph 114 address legal rather than factual matters and characterize the Advisory Opinion issued on December 30, 2020, which is the best evidence of its content. To the extent that Paragraph 114 makes any material allegations that are inconsistent with the Advisory Opinion or the underlying statute, they are denied.

115. The allegations in Paragraph 115 address legal rather than factual matters and characterize the Advisory Opinion issued on December 30, 2020, which is the best evidence of its content. To the extent that Paragraph 115 makes any material allegations that are inconsistent with the Advisory Opinion or the underlying statute, they are denied.

116. The allegations in the first sentence of Paragraph 116 characterize the Advisory Opinion issued on December 30, 2020, which is the best evidence of its content. To the extent that Paragraph 116 makes any material allegations that are inconsistent with the Advisory Opinion or the underlying statute, they are denied. Intervenors lack knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in the rest of Paragraph 116 and therefore deny the same.

117. The allegations in Paragraph 117 address legal rather than factual matters and characterize the Advisory Opinion issued on December 30, 2020 which is the best evidence of its content. To the extent that Paragraph 117 makes any material allegations that are inconsistent with the Advisory Opinion or the underlying statute, they are denied.

118. The allegations in Paragraph 118 address legal rather than factual matters and characterize the Advisory Opinion issued on December 30, 2020 which is the best evidence of its content. To the extent that Paragraph 118 makes any material allegations that are inconsistent with the Advisory Opinion or the underlying statute, they are denied.

119. The allegations in Paragraph 119 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors admit the allegations in Paragraph 119.

120. The allegations in Paragraph 120 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors admit that the ACA amendments required HHS to promulgate regulations establishing an ADR process but deny the remaining allegations in Paragraph 120.

121. The allegations in Paragraph 121 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors admit that Paragraph 121 correctly cites from 42 U.S.C. § 256b(d)(3) but deny the remaining allegations in Paragraph 121.

122. The allegations in Paragraph 122 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors admit that Paragraph 122 correctly cites 42 U.S.C. § 256b(d)(3) but deny the remaining allegations in Paragraph 122.

123. The allegations in Paragraph 123 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors admit correctly cites 42 U.S.C. § 256b(d)(3) but deny the remaining allegations in Paragraph 123.

124. The allegations in Paragraph 124 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations address legal rather than factual matters and characterize the ACA amendments, which are the best evidence of their content. To the extent that Paragraph 124 makes any material allegations that are inconsistent with the ACA amendments, they are denied.

125. The allegations in Paragraph 125 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention to the extent they may be deemed applicable, the Intervenors admit the allegations in Paragraph 125.

126. The allegations in Paragraph 126 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations characterize the NPRM which is the best evidence of its content.

127. The allegations in Paragraph 127 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations characterize the NPRM which is the best evidence of its content.

128. The allegations in Paragraph 128 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations characterize the NPRM which is the best evidence of its content.

129. The allegations in Paragraph 129 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations characterize the NPRM which is the best evidence of its content.

130. The allegations in Paragraph 130 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the

Intervenors lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny the same.

131. The allegations in Paragraph 131 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny the same.

132. The allegations in Paragraph 132 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors admit the allegations in Paragraph 132.

133. The allegations in Paragraph 133 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors admit the allegations in Paragraph 133.

134. The allegations in Paragraph 134 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny the same.

135. The allegations in Paragraph 135 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors admit the allegations in Paragraph 135.

136. The allegations in Paragraph 136 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors admit that HRSA published a final ADR rule on December 14, 2020 but lack

knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 136 and therefore deny the same.

137. The allegations in Paragraph 137 address legal rather than factual matters and characterize the ADR Rule published by HRSA, which is the best evidence of its content. To the extent that Paragraph 137 makes any material allegations that are inconsistent with the Rule, they are denied.

138. The allegations in Paragraph 138 address legal rather than factual matters and characterize the ADR Rule published by HRSA, which is the best evidence of its content. To the extent that Paragraph 138 makes any material allegations that are inconsistent with the Rule, they are denied.

139. The allegations in Paragraph 139 address legal rather than factual matters and characterize the ADR Rule published by HRSA, which is the best evidence of its content. To the extent that Paragraph 139 makes any material allegations that are inconsistent with the Rule, they are denied.

140. The allegations in Paragraph 140 address legal rather than factual matters and characterize the ADR Rule published by HRSA, which is the best evidence of its content. To the extent that Paragraph 140 makes any material allegations that are inconsistent with the Rule, they are denied.

141. The allegations in Paragraph 141 address legal rather than factual matters and characterize the ADR Rule published by HRSA, which is the best evidence of its content. To the extent that Paragraph 141 makes any material allegations that are inconsistent with the Rule, they are denied.

142. The allegations in Paragraph 142 address legal rather than factual matters and characterize the ADR Rule published by HRSA, which is the best evidence of its content. To the extent that Paragraph 142 makes any material allegations that are inconsistent with the Rule, they are denied.

143. The allegations in Paragraph 143 address legal rather than factual matters and characterize the ADR Rule published by HRSA, which is the best evidence of its content. To the extent that Paragraph 143 makes any material allegations that are inconsistent with the Rule, they are denied.

144. The allegations in Paragraph 144 address legal rather than factual matters and characterize the ADR Rule published by HRSA, which is the best evidence of its content. To the extent that Paragraph 144 makes any material allegations that are inconsistent with the Rule, they are denied.

145. The allegations in Paragraph 145 address legal rather than factual matters and characterize the ADR Rule published by HRSA, which is the best evidence of its content. To the extent that Paragraph 145 makes any material allegations that are inconsistent with the Rule, they are denied.

146. The allegation in Paragraph 146 is a conclusion of law to which no response is required. To the extent it may be deemed to be a factual allegation, it is denied.

147. The allegations in Paragraph 147 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

148. The allegations in Paragraph 148 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

149. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 149 and therefore deny the same.

150. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 150 and therefore deny the same.

151. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 151 and therefore deny the same.

152. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 152 and therefore deny the same.

153. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 153 and therefore deny the same.

154. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 154 and therefore deny the same.

155. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 155 and therefore deny the same.

156. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 156 and therefore deny the same.

157. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 157 and therefore deny the same.

158. The allegations in Paragraph 158 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors admit the allegations in paragraph 158.

159. The allegations in Paragraph 159 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the

Intervenors lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny the same.

160. The allegations in Paragraph 160 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny the same.

161. The allegations in Paragraph 161 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny the same.

162. The allegations in Paragraph 162 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny the same.

163. The allegations in Paragraph 163 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

CLAIMS FOR RELIEF

I. Claims Regarding the December 30 Decision

**COUNT I
(Violation of the Administrative Procedure Act
Failure to Provide Notice and Comment)**

164. Intervenors hereby incorporate their answers to the allegations in Paragraphs 1–163.

165. The allegations in Paragraph 165 address legal rather than factual matters and characterize The Declaratory Judgment Act which is the best evidence of its content. To the extent that Paragraph 165 makes any material allegations that are inconsistent with the statute, they are denied.

166. The allegations in Paragraph 166 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content. To the extent that Paragraph 166 makes any material allegations that are inconsistent with the statute, they are denied.

167. The allegations in Paragraph 167 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content. To the extent that Paragraph 167 makes any material allegations that are inconsistent with the statute, they are denied.

168. The allegations in Paragraph 168 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content. To the extent that Paragraph 168 makes any material allegations that are inconsistent with the statute, they are denied.

169. The allegations in Paragraph 169 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content. To the extent that Paragraph 169 makes any material allegations that are inconsistent with the statute, they are denied.

170. The allegations in Paragraph 170 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content. To the extent that Paragraph 170 makes any material allegations that are inconsistent with the statute, they are denied.

171. The allegations in Paragraph 171 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content. To the extent that Paragraph 171 makes any material allegations that are inconsistent with the statute, they are denied.

172. The allegations in Paragraph 172 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content. To the extent that Paragraph 172 makes any material allegations that are inconsistent with the statute, they are denied.

173. The allegations in Paragraph 173 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content. To the extent that Paragraph 173 makes any material allegations that are inconsistent with the statute, they are denied.

174. The allegations in Paragraph 174 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

175. The allegations in Paragraph 175 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

176. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 176 and therefore deny the same.

177. The allegations in Paragraph 177 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

178. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 178 and therefore deny the same.

179. The allegations in Paragraph 179 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

COUNT II
(Violation of Administrative Procedure Act
Exceeding Statutory Authority)

180. Intervenors hereby incorporate their answers to the allegations in Paragraphs 1–179.

181. The allegations in Paragraph 181 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content. To the extent that Paragraph 181 makes any material allegations that are inconsistent with the statute, they are denied.

182. The allegations in Paragraph 182 address legal rather than factual matters and characterize the 340B statute, which is the best evidence of its content. To the extent that Paragraph 182 makes any material allegations that are inconsistent with the statute, they are denied.

183. The allegations in Paragraph 183 address legal rather than factual matters and characterize the 340B, which is the best evidence of its content. To the extent that Paragraph 183 makes any material allegations that are inconsistent with the statute, they are denied.

184. The allegations in Paragraph 184 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

185. The allegations in Paragraph 185 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

186. The allegations in Paragraph 186 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

187. The allegations in Paragraph 187 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

COUNT III
(Violation of the Administrative Procedure Act
Arbitrary and Capricious Agency Action)

188. Intervenors hereby incorporate their answers to the allegations in Paragraphs 1–187.

189. The allegations in Paragraph 189 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content. To the extent that Paragraph 189 makes any material allegations that are inconsistent with the statute, they are denied.

190. The allegations in Paragraph 190 address legal rather than factual matters and characterize *Motor Vehicle Manufacturers. Ass'n of U.S., Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 43 (1983), which is the best evidence of its content. To the extent that

Paragraph 190 makes any material allegations that are inconsistent with that decision, they are denied.

191. The allegations in Paragraph 191 address legal rather than factual matters and characterize *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) and *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016), which are the best evidence of their content. To the extent that Paragraph 191 makes any material allegations that are inconsistent with that decision, they are denied.

192. The allegations in Paragraph 192 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

193. The allegations in Paragraph 193 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

194. The allegations in Paragraph 194 address legal rather than factual matters and characterize the 340B statute, which is the best evidence of its content. To the extent that Paragraph 194 makes any material allegations that are inconsistent with the statute, they are denied.

195. The allegations in Paragraph 195 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

COUNT IV
(Violation of the Administrative Procedure Act
Contrary to the Fifth Amendment to and Article I of the U.S. Constitution)

196. Intervenors hereby incorporate their answers to the allegations in Paragraphs 1–195.

197. The allegations in Paragraph 197 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content. To the

extent that Paragraph 197 makes any material allegations that are inconsistent with the statute, they are denied.

198. The allegations in Paragraph 198 address legal rather than factual matters and characterize the Takings Clause of the Fifth Amendment, which is the best evidence of its content. To the extent that Paragraph 198 makes any material allegations that are inconsistent with the Fifth Amendment, they are denied.

199. The allegations in Paragraph 199 address legal rather than factual matters and characterize *Squires-Cannon v. Forest Preserve District*, 897 F.3d 797, 798 (7th Cir. 2018), *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922), and *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 537 (2005) which are the best evidence of their content. To the extent that Paragraph 199 makes any material allegations, they are denied.

200. The allegations in Paragraph 200 address legal rather than factual matters and characterize *Horne v. Department of Agriculture*, 576 U.S. 350, 358 (2015) and *Eastern Enterprises v. Apfel*, 524 U.S. 498, 529 (1998), which are the best evidence of their content. To the extent that Paragraph 200 makes any material allegations, they are denied.

201. The allegations in Paragraph 201 address legal rather than factual matters and characterize *Kaiser Aetna v. United States*, 444 U.S. 164, 175 (1979) and *Davon, Inc. v. Shalala*, 75 F.3d 1114, 1127 (7th Cir. 1996), which are the best evidence of their content. To the extent that Paragraph 201 makes any material allegations, they are denied.

202. The allegations in Paragraph 202 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

203. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of Paragraph 203 and therefore deny the same.

The remaining allegations in Paragraph 203 are conclusions of law to which no response is required. To the extent they may be deemed factual allegations, they are denied.

204. The allegations in Paragraph 204 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

205. The allegations in Paragraph 205 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

206. The allegations in Paragraph 206 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

207. The allegations in Paragraph 207 address legal rather than factual matters and characterize *Libertarian Party of Indiana v. Packard*, 741 F.2d 981, 988 (7th Cir. 1984), *Koontz v. St. Johns River Water Management District*, 570 U.S. 595, 606 (2013), *Dolan v. City of Tigard*, 512 U.S. 374, 385 (1994), and *Nollan v. California Coastal Commission*, 483 U.S. 825, 837 (1987), which are the best evidence of their content. To the extent that Paragraph 207 makes any material allegations, they are denied.

208. The allegations in Paragraph 208 include conclusions of law, to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

209. The allegations in Paragraph 209 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

210. The allegations in Paragraph 210 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

II. Claims Regarding The ADR Rule

COUNT V (Violation of the Administrative Procedure Act Contrary to Article II of the U.S. Constitution)

211. Intervenor hereby incorporate their answers to the allegations in Paragraphs 1–210.

212. The allegations in Paragraph 212 are not applicable to Plaintiffs’ allegations that are the basis for Intervenor’s intervention. To the extent they may be deemed applicable, the allegations address legal rather than factual matters and characterize the APA, which is the best evidence of its content. To the extent that Paragraph 212 makes any material allegations that are inconsistent with the statute, they are denied.

213. The allegations in Paragraph 213 are not applicable to Plaintiffs’ allegations that are the basis for Intervenor’s intervention. To the extent they may be deemed applicable, the allegations address legal rather than factual matters and characterize the Appointments Clause of the U.S. Constitution, which is the best evidence of its content. To the extent that Paragraph 213 makes any material allegations that are inconsistent with the Constitution, they are denied.

214. The allegations in Paragraph 214 are not applicable to Plaintiffs’ allegations that are the basis for Intervenor’s intervention. To the extent they may be deemed applicable, the allegations address legal rather than factual matters and characterize the Appointments Clause of the U.S. Constitution, which is the best evidence of its content. To the extent that Paragraph 214 makes any material allegations that are inconsistent with the Constitution, they are denied.

215. The allegations in Paragraph 215 are not applicable to Plaintiffs’ allegations that are the basis for Intervenor’s intervention. To the extent they may be deemed applicable, the allegations address legal rather than factual matters and characterize the Appointments Clause of the U.S. Constitution, which is the best evidence of its content. To the extent that Paragraph 215 makes any material allegations that are inconsistent with the Constitution, they are denied.

216. The allegations in Paragraph 216 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

217. The allegations in Paragraph 217 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

218. The allegations in Paragraph 218 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations address legal rather than factual matters and characterize Supreme Court cases, which are the best evidence of their content. To the extent that Paragraph 218 makes any material allegations that are inconsistent with Supreme Court caselaw, they are denied.

219. The allegations in Paragraph 219 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

220. The allegations in Paragraph 220 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations address legal rather than factual matters and characterize Supreme Court caselaw and the ADR Rule which are the best evidence of their content. To the extent that Paragraph 220 makes any material allegations that are inconsistent with Supreme Court caselaw and the ADR rule, they are denied.

221. The allegations in Paragraph 221 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

222. The allegations in Paragraph 222 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations address legal rather than factual matters and characterize *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1335 (Fed. Cir. 2019), which is the best evidence of its content. To the extent that Paragraph 222 makes any material allegations that are inconsistent with *Arthrex*, they are denied.

COUNT VI
(Violation of the Administrative Procedure Act
Contrary to Article III of the U.S. Constitution)

223. Intervenors hereby incorporate their answers to the allegations in Paragraphs 1–222.

224. The allegations in Paragraph 224 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations address legal rather than factual matters and characterize Article III of the U.S. Constitution which is the best evidence of its content. To the extent that Paragraph 224 makes any material allegations that are inconsistent with the Constitution, they are denied.

225. The allegations in Paragraph 225 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations address legal rather than factual matters and characterize Article III of the U.S. Constitution which is the best evidence of its content. To the extent that Paragraph 225 makes any material allegations that are inconsistent with the Constitution, they are denied.

226. The allegations in Paragraph 226 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations address legal rather than factual matters and characterize Article III of the U.S. Constitution and Supreme Court caselaw which are the best evidence of their content. To the extent

that Paragraph 226 makes any material allegations that are inconsistent with the Constitution or Supreme Court caselaw, they are denied.

227. The allegations in Paragraph 227 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may deemed applicable, the allegations address legal rather than factual matters and characterize Article III of the U.S. Constitution and Supreme Court caselaw which are the best evidence of their content. To the extent that Paragraph 227 makes any material allegations that are inconsistent with the Constitution or Supreme Court caselaw, they are denied.

228. The allegations in Paragraph 228 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may deemed applicable, the allegations are conclusions of law to which no response is required.

229. The allegations in Paragraph 229 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may deemed applicable, the allegations address legal rather than factual matters and characterize Supreme Court cases which are the best evidence of their content. To the extent that Paragraph 229 makes any material allegations that are inconsistent with Supreme Court caselaw, they are denied.

230. The allegations in Paragraph 230 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may deemed applicable, the allegations are conclusions of law to which no response is required.

231. The allegations in Paragraph 231 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may deemed applicable, the allegations are conclusions of law to which no response is required.

COUNT VII
(Violation of the Administrative Procedure

Act Exceeding Statutory Authority)

232. Intervenors hereby incorporate their answers to the allegations in Paragraphs 1–
231.

233. The allegations in Paragraph 233 are not applicable to Plaintiffs’ allegations that are the basis for Intervenors’ intervention. To the extent they may deemed applicable, the allegations address legal rather than factual matters and characterize the APA which is the best evidence of its content. To the extent that Paragraph 233 makes any material allegations that are inconsistent with the APA, they are denied.

234. The allegations in Paragraph 234 are not applicable to Plaintiffs’ allegations that are the basis for Intervenors’ intervention. To the extent they may deemed applicable, the allegations are conclusions of law to which no response is required.

235. The allegations in Paragraph 235 are not applicable to Plaintiffs’ allegations that are the basis for Intervenors’ intervention. To the extent they may deemed applicable, the address legal rather than factual matters and characterize the 340B statute which is the best evidence of its content. To the extent that Paragraph 235 makes any material allegations that are inconsistent with the 340B statute, they are denied.

236. The allegations in Paragraph 236 are not applicable to Plaintiffs’ allegations that are the basis for Intervenors’ intervention. To the extent they may deemed applicable, the allegations are conclusions of law to which no response is required.

237. The allegations in Paragraph 237 are not applicable to Plaintiffs’ allegations that are the basis for Intervenors’ intervention. To the extent they may deemed applicable, the allegations are conclusions of law to which no response is required.

**COUNT VIII
(Violation of the Administrative Procedure Act
Failure to Provide Notice and Comment)**

238. Intervenor hereby incorporate their answers to the allegations in Paragraphs 1–237.

239. The allegations in Paragraph 239 are not applicable to Plaintiffs’ allegations that are the basis for Intervenor’s intervention. To the extent they may deemed applicable, the allegations address legal rather than factual matters and characterize the APA which is the best evidence of its content. To the extent that Paragraph 239 makes any material allegations that are inconsistent with the APA, they are denied.

240. The allegations in Paragraph 240 are not applicable to Plaintiffs’ allegations that are the basis for Intervenor’s intervention. To the extent they may deemed applicable, the allegations address legal rather than factual matters and characterize the APA which is the best evidence of its content. To the extent that Paragraph 240 makes any material allegations that are inconsistent with the APA, they are denied.

241. The allegations in Paragraph 241 are not applicable to Plaintiffs’ allegations that are the basis for Intervenor’s intervention. To the extent they may deemed applicable, the allegations address legal rather than factual matters and characterize the APA which is the best evidence of its content. To the extent that Paragraph 241 makes any material allegations that are inconsistent with the APA, they are denied.

242. The allegations in Paragraph 242 are not applicable to Plaintiffs’ allegations that are the basis for Intervenor’s intervention. To the extent they may deemed applicable, the allegations are conclusions of law to which no response is required.

243. The allegations in Paragraph 243 are not applicable to Plaintiffs’ allegations that are the basis for Intervenor’s intervention. To the extent they may deemed applicable, the allegations are conclusions of law to which no response is required.

244. The allegations in Paragraph 244 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors lack knowledge or information sufficient to form a belief about the truth of these allegations and respectfully refer the Court to the referenced exhibit for a true and accurate statement of its contents.

245. The allegations in Paragraph 245 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

246. The allegations in Paragraph 246 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny the same.

247. The allegations in Paragraph 247 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny the same.

248. The allegations in Paragraph 248 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

249. The allegations in Paragraph 249 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

250. The allegations in Paragraph 250 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

COUNT IX
(Violation of the Administrative Procedure Act
Arbitrary and Capricious Agency Action)

251. Intervenors hereby incorporate their answers to the allegations in Paragraphs 1–250.

252. The allegations in Paragraph 252 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations address legal rather than factual matters and characterize the APA which is the best evidence of its content. To the extent that Paragraph 252 makes any material allegations that are inconsistent with the APA, they are denied.

253. The allegations in Paragraph 253 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations address legal rather than factual matters and characterize *Motor Vehicle Manufacturers Ass'n of U.S., Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 43 (1983), which is the best evidence of its content. To the extent that Paragraph 253 makes any material allegations that are inconsistent with the case, they are denied.

254. The allegations in Paragraph 254 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

255. The allegations in Paragraph 255 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

256. The allegations in Paragraph 256 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

257. The allegations in Paragraph 257 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the Intervenors lack knowledge or information sufficient to form a belief about the truth of these allegations and respectfully refer the Court to the referenced exhibit for a true and accurate statement of its contents.

258. The allegations in Paragraph 258 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

259. The allegations in Paragraph 259 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

260. The allegations in Paragraph 260 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

261. The allegations in Paragraph 261 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

262. The allegations in Paragraph 262 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

263. The allegations in Paragraph 263 are not applicable to Plaintiffs' allegations that are the basis for Intervenors' intervention. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

AFFIRMATIVE AND OTHER DEFENSES

1. Plaintiffs fail to state a claim upon which relief may be granted.
2. The challenged December 30, 2020 Advisory Opinion issued by the General Counsel of HHS is consistent with and required by the 340B statute.
3. The challenged December 30, 2020 Advisory Opinion issued by the General Counsel of HHS does not violate the Administrative Procedures Act because it interprets a statutory requirement.
4. The challenged December 30, 2020 Advisory Opinion issued by the General Counsel of HHS is constitutional.
5. Intervenors reserve the right to amend their answer and defenses as more information is obtained.

Respectfully submitted,

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**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**

ELI LILLY AND COMPANY,
Lilly Corporate Center
893 Delaware Street
Indianapolis IN 46225, *et al.*,

Plaintiffs,

–v–

NORRIS COCHRAN
200 Independence Avenue, SW
Washington, DC 20201, *et al.*,

Defendants.

Case No. 1:21-cv-81-SEB-MJD

[PROPOSED] ORDER GRANTING MOTION TO INTERVENE

Before this Court are the American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, National Association of Children's Hospitals d/b/a the Children's Hospital Association, and American Society of Health-System Pharmacists' motion to Intervene as Defendants, and a memorandum in support thereof. Having considered the briefs and arguments of the parties, this Court finds that Proposed Intervenor have timely filed their motion, that they have an interest in the outcome of this case that will be prejudiced if they are not permitted to intervene and that the existing parties cannot adequately represent their interests. Accordingly, the Motion to Intervene is hereby GRANTED.

Proposed Intervenor are hereby ORDERED to File their Answer to the First Amended Complaint within 5 days.

IT IS SO ORDERED

Dated: February __, 2021

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**

ELI LILLY AND COMPANY,
Lilly Corporate Center
893 Delaware Street
Indianapolis IN 46225, *et al.*,

Plaintiffs,

–v–

NORRIS COCHRAN
200 Independence Avenue, SW
Washington, DC 20201, *et al.*,

Defendants.

Case No. 1:21-cv-81-SEB-MJD

**THE AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AMERICA'S
ESSENTIAL HOSPITALS, THE ASSOCIATION OF AMERICAN MEDICAL
COLLEGES, THE CHILDREN'S HOSPITAL ASSOCIATION, AND THE AMERICAN
SOCIETY OF HEALTH-SYSTEM PHARMACIST'S MEMORANDUM IN SUPPORT
OF THEIR MOTION TO INTERVENE**

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The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, National Association of Children's Hospitals d/b/a the Children's Hospital Association, and American Society of Health-System Pharmacists (collectively the Proposed Intervenors) move this Court, pursuant to Federal Rule of Civil Procedure 24(a), or in the alternative pursuant to Federal Rule of Civil Procedure 24(b), for an Order granting their Motion to Intervene in this lawsuit regarding the 340B Drug Discount Program.

The 340B Program, established by section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires, as a condition of participating in Medicaid and Medicare Part B, that pharmaceutical manufacturers sell outpatient drugs at a discounted price (no more than the 340B ceiling price) to certain public and not-for-profit hospitals, community health centers, and other federally funded clinics that serve communities with a large numbers of low income patients ("340B providers" (described in the statute as "covered entities")) in order to increase the funding these entities have available to meet the needs of their patients.

Since the beginning of the program, 340B providers have dispensed covered outpatient drugs to their patients through in-house pharmacies and through community pharmacies that have entered into written contracts with hospitals and other providers ("contract pharmacies"). Under such arrangements, the 340B provider orders and pays for the 340B drugs, which are then shipped to the contract pharmacy where the drugs are dispensed to the 340B provider's patients. For more than 20 years, all drug companies, including Eli Lilly and Company ("Lilly"), worked cooperatively with 340B providers that dispensed discounted drugs to their patients through contract pharmacies. Overall, a quarter of the benefit that 340B hospitals receive from the 340B discount comes from 340B drugs dispensed through contract pharmacy arrangements. This varies

by hospital type, with Critical Access Hospitals (small hospitals in rural areas) reporting that an average of 51% of their 340B benefit from the 340B discount comes from drugs distributed through contract pharmacies, while Disproportionate Share Hospitals (DSH hospitals) (hospitals that serve a significantly disproportionate number of low-income patients) report that an average of 61% of their 340B benefit from the 340B discount comes from drugs distributed through contract pharmacies.¹

Plaintiffs' complaint requests the Court to adopt an implausible interpretation of the 340B statute that would deny Proposed Intervenors' members access to drug discounts for drugs dispensed to their patients at most contract pharmacies. Intervention by Proposed Intervenors is necessary to protect their members' interests in this lawsuit and to ensure that patients have adequate access to 340B drugs — which it is not apparent the government defendant will sufficiently do — and to defend the correct interpretation of the 340B statute to include the availability of discounts when distribution is through contract pharmacies. The Proposed Intervenors have standing to intervene because at least one or more of each association's members has been and continues to be significantly harmed by Eli Lilly's failure to offer 340B drug discounts to 340B covered entities when drugs are dispensed through contract pharmacies.

Proposed Intervenors meet the standard for intervention of right. First, Proposed Intervenors' members clearly have a direct stake in the outcome. If Plaintiffs were to obtain a ruling adopting their (incorrect) interpretation of the statute, Proposed Intervenors' members' 340B savings will continue to diminish, seriously hampering their ability to serve vulnerable communities as Congress intended. Moreover, the drug companies that have not already adopted policies comparable to Lilly's would be incented to adopt one, resulting in even greater losses of

¹ See Ex. A Testoni Decl., ECF No. 39-1, ¶¶ 4–6.

the 340B discounts and the services to the communities those discounts fund. Likewise, there is no question that an adverse outcome in this case would impair Proposed Intervenor’s members’ interests—not just in the correct interpretation and application of federal law, but in receiving the discounts to which they are entitled. Defendants cannot adequately defend Proposed Intervenor’s interests. In fact, to date, the Department of Health and Human Services (HHS) has refused to take any action to stop Lilly from denying Proposed Intervenor’s members the statutory discounts to which they are entitled. Alternatively, because Proposed Intervenor and Plaintiffs both seek to have this Court resolve the same question of law – namely whether the 340B statute requires Plaintiffs to provide covered entities covered outpatient drugs at or below the 340B ceiling price when dispensed through a contract pharmacy – Proposed Intervenor also meet the standard for permissive intervention. Accordingly, the Court should grant Proposed Intervenor’s motion to intervene.

BACKGROUND

Seven months ago, Lilly became the first drug company to abandon its 20-year compliance with the statutory requirement to provide 340B providers with drugs at or below 340B ceiling prices when dispensed through contract pharmacies. In May 2020, Lilly floated the idea of applying its “no contract pharmacy” policy to a single drug, Cialis[®] with the division of HHS that administers the 340B program, the Health Resources and Services Administration (HRSA).² When HRSA failed even to inform Lilly that this practice would be illegal,³ Lilly was emboldened to

² Letter Re: Availability of 340B-Priced Cialis[®] (tadalafil) Erectile Dysfunction Presentations to Contract Pharmacies, Lilly (May 18, 2020), <https://www.dropbox.com/s/ttjou3z9zo7q33w/Lilly%20letter%20to%20HRSA%2005.18.2020.pdall=0>.

³ Ex. C to Pls.’ Am. Compl., ECF No. 17-4.

expand its discount denials to all of its drugs.⁴ Not surprisingly, to date, five other drug companies followed suit with similar policies.⁵

HRSA's inaction precipitated three lawsuits. Two lawsuits challenged HRSA's failure to issue an Administrative Dispute Resolution (ADR) regulation, which they alleged was needed to resolve the disagreement over contract pharmacy arrangements. *See Ryan White Clinics for 340B Access v. Azar*, No. 1:20-cv-2906 (D.D.C.); *Nat'l Ass'n of Cmty. Health Ctrs. v. Azar*, No. 1:20-cv-3032 (D.D.C.). In addition, Proposed Intervenor and three hospitals filed suit to obtain a ruling that the refusal by Lilly and the other drug companies to provide 340B providers 340B discounts for drugs dispensed through contract-pharmacies was illegal and to require HHS to develop an enforcement plan aimed at stopping the drug companies from continuing to implement these illegal policies. *See* Compl., ECF No. 1, *Am. Hosp. Ass'n v. Azar*, No. 4:20-cv-8806 (N.D. Cal. Dec. 11, 2020). Lilly and three of the other drug companies with similar contract pharmacy policies filed motions to intervene in those cases. Eli Lilly & Co.'s Mot. to Intervene as Def., [ECF No. 12](#), *Ryan White Clinics*, No. 1:20-cv-2906 (D.D.C. Nov. 20, 2020); Mot. of Sanofi-Aventis U.S. LLC to Intervene as a Def., [ECF No. 13](#), *Ryan White Clinics*, No. 1:20-cv-2906 (D.D.C. Nov. 20, 2020); AstraZeneca LP's Mot. to Intervene as Def., [ECF No. 29](#), *Ryan White Clinics*, No. 1:20-cv-2906 (D.D.C. Nov. 24, 2020); Proposed Intervenor-Def. Eli Lilly & Co.'s Not. of Mot., Mot., & Mem. in Supp. of its Mot. to Intervene, [ECF No. 28](#), *Am. Hosp. Ass'n*, No. 4:20-cv-8806 (N.D. Cal. Dec.

⁴ Limited Distribution Plan Notice for Eli Lilly and Company Products, https://www.340bhealth.org/files/200901_Eli_Lilly_and_Company_Limited_Distribution_Plan_Public_Notice.pdf.

⁵ *See* Sanofi Notice (July 2020), https://www.340bhealth.org/files/Sanofi_Notice_10_1_20.pdf; Letter Re: 340B Contract Pharmacy Pricing, AstraZeneca (Aug. 17, 2020), <https://www.dropbox.com/s/gethwns6m7zzkoh/AstraZeneca%20Retail%20Communication%20-%20340B%20-%20Final.pdf?dl=0>; New policy related to the 340B program, Novartis (Oct. 30, 2020), <https://www.novartis.us/news/statements/new-policy-related-340b-program>; Letter Re: United Therapeutics Corporation 340B Contract Pharmacy Policy Effective November 20, 2020, United Therapeutics Corp. (Nov. 18, 2020), <https://www.dropbox.com/s/swyrookjcwqxe58/United%20Therapeutics%20Letter%2011.20.2020%20%281%29.pdf?dl=0>; Notice Regarding Limitation on Hospital Contract Pharmacy Distribution, Novo Nordisk (Dec. 1, 2020), https://www.340bhealth.org/files/Novo_Nordisk_12-1-2020.pdf.

28, 2020); AstraZeneca LP's Not. of Mot., Mot., & Mem. in Supp. of Mot. to Intervene, [ECF No. 35](#), *Am. Hosp. Ass'n*, No. 4:20-cv-8806 (N.D. Cal. Dec. 28, 2020); Proposed Intervenor-Def. Sanofi-Aventis U.S. LLC's Not. of Mot., Mot. to Intervene, & Mem. of P. & A. in Supp., [ECF No. 38](#), *Am. Hosp. Ass'n*, No. 4:20-cv-8806 (N.D. Cal. Dec. 28, 2020); Proposed Intervenor-Defendant Novo Nordisk Inc.'s Not. of Mot., Mot., & Mem. in Supp. of Mot. to Intervene, [ECF No. 62](#), *Am. Hosp. Ass'n*, No. 4:20-cv-8806 (N.D. Cal. Jan. 10, 2021).

In response to these lawsuits, HHS did two things. First, it finalized the proposed ADR regulation (which had been withdrawn). *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020) (to be codified at 42 C.F.R. pt. 10). And, on December 30, 2020, its General Counsel issued an Advisory Opinion recognizing that the 340B statute requires drug companies to offer 340B discounts to covered entities for drugs dispensed through contract pharmacies. *See Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (Dec. 30, 2020). Nevertheless, even though it stated that the drug company policies with respect to contract pharmacies are illegal, HHS has taken no action to enforce the statute. *Id.*

In its complaint, Eli Lilly challenges the December 30, 2020 Advisory Opinion. ECF No. 1. Subsequently, Eli Lilly filed an amended complaint which includes additional claims related to HRSA's ADR regulations. ECF No. 17. At the same time, Lilly filed a motion seeking to preliminarily enjoin HRSA from implementing the ADR regulation. ECF No. 18.

Proposed Intervenor's interest in this lawsuit relates only to Lilly's claims regarding the Advisory Opinion. Intervention in this case would thus not affect or delay this Court's resolution of Lilly's motion for a preliminary injunction which addresses a different issue, namely the legality of the recently issued ADR regulation.

ARGUMENT

“Intervention of Right should be permitted upon timely application ‘when the applicant claims an interest relating to the property or transaction which is the subject of the action and the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant’s ability to protect that interest, unless the applicant’s interest is adequately represented by existing parties.’ A party may be permitted to intervene in an action (upon timely application) when ‘an applicant’s claim or defense and the main action have a question of law or fact in common.’” *Am. Std. Ins. Co. of Wis. v. Rogers*, 123 F. Supp. 2d 461, 469 n.5 (S.D. Ind. 2000) (quoting Fed. R. Civ. P. 24(a)(2), (b)(2)). Proposed Intervenors meet both of these standards because the Advisory Opinion, which Plaintiffs challenge, impacts their members’ right to statutory discounts under the 340B program.

I. Proposed Intervenors Have a Right to Intervene Under Rule 24(a).

Pursuant to Federal Rule of Civil Procedure 24(a)(2), “a party seeking intervention of right must show: (1) timeliness; (2) an interest relating to the subject matter of the main action, (3) at least potential impairment of that interest if the action is resolved without the intervenor, and (4) lack of adequate representation by existing parties.” *Buquer v. City of Indianapolis*, No. 1:11-cv-708, 2013 WL 1332137, at *2 (S.D. Ind. Mar. 28, 2013) (citation omitted); *see also Planned Parenthood of Wis., Inc. v. Kaul*, 942 F.3d 793, 797 (7th Cir. 2019). “The rule is straightforward: the court *must* permit intervention” if those four factors are met. *Driftless Area Land Conservancy v. Huebsch*, 969 F.3d 742, 746 (7th Cir. 2020).

As in most other circuits, the Seventh Circuit courts construe Rule 24(a)(2) motions liberally. *Elouarrak v. Firstsource Advantage, LLC*, No. 1:19-cv-3666, 2020 WL 291364, at *1 (N.D. Ill. Jan. 21, 2020) (citing *Planned Parenthood of Wis.*, 942 F.3d at 799; *Lopez-Aguilar v. Marion Cty. Sheriff’s Dep’t*, 924 F.3d 375, 391 (7th Cir. 2019)). Courts should resolve doubts in

favor of allowing intervention. *Michigan v. U.S. Army Corps of Eng'r's*, No. 10-cv-4457, 2010 WL 3324698, at *2 (N.D. Ill. Aug. 20, 2010).

A motion to intervene as a matter of right, therefore should not be denied unless “it appears to a certainty that the intervenor is not entitled to relief under any set of facts which could be proved under the complaint.” *State v. City of Chicago*, 912 F.3d 979, 984 (7th Cir. 2019) (citations omitted). Courts “must accept as true the non-conclusory allegations of the motion.” *Id.* (citations omitted). A court should not deny a motion to intervene “unless it is certain that the proposed intervenor cannot succeed in its case under any set of facts which could be proved under the complaint.” *Michigan*, 2010 WL 3324698, at *2 (citations omitted).

A. Timeliness

The Seventh Circuit considers four factors to determine whether a motion to intervene is timely: “(1) the length of time the intervenor knew or should have known of his interest in the case; (2) the prejudice caused to the original parties by the delay; (3) the prejudice to the intervenor if the motion is denied; and (4) any other unusual circumstances.” *Sokaogon Chippewa Cmty. v. Babbitt*, 214 F.3d 941, 949 (7th Cir. 2000) (alteration and citation omitted). In addition, the “test for timeliness is essentially one of reasonableness: ‘potential intervenors need to be reasonably diligent in learning of a suit that might affect their rights, and upon so learning they need to act reasonably promptly.’ We further note that, when intervention of right is sought, because ‘the would-be intervenor may be seriously harmed if intervention is denied, courts should be reluctant to dismiss such a request for intervention as untimely, even though they might deny the request if the intervention were merely permissive.’” *Lopez-Aguilar*, 924 F.3d at 388–89 (citations omitted).

Lilly filed its complaint challenging the December 30, 2020 Advisory Opinion on January 12, 2021 and filed an amended complaint and a motion for preliminary injunction related to the ADR process on January 25, 2021. Proposed Intervenors have promptly moved to intervene.

According to the Court's recently issued scheduling order, Defendants' response to the preliminary injunction motion was due February 16, 2021. ECF No. 27. As noted above, however, Proposed Intervenor will not be responding to that motion which relates only to the ADR regulation. With respect to the remaining claims for relief (regarding the Advisory Opinion), there currently is no schedule and Proposed Intervenor are prepared to participate in that aspect of the case on whatever schedule the Court sets. Moreover, Proposed Intervenor have attached their Answer to the First Amended Complaint to its Motion to Intervene. Ex. B ECF No. 39-2. Lilly therefore would not be prejudiced because there would be no delay. If the motion were denied, however, Proposed Intervenor would be prejudiced. Thus, the timeliness requirement is met.

B. Interest

The second element under Rule 24(a)(2) is that "the proposed intervenor must have a direct, significant, and legally protectable interest in the question at issue in the lawsuit," which "must be unique to the proposed intervenor" meaning it is "based on a right that belongs to the proposed intervenor rather than to an existing party in the suit." *Elouarrak*, 2020 WL 291364, at *2 (alterations and citations omitted). "Interest in 'the subject of the action' is a broad formulation." *Nat'l Fire Ins. Co. of Hartford v. Tri-State Hose & Fitting, Inc.*, No. 06 C 5256, 2007 WL 9814578, at *4 (N.D. Ill. June 21, 2007).

Proposed Intervenor and their members have a direct, significant and legally protected interest in obtaining discounts to which they are entitled under the 340B statute.⁶ Proposed Intervenor's member hospitals use the benefit from 340B discounts for 340B drugs dispensed through contract pharmacies to support programs and services offered by 340B hospitals. These

⁶ "An association has standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests at stake are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000).

discounts, for example, allow them to (1) provide and maintain more patient care services; (2) provide and maintain more uncompensated and unreimbursed care; (3) provide and maintain more services in underserved areas; and (4) develop and maintain targeted programs to serve vulnerable patients; and (5) keep their doors open. Testoni Decl., Ex. A ECF No. 39-1 ¶ 8.

These discounts are precisely the subject of the General Counsel's Advisory Opinion that Lilly challenges. Lilly seeks an outcome directly contrary to the Advisory Opinion (*i.e.*, that it not be required to provide discounts for covered outpatient drugs when such drugs are dispensed through a contract pharmacy). Defendants' interests also diverge, as they disagree with Proposed Intervenor that HHS has the authority and obligation to enforce this requirement. Accordingly, the interest factor is met.

C. Interest Impaired

The disposition of Lilly's lawsuit in Lilly's favor would adversely affect Proposed Intervenor's members, and the communities they serve. If Lilly were to successfully convince this Court to adopt its (incorrect) interpretation of the statute, Proposed Intervenor's members would continue to lose access to 340B discounts when their covered outpatient drugs are dispensed from a contract pharmacy. This would not only encourage the other five drug companies with similar policies to continue their policies, but it would likely encourage other drug companies to adopt the same types of policies. This would significantly, adversely impact the services all 340B covered entities provide to vulnerable populations. Testoni Decl., Ex. A ECF No. 39-1 ¶¶ 7, 9. This hardship, which 340B providers are already facing due to the six drug companies' current policies, comes amidst a pandemic that is putting an enormous strain on hospitals' financial resources and accordant ability to care for their patients. On the other hand, if Plaintiffs' claims were rejected, then Proposed Intervenor's members would be able to continue receiving the discounts to which they are entitled and have received since the beginning of the 340B program.

D. Inadequate Representation

The government Defendants in this lawsuit do not adequately represent Proposed Intervenor's interests. The Seventh Circuit held that the burden of making this showing should be treated as “minimal,” and that a party seeking intervention as of right must only make a showing that the representation “may be” inadequate. *Ligas ex rel. Foster v. Maram*, 478 F.3d 771, 774 (7th Cir. 2007) (quoting *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538 n.10 (1972)).

There is no doubt that HHS has different interests than the Proposed Intervenor's in this case. Since Lilly first instituted the contract pharmacy policy at issue, Proposed Intervenor's, 340B covered entities and other 340B covered entity trade associations have been trying to get the government to take action.⁷ Despite periodically stating that it was looking into the issue,⁸ and after its General Counsel issued an Advisory Opinion agreeing with Proposed Intervenor's statutory interpretation, HHS has never taken the position that it can or will enforce the statutes as interpreted. The only thing HHS has done is to issue the ADR regulation that is being challenged in several lawsuits, including this one, and even that process has been unilaterally placed on hold.⁹ Finally, Proposed Intervenor's have brought suit against HHS asserting that the Department has

⁷ See, e.g., Letter Re: Recent Actions by Pharmaceutical Manufacturers Eli Lilly and Merck Impacting 340B Covered Entities, 340B Coalition (July 16, 2020), <https://nysarh.org/wp-content/uploads/2020/08/340B-Coalition-Letter-Final-7.16.20.pdf>; Letter, AHA (July 30, 2020), <https://www.aha.org/system/files/media/file/2020/07/aha-urges-hhs-take-action-against-drug-manufacturers-for-limiting-distribution-340b-drugs-letter-7-30-2020.pdf>; Letter Re: Pharmaceutical Company Actions Undermining 340B Drug Pricing Program, AEH (Aug. 28, 2020), <https://essentialhospitals.org/wp-content/uploads/2020/08/AEH-Letter-340B-Contract-Pharmacy-8-28-20.pdf>; Letter, AHA (Sept. 8, 2020), <https://www.aha.org/system/files/media/file/2020/09/aha-again-urges-hhs-to-protect-340b-program-from-drug-companies-actions-letter-9-8-20.pdf>; Letter, AHA (Oct. 16, 2020), <https://www.aha.org/system/files/media/file/2020/10/aha-urges-hhs-stop-drug-companies-refusal-provide-required-340b-discounts-letter-10-16-20.pdf>.

⁸ See, e.g., Letter from Robert Charrow to Anat Hakim, Lilly (Sept. 21, 2020) <https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf>; Letter from Krista M. Pedley to Maureen Testoni (Dec. 9, 2020), https://www.340bhealth.org/files/HRSA_Response_Letter_-_12-09-2020.pdf.

⁹ Cathy Kelly, *340B Dispute Resolution Process On Ice As Feuds Between Pharma, Providers, HHS Heat Up*, Pink Sheet, <https://pink.pharmaintelligence.informa.com/PS143652/340B-Dispute-Resolution-Process-On-Ice-As-Feuds-Between-Pharma-Providers-HHS-Heat-Up> (Jan. 22, 2021).

acted contrary to law and/or unlawfully withheld agency action. *See Am. Hosp. Ass'n v. Cochran*, No. 4:20-cv-8806 (N.D. Cal.). It is therefore not only possible but quite conceivable that the government's defense of its right to implement and/or enforce the December 30 decision, as the Plaintiffs seek to bar it from doing, may be inadequate. That alone is sufficient to demonstrate that the government cannot and will not adequately represent the interests of Proposed Intervenors.

In sum, Proposed Intervenors have met the requirements for intervention of right.

II. Alternatively, Proposed Intervenors Should be Permitted to Intervene Under Rule 24(b).

Proposed Intervenors also satisfy the requirements of Federal Rule of Civil Procedure 24(b). Under Rule 24(b), on "timely motion" the Court "may permit anyone to intervene" who "has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1)(B). Permissive intervenors must (1) share a common question of law or fact with a party, (2) be timely in their pursuit of intervention; and (3) not cause prejudice to existing parties. *Randall v. Rolls-Royce Corp.*, No. 1:06-cv-860, 2010 WL 1948222, at *3 (S.D. Ind. May 13, 2010); *see also Planned Parenthood of Wis.*, 942 F.3d at 803.

"The inquiry into whether a common claim or defense exists is a broad one." *Joe Sanfelippo Cabs Inc. v. City of Milwaukee*, No. 14-cv-1036, 2015 WL 1728123, at *2 (E.D. Wis. Apr. 15, 2015) (citing *Bond v. Utreras*, 585 F.3d 1061, 1070 (7th Cir. 2009)). As this Court has noted, "if there are issues of fact and/or law in common, it is the timeliness of the intervention request which is scrutinized most closely." *Walker v. Floyd Cty.*, No. 4:07-cv-14, 2009 WL 2222886, at *1 (S.D. Ind. July 22, 2009) (citations omitted). The common question of law in this case is whether the 340B statute requires pharmaceutical manufacturers to offer 340B discounts to covered entities that dispense their 340B drugs through contract pharmacies. For the reasons described above, *see* Sec. I.A., this motion is timely and thus will not delay the proceedings or

prejudice Lilly or the Defendants. Accordingly, at a minimum Proposed Intervenor should be permitted to intervene under Rule 24(b).

CONCLUSION

For the foregoing reasons, Proposed Intervenor request the Court to grant their motion to intervene of right under Rule 24(a) or, in the alternative, to allow Proposed Intervenor to intervene under Rule 24(b).

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Respectfully submitted,

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