

**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

Alice M. Morical  
Christopher D. Wagner  
HOOVER HULL TURNER LLP  
111 Monument Circle, Suite 4400  
P.O. Box 44989  
Indianapolis, IN 46244-0989  
Tel: (317) 822-4400  
Fax: (317) 822-0234  
[amorical@hooverhullturner.com](mailto:amorical@hooverhullturner.com)  
[cwagner@hooverhullturner.com](mailto:cwagner@hooverhullturner.com)

William B. Schultz (*pro hac vice forthcoming*)  
Margaret M. Dotzel (*pro hac vice forthcoming*)  
Casey Trombley-Shapiro Jonas (*pro hac vice forthcoming*)  
ZUCKERMAN SPAEDER LLP  
1800 M Street NW, Suite 1000  
Washington, DC 20036  
Tel: (202) 778-1800  
Fax: (202) 822-8106  
[wschultz@zuckerman.com](mailto:wschultz@zuckerman.com)  
[mdotzel@zuckerman.com](mailto:mdotzel@zuckerman.com)  
[cjonas@zuckerman.com](mailto:cjonas@zuckerman.com)

# 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.

A handwritten signature in blue ink, appearing to read "Maureen Testoni", is written over a horizontal line.

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

78. Intervenor's admit the allegations contained in Paragraph 78.

79. Intervenor's admit the allegations contained in Paragraph 79.

80. Intervenor's admit that Lilly implemented an exception process for covered entities that do not have their own in-house pharmacy. Intervenor's lack 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's deny the allegations contained in Paragraph 81.

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

88. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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. Intervenor's 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 Intervenor's intervention. To the extent they may be deemed applicable, the Intervenor admits the allegations in Paragraph 119.

120. The allegations in Paragraph 120 are not applicable to Plaintiffs' allegations that are the basis for Intervenor's intervention. To the extent they may be deemed applicable, the Intervenor admits 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 Intervenor's intervention. To the extent they may be deemed applicable, the Intervenor admits 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 Intervenor's intervention. To the extent they may be deemed applicable, the Intervenor admits 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 Intervenor's intervention. To the extent they may be deemed applicable, the Intervenor admits 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 Intervenor's 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 Intervenor's intervention to the extent they may be deemed applicable, the Intervenor admits the allegations in Paragraph 125.

126. The allegations in Paragraph 126 are not applicable to Plaintiffs' allegations that are the basis for Intervenor's 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 Intervenor's 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 Intervenor's 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 Intervenor's 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 Intervenor's 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. Intervenor 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. Intervenor 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. Intervenor 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. Intervenor 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. Intervenor 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. Intervenor 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. Intervenor 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. Intervenor 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. Intervenor 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 Intervenor's intervention. To the extent they may be deemed applicable, the Intervenor admit the allegations in paragraph 158.

159. The allegations in Paragraph 159 are not applicable to Plaintiffs' allegations that are the basis for Intervenor's 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. Intervenor 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. Intervenor 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. Intervenor 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. Intervenor 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. Intervenor 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. Intervenorors 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 Intervenor's 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 Intervenor's 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 Intervenor's 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 Intervenor's 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 Intervenor's 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 Intervenor's 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 Intervenor's 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. Intervenor 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 Intervenor's 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 Intervenor's 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 Intervenor's 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 Intervenor's 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 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 Intervenor's intervention. To the extent they may be 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 Intervenor's 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 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 Intervenor's intervention. To the extent they may be 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 Intervenor's intervention. To the extent they may be 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. Intervenor 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 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 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 Intervenor’s 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 Intervenor’s 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 Intervenor’s 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 Intervenor’s 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 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 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 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 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 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 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 be 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 be 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 Intervenor's intervention. To the extent they may be deemed applicable, the Intervenor lacks knowledge or information sufficient to form a belief about the truth of these allegations and respectfully refers 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 Intervenor's 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 Intervenor's intervention. To the extent they may be deemed applicable, the Intervenor lacks knowledge or information sufficient to form a belief about the truth of these allegations and therefore denies the same.

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

248. The allegations in Paragraph 248 are not applicable to Plaintiffs' allegations that are the basis for Intervenor's 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 Intervenor's 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 Intervenor's 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. Intervenor hereby incorporates 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 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 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 Intervenor's 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 Intervenor's 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 Intervenor's 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 Intervenor's 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 Intervenor's intervention. To the extent they may be deemed applicable, the Intervenor lacks knowledge or information sufficient to form a belief about the truth of these allegations and respectfully refers 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 Intervenor's 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 Intervenor's 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 Intervenor's 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 Intervenor's 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 Intervenor's 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 Intervenor's 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. Intervenor reserves the right to amend their answer and defenses as more information is obtained.

Respectfully submitted,

---

Alice M. Morical  
Christopher D. Wagner  
HOOVER HULL TURNER LLP  
111 Monument Circle, Suite 4400  
P.O. Box 44989  
Indianapolis, IN 46244-0989  
Tel: (317) 822-4400  
Fax: (317) 822-0234  
[amorical@hooverhullturner.com](mailto:amorical@hooverhullturner.com)  
[cwagner@hooverhullturner.com](mailto:cwagner@hooverhullturner.com)

William B. Schultz (*pro hac vice forthcoming*)  
Margaret M. Dotzel (*pro hac vice forthcoming*)  
Casey Trombley-Shapiro Jonas (*pro hac vice forthcoming*)  
ZUCKERMAN SPAEDER LLP  
1800 M Street NW, Suite 1100  
Washington, DC 20036  
Tel: (202) 778-1800  
Fax: (202) 822-8106  
[wschultz@zuckerman.com](mailto:wschultz@zuckerman.com)  
[mdotzel@zuckerman.com](mailto:mdotzel@zuckerman.com)  
[cjonas@zuckerman.com](mailto:cjonas@zuckerman.com)

**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

---