# UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF NORTH CAROLINA DURHAM DIVISION

AMY BRYANT, MD,	)
Plaintiff,	) )
v.	) )
JOSHUA H. STEIN, in his official capacity as Attorney General for the State of North Carolina; JEFF NIEMAN, in his official capacity as District Attorney for North Carolina 18th Prosecutorial District; KODY H. KINSLEY, in his official capacity as the North Carolina Secretary of Health and Human Services; MICHAUX R. KILPATRICK, MD, PhD, in her official capacity as President of the North Carolina Medical Board; and CHRISTINE M. KHANDELWAL, DO; DEVDUTTA G. SANGVAI, MD, MBA; JOHN W. RUSHER, MD, JD; WILLIAM M. BRAWLEY; W. HOWARD HALL, MD; SHARONA Y. JOHNSON, PhD, FNP-BC; JOSHUA D. MALCOLM, JD; MIGUEL A. PINEIRO, PA-C, MHPE; MELINDA H. PRIVETTE, MD, JD; ANURADHA RAO-PATEL, MD; and ROBERT RICH, JR., MD, in their official capacities as Board Members of the North Carolina Medical Board,	) ) ) ) Case No. 1:23-cv-77 )  MOTION TO INTERVENE AS ) DEFENDANTS ) ) ) ) ) ) ) ) ) ) ) ) ) ) ) ) ) ) )
Defendants	1

Pursuant to Federal Rule of Civil Procedure 24 and local rule 7.3, Philip E. Berger, President *Pro Tempore* of the North Carolina Senate, and Timothy K. Moore, Speaker of the North Carolina House of Representatives, respectfully move to intervene on behalf of the General Assembly and as agents of the State of North Carolina to defend N.C. Gen. Stat. §§ 14-44, 14-45, 14-45.1, 90-21.82, 90-21.90, and 10A N.C. Admin. Code Subchapter 14E. The Motion to Intervene should be granted for the reasons stated in the accompanying Memorandum in Support of Motion to Intervene.

To satisfy the pleading requirement of Rule 24(c), the Motion to Intervene is also accompanied by a Proposed Answer to the Complaint, attached as Exhibit 1. However, should this Court grant intervention, the President *Pro Tempore* and Speaker intend to file a Motion to Dismiss the Complaint.

Respectfully submitted this 21st day of February, 2023.

/s/ W. Ellis Boyle

W. Ellis Boyle

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1

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Attorneys for Intervenor-Defendants Moore and Berger

<sup>\*</sup> This email address must be used in order to effectuate service under the Federal Rules of Civil Procedure.

<sup>\*\*</sup> Email address to be used for all communications other than service.

<sup>\*\*\*</sup> Special appearance forthcoming.

## CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of February, 2023, a copy of the foregoing document was served via the Court's CM/ECF system which served notice of this filing to all counsel of record.

/s/ W. Ellis Boyle W. Ellis Boyle

# UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF NORTH CAROLINA DURHAM DIVISION

AMY BRYANT, MD,	)
Plaintiff,	)
v.	)
JOSHUA H. STEIN, in his official capacity as Attorney General for the State of North Carolina; JEFF NIEMAN, in his official capacity as District Attorney for North Carolina 18th Prosecutorial District; KODY H. KINSLEY, in his official capacity as the North Carolina Secretary of Health and Human Services; MICHAUX R. KILPATRICK, MD, PhD, in her official capacity as President of the North Carolina Medical Board; and CHRISTINE M. KHANDELWAL, DO; DEVDUTTA G. SANGVAI, MD, MBA; JOHN W. RUSHER, MD, JD; WILLIAM M. BRAWLEY; W. HOWARD HALL, MD; SHARONA Y. JOHNSON, PhD, FNP-BC; JOSHUA D. MALCOLM, JD; MIGUEL A. PINEIRO, PAC, MHPE; MELINDA H. PRIVETTE, MD, JD; ANURADHA RAO-PATEL, MD; and ROBERT RICH, JR., MD, in their official capacities as Board Members of the North Carolina Medical Board, and PHILIP E. BERGER, in his official capacity as President Pro Tempore of the North Carolina Senate, and TIMOTHY K. MOORE, in his official capacity as Speaker of the North Carolina House of Representatives,	) Case No. 1:23-cv-77 ) PROPOSED ANSWER ) OF INTERVENORS ) PHILIP E. BERGER, IN HIS OFFICIAL ) CAPACITY AS ) PRESIDENT PRO ) TEMPORE OF THE ) NORTH CAROLINA ) SENATE, AND ) TIMOTHY K. ) MOORE, IN HIS ) OFFICIAL ) CAPACITY AS ) SPEAKER OF THE ) NORTH CAROLINA ) HOUSE OF ) REPRESENTATIVES
Defendants.	)

Intervenors, Philip E. Berger, in his official capacity as President *Pro Tempore* of the North Carolina Senate, and Timothy K. Moore, in his official capacity as Speaker of the North Carolina House of Representatives (together the "Intervenors" or "Legislative Leaders"), through counsel, answer Plaintiff's Complaint as follows:

- 1. This paragraph is a legal statement to which no answer is necessary. Intervenors deny that the FDA has acted within the bounds of its authority and deny that States may not impose controls concerning abortion drugs.
- 2. This paragraph is a legal statement to which no answer is necessary. Intervenors deny that the FDA has exclusive authority to impose controls or restrictions concerning abortion drugs.
- 3. Intervenors admit that in 2000 FDA approved mifepristone for the termination of pregnancy in a two-drug regimen with misoprostol. Intervenors deny all remaining allegations in this paragraph.
- 4. Intervenors admit that chemical abortion has killed millions of unborn children and accounts for a large percentage of abortions nationwide. Intervenors deny all remaining allegations in this paragraph.
- 5. Intervenors admit that FDA has modified the mifepristone REMS, and that current regulations require providers to prescribe mifepristone under a Certified Prescriber Agreement and that the patient consent by signing a Patient Agreement Form. Intervenors lack sufficient information at this time to admit or deny the remaining allegations in this paragraph, and thus deny them.

- 6. Intervenors admit that North Carolina adopted regulations governing abortion, which apply to chemical abortion. Intervenors deny all remaining allegations in this paragraph.
- 7. Intervenors lack sufficient knowledge or information necessary to admit or deny the allegations in this paragraph, and thus deny them.
- 8. Intervenors lack sufficient knowledge or information necessary to admit or deny the allegations in this paragraph, and thus deny them.
- 9. Intervenors lack sufficient knowledge or information necessary to admit or deny the allegations in this paragraph, and thus deny them.
- 10. Intervenors lack sufficient knowledge or information necessary to admit or deny the allegations in this paragraph, and thus deny them.
- 11. Intervenors admit that FDA has eliminated safeguards on chemical abortion. Intervenors deny all remaining allegations in this paragraph.
- 12. This paragraph is a legal statement to which no answer is necessary. To the extent any response is necessary, denied.
- 13. This paragraph is a legal statement to which no answer is necessary. To the extent any response is necessary, denied.

## **PARTIES**

- 14. Intervenors lack sufficient knowledge or information necessary to admit or deny the allegations in this paragraph, and thus deny them.
  - 15. Admitted.
  - 16. Admitted.
  - 17. Admitted.
  - 18. Admitted.

- 19. Admitted.
- 20. Admitted.
- 21. Admitted.
- 22. Admitted.
- 23. Admitted.
- 24. Admitted.
- 25. Admitted.
- 26. Admitted.
- 27. Admitted.
- 28. Admitted.
- 29. Admitted.

#### JURISDICTION AND VENUE

- 30. This paragraph is a legal statement to which no answer is necessary. To the extent that a response is necessary, denied.
- 31. This paragraph is a legal statement to which no answer is necessary. To the extent that a response is necessary, Intervenors lack sufficient knowledge or information necessary to admit or deny the allegations in this paragraph, and thus deny them.
- 32. This paragraph is a legal statement to which no answer is necessary. To the extent that a response is necessary, Intervenors lack sufficient knowledge or information necessary to admit or deny the allegations in this paragraph, and thus deny them.
- 33. This paragraph is a legal statement to which no answer is necessary. To the extent that a response is necessary, admitted.

- 34. This paragraph is a legal statement to which no answer is necessary. To the extent that a response is necessary, denied.
- 35. This paragraph is a legal statement to which no answer is necessary. To the extent that a response is necessary, denied.

### FACTUAL ALLEGATIONS

- 36. Admitted.
- 37. This paragraph is a legal statement to which no answer is necessary. To the extent that a response is necessary, Intervenors deny that drug sponsors or the FDA considered significant clinical trial data. Intervenors lack sufficient knowledge or information necessary to admit or deny the remaining allegations in this paragraph, and thus deny them.
  - 38. Admitted.
  - 39. Admitted.
- 40. This paragraph is a legal statement to which no answer is necessary. To the extent that a response is necessary, Intervenors admit that Congress created REMS but deny Plaintiff's characterization that doing so codified FDA authority or determinations. Intervenors lack sufficient knowledge or information necessary to admit or deny the remaining allegations in this paragraph, and thus deny them.
  - 41. Admitted.
  - 42. Admitted.
  - 43. Admitted.
  - 44. Admitted.
  - 45. Admitted.
  - 46. Admitted.

- 47. Admitted.
- 48. Admitted.
- 49. Intervenors admit that mifepristone is used in chemical abortion in a regimen with misoprostol to first block progesterone necessary for life which causes an unborn child to die. Intervenors deny all of the remaining allegations in this paragraph.
  - 50. Admitted.
- 51. Intervenors admit that FDA has made updates to regulatory controls on mifepristone in the years described. Intervenors deny all of the remaining allegations in this paragraph.
  - 52. Denied.
- 53. Intervenors admit that FDA approved the application for mifepristone. Intervenors deny all of the remaining allegations in this paragraph.
  - 54. Admitted.
  - 55. Admitted.
  - 56. Admitted.
  - 57. Admitted.
  - 58. Admitted.
  - 59. Admitted.
  - 60. Admitted.
- 61. Intervenors lack sufficient knowledge or information necessary to admit or deny the allegations in this paragraph, and thus deny them.
  - 62. Admitted.
  - 63. Admitted.

- 64. Intervenors lack sufficient knowledge or information necessary to admit or deny the allegations in this paragraph, and thus deny them.
  - 65. Admitted.
- 66. Intervenors lack sufficient knowledge or information necessary to admit or deny the allegations in this paragraph, and thus deny them.
  - 67. Admitted.
  - 68. Admitted.
  - 69. Admitted.
  - 70. Admitted.
  - 71. Admitted.
- 72. Intervenors admit that FDA released the cited quotation but deny that the benefits of mifepristone for chemical abortion outweigh the risks while minimizing the burden of controls. Intervenors deny all of the remaining allegations in this paragraph.
  - 73. Admitted.
  - 74. Denied.
- 75. Intervenors admit that a memorandum in President Biden's name was issued that included the quoted statements. Intervenors deny all of the remaining allegations in this paragraph.
  - 76. Denied.
  - 77. Denied.
- 78. This paragraph is a legal statement to which no answer is necessary. To the extent that a response is needed, Intervenors admit that North Carolina law provides the cited safeguards and requirements for

facilities providing abortion. Intervenors deny the remaining allegations in this paragraph.

- 79. This paragraph is a legal statement to which no answer is necessary. To the extent that a response is needed, Intervenors admit that North Carolina law provides the cited safeguards and requirements prior to making a permanent and life-ending decision regarding abortion. Intervenors deny the remaining allegations in this paragraph.
- 80. This paragraph is a legal statement to which no answer is necessary. To the extent that a response is necessary, denied.
  - 81. Denied.

#### CAUSE OF ACTION

- 82. This paragraph does not require a response.
- 83. Denied.
- 84. Denied.
- 85. Denied.
- 86. Denied.
- 87. Denied.

#### PRAYER FOR RELIEF

To the extent that Plaintiff's Prayer for Relief requires a response, Intervenors deny any such claims or facts or allegations and ask that the Court deny any request for injunctive relief and declare that these North Carolina laws in question are valid and enforceable under the United States Constitution, all federal laws and regulations, and in conformity with *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022). Intervenors further request that the Court award them costs, expenses, and attorneys'

fees; and such other and further relief as the Court deems just and proper under the law and in equity.

#### AFFIRMATIVE DEFENSES

- 1. This Court lacks subject-matter jurisdiction over Plaintiff's Complaint, which should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(1).
- 2. Plaintiff's Complaint fails to state a claim upon which relief could be granted and should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6).
  - 3. Plaintiff's Complaint is barred by the statute of limitations.
  - 4. Plaintiff's Complaint is barred by the doctrine of laches.
- 5. Plaintiff's claims of preemption and reliance on the Supremacy Clause are misplaced because North Carolina may regulate and legislate for the health, safety, and welfare of its citizens to include specifically restricting and regulating the place, manner, and licensure for the practice of medicine in any capacity.

WHEREFORE, Proposed Intervenors respectfully request that this Court dismiss Plaintiff's claims with prejudice, deny Plaintiff's prayer for relief, order Plaintiff to pay Proposed Intervenors' costs and attorneys' fees, and grant other relief deemed just and proper.

[SIGNATURES APPEAR ON NEXT PAGE]

## Respectfully submitted this the 21st day of February, 2023.

### /s/ W. Ellis Boyle

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\*\*Email address to be used for all communications other than service.

\*\*\* Special Appearance Forthcoming

## CERTIFICATE OF SERVICE

I hereby certify that on February 21, 2023, I electronically filed the foregoing paper with the Clerk of Court using the Court's CM/ECF system which will send notification of such filing to all counsel of record.

/s/ W. Ellis Boyle

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