No. 23-2194

IN THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

GENBIOPRO, INC.,
Plaintiff-Appellant,

v.

KRISTINA D. RAYNES, *in her official capacity as Prosecuting Attorney of Putnam County*, AND PATRICK MORRISEY, *in his official capacity as Attorney General of West Virginia*,
Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of West Virginia (Huntington),
No. 3:23-cv-00058, Hon. Robert C. Chambers

JOINT APPENDIX

Douglas P. Buffington, II
Chief Deputy Attorney General
Curtis R. A. Capehart
Deputy Attorney General
OFFICE OF THE ATTORNEY GENERAL
State Capitol Building
1900 Kanawha Boulevard E.
Building 1, Room E-26
Charleston, WV 25305
(304) 558-2021
doug.p.buffington@wvago.gov

Counsel for Patrick Morrisey, in his official capacity as Attorney General of the State of West Virginia

David C. Frederick
Ariela M. Migdal
Derek C. Reinbold
Eliana Margo Pfeffer
Mary Charlotte Y. Carroll
Abigail E. DeHart
KELLOGG, HANSEN, TODD, FIGEL & FREDERICK, P.L.L.C.
1615 M Street, N.W., Suite 400
Washington, D.C. 20036 (202) 326-7900
dfrederick@kellogghansen.com

Counsel for GenBioPro, Inc.

(*additional counsel listed on inside cover*)

February 7, 2024

Erin Morrow Hawley
Lincoln Davis Wilson
ALLIANCE DEFENDING FREEDOM
440 1st Street, N.W., Suite 600
Washington, D.C. 20001
(571) 707-4655
ehawley@adflegal.org

Julia Catherine Payne
ALLIANCE DEFENDING FREEDOM
15100 North 90th Street
Scottsdale, AZ 85260
(480) 444-0020
jpayne@adflegal.org

Counsel for Patrick Morrisey, in his official capacity as Attorney General of the State of West Virginia

Jennifer Scragg Karr
Assistant Prosecuting Attorney
OFFICE OF THE PROSECUTING ATTORNEY
Putnam County Judicial Building
12093 Winfield Rd.
Winfield, WV 25213
(304) 586-0205
jkarr@putnamwv.org

Counsel for Kristina Raynes, in her official capacity as Prosecuting Attorney for Putnam County

Skye L. Perryman
Carrie Y. Flaxman
DEMOCRACY FORWARD FOUNDATION
P.O. Box 34553
Washington, D.C. 20043
(202) 448-9090
sperryman@democracyforward.org

John P. Elwood
Daphne O'Connor
Robert J. Katerberg
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, N.W.
Washington, D.C. 20001
(202) 942-5000
john.elwood@arnoldporter.com

Counsel for GenBioPro, Inc.

TABLE OF CONTENTS

APPEAL,LC−A

United States District Court
Southern District of West Virginia (Huntington)
CIVIL DOCKET FOR CASE #: 3:23−cv−00058

GenBioPro, Inc. v. Raynes et al
Assigned to: Judge Robert C. Chambers
Cause: 28:2201 Constitutionality of State Statute(s)

Date Filed: 01/25/2023
Date Terminated: 11/06/2023
Jury Demand: None
Nature of Suit: 440 Civil Rights: Other
Jurisdiction: Federal Question

Plaintiff

GenBioPro, Inc.

represented by **Anthony J. Majestro**
POWELL & MAJESTRO
Suite P−1200
405 Capitol Street
Charleston, WV 25301
304−346−2889
Fax: 304−346−2895
Email: amajestro@powellmajestro.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Ariela M. Migdal
KELLOGG HANSEN TODD FIGEL & FREDERICK
Suite 400
1615 M Street, NW
Washington, DC 20036
202−326−7917
Fax: 202−326−7999
Email: amigdal@kellogghansen.com
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Christina L. Smith
POWELL & MAJESTRO
Suite P−1200
405 Capitol Street
Charleston, WV 25301
304−346−2889
Fax: 304−346−2895
Email: csmith@powellmajestro.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Daphne O'Connor
ARNOLD & PORTER KAYE SCHOLER
601 Massachusetts Avenue, NW
Washington, DC 20001−3743
202−942−6723
Email: daphne.oconnor@arnoldporter.com
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

David C. Frederick
KELLOGG HANSEN TODD FIGEL & FREDERICK
Suite 400
1615 M Street, NW
Washington, DC 20036

202−326−7951
Fax: 202−326−7999
Email: dfrederick@kellogghansen.com
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Eliana M. Pfeffer
KELLOGG HANSEN TODD FIGEL & FREDERICK
Suite 400
1615 M Street, NW
Washington, DC 20036
202−326−7981
Fax: 202−326−7999
Email: epfeffer@kellogghansen.com
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

John P. Elwood
ARNOLD & PORTER KAYE SCHOLER
601 Massachusetts Avenue, NW
Washington, DC 20001−3743
202−942−5996
Fax: 202−942−5999
Email: John.Elwood@arnoldporter.com
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Kristen P. Miller
DEMOCRACY FORWARD FOUNDATION
P. O. Box 34553
Washington, DC 20043
202−448−9090
Email: kmiller@democracyforward.org
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Mary Charlotte Carroll
KELLOGG HANSEN TODD FIGEL & FREDERICK
Suite 400
1615 M Street, NW
Washington, DC 20036
202−326−7932
Fax: 202−326−7999
Email: mcarroll@kellogghansen.com
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Robert Katerberg
ARNOLD & PORTER KAYE SCHOLER
601 Massachusetts Avenue, NW
Washington, DC 20001−3743
202−942−6289
Fax: 202−942−5999
Email: robert.katerberg@arnoldporter.com
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Skye Perryman
DEMOCRACY FORWARD FOUNDATION
P. O. Box 34553
Washington, DC 20043
202−448−9090
Email: sperryman@democracyforward.org
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

V.

Defendant

Mark A. Sorsaia
in his official capacity as Prosecuting Attorney of Putnam County and TERMINATED: 09/11/2023

represented by **Jennifer Scragg Karr**
Putnam County Judicial Building
12093 Winfield Road
Winfield, WV 25213
304−586−0205
Fax: 304−586−0269
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Defendant

Kris Raynes
in her official capacity as Prosecuting Attorney of Putnam County, and TERMINATED: 10/19/2023

represented by **Jennifer Scragg Karr**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Defendant

Kristina Raynes
in her official capacity as Prosecuting Attorney of Putnam County, AND

represented by **Jennifer Scragg Karr**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Defendant

Patrick Morrisey
in his official capacity as Attorney General of West Virginia

represented by **Curtis R. Capehart**
WEST VIRGINIA ATTORNEY GENERAL'S OFFICE
Building 1, Room 26e
1900 Kanawha Boulevard, East
Charleston, WV 25305
304−558−2021
Fax: 304−558−0140
Email: curtis.r.a.capehart@wvago.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Denise M. Harle
ALLIANCE DEFENDING FREEDOM
Suite D−1100
1000 Hurricane Shoals Road, NE
Lawrenceville, GA 30043
770−339−0774
Fax: 770−339−6744
Email: DHarle@shutts.com
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Douglas P. Buffington , II

WEST VIRGINIA ATTORNEY
GENERAL'S OFFICE
Building 1, Room 26e
1900 Kanawha Boulevard, East
Charleston, WV 25305
304−558−2021
Fax: 304−558−0140
Email: Doug.P.Buffington@wvago.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Erin Morrow Hawley
ALLIANCE DEFENDING FREEDOM
Suite 600
440 First Street NW
Washington, DC 20001
571−707−4655
Email: ehawley@adflegal.org
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Amicus

The State of Alabama represented by

Jeffrey A. Kimble
ROBINSON & MCELWEE
P. O. Box 128
Clarksburg, WV 26302
304/622−5022
Fax: 622−5065
Email: jak@ramlaw.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of Arkansas represented by

Asher Steinberg
OFFICE OF THE ARKANSAS
ATTORNEY GENERAL
323 Center Street
Little Rock, AR 72201
501−682−1051
Fax: 501−682−7395
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Dylan L. Jacobs
OFFICE OF THE ARKANSAS
ATTORNEY GENERAL
Suite 200
323 Center Street
Little Rock, AR 72201
501−682−3661
Email: dylan.jacobs@arkansasag.gov
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Jeffrey A. Kimble
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Nicholas J. Bronni
OFFICE OF THE ARKANSAS

ATTORNEY GENERAL
Suite 200
323 Center Street
Little Rock, AR 72201
501−682−6302
Email: nicholas.bronni@arkansasag.gov
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Amicus

The State of Florida represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of Georgia represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of Idaho represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of Indiana represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of Iowa represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of Kansas represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of Kentucky represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of Louisiana represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of Mississippi represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of Missouri represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of Montana represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of Nebraska represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of North Dakota represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of Ohio represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of Oklahoma represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of South Carolina represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of South Dakota represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of Tennessee represented by **Jeffrey A. Kimble**
and (See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

The State of Texas represented by **Jeffrey A. Kimble**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

David S. Cohen
JD

represented by **Beth E. Braiterman**
COVINGTON & BURLING
One CityCenter
850 Tenth Street, NW
Washington, DC 20001−4956
202−662−5864
Fax: 202−778−5864
Email: bbraiterman@cov.com
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Denise Esposito
COVINGTON & BURLING
One CityCenter
850 Tenth Street, NW
Washington, DC 20001−4956
202−662−5562
Fax: 202−778−5562
Email: desposito@cov.com
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Julia F. Post
COVINGTON & BURLING
One CityCenter
850 Tenth Street, NW
Washington, DC 20001−4956
202−662−5249
Fax: 202−778−5249
Email: jpost@cov.com
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Kaixin Fan
COVINGTON & BURLING
Salesforce Tower, Suite 5400
415 Mission Street
San Francisco, CA 94105−2533
415−591−7043
Fax: 415−955−6543
Email: kfan@cov.com
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Russell D. Jessee
STEPTOE & JOHNSON
P. O. Box 1588
Charleston, WV 25326−1588
304−353−8103
Fax: 304−353−8180
Email: Russell.Jessee@steptoe−johnson.com
ATTORNEY TO BE NOTICED

Amicus

Greer Donley
JD

represented by **Beth E. Braiterman**
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Denise Esposito
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Julia F. Post
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Kaixin Fan
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Russell D. Jessee
(See above for address)
ATTORNEY TO BE NOTICED

Amicus

Lewis Grossman
JD, PhD

represented by **Beth E. Braiterman**
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Denise Esposito
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Julia F. Post
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Kaixin Fan
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Russell D. Jessee
(See above for address)
ATTORNEY TO BE NOTICED

Amicus

Rachel Rebouche
JD, LLM

represented by **Beth E. Braiterman**
(See above for address)
LEAD ATTORNEY

PRO HAC VICE
ATTORNEY TO BE NOTICED

Denise Esposito
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Julia F. Post
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Kaixin Fan
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Russell D. Jessee
(See above for address)
ATTORNEY TO BE NOTICED

Amicus

Patricia J. Zettler
JD

represented by **Beth E. Braiterman**
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Denise Esposito
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Julia F. Post
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Kaixin Fan
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Russell D. Jessee
(See above for address)
ATTORNEY TO BE NOTICED

Amicus

I. Glenn Cohen
JD

represented by **Beth E. Braiterman**
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Denise Esposito
(See above for address)
LEAD ATTORNEY

PRO HAC VICE
ATTORNEY TO BE NOTICED

Julia F. Post
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Kaixin Fan
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Russell D. Jessee
(See above for address)
ATTORNEY TO BE NOTICED

Amicus

Peter Barton Hutt
LLM, LLB

represented by **Beth E. Braiterman**
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Denise Esposito
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Julia F. Post
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Kaixin Fan
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Russell D. Jessee
(See above for address)
ATTORNEY TO BE NOTICED

Amicus

Allison Whelan
JD, MA

represented by **Beth E. Braiterman**
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Denise Esposito
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Julia F. Post
(See above for address)
LEAD ATTORNEY

PRO HAC VICE
ATTORNEY TO BE NOTICED

Kaixin Fan
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Russell D. Jessee
(See above for address)
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
01/25/2023	1	COMPLAINT. Filing Fee $402.00. Receipt # AWVSDC−8350600. (Attachments: # 1 Proposed Summons as to Mark A. Sorsaia, # 2 Proposed Summons as to Patrick Morrisey, # 3 Civil Cover Sheet) (jsa) .
01/25/2023	2	ELECTRONIC SUMMONS ISSUED as to Patrick Morrisey, Mark A. Sorsaia, re: 1 Complaint. Summons returnable 21 days. Instructions to Counsel: This is your electronic summons. Please print as many copies of the Summons and Complaint as are necessary to effectuate service under Fed. R. Civ. P. 4. See Proof of Service page of this Summons form for filing a return of service if required by Fed. R. Civ. P. 4(l). (Attachment: # 1 summons as to Patrick Morrissey) (jsa).
01/25/2023	3	STANDING ORDER IN RE: ASSIGNMENT AND REFERRAL OF CIVIL ACTIONS AND MATTERS TO MAGISTRATE JUDGES ENTERED JANUARY 4, 2016. Discovery referred to Magistrate Judge Eifert. (cc: counsel of record; any unrepresented party) (jsa)
01/25/2023	4	NOTICE OF CHANGE OF ATTORNEY INFORMATION by Christina L. Smith updating name and/or firm information on behalf of GenBioPro, Inc. (Smith, Christina)
01/25/2023	5	STATEMENT OF VISITING ATTORNEY from Daphne O'Connor on behalf of GenBioPro, Inc. Local counsel: Anthony J. Majestro. Fee $50.00. Receipt # AWVSDC−8351204. (Attachment: # 1 WVSB receipt)(Majestro, Anthony)
01/25/2023	6	STATEMENT OF VISITING ATTORNEY from John Elwood on behalf of GenBioPro, Inc. Local counsel: Anthony J. Majestro. Fee $50.00. Receipt # AWVSDC−8351217. (Attachment: # 1 WVSB receipt)(Majestro, Anthony)
01/25/2023	7	STATEMENT OF VISITING ATTORNEY from Robert Katerberg on behalf of GenBioPro, Inc. Local counsel: Anthony J. Majestro. Fee $50.00. Receipt # AWVSDC−8351222. (Attachment: # 1 WVSB receipt)(Majestro, Anthony)
01/25/2023		CASE assigned to Judge Robert C. Chambers. (klc) (Entered: 01/26/2023)
01/27/2023	8	STATEMENT OF VISITING ATTORNEY from Ariela M. Migdal on behalf of GenBioPro, Inc. Local counsel: Anthony J. Majestro. Fee $50.00. Receipt # AWVSDC−8352878. (Attachment: # 1 WVSB receipt)(Majestro, Anthony)
01/27/2023	9	STATEMENT OF VISITING ATTORNEY from David C. Frederick on behalf of GenBioPro, Inc. Local counsel: Anthony J. Majestro. Fee $50.00. Receipt # AWVSDC−8352912. (Attachment: # 1 WVSB receipt)(Majestro, Anthony)
01/27/2023	10	STATEMENT OF VISITING ATTORNEY from Eliana M. Pfeffer on behalf of GenBioPro, Inc. Local counsel: Anthony J. Majestro. Fee $50.00. Receipt # AWVSDC−8352922. (Attachment: # 1 WVSB receipt)(Majestro, Anthony)
01/27/2023	11	STATEMENT OF VISITING ATTORNEY from Mary Charlotte Carroll on behalf of GenBioPro, Inc. Local counsel: Anthony J. Majestro. Fee $50.00. Receipt # AWVSDC−8352931. (Attachment: # 1 WVSB receipt)(Majestro, Anthony)
01/29/2023	12	STATEMENT OF VISITING ATTORNEY from Skye Perryman on behalf of GenBioPro, Inc. Local counsel: Anthony J. Majestro. Fee $50.00. Receipt #

		AWVSDC−8353966. (Attachment: # 1 WVSB receipt)(Majestro, Anthony)
01/29/2023	13	STATEMENT OF VISITING ATTORNEY from Kristen P. Miller on behalf of GenBioPro, Inc. Local counsel: Anthony J. Majestro. Fee $50.00. Receipt # AWVSDC−8353968. (Attachment: # 1 WVSB receipt)(Majestro, Anthony)
01/31/2023	14	SUMMONS RETURNED EXECUTED for Patrick Morrisey, re: 1 Complaint. Curtis Capehart, Deputy Attorney General, served on 1/30/2023 pursuant to his agreement to accept service via electronic mail on behalf of Patrick Morrisey, answer due 2/21/2023. (Majestro, Anthony) (Modified on 1/31/2023 to add the name of the person served and means of service) (mkw).
02/01/2023	15	SUMMONS RETURNED EXECUTED for Mark A. Sorsaia, re: 1 Complaint. Katelyn Barr, Legal Assistant, served on 1/31/2023 on behalf of Mark A. Sorsaia, answer due 2/21/2023. (Majestro, Anthony) (Modified on 2/1/2023 to add the name of the person served) (mkw).
02/03/2023	16	DISCLOSURE STATEMENT PURSUANT TO RULE 7.1, Federal Rules of Civil Procedure, by Plaintiff GenBioPro, Inc. (Majestro, Anthony)
02/16/2023	17	RULE 12(B)(1) AND RULE 12(B)(6) MOTION by Mark A. Sorsaia to Dismiss for Failure to State a Claim, re: 1 Complaint. (jsa)
02/16/2023	18	MEMORANDUM OF LAW by Mark A. Sorsaia in support of 17 RULE 12(B)(1) AND RULE 12(B)96) MOTION by Mark A. Sorsaia to Dismiss for Failure to State a Claim, re: 1 Complaint. (jsa)
02/21/2023	19	MOTION by Patrick Morrisey to Dismiss re: 1 Complaint. (Attachments: # 1 Proposed Order)(Capehart, Curtis) (Modified on 2/22/2023 to add link to #1 complaint) (mk).
02/21/2023	20	MEMORANDUM by Patrick Morrisey in support of 19 MOTION by Patrick Morrisey to Dismiss re: 1 Complaint. (Capehart, Curtis)
02/28/2023	21	STATEMENT OF VISITING ATTORNEY from Denise M. Harle on behalf of Patrick Morrisey. Local counsel: Curtis R. A. Capehart. Fee $50.00. Receipt # AWVSDC−8373158. (Capehart, Curtis)
02/28/2023	22	STATEMENT OF VISITING ATTORNEY from Erin M. Hawley on behalf of Patrick Morrisey. Local counsel: Curtis R. A. Capehart. Fee $50.00. Receipt # AWVSDC−8373175. (Capehart, Curtis)
02/28/2023	23	NOTICE OF APPEARANCE by Jeffrey A. Kimble on behalf of State of Alabama, State of Arkansas, State of Florida, State of Georgia, State of Idaho, State of Indiana, State of Iowa, State of Kansas, State of Kentucky, State of Louisiana, State of Mississippi, State of Missouri, State of Montana, State of Nebraska, State of North Dakota, State of Ohio, State of Oklahoma, State of South Carolina, State of South Dakota, State of Tennessee, State of Texas. (Kimble, Jeffrey)
02/28/2023	24	MOTION by State of Alabama, State of Arkansas, State of Florida, State of Georgia, State of Idaho, State of Indiana, State of Iowa, State of Kansas, State of Kentucky, State of Louisiana, State of Mississippi, State of Missouri, State of Montana, State of Nebraska, State of North Dakota, State of Ohio, State of Oklahoma, State of South Carolina, State of South Dakota, State of Tennessee, State of Texas for Leave to File Motion of Arkansas, Alabama, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, and Texas for Leave to File an Amicus Brief in Support of the Defendants in this matter, with proposed document attached. (Attachment: # 1 Exhibit)(Kimble, Jeffrey)
03/01/2023	25	UNOPPOSED MOTION by GenBioPro, Inc. to Extend Deadline to Respond to Defendant Mark A. Sorsaia's 17 MOTION to Dismiss to 3/7/2023. (Attachment: # 1 Proposed Order)(Majestro, Anthony) (Modified on 3/1/2023 to add link to #17 motion) (mkw).
03/02/2023	26	ORDER GRANTING PLAINTIFF'S MOTION TO EXTEND DEADLINE TO RESPOND TO DEFENDANT MARK A. SORSAIA MOTION TO DISMISS granting Plaintiff's 25 MOTION to Extend Deadline to Respond to Defendant Mark A. Sorsaia's Motion to Dismiss; Plaintiff shall file its response on 3/7/2023. Signed by

		Judge Robert C. Chambers on 3/2/2023. (cc: counsel of record who have registered to receive an electronic NEF) (cla)
03/03/2023	27	UNOPPOSED MOTION by GenBioPro, Inc. to Extend Deadline to Respond to 19 MOTION by Patrick Morrisey to Dismiss, re: 1 Complaint to 3/17/2023 and UNOPPOSED MOTION by GenBioPro, Inc. to Exceed Page Limit for its Response. (Attachment: # 1 Proposed Order)(Smith, Christina)
03/06/2023	28	ORDER GRANTING PLAINTIFF'S UNOPPOSED MOTION TO EXTEND DEADLINE AND PAGE LIMIT TO RESPOND TO DEFENDANT PATRICK MORRISEY'S MOTION TO DISMISS granting the 27 UNOPPOSED MOTION by GenBioPro, Inc. to Extend Deadline to Respond to 19 MOTION by Patrick Morrisey to Dismiss and to Exceed Page Limit for its Response; Plaintiff shall file its Response to Defendant Morrisey's Motion to Dismiss on 3/17/2023. Signed by Judge Robert C. Chambers on 3/6/2023. (cc: counsel of record who have registered to receive an electronic NEF) (jsa)
03/06/2023	29	ORDER granting the 24 MOTION by State of Alabama, State of Arkansas, State of Florida, State of Georgia, State of Idaho, State of Indiana, State of Iowa, State of Kansas, State of Kentucky, State of Louisiana, State of Mississippi, State of Missouri, State of Montana, State of Nebraska, State of North Dakota, State of Ohio, State of Oklahoma, State of South Carolina, State of South Dakota, State of Tennessee, State of Texas for Leave to File an Amicus Brief in Support of the Defendants; directing the Clerk to file the Amicus Brief. Signed by Judge Robert C. Chambers on 3/6/2023. (cc: counsel of record; any unrepresented parties) (jsa)
03/06/2023	30	AMICUS BRIEF by State of Alabama, State of Arkansas, State of Florida, State of Georgia, State of Idaho, State of Indiana, State of Iowa, State of Kansas, State of Kentucky, State of Louisiana, State of Mississippi, State of Missouri, State of Montana, State of Nebraska, State of North Dakota, State of Ohio, State of Oklahoma, State of South Carolina, State of South Dakota, State of Tennessee, State of Texas in support of 17 MOTION by Mark A. Sorsaia to Dismiss for Failure to State a Claim and 19 MOTION by Patrick Morrisey to Dismiss 1 Complaint. (jsa)
03/07/2023	31	OPPOSITION by GenBioPro, Inc. to 17 MOTION by Mark A. Sorsaia to Dismiss. (Smith, Christina) (Modified on 3/8/2023 to remove link to #18 memorandum in support) (mkw).
03/10/2023	32	STATEMENT OF VISITING ATTORNEY from Dylan L. Jacobs on behalf of State of Arkansas. Local counsel: Jeffrey A. Kimble. Fee $50.00. Receipt #AWVSDC−8373482. (Attachment: # 1 Receipt) (jsa) (Modified on 3/13/2023 to correct the filed date) (Entered: 03/13/2023)
03/10/2023	33	STATEMENT OF VISITING ATTORNEY from Asher Steinberg on behalf of State of Arkansas. Local counsel: Jeffrey A. Kimble. Fee $50.00. Receipt #AWVSDC−8373444. (Attachment: # 1 Receipt) (jsa) (Modified on 3/13/2023 to correct the filed date) (mkw). (Entered: 03/13/2023)
03/10/2023	34	STATEMENT OF VISITING ATTORNEY from Nicholas J. Bronni on behalf of State of Arkansas. Local counsel: Jeffrey A. Kimble. Fee $50.00. Receipt #AWVSDC−8373457 (Attachment: # 1 Receipt) (jsa) (Modified on 3/13/2023 to correct the filed date) (mkw). (Entered: 03/13/2023)
03/17/2023	35	OPPOSITION by GenBioPro, Inc. to 19 MOTION by Patrick Morrisey to Dismiss, re: 1 Complaint. (Attachment: # 1 Appendix Statutory Addendum)(Majestro, Anthony) (Modified on 3/20/2023 to remove link to #20 memorandum) (mkw).
03/20/2023	36	STATEMENT OF VISITING ATTORNEY from Kaixin Fan on behalf of Rachel Rebouche, Lewis Grossman, I. Glenn Cohen, Allison Whelan, Greer Donley, David S. Cohen, Patricia J. Zettler, Peter Barton Hutt. Local counsel: Russell D. Jessee. Fee $50.00. Receipt # AWVSDC−8385797. (Jessee, Russell)
03/20/2023	37	STATEMENT OF VISITING ATTORNEY from Beth Braiterman on behalf of Rachel Rebouche, Lewis Grossman, I. Glenn Cohen, Allison Whelan, Greer Donley, David S. Cohen, Patricia J. Zettler, Peter Barton Hutt. Local counsel: Russell Jessee. Fee $50.00. Receipt # AWVSDC−8385806. (Jessee, Russell)

03/20/2023	38	STATEMENT OF VISITING ATTORNEY from Julia F. Post on behalf of Rachel Rebouche, Lewis Grossman, I. Glenn Cohen, Allison Whelan, Greer Donley, David S. Cohen, Patricia J. Zettler, Peter Barton Hutt. Local counsel: Russell D. Jessee. Fee $50.00. Receipt # AWVSDC−8385822. (Jessee, Russell)
03/20/2023	39	STATEMENT OF VISITING ATTORNEY from Denise Esposito on behalf of Rachel Rebouche, Lewis Grossman, I. Glenn Cohen, Allison Whelan, Greer Donley, David S. Cohen, Patricia J. Zettler, Peter Barton Hutt. Local counsel: Russell D. Jessee. Fee $50.00. Receipt # AWVSDC−8385834. (Jessee, Russell)
03/20/2023	40	MOTION by David S. Cohen, I. Glenn Cohen, Greer Donley, Lewis Grossman, Peter Barton Hutt, Rachel Rebouche, Allison Whelan, Patricia J. Zettler for Leave to File An Amicus Curiae Brief in Support of Plaintiff's 35 Opposition to Defendants' Motions to Dismiss, with proposed document attached. (Attachment: # 1 Exhibit − Brief)(Jessee, Russell) (Modified on 3/21/2023 to add link to #35 opposition) (mkw).
03/23/2023	41	UNOPPOSED MOTION by Patrick Morrisey to Extend Deadline for Reply to Plaintiff's 35 Response In Opposition. (Capehart, Curtis) (Modified on 3/24/2023 to remove link to #19 motion and #1 complaint and add link to #35 opposition) (mkw).
03/24/2023	42	ORDER granting Defendant Patrick Morrisey's 41 UNOPPOSED MOTION to Extend Deadline for Reply in Support of Defendant's Morrisey's Motion to Dismiss; reply due by 3/31/2023. Signed by Judge Robert C. Chambers on 3/24/2023. (cc: counsel of record and any unrepresented parties) (cla)
03/27/2023	43	ORDER granting 40 MOTION by David S. Cohen, I. Glenn Cohen, Greer Donley, Lewis Grossman, Peter Barton Hutt, Rachel Rebouche, Allison Whelan, Patricia J. Zettler for Leave to File An Amicus Curiae Brief in Support of Plaintiff's Opposition to Defendants' Motions to Dismiss and directing the Clerk to file the Amicus Brief. Signed by Judge Robert C. Chambers on 3/27/2023. (cc: counsel and any unrepresented parties) (mkw)
03/27/2023	44	BRIEF by David S. Cohen, I. Glenn Cohen, Greer Donley, Lewis Grossman, Peter Barton Hutt, Rachel Rebouche, Allison Whelan, Patricia J. Zettler as Amici Curiae in support of 35 OPPOSITION by GenBioPro, Inc. to Defendants' Motions to Dismiss filed pursuant to the 43 Order. (mkw)
03/31/2023	45	REPLY by Patrick Morrisey to 35 Response In Opposition. (Capehart, Curtis)
04/12/2023	46	LETTER−FORM NOTICE by GenBioPro, Inc. in opposition to 17 MOTION by Mark A. Sorsaia to Dismiss for Failure to State a Claim and 19 MOTION by Patrick Morrisey to Dismiss and 45 Reply to Response. (Attachments: # 1 Exhibit A, # 2 Exhibit B)(Majestro, Anthony) (Modified on 4/13/2023 to remove link to #18 and #20 memorandums) (mkw).
04/13/2023	47	ORDER setting a hearing concerning the issue of standing for 4/24/2023 at 2:00 PM in Huntington before Judge Robert C. Chambers, re: 17 MOTION by Mark A. Sorsaia to Dismiss for Failure to State a Claim and 19 MOTION by Patrick Morrisey to Dismiss; one hour will be allotted for argument; Counsel arguing the motions will appear in person. Signed by Judge Robert C. Chambers on 4/13/2023. (cc: counsel of record; any unrepresented parties) (jsa)
04/18/2023	48	MOTION by Mark A. Sorsaia, Patrick Morrisey to Stay This Case Pending the Outcome of Alliance for Hippocratic Medicine v. U. S. Food & Drug Administration, No. 2:22−cv−00223 (N.D. Tex.). (Attachment: # 1 Exhibit A)(Capehart, Curtis) (Modified on 4/18/2023 to add party filer) (mkw).
04/18/2023	49	MEMORANDUM by Mark A. Sorsaia, Patrick Morrisey in support of 48 MOTION by Mark A. Sorsaia, Patrick Morrisey to Stay This Case Pending the Outcome of Alliance for Hippocratic Medicine v. U. S. Food & Drug Administration, No. 2:22−cv−00223 (N.D. Tex.) (Capehart, Curtis) (Modified on 4/18/2023 to add party filer) (mkw).
04/20/2023	50	OPPOSITION by GenBioPro, Inc. to 48 MOTION by Mark A. Sorsaia, Patrick Morrisey to Stay This Case Pending the Outcome of Alliance for Hippocratic Medicine v. U. S. Food & Drug Administration, No. 2:22−cv−00223 (N.D. Tex.). (Attachments: # 1 Exhibit A − Maryland Comp.) (Majestro, Anthony)

04/21/2023	51	REPLY by Patrick Morrisey to 50 Memorandum In Opposition. (Attachment: # 1 Exhibit A)(Capehart, Curtis)
04/21/2023	52	ORDER denying Defendants' 48 MOTION for Stay; to facilitate the argument scheduled for 4/24/2023, the Court informs the parties that Plaintiff will present its arguments first. Signed by Judge Robert C. Chambers on 4/21/2023. (cc: counsel of record; any unrepresented parties) (jsa)
04/24/2023	53	MOTION HEARING held by Judge Robert C. Chambers on 4/24/2023; Court Reporter: Catherine Schutte−Stant. (trj)
05/02/2023	54	MEMORANDUM OPINION AND ORDER denying in part Defendants' 17 and 19 MOTIONS to Dismiss as to their arguments concerning standing; holding in abeyance the remainder of the Motions; directing counsel to appear in person on 5/23/2023 at 1:30 p.m. in Huntington to argue the remaining issues raised in the Motions. Signed by Judge Robert C. Chambers on 5/2/2023. (cc: counsel of record; any unrepresented parties) (jsa)
05/11/2023	55	ORDER in consideration of the Supreme Court's opinion in National Pork Producers Council v. Ross, No. 21468, S. Ct. (2023), directing the parties to file supplemental briefing by Friday, May 19, 2023. Signed by Judge Robert C. Chambers on 5/11/2023. (cc: attys; any unrepresented parties) (mkw)
05/17/2023	56	TRANSCRIPT OF PROCEEDINGS of Motion Hearing held on 04/24/2023, before Judge Robert C. Chambers. Court Reporter Catherine Schutte−Stant, Telephone number 304−347−3151. Transcript may be viewed at the court public terminal or purchased through the Court Reporter before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Notice of Intent to Redact due 5/30/2023. Redaction Request due 6/7/2023. Redacted Transcript Deadline set for 6/20/2023. Release of Transcript Restriction set for 8/15/2023. (css)
05/17/2023	57	NOTICE OF FILING OF OFFICIAL TRANSCRIPT for pro se and non−electronic filers re 56 Transcript of Motion Hearing held on 04/24/2023, before Judge Robert C. Chambers. Court Reporter Catherine Schutte−Stant, Telephone number 304−347−3151. (klc)
05/19/2023	58	SUPPLEMENTAL BRIEFING by GenBioPro, Inc. in response to the Court's 55 Order. (Majestro, Anthony)
05/19/2023	59	SUPPLEMENTAL BRIEFING by Patrick Morrisey in response to the Court's 55 Order. (Capehart, Curtis)
05/22/2023	60	NOTICE OF FILING by GenBioPro, Inc. to correct page eleven of its Statutory Addendum attached to its 35 Opposition. (Attachment: # 1 Exhibit A)(Majestro, Anthony)
05/23/2023	61	MOTION HEARING held by Judge Robert C. Chambers on 5/23/2023; Court Reporter: Kathy Swinhart. (trj)
05/30/2023	62	TRANSCRIPT OF PROCEEDINGS of Motion Hearing held on May 23, 2023, before Judge Robert C. Chambers. Court Reporter Kathy Swinhart, Telephone number 304−528−7583. Transcript may be viewed at the court public terminal or purchased through the Court Reporter before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Notice of Intent to Redact due 6/9/2023. Redaction Request due 6/20/2023. Redacted Transcript Deadline set for 6/30/2023. Release of Transcript Restriction set for 8/28/2023. (kls)
06/02/2023	63	NOTICE OF FILING OF OFFICIAL TRANSCRIPT for pro se and non−electronic filers re 62 Transcript of Motion Hearing held on 05/23/2023, before Judge Robert C. Chambers. Court Reporter Kathy Swinhart, Telephone number 304−528−7583. (klc)
06/07/2023	64	TRANSCRIPT REQUEST by Jennifer Williams for proceedings held on 5/23/2023 before Judge Robert C. Chambers. (Attachment: # 1 Envelope) (jsa)
08/18/2023	65	NOTICE *of Supplemental Authority* by GenBioPro, Inc. in support of its 58 Response to Court Order. (Attachment: # 1 Exhibit − Alliance for Hippocratic Medicine v. US FDA)(Majestro, Anthony)

08/24/2023	66	MEMORANDUM OPINION AND ORDER granting in part and denying in part Defendants' 17 and 19 MOTIONS to Dismiss; Defendants' Motions to Dismiss Count I are DENIED as to the telemedicine restriction, and GRANTED as to the UCPA and other prior restrictions; Defendants' Motions to Dismiss Count II are GRANTED. Signed by Judge Robert C. Chambers on 8/24/2023. (cc: counsel of record; any unrepresented parties) (jsa) (Modified on 8/24/2023 to replace image) (mkw).
08/24/2023	67	ORDER AND NOTICE: Rule 12(b) Motions − 9/14/2023. Rule 26(f) Meeting − 9/25/2023. Last day to file report of Rule 26(f) Meeting − 10/2/2023. Scheduling/status conference at 11:30 AM on 10/16/2023 in Huntington. Entry of Scheduling Order − 10/23/2023. Last Day to make Rule 26(a)(1) disclosures − 10/30/2023. Signed by Judge Robert C. Chambers on 8/24/2023. (cc: counsel of record; any unrepresented parties) (jsa)
08/24/2023		NOTICE OF DOCKET CORRECTION re: 66 MEMORANDUM OPINION AND ORDER. Error: Image contained a typographical error. Correction: Replaced incorrect image with correct image. (mkw)
09/11/2023	68	NOTICE *of Substitution* by GenBioPro, Inc. (Majestro, Anthony)
10/02/2023	69	JOINT MOTION by GenBioPro, Inc., Kris Raynes, Patrick Morrisey for Extension of Time to File Rule 26(f) meeting report to October 10, 2023. (Capehart, Curtis)
10/03/2023	70	ORDER granting the parties' 69 JOINT MOTION for Extension of Time to File Rule 26(f) Meeting Report; directing the parties to file their Rule 26(f) Report by 10/10/2023. Signed by Judge Robert C. Chambers on 10/3/2023. (cc: counsel of record; any unrepresented parties) (jsa)
10/11/2023	71	JOINT MOTION by GenBioPro, Inc., Kris Raynes, Patrick Morrisey for Extension of the Dealing to File the Rule 26(f) Meeting Report to 10/18/2023. (Majestro, Anthony) (Modified on 10/12/2023 to add party filers) (kew).
10/12/2023	72	ORDER granting the parties' 71 JOINT MOTION for Further Extension for filing of the Rule 26(f) meeting report; extending the filing date to 10/18/2023; further CANCELING the Scheduling Conference on 10/16/2023. Signed by Judge Robert C. Chambers on 10/12/2023. (cc: counsel of record; any unrepresented parties) (skm)
10/18/2023	73	MOTION by GenBioPro, Inc. to Amend 1 Complaint and JOINT STIPULATION by GenBioPro, Inc., Kris Raynes, Patrick Morrisey; said parties stipulate and consent to the filing of Plaintiff's First Amended Complaint. (Attachments: # 1 Exhibit A − First Amended Complaint, # 2 Exhibit B − Redline of Complaint, # 3 Proposed Order Regarding Motion to Amend Complaint and Joint Stipulation)(Majestro, Anthony) (Modified on 10/19/2023 to add party filers) (mkw).
10/19/2023	74	ORDER REGARDING MOTION TO AMEND COMPLAINT AND JOINT STIPULATION granting the parties' 73 MOTION to Amend Complaint and Joint Stipulation; deeming Plaintiff's First Amended Complaint to be the operative complaint in this case. Signed by Judge Robert C. Chambers on 10/19/2023. (cc: counsel of record who have registered to receive an electronic NEF) (jsa)
10/19/2023	75	FIRST AMENDED COMPLAINT by GenBioPro, Inc. against Patrick Morrisey, Kristina Raynes. (jsa)
11/03/2023	76	JOINT STIPULATION AND JOINT MOTION by GenBioPro, Inc., Kristina Raynes, Patrick Morrisey for a a separate order of judgment on Plaintiff's First Amended Complaint; said parties further stipulate that the Court should enter a separate order of judgment on Plaintiff's 75 First Amended Complaint, as required by Federal Rule of Civil Procedure 58. (Attachment: # 1 Proposed Order)(Majestro, Anthony) (Modified on 11/3/2023 to add party filers and to add link to #75 first amended complaint) (mkw).
11/06/2023	77	ORDER REGARDING JOINT STIPULATION AND JOINT MOTION granting the parties' 76 JOINT STIPULATION AND JOINT MOTION; dismissing Plaintiff's 75 First Amended Complaint, entering judgment in favor of the Defendants, and closing this case. Signed by Judge Robert C. Chambers on 11/6/2023. (cc: counsel of record who have registered to receive an electronic NEF) (skm)

11/09/2023	78	NOTICE OF APPEAL WITH FEE PAID by GenBioPro, Inc. as to 77 ORDER REGARDING JOINT STIPULATION AND JOINT MOTION and from the 54 Memorandum Opinion and Order and 66 Memorandum Opinion and Order incorporated in that Judgment. Filing Fee $505. Receipt # AWVSDC−8533171. (Majestro, Anthony)
11/09/2023	79	TRANSMITTAL OF NOTICE OF APPEAL TO 4CCA via APPEAL TRANSMITTAL SHEET re: 78 Notice of Appeal to the 4CCA as to 77 ORDER REGARDING JOINT STIPULATION AND JOINT MOTION and from the 54 Memorandum Opinion and Order and 66 Memorandum Opinion and Order incorporated in that Judgment. (jsa)
11/15/2023	80	NOTICE OF APPELLATE CASE OPENING BY 4CCA re: 78 Notice of Appeal to the 4CCA in 4CCA Case No. 23−2194. Case Manager: Kirsten Hancock. (jsa)

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

Plaintiff,

v.

MARK A. SORSAIA, ***in his official capacity as Prosecuting Attorney of Putnam County*** **AND PATRICK MORRISEY,** ***in his official capacity as Attorney General of West Virginia,***

Defendants.

Civil Action No. 3:23-cv-00058

COMPLAINT

INTRODUCTION

1. This case is about a federally approved medication that Congress subjected to a substantial and detailed federal regulatory program with which West Virginia law interferes. That state law must give way to the comprehensive federal regime Congress enacted and the Food and Drug Administration ("FDA") implemented.

2. Plaintiff GenBioPro, Inc. ("GenBioPro") is a private company that spent almost a decade developing a generic version of the drug mifepristone to give patients a safe, effective, non-invasive medication option for terminating a pregnancy. Mifepristone is the first drug in a two-drug regimen FDA approved that facilitates a medication abortion: (1) mifepristone interrupts early pregnancy by blocking the effect of progesterone, a hormone necessary to maintain a pregnancy, and (2) misoprostol causes uterine contractions, leading to the contents of the uterus being expelled.

3. Since 2019, when it received approval from FDA to sell generic mifepristone, GenBioPro has marketed and sold approximately 850,000 units of generic mifepristone

throughout the United States. Between 2017 and 2020 (a year after GenBioPro began marketing its product), the number of medication abortions in the United States increased by 45 percent, even as the number of abortions overall has declined significantly since the 1990s.[1] Medication abortion now accounts for the majority of pregnancy terminations in the United States, despite the fact that people can use medication only to terminate early pregnancies.[2]

4. Medical termination of pregnancy offers patients significant advantages. Patients can take the medication at home, at a time of their choosing, and in complete privacy. Medication abortions do not require administration of anesthesia; many patients use over-the-counter analgesics like Advil to relieve the period-like cramps patients typically experience.[3] Medical termination often costs less than a surgical termination, too.[4]

5. FDA approved branded mifepristone ("Mifeprex") for sale in 2000 and, in doing so, imposed specific restrictions it determined were necessary to assure the drug's safe use. For example, in that early period FDA required that mifepristone be prescribed by a qualified physician, and be dispensed to patients by their physician, rather than at a pharmacy. Mifepristone joined the ranks of just fifteen other drugs that FDA had determined to warrant special restrictions.

---

[1] Rachel K. Jones, Marielle Kirstein & Jesse Philbin, *Abortion Incidence and Service Availability in the United States, 2020*, 54 Persps. on Sexual & Reprod. Health 128, 136 (Dec. 2022).

[2] *Id.*

[3] Univ. of Cal. S.F. Health ("UCSF"), *Aspiration Versus Medication Abortion*, https://www.ucsfhealth.org/education/aspiration-versus-medication-abortion (last visited Jan. 22, 2023); Am. College of Obstetricians & Gynecologists, *Medication Abortion Up to 70 Days of Gestation*, 136 Obstetrics & Gynecology e31, e37 (Oct. 2020, reaffirmed 2023), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation.

[4] Allison McCann, *What It Costs to Get an Abortion Now*, N.Y. Times (Sept. 28, 2022), https://www.nytimes.com/interactive/2022/09/28/us/abortion-costs-funds.html.

6. In 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. No. 110-85, 121 Stat. 823, codifying many of FDA's risk management regulations into law, and authorizing FDA to design and implement risk evaluation and mitigation strategies for drugs moving forward.

7. As part of the FDAAA, Congress specified that the 16 drugs FDA had already approved with "elements to assure safe use" — including mifepristone — would immediately be "deemed to have in effect an approved risk evaluation and mitigation strategy."[5] *Id.* § 909(b)(1), 121 Stat. 950-51, *reprinted at* 21 U.S.C. § 331 note. In other words, Congress approved of how FDA regulated medications that previously had been approved with "elements to assure safe use."

8. The FDAAA requires FDA to ensure that any elements to assure safe use of drugs subject to a risk evaluation and mitigation strategy "[p]rovid[e] safe access for patients" while "assur[ing the drug's] safe use." *Id.* § 505-1(f), 121 Stat. 926, 930 (codified at 21 U.S.C. § 355-1(f)). Restrictions may "not be unduly burdensome on patient access to the drug" and must "minimize the burden on the health care delivery system." *Id.* § 505-1(f)(2)(C)-(D), 121 Stat. 930 (codified at 21 U.S.C. § 355-1(f)(2)(C)-(D)).

9. Since Congress "deemed" mifepristone to have a risk evaluation and mitigation strategy in effect in 2007, FDA has regulated mifepristone under the FDAAA's special congressional mandate. As required by statute, FDA regularly reevaluates whether mifepristone should remain subject to this strategy and updates the restrictions on the drug in light of its

[5] FDA identified those 16 drugs by name in a list published in the Federal Register. Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007, 73 Fed. Reg. 16313 (Mar. 27, 2008).

assessment of evolving scientific evidence. Most recently, on January 3, 2023, FDA updated the REMS elements on mifepristone to enable patients to receive it through certified pharmacies.

10. Despite that federal statutory and regulatory regime, which carefully balances patient access and safety, West Virginia officials banned mifepristone.

11. In September 2022, in the wake of the Supreme Court's holding in *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), West Virginia's Legislature enacted the Unborn Child Protection Act (the "Criminal Abortion Ban" or the "Ban"). This law prohibits abortion in almost all cases, at any stage of pregnancy. W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8. The Criminal Abortion Ban severely constricted the market for mifepristone statewide.

12. Even before the Ban took effect, West Virginia law restricted the provision of mifepristone. *See id.* §§ 16-2I-2 (requiring a waiting period and counseling before an abortion procedure); 30-3-13a(g)(5) (prohibiting providers from prescribing mifepristone via telemedicine); *see also id.* § 30-1-26(b)(9) (providing for a rule banning prescribing mifepristone via telemedicine) (collectively "Restrictions").

13. The Ban declares that some of these Restrictions (such as the waiting period and counseling requirement) have "no effect" while the Ban is in force. But if a court rules any part of the Ban statute unconstitutional, the limitations on abortion the Ban paused will again "become immediately effective." *Id.* § 16-2R-9 (articles 2F, 2I, 2M, 2O, and 2Q of chapter 16 and article 42 of chapter 33).[6] Once back in effect, these Restrictions will obstruct West Virginia

[6] Article 2F contains provisions requiring parental notification before a minor undergoes an abortion procedure. W. Va. Code § 16-2F-1 *et seq.* Article 2I contains counseling and waiting period requirements patients must fulfill before obtaining an abortion. *Id.* § 16-2I-1 *et seq.* Article 2M prohibited providers from performing abortions after 20 weeks of gestation. *Id.* § 16-2M-1 *et seq.* Article 2O prohibited abortions using the dilation and evacuation method. *Id.*

residents' access to mifepristone and stifle GenBioPro's ability to conduct business in West Virginia.

14. Other restrictions, such as West Virginia's prohibitions on providers using telemedicine to prescribe mifepristone, are in force. *Id.* § 30-3-13a(g)(5); *see id.* § 30-1-26(b)(9).

15. Federal law preempts West Virginia's Ban and Restrictions. These laws impermissibly restrict patients' access to mifepristone and GenBioPro's opportunity and ability to market, promote, and sell the medication in the State. In "deem[ing]" mifepristone to be one of the few drugs subject to heightened FDA regulation, Congress authorized FDA, and only FDA, to impose restrictions on access to mifepristone. Before FDA may impose any restrictions, Congress requires the agency to determine that they are necessary for patient safety and will not unduly burden patient access. The Ban and Restrictions frustrate and conflict with that congressional mandate. West Virginia cannot override FDA's determinations about the appropriate restrictions on a medication that FDA approved for use and Congress subjected to this enhanced regulatory regime.

16. West Virginia's Ban and Restrictions also burden the healthcare delivery system in violation of the Supremacy Clause of the U.S. Constitution. U.S. Const. art. VI, cl. 2. The Ban and Restrictions make it impossible for providers to prescribe and dispense — and in turn,

§ 16-2O-1. Article 2P contains steps providers had to follow if an attempted abortion procedure resulted in a live birth. *Id.* § 16-2P-1. Article 2Q banned abortions sought because of fetal disability. *Id.* § 16-2Q-1. Article 42 of chapter 33 prohibited "partial-birth" abortions, defined as "abortion[s] in which the person performing the abortion partially vaginally delivers a living fetus before killing the fetus and completing the delivery." *Id.* § 33-42-3(3); *see id.* § 33-42-1 *et seq.*

make it nearly impossible for GenBioPro to market, promote, and sell — mifepristone for its indicated use.

17. West Virginia's Ban and Restrictions also violate the Commerce Clause of the U.S. Constitution. U.S. Const. art. I, § 8, cl. 3. Congress determined that mifepristone, a drug subject to a REMS, should be subject to FDA's determinations that balance risks against access. Individual state regulation of mifepristone destroys the national common market and conflicts with the strong national interest in ensuring access to a federally approved medication to end a pregnancy, resulting in the kind of economic fracturing the Framers intended the Clause to preclude. A State's police power does not extend to functionally banning an article of interstate commerce — the Constitution leaves that to Congress.

18. This Court should declare West Virginia's Ban and Restrictions invalid and enjoin their enforcement because they adversely affect the sale and use of mifepristone within the State.

JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1343(a)(3) because GenBioPro's claims present federal questions that arise under the laws of the United States, including the Supremacy and Commerce Clauses of the U.S. Constitution, Article VI, Clause 2 and Article I, Section 8, Clause 3, 21 U.S.C. § 355-1, and 42 U.S.C. § 1983.

20. This Court has authority to grant declaratory and injunctive relief under 42 U.S.C. § 1983 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

21. This Court has jurisdiction and equitable power to enjoin actions by state officials that are preempted by federal law. *See Ex parte Young*, 209 U.S. 123, 150-51 (1908).

22. Venue is proper in this district under 28 U.S.C. § 1391(b) because all Defendants maintain an office and conduct official duties in this judicial district and because a substantial part of the events giving rise to the claims at issue occurred in this district.

PARTIES

23. Plaintiff GenBioPro, Inc. is a Nevada corporation headquartered at 651 Lindell Road, Suite D1041 (P.O. Box 32011), Las Vegas, Nevada 89103. GenBioPro holds an approved abbreviated new drug application for generic mifepristone, No. 091178, and sells the drug nationwide. GenBioPro sells only generic mifepristone and misoprostol. Both drugs are used in medication abortions, and their sales are the company's sole source of revenue.

24. Defendant Mark A. Sorsaia is the Prosecuting Attorney for Putnam County, West Virginia, and maintains an office at 12093 Winfield Road, Winfield, West Virginia 25213. Defendant Sorsaia has authority to prosecute violations of the Criminal Abortion Ban and other criminal restrictions on abortion in Putnam County. *See* W. Va. Code § 7-4-1(a). Defendant Sorsaia has been quoted as stating publicly that "[a]s prosecutors we have a clear obligation to enforce the laws of our state. I believe if abortion is illegal then no responsible medical provider will be doing them."[7] This Complaint is brought against Defendant Sorsaia in his official capacity.

25. Defendant Patrick Morrisey is the Attorney General and chief legal officer of West Virginia and maintains an office at 1900 Kanawha Boulevard E., Charleston, West Virginia 25305. As Attorney General and chief legal officer, Defendant Morrisey has responsibility for enforcing the laws of West Virginia. Attorney General Morrisey recently signed a public letter

[7] Rachel Pellegrino, *West Virginia Lawmakers to Provide Clarity on* Roe v. Wade, WOWK (July 1, 2022), https://www.wowktv.com/news/local/west-virginia-lawmakers-to-provide-clarity-on-roe-v-wade.

calling FDA's determinations with respect to mifepristone "illegal and dangerous" and evincing his intent to stand by state law imposing restrictions on mifepristone notwithstanding FDA's determinations pursuant to its congressional mandate.[8] The Attorney General has the authority to enforce restrictions on abortion at the request of the Governor. *See* W. Va. Code § 5-3-1. This Complaint is brought against Defendant Morrisey in his official capacity.

26. This Court has equitable authority to enjoin these Defendants from enforcing unconstitutional state laws. *See Ex parte Young*, 209 U.S. at 150-51.

FACTUAL ALLEGATIONS

A. Congress Authorized FDA To Approve Drugs Like Mifepristone For Distribution And Sale In The United States

27. Congress first authorized FDA to regulate food and drugs more than a century ago in the Pure Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938).

28. In 1938, Congress created the modern framework for FDA's regulation of prescription drugs in the Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. § 301 *et seq.*). The FDCA authorized the agency to develop a comprehensive regulatory scheme governing medications sold in the United States and to promote the public health by reviewing clinical research promptly and taking appropriate action on applications for marketing those drugs. 21 U.S.C. § 393(b)(1). The FDCA prohibited a drug manufacturer from distributing a drug until it submitted a new drug application to FDA for review, and authorized FDA to reject an application if it determined the drug was unsafe. FDCA § 505(a), (d)-(e), 52 Stat. 1040, 1052 (codified at 21 U.S.C. § 355).

[8] *See* Letter from Att'ys Gen., to Robert Califf, Comm'r, U.S. Food & Drug Admin. (Jan. 13, 2023) ("Letter from Att'ys Gen."), https://www.alabamaag.gov/Documents/news/Letter_from_Ala_Atty_Gen_Steve_Marshall_et_al_to_FDA.pdf.

29. In 1951, Congress amended the FDCA to define a new category of drugs — drugs that must be prescribed by a healthcare provider (as opposed to drugs that patients could obtain over the counter). Act of Oct. 26, 1951, Pub. L. No. 82-215, 65 Stat. 648. These "prescription" drugs included medications that required medical supervision to ensure their safe use. *Id.*

30. In 1962, Congress amended the FDCA to further strengthen FDA's mandate "[t]o protect the public health" and "assure the safety, effectiveness, and reliability of drugs." Drug Amendments of 1962, Pub. L. No. 87-781, pmbl., 76 Stat. 780, 780. Before 1962, Congress required FDA to demonstrate that a drug was harmful to deny an application and keep the drug from entering interstate commerce; after the amendment, Congress required *manufacturers* to prove to FDA that their products were safe and effective. Once FDA approved a manufacturer's application, it authorized that manufacturer to sell and distribute its product nationwide.

31. The 1962 amendments included a provision stating: "Nothing in the amendments made by this Act . . . shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." *Id.* § 202, 76 Stat. 780, 793. When there is such a conflict, state law must yield.

32. In the half century since then, Congress has enacted additional statutes and amendments enhancing FDA's mandate to ensure safe and effective drugs are available to patients in the United States. *E.g.*, Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, §§ 101(j)(1), 202(e)(1), 98 Stat. 1585, 1603 (Sept. 24, 1984) (codified at 21 U.S.C. §§ 271(e)(1), 355(j)(1)) (establishing an expedited approval process for generic drugs along with incentives for generic manufacturers to make generic drugs available on the

market quickly)[9]; 21 U.S.C. § 393(b)(1), (2) (enacted in 1997) (requiring FDA to "promptly and efficiently review[ ] clinical research and tak[e] appropriate action on the marketing of regulated products in a timely manner"); *id.* § 360bbb(b), (c) (enacted in 1997) (authorizing FDA to "[e]xpand[ ] access to unapproved therapies and diagnostics," by allowing access to "investigational drug[s]" under certain circumstances); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-15, § 101(1), 111 Stat. 2296, 2298 (Nov. 21, 1997), *reprinted at* 21 U.S.C. § 379g note (stating that "prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease"); 21 U.S.C. § 356c(g) (enacted in 2012) (requiring FDA to mitigate and prevent shortages of certain drugs), *id.* § 356c-1 (enacted in 2012) (requiring FDA to report annually to Congress its actions to prevent or mitigate drug shortages).

33. The FDCA also requires manufacturers to label drugs with adequate instructions for their safe use, prescribing information, and the treatment for which that drug is approved (the "indication"). 21 U.S.C. §§ 352(f), 355(a); *see also* 21 C.F.R. § 201.57(c).

1. For The Past Forty Years, FDA Has Developed And Implemented Strategies For Ensuring The Safety Of Certain Drugs

34. While Congress charges FDA with assessing drug safety, FDA's determination that a drug is safe for use for an indication does not mean that the drug is completely risk free. All drugs, even over-the-counter drugs, carry some risk. Rather, FDA approves a drug if its benefits to patients outweigh those risks. Furthermore, FDA can impose special regulatory

[9] *See also Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (explaining that the purpose of the 1984 amendments was to "get generic drugs into the hands of patients at reasonable prices — fast" (citation omitted)).

programs to mitigate a drug's risks that facilitate regulatory approval of the drug and its availability to patients.

35. FDA began developing risk management programs to mitigate drug risks in the 1980s. One early example is FDA's risk management program for isotretinoin (then sold as "Accutane"), a drug that treats severe acne. After approving Accutane in 1982, FDA determined that, if taken by a pregnant person, Accutane could affect fetal development. To minimize the risk that a pregnant person might take Accutane, FDA created special package inserts and developed educational programs to warn providers and patients.

36. By the 1990s, FDA had promulgated regulations enabling it to approve drugs that treat "serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments" subject to certain "restrictions to assure safe use." *See* 21 C.F.R. §§ 314.500, 314.520. These regulations (known as "Subpart H") limited any restriction FDA could impose to those "commensurate with the specific safety concerns presented by the drug product." *Id.* § 314.520.

37. Under Subpart H, FDA implemented risk management programs with "elements to assure safe use" for only 16 drugs and biologics.[10] One of those drugs was mifepristone.

2. After Determining That It Was Safe And Effective, FDA Approved Branded Mifepristone Under Subpart H

38. French pharmaceutical company Roussel Uclaf developed mifepristone in 1980. Since its development, more than eighty countries have approved mifepristone's use in

[10] The 16 drugs and biologics included: abarelix, alosetron, ambrisentan, bosentan, clozapine, dofetilide, eculizumab, fentanyl PCA, fentanyl citrate, isotretinoin, lenalidomide, mifepristone, natalizumab, the smallpox vaccine, sodium oxybate, and thalidomide.

medication abortions.[11] The United States joined those ranks in 2000, when FDA approved a new drug application for Mifeprex — the brand name for mifepristone as distributed and marketed by Danco Laboratories, LLC ("Danco") — for the medical termination of intrauterine pregnancy through 49 days' gestation.

39. In approving Mifeprex for sale, FDA determined that it treats a serious or life-threatening condition (*i.e.*, unwanted or unintended pregnancies), and provides a "meaningful therapeutic benefit to some patients over surgical abortion."[12] According to FDA, "unwanted pregnancy, like a number of illnesses or conditions, can be serious for certain populations or under certain circumstances."[13] FDA recognized that, despite being associated with some risks, mifepristone conferred important therapeutic benefits and therefore approved Mifeprex subject to certain restrictions under Subpart H.

3. In The FDAAA, Congress Authorized FDA To Create Risk Evaluation And Mitigation Strategies And Imposed A Strategy On Mifepristone

40. In 2007, Congress enacted the FDAAA to require FDA to ensure patient access to medications for which there is a potential risk of a serious adverse drug experience. 21 U.S.C. § 355-1. The FDAAA functionally codified FDA's risk management regulations and instructed FDA to continue regulating access to particular drugs to ensure that they remain available, and that any restrictions do not unduly burden patient access or the healthcare delivery system.

---

[11] U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 4, 2023), https://perma.cc/AB7X-64A5.

[12] *Id.*

[13] *See* Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Amin., to Donna Harrison, Executive Dir., Am. Ass'n of Pro Life Obstetricians & Gynecologists, Gene Rudd, Sr. Vice Pres., Christian Med. & Dental Ass'ns, & Penny Young Nance, CEO & Pres., Concerned Women for Am. (Mar. 29, 2016) ("Woodcock Letter").

41. To do so, Congress authorized FDA to implement a program called a Risk Evaluation and Mitigation Strategy ("REMS"). A REMS represents a determination by FDA that when a drug is prescribed or administered in a particular manner, that drug's benefits outweigh the risk of a serious adverse drug experience. *See id.* § 355-1(a).

42. After amending the FDCA with the FDAAA, Congress directed that drugs FDA had previously approved with restrictions under Subpart H — including Mifeprex — would be "deemed to have in effect" an approved REMS. FDAAA § 909(b)(1), 121 Stat. 950-51. Congress thereby codified the restrictions FDA had imposed under Subpart H on this group of drugs, including Mifeprex. *See id.*

43. As part of the FDAAA, Congress required those 16 drugs' sponsors to submit new REMS to FDA for the agency's consideration. *Id.* The FDAAA authorized FDA to modify, or even remove, the REMS for those drugs. *E.g.*, 21 U.S.C. § 355-1(g)(4)(B), (h).

44. The FDAAA specifies how FDA must assess whether a REMS is appropriate. It requires FDA first to determine whether a REMS is necessary and evaluate "[t]he seriousness of any known or potential adverse events that may be related to the drug." *Id.* § 355-1(a). If FDA concludes the drug poses a risk of an "adverse drug experience" and determines a REMS is necessary to ensure that the drug's benefits outweigh its risks, FDA must design and implement a REMS. *Id.* An adverse drug experience includes "any adverse event associated with the use of a drug . . . whether or not" the adverse event is "considered drug related." *Id.* § 355-1(b)(1).

45. In imposing a REMS, FDA can require drug companies to include medication guides or inserts for patients, implement communications plans (which may include sending letters to healthcare providers), or dispense the drug in special packaging to ensure patients use the drug safely. *Id.* § 355-1(e).

46. The statute authorizes FDA to impose additional REMS elements "necessary to assure safe use of the drug" (also referred as "ETASU"). These elements may be imposed only if FDA determines the drug is "associated with a serious adverse drug experience" and requires a REMS to mitigate that "specific serious risk." *Id.* § 355-1(f)(1). A "serious risk" or "serious adverse drug experience" includes adverse drug experiences that could result in "inpatient hospitalization" or a "substantial disruption of the ability to conduct normal life functions." *Id.* § 355-1(b)(4), (5).

47. The elements FDA imposes must be "commensurate with the specific serious risk listed" on the drug's label. *Id.* § 355-1(f)(2)(A). For example, FDA may restrict dispensing of the drug to certain settings, like hospitals. *Id.* § 355-1(f)(1), (3).

48. If FDA determines that it can approve a drug only with a REMS that incorporates such additional elements to assure safe use, Congress directs FDA to ensure that these elements "[p]rovid[e] safe access for patients to [these] drugs." *Id.* § 355-1(f).

49. In a provision entitled, "Assuring access and minimizing burden," Congress mandates that these elements to assure safe use, considering the drug's risk, "not be unduly burdensome on patient access to the drug," taking into account three considerations: patients with serious or life-threatening conditions, patients with difficulty accessing healthcare (such as patients in "rural or medically underserved areas"), and patients with functional limitations. *Id.* § 355-1(f)(2)(A), (C)(i)-(iii). Congress requires any additional elements or restrictions to be compatible with the requirements for similar drugs and compatible with established drug distribution systems, "so as to minimize the burden on the health care delivery system." *Id.* § 355-1(f)(2)(D).

50. In creating a REMS, FDA must seek input from patients and healthcare providers in evaluating the restrictions to ensure they are not "unduly burdensome on patient access to the drug," *id.* § 355-1(f)(5), and minimize the "burden on the health care delivery system," *id.* § 355-1(f)(2)(D). In other words, Congress mandated that FDA balance two competing values: the safety of the drug and patient access to the drug.

51. Any person can petition FDA to amend a drug's REMS by submitting a citizen petition pursuant to 21 C.F.R. § 10.30.

52. Section 355-1 requires FDA to reassess a drug's REMS periodically. 21 U.S.C. § 355-1(d). After each reassessment, FDA may eliminate a REMS — or a component of a REMS — if it determines that the REMS elements are no longer necessary to ensure a medication's benefits outweigh its risks.

53. Congress provided that, although either a drug's manufacturer or FDA can propose a modification to a REMS, any such modification requires prior FDA approval. Without that approval, the existing REMS remains in effect. *Id.* § 355-1(g)(1), (h)(1), (h)(2)(A)-(B).

54. Of the more than 20,000 prescription drugs FDA has approved for marketing in the United States, the agency has subjected only 301 to a REMS.[14] FDA has subjected 97 of those drugs to additional elements to assure safe use.[15]

[14] U.S. Food & Drug Admin., *FDA Risk Evaluation and Mitigation Strategy (REMS) Public Dashboard* (Jan. 17, 2023), https://fis.fda.gov/sense/app/ca606d81-3f9b-4480-9e47-8a8649da6470/sheet/994e7e67-d815-4204-8758-095c2abe2eda/state/analysis.

[15] *Id.*

B. FDA Determined That Mifepristone Requires A REMS With Additional Elements To Assure Safe Use

1. The Early Mifeprex REMS

55. After Congress mandated that Mifeprex be "deemed to have in effect" an approved REMS in the FCAAA, in September 2008, Danco submitted a supplemental new drug application proposing a REMS for Mifeprex. FDA approved the proposed REMS in June 2011.

56. As approved, the 2011 REMS required that only certified physicians prescribe Mifeprex; specified that Mifeprex be dispensed only in certain healthcare settings such as clinics (known as the "in-person dispensing requirement") and taken in a provider's clinic; and required Danco to ensure that every doctor prescribing Mifeprex was specially certified.

57. In approving these REMS, FDA "determined that a REMS [wa]s necessary" for Mifeprex "to ensure the benefits of the drug outweigh[ed] the risks of serious complications by requiring prescribers to certify that they [were] qualified to prescribe" the drug, and could "assure patient access to appropriate medical facilities to manage any complications."[16]

58. In 2015, Danco submitted a supplemental new drug application to FDA to revise Mifeprex's label and REMS. FDA approved almost all of Danco's proposed modifications to the label and REMS, including: increasing the gestational age through which Mifeprex is indicated from 49 days to 70 days; reducing the number of patient visits to a clinic; and expanding those who could be certified to prescribe Mifeprex to include "healthcare providers," rather than just "physicians."

[16] Letter from Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., to Danco Labs., LLC 1 (June 8, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/020687s014ltr.pdf.

59. FDA determined that the remaining REMS requirements, such as the in-person dispensing requirement, "remain[ed] necessary to ensure that the drug's benefits outweigh its risks"[17] and to assure Mifeprex's safe use.[18]

2. FDA Approved GenBioPro's Generic Mifepristone

60. GenBioPro spent almost a decade bringing a generic version of mifepristone to market. On April 11, 2019, FDA approved GenBioPro's application to manufacture and market generic mifepristone within the United States. As required by section 355, GenBioPro's generic mifepristone and Danco's Mifeprex have substantively identical labels. *See* 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G).

61. FDA subjected GenBioPro's generic mifepristone to a REMS pursuant to 21 U.S.C. § 355-1(i). FDA determined that the branded and generic mifepristone should share a single REMS, to be called the "Mifepristone REMS Program."

3. FDA Halted Enforcement Of, And Reevaluated Part Of, The Mifepristone REMS

62. In April 2021, FDA announced it would stop enforcing the in-person dispensing requirement of the Mifepristone REMS Program. The agency determined that requiring a patient to visit a clinic during the COVID-19 public health emergency could pose serious risks to patients and healthcare personnel and that new clinical data demonstrated that the in-person dispensing requirement was not necessary to ensure mifepristone remained safe for patients.

---

[17] Letter from Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., to Danco Labs., LLC 2 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/020687Orig1s020ltr.pdf.

[18] *See* U.S. Gov't Accountability Off., GAO-18-292, Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts 12 (2018).

63. FDA continued its review of the Mifepristone REMS Program during the COVID-19 pandemic. In addition to analyzing newly published scientific literature, FDA evaluated safety information submitted to the agency during the COVID-19 public health emergency, reports of adverse events related to the drug, the first REMS assessment report for the Mifepristone REMS Program, and other information provided by the public. In December 2021, FDA announced its determination that certain elements of the Mifepristone REMS Program remained necessary to assure the drug's safe use, while other elements would need to be modified "to reduce burden on patient access and the health care delivery system and to ensure the benefits of [mifepristone] outweigh [its] risks."[19]

64. After completing that review, FDA instructed Danco and GenBioPro to modify the Mifepristone REMS Program by removing the requirement that mifepristone be dispensed only in certain healthcare settings and adding a requirement that pharmacies dispensing mifepristone be specially certified.

65. In December 2021, FDA responded to a Citizen's Petition from American Association of Pro Life Obstetricians and Gynecologists, the Christian Medical Association, and Concerned Women for America, rejecting their requests to impose additional burdens on access to mifepristone, including (1) limiting mifepristone's indication to 49 days' gestation; (2) requiring physicians, and not other providers, to prescribe mifepristone; (3) requiring patients to make three different office visits to their physicians as part of the REMS; and (4) requiring that mifepristone be dispensed only in certain healthcare settings.[20]

---

[19] U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Dec. 16, 2021), https://perma.cc/V7RX-ZUAX.

[20] *See* Woodcock Letter, *supra* note 13, at 5, 9, 13-15, 18-19, 25.

4. FDA Updated The Mifepristone REMS Program, Expanding Methods By Which Patients May Access Mifepristone

66. On January 3, 2023, FDA published a new, shared system REMS for mifepristone (the "2023 REMS") covering both Mifeprex and generic mifepristone.[21] Consistent with FDA's December 2021 statements, the 2023 REMS no longer limits mifepristone dispensing to certain healthcare settings; patients may receive mifepristone by mail or from a specially certified pharmacy.

67. The 2023 REMS requires patients to sign a Patient Agreement Form before receiving a prescription for mifepristone.[22] This form includes a section in which patients acknowledge having "decided to take "mifepristone and misoprostol to end [their] pregnancy" and agreeing to "follow [their] healthcare provider's advice about when to take each drug and what to do in an emergency."[23] The form requires patients to assert that they "understand" that they "will take mifepristone" and then "the misoprostol tablets 24 to 48 hours after" taking mifepristone.[24] FDA determined that these new REMS "continue to ensure the benefits of mifepristone for medical abortion outweigh the risks while minimizing the burden imposed by the REMS on healthcare providers and patients."[25]

---

[21] U.S. Food & Drug Admin., *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200mg* (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf.

[22] U.S. Food & Drug Admin., *Patient Agreement Form* (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf.

[23] *Id.*

[24] *Id.*

[25] *Id.*

C. West Virginia Law Restricts Patients' Access To Mifepristone And Regulates How The Healthcare Delivery System Provides Mifepristone

68. On September 13, 2022, the West Virginia governor signed the "Unborn Child Protection Act," banning abortion at all stages of pregnancy except in limited circumstances. *See* W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8. The law also declared that several provisions of the West Virginia Code related to abortion, including the counseling and waiting period requirements, would have "no force or effect unless any provision of the . . . Act is judicially determined to be unconstitutional." 2022 W. Va. H.B. 302; *see id.* § 16-2I-9. If a court invalidates any part of the law, those restrictions are reactivated.

69. The Ban states that "[a]n abortion may not be performed or induced or be attempted to be performed or induced unless in the reasonable medical judgment of a licensed medical professional: (1) The embryo or fetus is nonviable; (2) The pregnancy is ectopic; or (3) A medical emergency exists." *Id.* § 16-2R-3(a).[26] As a result, West Virginians no longer have a meaningful choice about whether to carry a pregnancy to term or to terminate using medication abortion. *Id.* §§ 16-2R-3, 16-2R-7.

70. The Ban amends mifepristone's indication by changing the time for which mifepristone is indicated from a period spanning 70 days' gestation, to no time at all for most patients.

71. While the Ban does not punish patients who terminate their pregnancies, it subjects certain healthcare providers who perform abortions to loss of their professional license, *id.* § 16-2R-7, and makes it a felony punishable by imprisonment for any other "person" to

[26] The Ban also includes limited exceptions for a pregnancy that is within eight weeks' gestation (or, if a minor or incompetent or incapacitated adult, 14 weeks) and is the result of sexual assault or incest that the patient has reported to law enforcement. W. Va. Code § 16-2R-3(b), (c).

induce an abortion, *id.* § 61-2-8(a). The Ban imposes criminal penalties on some healthcare providers eligible to prescribe mifepristone under the 2023 REMS if they prescribe mifepristone to induce an abortion. *Id.* (defining "licensed medical professional" to exclude certain REMS-authorized providers); *see id.* § 16-2R-2.

72. In imposing the Ban, West Virginia officials eliminated access to mifepristone in the State in almost all circumstances. Even before the Ban, however, West Virginia regulated access to mifepristone in a manner restricting GenBioPro's ability to distribute its FDA-approved product to West Virginians who qualified for access to it in compliance with FDA requirements.

73. As part of these Restrictions, West Virginia:

(a) required providers to obtain "informed consent" from patients at least 24 hours before having a medication abortion, delaying care when, medically, it should be provided as soon as possible to ensure safety and effectiveness and avoid forcing patients out of the 70-day window in which mifepristone is indicated for use. *Id.* § 16-2I-2(a). The law enacting the Ban provides that this waiting-period requirement "is of no force or effect unless" a court rules any provision of the Ban (§ 16-2R-1 *et seq.*) unconstitutional. *Id.* § 16-2I-9.

(b) required providers to communicate specific information to patients that is not part of the Mifepristone REMS Program, including that: "[s]ome suggest that it may be possible to counteract the intended effects of a mifepristone chemical abortion by taking progesterone if the female changes her mind, before taking the second drug," *id.* § 16-2I-2(a)(4)(A); and "the father, if his identity can be determined, is liable to assist in the support of

her child," *id.* § 16-2I-2(b)(2). The law enacting the Ban provides that this counseling requirement "is of no force or effect unless" a court rules any provision of the Ban (§ 16-2R-1 *et seq.*) is unconstitutional. *Id.* § 16-2I-9.

(c) bans providers from using telemedicine to prescribe mifepristone, which means patients must visit a provider in person to obtain a prescription. *Id.* § 30-3-13a(g)(5) (stating that a "physician or health care provider may not prescribe any drug with the intent of causing an abortion" via telemedicine); *see id.* § 30-1-26(b)(9).

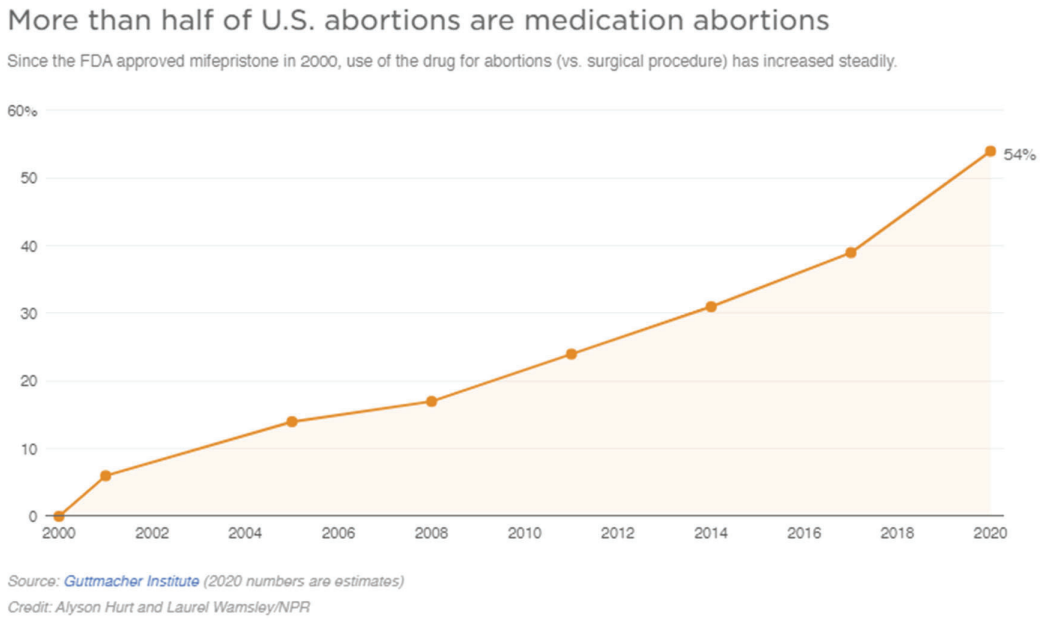
74. These Restrictions, which are in force or would become operative again if any portion of the Ban is judicially determined to be unconstitutional, constrict GenBioPro's ability to market its FDA-approved product to West Virginians who need it. The Ban makes such commercial opportunities virtually impossible.

75. On January 13, 2023, shortly after FDA issued the 2023 REMS, Defendant Morrisey, the Attorney General of West Virginia, joined a letter in which a number of state attorneys general proclaimed to FDA that they "will not yield" to FDA's federally based authority to approve drugs and to strike the optimal regulatory balance between risk mitigation and ensuring patient access because, in their view, the 2023 REMS fail "to protect women's health and safety." Defendant Morrisey and his co-signers wrote that "[t]o be crystal clear," FDA "ha[s] not negated any of our laws that forbid the remote prescription, administration, and use of abortion-inducing drugs" and "[n]othing in the FDA's recent changes affects" how they will enforce those laws.[27]

[27] Letter from Att'ys Gen., *supra* note 8, at 3.

D. West Virginia's Abortion Ban And Restrictions Harm GenBioPro And Prevent Patients From Accessing A Federally Approved Medication

76. More than eighty countries have approved mifepristone's use in medication abortions, and many patients in the United States use mifepristone.[28] In 2020, approximately 492,210 medication abortions occurred in the United States, up from approximately 339,650 just three years earlier.[29] The market for mifepristone is strong and sales have grown over time, even as the number of total U.S. abortions (including surgical) has declined.[30] Medication abortions account for more than half of U.S. abortions, despite the fact that FDA approves of mifepristone's use only up to 70 days' gestation.[31]



[28] U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 4, 2023), https://perma.cc/AB7X-64A5.

[29] Rachel K. Jones et al., *supra* note 1, at 135.

[30] *Id.*

[31] *Id.*; Laurel Wamsley, *How Medication Abortion Works and What the End of* Roe v. Wade *Could Mean for It*, NPR (May 13, 2022), https://www.npr.org/2022/05/13/1098000879/abortion-pills-medication-abortion-roe-v-wade.

77. Although Congress and FDA granted GenBioPro authority to sell mifepristone nationwide, West Virginia's severe abortion Restrictions and Criminal Abortion Ban make it impossible for GenBioPro to promote and market its product in West Virginia as it does in other states. The State has long had only a single clinic providing abortions.

78. Major national pharmacy chains, including Walgreens and CVS, which operate stores in Hurricane and Winfield, have indicated publicly that they intend to sell mifepristone now that the REMS permits them to do so.[32] Providing mifepristone through such pharmacies would enable GenBioPro to serve more patients with its product. West Virginia's Ban and Restrictions, however, block GenBioPro from providing mifepristone through these integral healthcare distribution mechanisms in West Virginia. HoneyBee Health, which ships prescription drugs nationwide, is also prevented by West Virginia's Ban and Restrictions from providing mifepristone to patients in West Virginia.[33]

79. West Virginia's Criminal Abortion Ban and Restrictions have caused significant, ongoing economic injury to GenBioPro in the form of lost sales, customers, and revenue. Defendants' enforcement of the Ban and Restrictions severely constricts GenBioPro's pool of potential customers — including healthcare providers that purchase from GenBioPro and certified pharmacies — and impermissibly constrains GenBioPro's ability to market its product in West Virginia.

---

[32] Spencer Kimball & Bertha Coombs, *CVS and Walgreens Plan to Sell Abortion Pill Mifepristone at Pharmacies After FDA Rule Change*, CNBC (Jan. 5, 2023), https://www.cnbc.com/2023/01/05/abortion-cvs-and-walgreens-will-sell-mifepristone-in-pharmacies.html.

[33] Celine Castronuovo, *Abortion Pill Access to Ease with First FDA-Certified Pharmacy*, Bloomberg News (Jan. 3, 2023), https://news.bloomberglaw.com/health-law-and-business/abortion-pill-access-to-ease-with-first-fda-certified-pharmacy.

80. GenBioPro further alleges that, based on the foregoing, healthcare providers in West Virginia would prescribe mifepristone to their patients and purchase that mifepristone from GenBioPro, and that pharmacies in West Virginia would dispense GenBioPro's mifepristone to their customers, but do not because of the Ban and the Restrictions.

E. West Virginia's Abortion Ban And Other Restrictions Conflict With Federal Law And Regulate Access To Mifepristone, A Function Congress Delegated Exclusively To FDA

81. West Virginia's Ban and abortion Restrictions frustrate and conflict with Congress's determination that FDA must exercise regulatory authority through REMS and elements to assure safe use under 21 U.S.C. § 355-1(f) that States are not free to second-guess or override. Developing such a REMS requires FDA to first determine that restrictions are necessary to ensure that the drug's benefits outweigh its risks, and then to impose restrictions that address the drug's risks while minimizing the burden on patients' access to the drug and on the healthcare delivery system. *See* 21 U.S.C. § 355-1(f)(2).

82. Section 355-1(f)(2) requires FDA to balance competing obligations, to maximize safety while minimizing burden, and to regulate patients' access to, and the healthcare delivery system's distribution of, mifepristone. The statute delegates to FDA exclusive authority to conduct that balancing, deploying its unique expertise in determining whether scientific evidence demonstrates that a serious adverse experience is associated with a drug, and how best to mitigate that risk while ensuring that its efforts do not unduly burden patient access to the drug. FDA's REMS therefore necessarily establishes both a "floor" and "ceiling" on permissible regulation of mifepristone. The elements FDA determined are necessary to ensure mifepristone's safety are the *only* restrictions that may be imposed on a patient's access to, and the healthcare delivery system's distribution of, mifepristone. Just as a state may not pass a law purporting to remove one of the REMS requirements (such as waiving the requirement of a

Patient Agreement Form), it also may not impose any other elements restricting access. Doing so would disturb the balancing that Congress required FDA to conduct in regulating access to mifepristone via the Mifepristone REMS Program.

83. West Virginia's Ban prevents almost all patients from accessing mifepristone, including those who otherwise would be eligible to receive the drug under the 2023 REMS. In so doing, it functionally displaces FDA's judgment in approving mifepristone and imposing a REMS. West Virginia's Ban also prevents the healthcare delivery system from distributing mifepristone to patients for whom providers would otherwise prescribe the drug. It burdens both the patient's access to mifepristone and the healthcare delivery system by imposing criminal and professional penalties on the prescription and distribution of mifepristone. *See* W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8.

84. The State's laws interfere with and seek to contradict Congress's directive to FDA to determine what elements will assure safe use of a REMS drug without being "unduly burdensome on patient access" and "minimiz[ing] the burden on the health care delivery system." 21 U.S.C. § 355-1(f)(2)(C), (D).

85. The Ban and Restrictions conflict with FDA's determinations pursuant to section 355-1(f)(2). The Ban and Restrictions make it impossible for GenBioPro to market and distribute mifepristone in West Virginia in accordance with FDA's requirements and determinations as to the balance Congress mandated between safety-based restrictions and patient access to the drug.

86. Even if the Ban is invalidated or repealed, the telemedicine ban will be in force and the counseling and waiting period requirements would again come into force. Each of these Restrictions conflicts with the 2023 REMS and regulates in an arena that Congress left to FDA.

87. West Virginia's waiting period and counseling requirements, W. Va. Code § 16-2I-2, require providers to obtain "informed consent" from patients at least 24 hours before prescribing mifepristone and require providers to communicate specific information to patients that is not part of the counseling required by the Mifepristone REMS Program. The prescriber agreement in the REMS requires only that a physician review the Patient Agreement Form, "fully explain[ ]" the "risks of the mifepristone treatment regimen," answer any "questions the patient may have," and ensure the patient receives and signs the Patient Agreement Form.[34]

88. West Virginia's telemedicine restrictions, *id.* § 30-3-13a(g)(5); *see id.* § 30-1-26(b)(9), purport to bar healthcare providers from prescribing any abortion drug via telemedicine. The Mifepristone REMS Program does not prohibit providers from using telemedicine to prescribe mifepristone. In 2019, several advocacy groups asked FDA to add a requirement to the REMS that a provider prescribe mifepristone in person, rather than by telemedicine or over the Internet. FDA specifically considered and rejected the proposed requirement as unnecessary to ensure mifepristone's safety. West Virginia's Restriction conflicts with this FDA determination.

89. West Virginia's Ban and Restrictions conflict with mifepristone's label and indication. FDA determined that mifepristone is indicated for use up to 70 days' gestation, but West Virginia law conflicts with that determination by banning use of mifepristone by nearly all patients at any stage of pregnancy and limiting mifepristone to emergency use.

90. By enacting the FDCA and its amendments, Congress authorized FDA to approve drugs in the United States and determine whether a manufacturer can sell its product in interstate

[34] U.S. Food & Drug Admin., *Patient Agreement Form* (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf.

commerce. *See*, *e.g.*, Act of Oct. 10, 1962, Pub. L. No. 87-781, § 104, 76 Stat. 780, 784; 21 U.S.C. § 393(b)(1). A state ban like West Virginia's constitutes a determination on the part of state legislators that a manufacturer *cannot* sell its product in the State, creating a direct conflict with federal law. *See* Act of Oct. 10, 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781.

91. A favorable decision from this Court declaring the laws at issue invalid as applied to the sale and distribution of mifepristone and enjoining their enforcement by state officials due to their constitutional infirmities will remedy these conflicts and redress GenBioPro's economic injury by enabling West Virginians to access its product. And if this Court rules any part of the Ban statute unconstitutional as applied to mifepristone, the entire Ban is invalidated. W. Va. Code § 16-2R-9.

92. Settled preemption and Commerce Clause principles govern states' efforts to restrict access to an FDA-approved medication. The Supreme Court's decision in *Dobbs* did not displace Congress's and FDA's roles in protecting the public health by deciding whether drugs are safe and effective, determining which precautions — if any — are necessary to ensure a drug's safe use, and ensuring safe and effective drugs are available to the public. *Dobbs* addressed only the underlying personal constitutional privacy right as it pertains to abortion; it did not speak to federal law regulating a drug maker's sale and distribution of, or a patient's access to, medication that is FDA-approved for distribution nationwide.

CLAIMS FOR RELIEF

COUNT I

Declaratory and Injunctive Relief — 42 U.S.C. § 1983 — Federal Law Preempts West Virginia's Ban and Restrictions

93. GenBioPro re-alleges and incorporates by reference each of the preceding paragraphs.

94. The U.S. Constitution's Supremacy Clause makes federal laws enacted under the authority of the United States the "supreme Law of the Land." U.S. Const. art. VI, cl. 2. Under the Clause, federal law preempts any state regulation to the contrary. *See Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992).

95. West Virginia's Ban, W. Va. Code §§ 16-2R-1 *et seq.*, 61-2-8, and Restrictions, *id.* §§ 16-2I-2, 16-2I-9, 30-1-26(b)(9), 30-3-13a(g)(5), are preempted by the FDCA as amended, 21 U.S.C. § 355-1. States may not restrict access to FDA-approved drugs in ways that countermand the agency's specific safety considerations or restrictions.

96. West Virginia's Ban and Restrictions conflict with that mandate, including by imposing the burden of criminal penalties on REMS-eligible providers' prescription of mifepristone. The Ban and Restrictions frustrate FDA's determinations about how mifepristone should be regulated and invade an area Congress determined only FDA may occupy. *See*, *e.g.*, *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 479-80 (2013); *Arizona v. United States*, 567 U.S. 387, 403 (2012); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000). The Ban and Restrictions further stand as an obstacle to FDA's determination that GenBioPro's mifepristone is safe and effective, and GenBioPro may distribute it to patients pursuant to the REMS.

97. Federal law therefore preempts Article 2R, Chapter 16 of the West Virginia Code and Section 61-2-8, insofar as these statutes ban patients from using mifepristone in almost all instances.

98. Federal law preempts West Virginia Code §§ 16-2I-2, 16-2I-9 insofar as it requires patients seeking mifepristone to fulfill waiting period and counseling requirements.

99. Federal law preempts West Virginia Code § 30-3-13a(g)(5) insofar as it bans prescribing mifepristone via telemedicine and West Virginia Code § 30-1-26(b)(9) insofar as it provides for a rule banning prescribing mifepristone via telemedicine.

100. Section 1983 of Title 42 of the United States Code provides that "Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State . . . , subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress . . . ."

101. West Virginia's Ban and Restrictions conflict with the rights, privileges, or immunities secured by FDA approval of mifepristone under Title 21 of the United States Code and the REMS to market and distribute its FDA-approved product in West Virginia subject only to those regulations and restrictions FDA imposed pursuant to its mandate under the FDCA as amended, 21 U.S.C. § 355-1.

COUNT II

Declaratory and Injunctive Relief — 42 U.S.C. § 1983 —
West Virginia's Ban and Restrictions Violate the Commerce Clause

102. GenBioPro re-alleges and incorporates by reference each of the preceding paragraphs.

103. The Commerce Clause grants Congress alone the power to "regulate Commerce . . . among the several States." U.S. Const. art. I, § 8, cl. 3. It prevents a state from taking any action that may impede the free flow of trade in the national common market or create an undue burden on access to an article of commerce that requires uniform national regulation.

104. The Commerce Clause renders invalid state laws that impose "undue burdens" on interstate commerce, including by regulating articles of commerce Congress determined require a uniform system of regulation at the national level. *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2091 (2018). The Clause likewise invalidates state laws, such as West Virginia's Ban and Restrictions, that preclude the use of a drug manufactured out of state for use in the State to terminate a pregnancy, *see Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989) (laws that, if imposed by several states, would have the "practical effect" of regulating commerce outside the state violate the Commerce Clause), or of banning an article of commerce, *see Schollenberger v. Pennsylvania*, 171 U.S. 1, 13 (1898).

105. Section 1983 of Title 42 of the United States Code provides a remedy for any person who suffers deprivation of rights, privileges, and immunities secured by the U.S. Constitution, including the Commerce Clause.

106. West Virginia's Ban, W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8, and Restrictions, *id.* §§ 16-2I-2, 16-2I-9, 30-1-26(b)(9), 30-3-13a(g)(5), interfere with the uniform regulation of mifepristone, a drug subject to extensive federal regulation at the national level, thereby destroying the common market for mifepristone.

107. Article 2R, Chapter 16 of the West Virginia Code and § 61-2-8 violate the Commerce Clause by, in effect, banning an article of commerce and preventing GenBioPro from developing a market for its product, mifepristone, in West Virginia.

108. West Virginia Code § 16-2I-2 violates the Commerce Clause by forcing patients to fulfill waiting period and counseling requirements before accessing mifepristone. This State law disrupts FDA's federal regulatory scheme and undermines the need for national uniformity in the regulation of REMS drugs such as mifepristone.

109. West Virginia Code § 30-3-13a(g)(5) violates the Commerce Clause by preventing providers from prescribing mifepristone via telemedicine, meaning that patients are required to visit a healthcare professional in person to obtain a prescription. *See id.* § 30-1-26(b)(9). This State law disrupts FDA's federal regulatory scheme and undermines the need for national uniformity in the regulation of mifepristone, as subject to the FDA's REMS.

110. Each of these Restrictions and West Virginia's Ban constrict the market for GenBioPro's product, excessively burden interstate commerce, and vitiate the national common market the Framers envisioned.

111. West Virginia's Ban and Restrictions conflict with the rights, privileges, or immunities secured by FDA approval of mifepristone under Title 21 of the United States Code and the REMS to market and distribute the drug under applicable federal rules. As such, 42 U.S.C. § 1983 provides a cause of action and remedy for such violations.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter an order and judgment as follows:

A. A declaratory judgment, pursuant to 28 U.S.C. § 2201, that West Virginia Code §§ 16-2R-1 *et seq*., 16-2I-2, 16-2I-9, 30-1-26(b)(9), 30-3-13a(g)(5), and 61-2-8 are invalid and unenforceable because they violate both the Supremacy Clause and the Commerce Clause of the U.S. Constitution;

B. Such further relief as permitted under 28 U.S.C. § 2202, including a permanent injunction enjoining Defendants from enforcing the challenged provisions;

C. Injunctive relief under this Court's equitable power to enjoin enforcement of unconstitutional state laws;

D. An order awarding GenBioPro its costs and attorneys' fees pursuant to 42 U.S.C. § 1988; and

E. Such other and further relief as the Court deems just and proper.

Dated: January 25, 2023

Respectfully submitted,

/s/ Anthony J. Majestro

Anthony J. Majestro
W. Va. Bar No. 5165
Christina L. Smith
W. Va. Bar No. 7509
POWELL & MAJESTRO P.L.L.C.
405 Capitol Street
Suite P-1200
Charleston, WV 25301
Tel: (304) 346-2889
amajestro@powellmajestro.com
csmith@powellmajestro.com

David C. Frederick*
Ariela M. Migdal*
Eliana Margo Pfeffer*
Mary Charlotte Y. Carroll*
KELLOGG, HANSEN, TODD, FIGEL & FREDERICK, P.L.L.C.
1615 M Street, N.W., Suite 400
Washington, D.C. 20036
Tel: (202) 326-7900
dfrederick@kellogghansen.com
amigdal@kellogghansen.com
epfeffer@kellogghansen.com
mcarroll@kellogghansen.com

Skye L. Perryman*
Kristen Miller*
DEMOCRACY FORWARD FOUNDATION
P.O. Box 34553
Washington, D.C. 20043
Tel: (202) 448-9090
sperryman@democracyforward.org
kmiller@democracyforward.org

John P. Elwood*
Daphne O'Connor*
Robert J. Katerberg*
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, N.W.
Washington, D.C. 20001
john.elwood@arnoldporter.com
daphne.oconnor@arnoldporter.com
robert.katerberg@arnoldporter.com

** pro hac vice forthcoming*

Counsel for Plaintiff GenBioPro, Inc.

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

HUNTINGTON DIVISION

GENBIOPRO, INC.

Plaintiff

vs.

Civil Action No: 3:23-cv-00058
(CHAMBERS)

MARK A. SORSAIA, ***in his official capacity as Prosecuting Attorney of Putnam County,*** **and, PATRICK MORRISEY,** ***in his official capacity as Attorney General in West Virginia,***

Defendants

DEFENDANT MARK SORSAIA'S RULE 12(B)(1) AND RULE 12(B)(6) MOTION TO DISMISS

Pursuant to Fed. R. Civ. P 12(b)(1) and 12(b)(6), Defendant, Mark A. Sorsaia, hereby moves this Court to dismiss, with prejudice, all claims asserted against him by the Plaintiff in this civil action. This motion is made upon the following grounds.

1. This Court lacks jurisdiction over the claims asserted by Plaintiff against this Defendant because there is no actual case in controversy as between Plaintiff and Defendant. To establish a justiciable case, the Plaintiff must show (1) "that he 'has sustained or is immediately in danger of sustaining some direct injury . . . or threat of injury [that is] both 'real and immediate,' not 'conjectural' or 'hypothetical'"; (2) that is fairly traceable to "the challenged official conduct"; and (3) the injury "is likely to be redressed by a favorable judicial decision." *Shenandoah Valley Network v. Capka*, 669 F.3d 194, 202 (4th Cir. 2012) (quoting *City of L.A. v. Lyons*, 461 U.S. 95, 101-02, 103 S. Ct. 1660, 75 L. Ed. 2d 675 (1983) (citations omitted); *Lujan v. Defs. of Wildlife*,

504 U.S. 555, 560-61, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992)). In this case. Plaintiff cannot make any of these required showings. Therefore, Defendant Sorsaia is entitled to an Order dismissing all claims against him in accordance with Fed. R. Civ. P 12(b)(1).

2. Plaintiff has failed to state any claims against Defendant Sorsaia upon which relief may be granted. In *Iqbal v. Ashcroft* 556 U.S, 662 (2009) the United States Supreme Court reiterated and amplified upon the principles relating to pleading a viable cause of action that it had announced two years earlier in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007). Specifically, the Supreme Court in *Iqbal* held:

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." … . A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.

556 U.S. at 678.

In this case, the Complaint alleges no facts from which this Court may reasonably infer that Defendant Sorsaia is liable for any misconduct toward Plaintiff. The entire thrust of Plaintiff's Complaint is to prevent statewide enforcement of the Criminal Abortion Ban as related to distribution and sale of mifepristone. Defendant Sorsaia is not alleged to have initiated or threatened any prosecutions in Putnam County to enforce the Criminal Abortion Ban as relating to distribution and sale of mifepristone and no specific facts been plead to indicate that Plaintiff or any other parties faces any imminent risk of such prosecution in Putnam County. The Complaint lacks the facial plausibility required by *Iqbal* to demonstrate that Plaintiff is at risk of suffering any harm due to the conduct of Defendant Sorsaia. Therefore, Defendant Sorsaia is entitled to an Order dismissing all claims against him in accordance with Fed. R. Civ. P 12(b)(6).

WHEREFORE, and for the reasons stated above, Defendant, Mark A. Sorsaia, moves that this Court enter an Order dismissing the Complaint filed against him, with prejudice, and grant him such other relief to which the Court may deem that he is entitled.

MARK A SORSAIA, ***in his official capacity as Prosecuting Attorney of Putnam County***

By Counsel

/s/ Jennifer Scragg Karr
Jennifer Scragg Karr (WV Bar #8051)
Assistant Prosecuting Attorney
Putnam County Judicial Building
12093 Winfield Road
Winfield, WV 25213
(O) 304-586-0205
(F) 304-586-0269
jkarr@putnamwv.org

Attorney for Defendant Mark A. Sorsaia

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

HUNTINGTON DIVISION

GENBIOPRO, INC.

Plaintiff

vs.

Civil Action No: 3:23-cv-00058 (CHAMBERS)

MARK A. SORSAIA, ***in his official capacity as Prosecuting Attorney of Putnam County,*** **and, PATRICK MORRISEY,** ***in his official capacity as Attorney General in West Virginia,***

Defendants

CERTIFICATE OF SERVICE

I, the undersigned, counsel for Defendant, Mark A. Sorsaia, do hereby certify that on this 16th day of February, 2023 I served a copy of the foregoing ***Defendant Mark Sorsaia's Rule 12(b)(1) and Rule 12(b)(6) Motion to Dismiss*** with the Clerk of the Court using the CM/ECF system that will send notification of such filing to all counsel of record.

/s/ Jennifer Scragg Karr
Jennifer Scragg Karr (WV Bar #8051)
Assistant Prosecuting Attorney
Putnam County Judicial Building
12093 Winfield Road
Winfield, WV 25213
(O) 304-586-0205
(F) 304-586-0269
jkarr@putnamwv.org

Attorney for Defendant Mark A. Sorsaia

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

HUNTINGTON DIVISION

GENBIOPRO, INC.

Plaintiff

vs.

Civil Action No: 3:23-cv-00058
(CHAMBERS)

MARK A. SORSAIA, ***in his official capacity as Prosecuting Attorney of Putnam County,***
and, PATRICK MORRISEY, ***in his official capacity as Attorney General in West Virginia,***

Defendants

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT, MARK SORSAIA'S, RULE 12(B)(1) AND RULE 12(B)(6) MOTION TO DISMISS

Introduction

Plaintiff,GenBioPro, Inc., brings this action to challenge the constitutionality of the *West Virginia Unborn Children Protection Act* ("Criminal Abortion Ban") as related to its potential impact upon the distribution and sale of the drug mifepristone across West Virginia. Plaintiff asserts that the only remedy necessary to provide the full relief it is seeking in this case is a favorable ruling by this Court that the Criminal Abortion Ban is unconstitutional and thereby unenforceable as related to the distribution and sale of mifepristone across West Virginia. [Doc. 1 at par. 91]. To this end, Plaintiff names as a defendant Patrick Morrisey, in his official capacity as Attorney General of West Virginia, because, as Plaintiff alleges, he is vested with statewide authority to enforce restrictions relating to abortion. [Doc. 1, at par. 25].

Plaintiff has also named as a party defendant in this case, Mark A. Sorsaia, in his official capacity as the Prosecutor of Putnam County. However, there is no actual case in controversy existing between Plaintiff and Defendant Sorsaia because there are no pending or imminently threatened prosecutions in Putnam County relating to the drug mifepristone. The Complaint also fails to state any valid causes of action against Defendant Sorsaia as there are insufficient facts plead that would allow this Court to reasonably infer that Defendant Sorsaia is liable for causing any harm to Plaintiff. Therefore, Defendant Sorsaia moves, pursuant to *Fed. R. Civ. P* 12(b)(1) and 12(b)(6), to be dismissed as a party to this case.

Relevant Allegations Pertaining to Defendant Sorsaia

The Complaint filed in this case consists of 33 pages and 111 paragraphs of allegations. [Doc. 1]. Only one paragraph makes specific reference to Defendant Sorsaia [Doc. 1, at par. 24]. Plaintiff alleges that Defendant Sorsaia is the Prosecuting Attorney for Putnam County, West Virginia, and has authority to prosecute violations of the Criminal Abortion Ban and other criminal restrictions on abortion in Putnam County. *Id.* Plaintiff also attributes the following quote to Defendant Sorsaia:

> "[a] s prosecutors we have a clear obligation to enforce the laws of our state. I believe if abortion is illegal no responsible medical provider will be doing them."

Id. Plaintiff further alleges in its Complaint that major national pharmacy chains, including, Walgreens and CVS, have indicated publicly that they intend to sell mifepristone and that West Virginia's abortion laws and restrictions may block Plaintiff from providing mifepristone through these healthcare distribution mechanisms. [Doc. 1, at par. 78]. Plaintiff alleges that Walgreens and CVS operate stores in Hurricane and Winfield. *Id.* Those named communities are located within Putnam County, West Virginia.

Argument

1. Plaintiff has failed to allege any justiciable claim against Defendant Sorsaia and therefore the claims asserted against him must be dismissed under Rule 12(b)(1).

Article III of the United States Constitution bestows upon the Judicial Branch the authority to adjudicate "Cases" and "Controversies." *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 90, 133 S. Ct. 721, 184 L. Ed. 2d 553 (2013) (citing U.S. Const. art. III, § 2). To establish a justiciable case, a plaintiff must show (1) "that he 'has sustained or is immediately in danger of sustaining some direct injury . . . or threat of injury [that is] both 'real and immediate,' not 'conjectural' or 'hypothetical'"; (2) that is fairly traceable to "the challenged official conduct"; and (3) the injury "is likely to be redressed by a favorable judicial decision." *Shenandoah Valley Network v. Capka*, 669 F.3d 194, 202 (4th Cir. 2012) (quoting *City of L.A. v. Lyons*, 461 U.S. 95, 101-02, 103 S. Ct. 1660, 75 L. Ed. 2d 675 (1983) (citations omitted); *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992))

Plaintiff cannot satisfy any of these required showings with respect to its claims against Defendant Sorsaia. First, Plaintiff has not alleged to have sustained or be in any immediate danger of sustaining any injury due to any official acts by Defendant Sorsaia in Putnam County. Plaintiff does not allege that it maintains any corporate presence within Putnam County, West Virginia or that is has engaged in any sales or marketing efforts relating to mifepristone in Putnam County.[1] Plaintiff has not alleged that there are any pending or threatened prosecutions in Putnam County relating to the sale or distribution of mifepristone. Nor has Plaintiff plead any specific facts or circumstances to indicate such a prosecution is reasonably probable. Plaintiff's claims against Defendant Sorsaia are tenuously based upon an alleged public quote that made no mention of the

[1] A search on the West Virginia Secretary of State's Office' website does not reflect that Plaintiff has yet registered as a foreign corporation seeking authorization to do business in West Virginia.

drug mifepristone and an allegation that the national chains Walgreens and CVS are motivated to sell mifepristone and maintain certain stores in Putnam County. The coexistence in Putnam County of a prosecutor who has generally spoken about a new abortion law and non-party businesses with some potential incentive to sell mifepristone is wholly insufficient so as to create an actual case in controversy as between Plaintiff and Defendant Sorsaia. Instead, any potential danger that Plaintiff is attributing to Defendant Sorsaia in this case is purely hypothetical and conjectural.

Second, the alleged harm that Plaintiff is alleging in this civil action is not traceable to Defendant Sorsaia. Plaintiff is not complaining about any actual or threatened prosecutions in Putnam County but about the potential adverse economic impacts of a statewide enforcement of the Criminal Abortion Ban that would restrict the distribution and sale of mifepristone. [Doc. 1, at par. 79]. The Complaint fails to set forth any facts to explain why this alleged economic injury is any more traceable to Defendant Sorsaia than it is to any of the other fifty-four (54) West Virginia County prosecutors who might seek to enforce the Criminal Abortion Ban.

Third, any order enjoining Defendant Sorsaia from initiating a prosecution in Putnam County relating to the sale of mifepristone will not afford the relief that Plaintiff desires. Plaintiff has plainly articulated that the relief it is seeking is a declaration by this Court that the Criminal Abortion Ban impact on mifepristone is unconstitutional on a statewide basis. [Doc. 1, at par. 91]. Plaintiff asserts that such a favorable ruling "will remedy these conflicts and redress GenBioPro's economic injury by enabling West Virginia to access its product." *Id.* In short, Plaintiff's ultimate success in this case does not depend upon obtaining any relief against Defendant Sorsaia.

2. Plaintiff has failed to allege any viable cause of action against Defendant Sorsaia and any claims against him must be dismissed under Rule 12(b)(6).

Plaintiff asserts two claims for relief in this case. Count I seeks this Court to declare that federal law preempts the West Virginia Abortion Ban. [Doc. 1, par. 93-101]. Count II seeks this Court to declare that the West Virginia Abortion Ban violates the Commerce Clause of the *United States Constitution*. [Doc. 1, par. 102-111]. Neither claim makes any specific reference to Defendant Sorsaia or to any specific facts or circumstances arising in Putnam County, West Virginia. The injunctive relief being sought by Plaintiff in connection with each claim is necessarily statewide.

In *Iqbal v. Ashcroft* 556 U.S, 662 (2009) the United States Supreme Court reiterated and amplified upon the principles relating to pleading a viable cause of action that it had announced two years earlier in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007). Specifically, the Supreme Court in *Iqbal* held:

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." … . A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.

556 U.S. at 678.

In this case, there is nothing alleged within the Complaint from which this Court may reasonably infer that Defendant Sorsaia is liable for any misconduct toward Plaintiff. The entire thrust of Plaintiff's Complaint is to prevent statewide enforcement of the Criminal Abortion Ban as related to distribution and sale of mifepristone. Unlike Defendant Morrisey, Defendant Sorsaia is vested with no legal authority or responsibility for defending these laws in the face of a constitutional challenge. Notably, *Fed. R. Civ. P.* 5.1(a)(2) expressly requires that a party

challenging the constitutionality of a state statute serve notice upon the state attorney general. There is no requirement that such notice be served upon any county prosecutors.

Moreover, Defendant Sorsaia is not alleged to have initiated or threatened any prosecutions to enforce the Criminal Abortion Ban nor have any specific facts been plead to indicate that Plaintiff or any other party is at risk of facing any such a prosecution in Putnam County. Again, Defendant Sorsaia's alleged general quote about the new abortion law together with presence of national chain pharmacy stores in Putnam County are wholly insufficient facts to give rise to a viable cause of action. Walgreens and CVS are not even named parties to this case, and the Complaint alleges no facts to show why these businesses are at greater risk of suffering harm in Putnam County. If Plaintiff had any serious concern when filing this case that Mr. Sorsaia was going to prosecute the distribution or sale of mifepristone in Putnam County, it would have surely sought a preliminary injunction to prevent such a prosecution pending the resolution of this case on the merits. In short, the Complaint lacks the facial plausibility required by *Iqbal* to demonstrate that Plaintiff is at risk of suffering any imminent harm due to the conduct of Defendant Sorsaia.

WHEREFORE, and for the reasons and grounds stated above, Defendant, Mark A. Sorsaia, moves that this Court enter an Order dismissing the Complaint filed against him, with prejudice, and grant him such other relief to which the Court may deem he is entitled.

MARK A SORSAIA, ***in his official capacity as Prosecuting Attorney of Putnam County***

By Counsel

/s/ Jennifer Scragg Karr
Jennifer Scragg Karr (WV Bar #8051)
Assistant Prosecuting Attorney
Putnam County Judicial Building
12093 Winfield Road
Winfield, WV 25213
(O) 304-586-0205
(F) 304-586-0269
jkarr@putnamwv.org

Attorney for Defendant Mark A. Sorsaia

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

HUNTINGTON DIVISION

GENBIOPRO, INC.

Plaintiff

vs.

Civil Action No: 3:23-cv-00058 (CHAMBERS)

MARK A. SORSAIA, ***in his official capacity as Prosecuting Attorney of Putnam County,*** **and, PATRICK MORRISEY,** ***in his official capacity as Attorney General in West Virginia,***

Defendants

CERTIFICATE OF SERVICE

I, the undersigned, counsel for Defendant, Mark A. Sorsaia, do hereby certify that on this 16th day of February, 2023 I served a copy of the foregoing ***Memorandum of Law in Support of Defendant Mark Sorsaia's Rule 12(b)(1) and Rule 12(b)(6) Motion to Dismiss*** with the Clerk of the Court using the CM/ECF system that will send notification of such filing to all counsel of record.

/s/ Jennifer Scragg Karr
Jennifer Scragg Karr (WV Bar #8051)
Assistant Prosecuting Attorney
Putnam County Judicial Building
12093 Winfield Road
Winfield, WV 25213
(O) 304-586-0205
(F) 304-586-0269
jkarr@putnamwv.org

Attorney for Defendant Mark A. Sorsaia

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

***Plaintiff*,**

v. **Civil Action No. 3:23-cv-00058**

MARK A. SORSAIA, in his official capacity, AND PATRICK MORRISEY, in his official capacity, **Hon. Robert C. Chambers**

Defendants.

MOTION TO DISMISS

Defendant, Patrick Morrisey, in his official capacity as Attorney General of the State of West Virginia, respectfully moves this Court under Fed. R. Civ. P. 12(b) for an order dismissing Plaintiff's complaint. As further explained in the Memorandum in Support of this Motion filed contemporaneously herewith, dismissal is proper here because Plaintiff lacks standing, as it has not shown an injury in fact or redressability, *see* Fed. R. Civ. P. 12(b)(1), and Plaintiff fails to state claims upon which relief may be granted, *see* Fed. R. Civ. P. 12(b)(6).

For these reasons, as laid out in full in the accompanying memorandum in support, the Court should dismiss the Complaint.

Respectfully submitted,

By counsel,

PATRICK MORRISEY
West Virginia Attorney General

/s/ Curtis R. A. Capehart
Douglas P. Buffington II (WV Bar # 8157)
Chief Deputy Attorney General
Curtis R.A. Capehart (WV Bar # 9876)
Deputy Attorney General

OFFICE OF THE WEST VIRGINIA ATTORNEY GENERAL
State Capitol Complex
1900 Kanawha Blvd. E, Building 1, Room E-26
Charleston, WV 25305-0220
Telephone: (304) 558-2021
Facsimile: (304) 558-0140
Email: Curtis.R.A.Capehart@wvago.gov

Denise M. Harle *
ALLIANCE DEFENDING FREEDOM
1000 Hurricane Shoals Rd. NE, Ste. D-1100
Lawrenceville, GA 30043
Tel.: (770) 339-0774
Fax: (770) 339-6744
dharle@adflegal.org

Erin M. Hawley *
ALLIANCE DEFENDING FREEDOM
440 First Street NW, Ste. 600
Washington, DC 20001
Tel.: (202) 393-8690
Fax: (202) 347-3622
ehawley@adflegal.org

* Visiting Attorneys (visiting attorney fees paid to West Virginia State Bar; Statements of Visiting Attorneys forthcoming)

Counsel for Defendant, Patrick Morrisey, in his official capacity as Attorney General of the State of West Virginia

DATE: February 21, 2023

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

***Plaintiff*,**

v. **Civil Action No. 3:23-cv-00058**

MARK A. SORSAIA, in his official capacity, AND PATRICK MORRISEY, in his official capacity, **Hon. Robert C. Chambers**

Defendants.

CERTIFICATE OF SERVICE

I hereby certify that, on this 21st day of February, I electronically filed the foregoing "Motion to Dismiss" with the Clerk of Court and all parties using the CM/ECF System.

/s/ Curtis R. A. Capehart
Curtis R. A. Capehart
Deputy Attorney General

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

***Plaintiff*,**

v. **Civil Action No. 3:23-cv-00058**

MARK A. SORSAIA, in his official capacity, AND PATRICK MORRISEY, in his official capacity, **Hon. Robert C. Chambers**

Defendants.

[PROPOSED] ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

Defendant, Patrick Morrisey, in his official capacity as Attorney General of the State of West Virginia, through counsel, filed a motion to dismiss [ECF No. XX] on February 21, 2023. Having considered Defendant's Memorandum in Support [ECF No. XX], Plaintiff's Response in Opposition [ECF No. XX], and Defendants' Reply [ECF No. XX], the Court concludes both that Plaintiff lacks standing to bring its claims, and, even if it had standing, its counts fail to state a claim upon which relief can be granted. *See* Fed. R. Civ. P. 12(b)(1), (6). Accordingly, the Court **GRANTS** Defendant's motion and **ORDERS** that the complaint [ECF No. 1] be dismissed.

ORDERED:_____, 2023
/s/_____
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

***Plaintiff*,**

v. **Civil Action No. 3:23-cv-00058**

MARK A. SORSAIA, in his official capacity, AND PATRICK MORRISEY, in his official capacity, **Hon. Robert C. Chambers**

Defendants.

MEMORANDUM IN SUPPORT OF MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Rules

Constitutional Provisions

Legislative Materials

INTRODUCTION

Plaintiff GenBioPro, a pharmaceutical company that manufacturers the chemical abortion drug mifepristone,[1] makes the sweeping claim that the Food and Drug Administration's ("FDA") approval of the drug and its imposition of additional safety requirements somehow preempts any state law that results in some impact on the drug's use or sale, including every state law regulating abortion, and that any such law is invalid under the dormant Commerce Clause. GenBioPro's ("GBP") claims turn on the peculiar argument that Congress gave a federal agency the power to mandate nationwide abortion access vis-à-vis an administrative review process focused on patient safety and effectiveness as well as an obscure and rarely used provision in the Federal Food Drug and Cosmetic Act ("FDCA"). To be clear, nothing in the text of the FDCA suggests that Congress authorized FDA to exercise such extraordinary power to displace states in addressing matters of health care practice and prescriptive authority, let alone over the social and political issue that is abortion. Also, it more than strains belief to suggest that the U.S. Supreme Court in *Dobbs* failed to recognize the FDCA's alleged import when it held that the people of the states may enact laws protecting unborn life "at every stage of development." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022). In reality, FDA has long existed as gatekeeper setting a federal floor on which complementary state legislation may build. This Court should dismiss this lawsuit.

FACTS

A. The Federal Food, Drug, and Cosmetic Act

In 1906, Congress passed the Federal Food and Drugs Act to "supplement[]" "state regulation" of adulterated and misbranded drugs. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). In 1938, Congress enacted the FDCA which, as amended, requires a manufacturer to show its drug

[1] The Complaint states that GenBioPro also manufactures misoprostol, which is the second drug in a 2-drug series with mifepristone used to cause a chemical abortion.

is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling before it [can] distribute the drug." *Id.* at 567 (cleaned up). Through many iterations and amendments to the FDCA, "Congress took care to preserve" parallel state laws protecting the public health. *Id.* The 1962 amendments, in particular, included an express saving clause, providing that "a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA." *Id.*

In 2007, Congress amended the FDCA to subject medications that present "serious safety concerns" to additional restrictions. Pub. L. No. 110-85, 121 Stat. 823 (2007). That amendment directed FDA to adopt a new "drug safety program," known as the "Risk Evaluation and Mitigation Strategy" (REMS), when necessary to ensure a drug's benefits outweigh its risks. 21 U.S.C. § 355-1. And for "drugs with known serious risks," that are "associated with a serious adverse" experience, the REMS must include "elements to assure safe usage" ("ETASUs"). *Id.* § 355-1(e)-(f). Because of serious safety concerns and documented adverse experiences, FDA established both REMS and ETASUs for mifepristone. Compl. ¶ 54, ECF No. 1 (only 97 of more than 20,000 FDA-approved prescription drugs were concerning enough for ETASUs).

In 2016, FDA revised the REMS for mifepristone to increase the gestational age limit, change the dosage and route of administration, reduce the number of required in-person office visits, allow non-physicians to prescribe and administer the drug, and eliminate the requirement for prescribers to report nonfatal adverse events. Then, in 2021, FDA revised the REMS again, allowing prescribers to dispense mifepristone by mail or mail-order pharmacy.[2]

[2] These various decisions relative to mifepristone are the subject of ongoing litigation elsewhere.

B. The West Virginia Legislature's efforts to protect unborn life

Like most states, West Virginia long had a statute protecting unborn life and prohibiting abortion, which here included an exception for abortions "done in good faith, with the intention of saving the life of such woman or child." W. VA. CODE § 61-2-8. This statute protected unborn life until the Supreme Court issued *Roe v. Wade* in 1973.

Thereafter, the West Virginia Legislature (the "Legislature") continued to do what it could to protect unborn life and maternal health, as well as related medical practice, over the coming decades, enacting numerous statutes in the 20th century.[3] Since 2000, the Legislature enacted yet more statutes,[4] including 2017's amendment to § 30-3-13a(g)(5) limiting telemedicine prescribing authority for drugs to cause an abortion, effectively requiring in-person examination to determine gestational age and detect ectopic pregnancies.

In June 2022, the Supreme Court overturned *Roe v. Wade* and held that abortion is an issue the Constitution entrusts to "the people and their elected representatives." *Dobbs*, 142 S. Ct. at 2284. As a result, the Court returned the issue to "the citizens of each State," holding that States may protect their "legitimate interests" in protecting unborn life, maternal health, and protecting the integrity of the medical profession. *Id.*

In a special session in September 2022, the Legislature largely replaced its previous abortion regulations with the Unborn Child Protection Act. W. VA. CODE §§ 16-2R-1–9 (the

[3] *See, e.g.*, W. VA. CODE § 16-2F-3–8 (parental notification and reporting requirements adopted in 1984); § 9-2-11 (enacted in 1993, prohibited state funds from paying for abortions); § 33-42-8 (enacted in 1998, subjected the doctors who performed partial-birth abortions to criminal penalties).

[4] *See, e.g.*, W. VA. CODE §§ 16-2I-1–8 (enacted in 2003, required informed-consent); § 61-2-30 (enacted in 2005, the Unborn Victims of Violence Act, making "a pregnant woman" and her child "separate and distinct victims" of crimes); § 16-2M-2–6 (a pain-capable law enacted in 2015); §16-2O-1 (enacted in 2016, prohibited dismemberment abortions); § 16-2P-1 (enacted in 2020, required medical care for a baby born-alive via abortion); §16-2Q-1 (prohibited abortions based on disability discrimination, enacted in 2022).

"UCPA" or the "Act").[5] That statute made abortions unlawful except (1) when, "in the reasonable medical judgment of a licensed medical professional," the child is not viable, the pregnancy is ectopic, or there is a medical emergency; or (2) in cases of rape or incest before 8 weeks, or 14 weeks for a minor. *Id.* § 16-2R-3(a)–(c). The Act defines "abortion" to exclude miscarriages, stillbirths, and in vitro fertilization. *Id.* Any "licensed medical professional" as defined in the Act[6] who violates §16-2R-3 shall have their license revoked. *Id.* § 16-2R-7.

In the same bill, West Virginia amended its pre-*Roe* criminal statute to clarify that non-licensed medical professionals are prohibited from performing abortions. *Id*. § 61-2-8. That bill also required health care boards to adopt implementing rules regarding "[a] prohibition of prescribing or dispensing an abortifacient" relative to telemedicine. *Id*. § 30-1-26(b)(9).[7]

On January 25, 2023, GBP filed this Complaint, asking the Court to declare the UCPA unconstitutional, along with: (1) the criminal prohibition on non-licensed medical professionals providing abortions, *id.* § 61-2-8; (2) the telemedicine prescribing authority limitations regarding abortifacients and related directive regarding health care board rules, *id.* §§ 30-1-26(b)(9), 30-3-13a(g)(5); and (3) two of the dormant provisions requiring informed consent and patient counseling, *id.* §§ 16-2I-2, 16-2I-9, under the Supremacy and Commerce Clauses of the United States Constitution.

---

[5] The Unborn Child Protection Act provides that most prior abortion regulations are "of no force or effect" unless any part of the Act was declared unconstitutional. 2022 W. Va. H.B. 302 (making inoperative § 16-2F-1–9) (parental notification and reporting requirements), e.g., § 16-2I-1–9 (informed consent).

[6] Those licensed under Chapter 30, Articles 3 (Medical Practice Act) and 14 (Osteopathic Physicians and Surgeons).

[7] The Legislature had previously limited telehealth prescribing authority in this area in 2019, adding language directing that "A physician or health care provider may not prescribe any drug with the intent of causing an abortion." W. VA. CODE §30-3-13a(g)(5).

LEGAL STANDARD

Under Fed. R. Civ. P. 12(b)(1), a complaint must be dismissed when the court lacks subject-matter jurisdiction, *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998), as when the facts are undisputed and "the moving party is entitled to prevail as a matter of law," *Napper v. United States*, 374 F. Supp. 3d 583, 587 (S.D. W. Va. 2019). Proving jurisdiction is GBP's burden. *Richmond, Fredericksburg & Potomac R.R. Co. v. United States*, 945 F.2d 765, 768 (4th Cir. 1991).

Under Fed. R. Civ. P. 12(b)(6), a complaint states a claim if it contains "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (cleaned up). The factual allegations must "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). The Court need not "accept as true a legal conclusion couched as a factual allegation." *Id.* at 555.

ARGUMENT

GBP requests that this Court declare unconstitutional multiple acts of the Legislature on proper matters of state regulation because, in essence, these laws get in the way of GBP marketing and selling as many chemical abortion drugs as possible everywhere. GBP clothes such financially motivated claims in theories of preemption and the "Dormant" Commerce Clause. But both of those theories would require this Court to determine that Congress delegated authority—not just as to judgments of medication safety and efficacy—but to set national policy on the regulation of medical practice and abortion as a coincidence of safety and efficacy determinations That claim fails the straight-face test.

First, GBP fails to meet the most basic Article III requirement of injury in fact. It does not even allege that it has *ever* sold its chemical abortion drug in West Virginia. That admission is fatal to Article III jurisdiction and forecloses all of GBP's claims.

Second, under separation of powers principles, the major questions doctrine, and, indeed, ordinary statutory interpretation principles, GBP must point to clear congressional authorization empowering the FDA to mandate matters of medical practice, including nationwide abortion. But it cannot. Congress did not silently cede this vast area of historically state regulation to the FDA. *Hillsborough Cnty. v. Automated Med. Laboratories,* 471 U.S. 707, 719 (1985) (regulating "health and safety matters is primarily, and historically, a matter of local concern"). *Dobbs* unequivocally reaffirms this in the abortion context.

GBP's preemption claims doubly fail because Plaintiff has failed to establish any federal policy supporting its claimed right to "promote and market" abortion drugs nationwide. GBP argues that the FDA created national abortion access and removed states' ability to regulate abortion simply by approving one drug. That is a specious interpretation of the FDCA, which itself. is notably silent on the issue of abortion, and GBP fails to show that the FDCA has *ever* been interpreted to require nationwide access to any drug.[8] Congress defines the FDA's purpose much more narrowly "ensuring that … drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B). GBP cannot show any conflict with federal law or policy; its preemption claims must fail.

Third, GBP's Commerce Clause claims fail because a minor decrease in a pharmaceutical company's bottom line in West Virginia does not outweigh the State's legitimate interests in protecting its most vulnerable lives. This Court should dismiss the Complaint.

I. GBP lacks standing.

To ensure an Article III case or controversy, a plaintiff must show the "irreducible constitutional minimum of standing," which "contains three elements": (1) "an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be

[8] Indeed, other federal laws prohibit the mailing of abortion drugs.

redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 n.7 (2016). "[S]tanding cannot be inferred argumentatively from averments in the pleadings"; a plaintiff must allege facts "essential to show jurisdiction." *FW/PBS, Inc. v. Dallas*, 493 U.S. 215, 231 (1990).

GBP fails to allege an injury in fact. An injury in fact must be "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Spokeo*, 578 U.S. at 339 (cleaned up). Most of GBP's alleged harms—those regarding patient access, Compl. ¶¶ 15, 73(a)–(c), 83, and provider options, *id.* ¶ 16—are not particularized because they do not affect Plaintiff "in a personal and individual way." *Spokeo*, 578 U.S. at 339; *Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004) (party must assert its own rights and interests).

GBP's other allegations are conjectural and hypothetical. Nowhere does GBP allege that it has ever sold chemical abortion drugs in West Virginia, nor does it allege any specific plan to do so. Rather, it claims the challenged laws have hurt its "*opportunity* and *ability* to market, promote, and sell" its drugs, Compl. ¶ 15; *accord* ¶¶ 77, 85, which, in turn, restricts its "pool of *potential* customers," thus costing it "lost sales, customers, and revenue," *id.* ¶ 79 (emphasis added). But Plaintiff's "'some day' intentions—without any description of concrete plans, or indeed even any specification of *when* the some day will be—do not support a finding of the 'actual or imminent' injury that our cases require." *Lujan v. Defs. of Wildlife,* 504 U.S. 555, 564 (1992). *See also Doe v. Obama*, 631 F.3d 157, 162 (2011) (parents "actively considering adopting" human embryos did not satisfy *Lujan*'s requirement that injuries "proceed with a high degree of immediacy").

GBP also fails to show redressability. First, it is much "more difficult to show standing" when one's "asserted injury arises from … allegedly unlawful regulation of someone else" because redressability then hinges on that third party's response. *Lujan*, 504 U.S. at 562. In such a case, the plaintiff must "adduce facts showing that those choices have been or will be made in such

manner as to … permit redressability of injury." *Id.* Here, the challenged laws address licensed medical professionals, not drug manufacturers like GBP. And GBP has not sufficiently alleged that, even if the challenged laws were overturned, its product would necessarily benefit.

Second, a favorable decision by this Court will not redress GBP's injuries because their business model to ship drugs into West Virginia is illegal under federal law. *See* 18 U.S.C. §§ 1461, 1462 (criminalizing using the mail and common carriers to move abortion drugs across state lines).

Third, GBP cannot possibly show redressability for W. VA. CODE §§ 16-2I-2 and 16-2I-9. As GBP notes, those provisions are not operative now and become operative only if part of the UCPA is held unconstitutional. Compl. ¶ 68. But GBP's UCPA claims fail, *see infra* Sections II and III, leaving Plaintiff no standing to challenge §§ 16-2I-2 and 16-2I-9. *California v. Texas*, 141 S. Ct. 2104, 2116 (2021) (unenforceable statutory provision is incapable of meeting the redressability requirement).

II. Congress did not delegate the ability to set nationwide abortion policy or displace state laws regulating medical practice.

A. FDA does not have the authority to set national abortion policy.

GBP claims that the FDCA "delegates to FDA exclusive authority" to balance the competing interests on abortion—one of the most consequential social and moral issues of our day—and mandate *nationwide* abortion access. Compl. ¶ 82. GBP believes Congress gave FDA the authority to unilaterally decide that chemical abortion should be legal in all 50 States and that FDA has exercised that authority by approving mifepristone.

That is a breathtaking assertion of federal agency power. It is blackletter law that FDA—like any other federal agency—has only the power given it by Congress. Thus, before this Court need even address GBP's preemption claim, it must first confront a more fundamental question of

agency power: "whether Congress in fact meant to confer the power the agency has asserted." *West Virginia v. Env't Prot. Agency*, 142 S. Ct. 2587, 2607–08 (2022). Nothing in the text of the FDCA suggests that Congress accorded FDA the unilateral—and indeed, "exclusive" power, to use GBP's word—to set national abortion policy. Under ordinary principles of statutory interpretation, that contention fails; the FDCA's text does not so much as mention abortion. Nor does it direct FDA to consider the legitimate and important state interests in protecting unborn life, maternal health, and the integrity of the medical profession—interests that the Supreme Court in *Dobbs* returned to elected representatives. This conclusion is reinforced by separation-of-powers principles, which compel reviewing courts to find "clear congressional authorization" for expansive assertions of agency authority, such as here. *Id*.

Under the major questions doctrine, "courts expect Congress to speak clearly if it wishes to assign to an agency decisions of vast economic and political significance." *Util. Air Regul. Grp. v. Env't Prot. Agency*, 573 U.S. 302, 324 (2014) (cleaned up); *see also West Virginia*, 142 S. Ct. at 2609 (courts must "presume that Congress intends to make major policy decisions itself, not leave those decisions to agencies") (cleaned up). Terminating a pregnancy is an issue with "profound moral and spiritual implications … even [at] its earliest stage." *Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 850 (1992). "[T]his is a major questions case." *West Virginia*, 142 S. Ct. at 2610. Accordingly, GBP must more than a "plausible textual basis" for its claim that Congress yielded nationwide abortion policy to the FDA. *Id.* at 2609. It must (but cannot) proffer "clear congressional authorization." *Id.*

The only statutory support GBP offers is the REMS provision, 21 U.S.C. § 355-1. But that provision merely requires FDA to ensure that the *additional* safety requirements that FDA *itself* imposes on drugs with known serious risks associated with adverse reactions are not "unduly

burdensome on patient access to the drug." *Id.* § 355-1(f)(2)(C). In no way does that provision give FDA "clear congressional authorization" to overrule the policy judgment of states on a different question: whether they will allow abortions and, if so, when and how. It would be strange indeed for such an "extraordinary grant[] of regulatory authority" to be accomplished through such a "subtle device" like the REMS requirement. *See West Virginia*, 142 S. Ct. at 2609 (cleaned up).

Further, the FDCA has long been understood to set a federal *floor* on the approval of drugs, allowing complementary state regulations. *See Wyeth*, 555 U.S. at 555. Plaintiffs therefore "claim[] to discover in a long-extant statute an unheralded power" representing a "transformative expansion in [FDA's] regulatory authority." *UARG*, 573 U. S. at 324. This "newfound power" to regulate abortion hidden "in the vague language of an ancillary provision" of the FDCA, would allow FDA "to adopt a regulatory program that Congress ha[s] conspicuously and repeatedly declined to enact itself," *West Virginia,* 142 S. Ct. at 2610; *see* Women's Health Protection Act of 2021, H.R.3755, 117th Cong. (2021) (failed to pass). As the Supreme Court said in another FDA case, "Congress could not have intended to delegate" such a sweeping and consequential authority "in so cryptic a fashion." *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000). Such is the case here, and GBP's claims fail as a matter of law.

B. FDA's approval of mifepristone plus a REMS does not preempt state law.

Even if Congress had given FDA the authority to mandate abortion nationwide (it did not), GBP's preemption claim fails as a matter of law. GBP argues that FDA's approval of mifepristone coupled with the imposition of additional REMS restrictions placed on drugs with elevated risks somehow preempts the ability of the people in every state, including West Virginia, to address abortion anew as permitted under *Dobbs*.

The Supremacy Clause makes federal law "the supreme Law of the Land." U.S. CONST. art. VI, cl. 2. Yet a preemption analysis starts with the assumption that "the historic police powers

of the States are not [to be] superseded unless that was the clear and manifest purpose of Congress." *Arizona v. United States*, 567 U.S. 387, 400 (2012) (cleaned up). This is especially true when Congress legislates "in a field which the States have traditionally occupied," such as public health and safety regulations. *Wyeth*, 555 U.S. at 565.

GBP does not pretend that any law expressly grants FDA preemption authority over West Virginia's ability to protect life or health or regulate the practice of medicine, so it is left only with disfavored "implied preemption." *See Kansas v. Garcia*, 140 S. Ct. 791, 807–08 (2020) (Thomas, J., concurring). There are three kinds of implied preemption: (1) field preemption, inferred from a "pervasive" framework of regulation; (2) impossibility preemption where "compliance with both federal and state regulations is a physical impossibility"; and (3) obstacle preemption where "the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona*, 567 U.S. at 399 (cleaned up). GBP cannot show field preemption, gesturing instead towards impossibility and obstacle preemption. Both theories fail.

1. Compliance with both federal and state law is not impossible.

Under impossibility preemption, federal law preempts state law only when state law "directly conflict[s]" with federal law. *AT&T Co. v. Cent. Off. Tel., Inc.*, 524 U.S. 214, 227 (1998). Or, put differently, when the "state law penalizes what federal law requires." *Geier v. Am. Honda Motor Co.,* 120 S. Ct. 1913, 1921 (2000). This "is a demanding" standard to meet. *Wyeth*, 555 U.S. at 573. The "*possibility* of impossibility [is] not enough." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 625, n. 8 (2011) (emphasis added) (cleaned up). Rather, the Court must see "clear evidence" of impossibility, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678 (2019), and will not find "impossibility where the laws of one sovereign permit an activity that the laws of the other sovereign restrict or even prohibit." *Id.*

GBP argues that it cannot comply with both West Virginia's challenged laws and the mifepristone REMS.[9] Compl. ¶ 85. This is untrue. For a finding of impossibility preemption, state law must command something that federal law forbids or forbid something that federal law commands. *Mensing*, 564 U.S. at 620. Nothing in West Virginia law prevents GBP from complying with mifepristone's REMS requirements. In fact, West Virginia law does not require GBP to do anything or prevent it from marketing or selling mifepristone. This reveals GBP's real complaint: it believes West Virginia law negatively impacts its "opportunity and ability to market, promote, and sell the [chemical abortion drug] in the State," Compl. ¶ 15, and that is an impossibility-preemption nonstarter. While GBP may desire to sell lots of mifepristone in West Virginia, the company is under no *federal requirement* to do so—or to sell any— and its claim of impossibility preemption fails as a matter of law.[10]

2. The Unborn Child Protection Act does not conflict with federal law.

GBP next contends that the UCPA's provisions "frustrate and conflict" with federal law, namely its purported "authority to sell mifepristone nationwide." Compl. ¶ 15. Yet Congress has clearly stated FDA's purpose: to "protect the public health by ensuring that … drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B).

The UCPA does not second-guess FDA's determinations as to the safety or efficacy of mifepristone. Rather, the FDCA does something else entirely: it protects unborn human life. The Legislature's determination that unborn human life is worthy of protection has nothing to do with the safety or efficacy of any drug, including mifepristone. The UCPA is no more about mifepristone than it is about scalpels. Indeed, mifepristone may still be used in West Virginia to

[10] To the extent GBP focuses on specific restrictions under West Virginia law, *i.e*, the telehealth and dormant counseling and informed consent provisions, those laws do not directly conflict with any REMS, either.

treat Cushing syndrome or cancer and to complete a miscarriage. That the law does not prevent mifepristone from being used as an abortifacient in the few situations exempt from the general prohibition on abortions conclusively demonstrates that the Legislature was concerned with saving unborn lives, not assessing the safety of any drug.

GBP's claim that FDA approval requires nationwide drug access would work a fundamental change in the FDCA. That statute has never been interpreted to require national access. Thus, FDA has never required pharmaceutical companies to sell approved drugs or placed price caps on approved products to ensure access. Indeed, were GBP correct that the mere approval of a drug forces states to allow the use of the drug despite a state's authority to prohibit criminal conduct, FDA approval of a euthanasia drug would preempt state laws forbidding the practice. *But see Washington v. Glucksberg*, 521 U.S. 702, 719–26 (1997) (upholding ban on assisted suicide).[11]

Perhaps recognizing that FDA's mere approval of a drug has never been understood to mandate nationwide access, GBP next suggests there is something special about REMS. According to Plaintiff, FDA's additional imposition of REMS safety requirements "establishes both a 'floor' and 'ceiling' on permissible regulation of mifepristone" and thus preempts West Virginia law. *See ibid*. at ¶ 82, ¶¶ 87–90. GBP thus makes the counterintuitive argument that the graver the danger from a drug (reflected in greater protective requirements from FDA), the more certain it is that states have no place to take any action that could impact that drug. That argument fails for several reasons.

[11] *Zogenix, Inc. v. Patrick*, 2014 WL 1454696 (D. Mass. Apr. 15, 2014) is not to the contrary. In completely banning Zohydro ER, Massachusetts was not concerned with the underlying conduct – pain management – but with FDA's safety determination, banning the drug due to concerns it would "lead to opioid addiction and overdose fatalities." 2014 WL 1454696, at *1. And, again, West Virginia law does nothing to ban mifepristone.

First, it defies belief to suggest that the FDA's imposition of *additional* safeguards on objectively more dangerous drugs would somehow displace the states' traditional authority to regulate for health and safety, regulate the state-licensed practice of medicine, and implement criminal law.

Second, such an interpretation runs headlong into the "touchstone" of preemption analysis: "the purpose of Congress." *Wyeth*, 555 U.S. at 565. GBP's reading cannot be drawn from historical context or statutory language, and the statute itself is silent on abortion. And through many FDCA amendments, "Congress took care to preserve" parallel state laws protecting the public health, expressly providing that "a provision of state law would *only* be invalidated upon a 'direct and positive conflict' with the FDCA." *Wyeth*, 555 U.S. at 567 (emphasis added). Such direct and positive conflict is simply absent here.

Third, GBP rests its novel interpretation of FDA's "determinations as to the balance Congress mandated between safety-based restrictions and patient access to the drug." Compl. ¶ 85. But that statutory directive is plainly tasking FDA with ensuring that its own restrictions do not unduly limit access to inherently dangerous drugs; the text does not suggest these dangerous drugs must be uniformly accessible for all purposes or that states may not impose regulation based on interests the FDA did not consider. In fact, the *Wyeth* Court rejected a similar argument—that the "precise balancing of risks and benefits" required by the FDCA left "no room for different state-law judgments." 555 U.S. at 575. That argument, according to the Court, "relie[d] on an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law." *Id*. at 573.

The same is manifest here in GBP's Complaint. Its arguments about balancing drives home the point that Congress did *not* delegate the authority to regulate abortion to the FDA. Were

Congress in fact to delegate to an agency the authority to decide nationwide abortion policy or otherwise displace traditional state issues, it would have at a minimum included the relevant factors. Yet none of the REMS factors say anything about considering interests in protecting unborn life – an undeniable part of any abortion decision. *See Casey*, 505 U.S. at 866–67. Nor do the REMS factors say anything about other important interests like "the elimination of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical profession; the mitigation of fetal pain; and the prevention of discrimination on the basis of race, sex, or disability." *Dobbs*, 142 S. Ct. at 2284.

At the end of the day, GBP can identify no federal law or policy mandating nationwide abortion access up to ten weeks gestational age (or any other time frame) that is frustrated by West Virginia law. Not a page of the voluminous briefing in *Dobbs* nor any one of the Court's many separate opinions flagged that there might be a national 10-week protection for chemical abortions either. In fact, Congress specifically declined to enact such a law following the Supreme Court's decision in *Dobbs*. H.R.3755, 117th Cong. (2021). And federal law points the opposite direction, by limiting access to abortion drugs, not promoting it. *See* 18 U.S.C. §§ 1461, 1462 (shipping abortifacients is illegal).

Were there any doubt as to whether Congress might have delegated the authority to mandate nationwide access (and there is not), it would be foreclosed by the presumption against preemption. Where, as here, the area involves matters of historically local concern, the Court "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). It is impossible to find that it was the "clear and manifest purpose of Congress" in enacting the FDCA to "supersede[ ]" the States' "historic police power"

to protect the health and safety of its citizens, regulate the practice of medicine, and implement criminal law. *Wyeth*, 555 U.S. at 565. This Court should dismiss the preemption challenge to the UCPA.

3. West Virginia's other challenged laws do not conflict with federal law.

Plaintiff also seeks to invalidate as preempted West Virginia's determination that certain drugs should only be prescribed during in-person visits and not via telemedicine, W. VA. CODE §§ 30-1-26(b)(9), 30-3-13a(g)(5), as well as two dormant provisions of law requiring informed consent and patient counseling, *id.* §§ 16-2I-2, 16-2I-9.

The presumption against preemption applies with full force here, too. West Virginia retains the police power to regulate how drugs may be prescribed and dispensed by medical professionals. *See Gonzales v. Oregon*, 546 U.S. 243, 270–71 (2006). This presumption ensures that "the federal-state balance," will not "be disturbed unintentionally by Congress." *Jones*, 430 U.S. At 525. And as explained above, Congress has long recognized the complementary nature of additional state regulations, enacting a specific savings clause. It could have explicitly preempted state laws governing pharmaceuticals—as it did with medical devices—but "did not do so." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008). Congress's refusal to do so, coupled with long-time state regulations, is powerful evidence that it did not intend FDA's oversight role to replace state legislation. *See Wyeth*, 555 U.S. at 574.

Indeed, FDA has never pretended the FDCA preempts state regulation of chemical abortion procedures. Just the opposite. Mifepristone's current REMS says certain healthcare providers may prescribe the drug, but that state law will govern whether non-physicians may do so: "Some states allow healthcare providers other than physicians to prescribe medications. Healthcare providers

should check their individual state laws." FDA, *Q&A on Mifeprex*, https://tinyurl.com/4jtfrjm8. This is an express acknowledgement that providers must comply with state law.[12]

In any event, the challenged laws complement rather than frustrate the purpose of the REMS. With respect to mifepristone, in-person appointments allow a physician to safely care for a pregnant mother by determining gestational age and for any other purpose, such as diagnosing an ectopic pregnancy. There is no conflict between the REMS and these modest regulations—regulations that are not even focused on mifepristone—or the patient counseling and informed consent provisions, certainly not one "strong enough to overcome the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation." *Hillsborough Cnty.*, 471 U.S. at 716.

Finally, as noted above, it is especially unlikely that a state prescription law preventing the prescription of abortifacients via telemedicine care violates any congressional objective given that Congress has prohibited the transmission of such drugs via the mails. *See* 18 U.S.C. §§ 1461, 1462. Given these laws, there is no basis for concluding that West Virginia's limitation on prescribing authority in such circumstances undermine any federal purpose.

III. GBP's Commerce Clause claim fails.

GBP argues that West Virginia's challenged laws violate the dormant aspect of the Commerce Clause. Compl. ¶ 17. Federal courts have "a two-tiered approach to" Dormant Commerce Clause challenges. *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 578 (1986). "First, state regulations may not discriminate against interstate commerce; and

[12] REMS are not even "agency regulation[s] with the force of law [that] can pre-empt conflicting state requirements," *Wyeth*, 555 U.S. at 576, because they are not adopted under the Administrative Procedures Act. *See Anderson v. Eby*, 998 F.2d 858, 863 (10th Cir. 1993) ("to have the force of law, at a minimum" a regulation must be "adopted according to the procedures embodied in the Administrative Procedures Act").

second, States may not impose undue burdens on interstate commerce." *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2091 (2018). There is no reasonable argument that West Virginia's abortion law discriminates against interstate commerce—either "facially, in its practical effect, or in its purpose." *McBurney v. Young*, 667 F.3d 454, 468 (4th Cir. 2012). Beyond that, GBP's claim that West Virginia's law unduly burdens interstate commerce, *see* Compl. ¶ 104, fails for two reasons.

First, the challenged laws survive because they do not unduly burden interstate commerce under *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). "Where the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *Id.*

Pike is a deferential test, with federal courts "recognizing [their] own institutional limitations" and "giving due deference to [the legislature] whose primary responsibility it is to judge the benefits and burdens" of state legislation. *Colon Health Centers of Am., LLC v. Hazel*, 813 F.3d 145, 156 (4th Cir. 2016). Federal courts are doubly cautious when considering healthcare legislation because that field "is infamously complicated, with patients, providers, insurers, government, and many others all attempting to come to terms over a particular service touching physical wellbeing and *sometimes even life itself*." *Id.* at 159–60 (emphasis added).

Legitimate interests. The court need not search far for legitimate state interests "because the Supreme Court has already done so." *Sandlands C & D LLC v. Cnty. of Horry*, 737 F.3d 45, 53 (4th Cir. 2013). West Virginia's important interests include: preserving unborn life and mitigating fetal pain, protecting a mother's health and safety, eliminating "gruesome or barbaric medical procedures," maintaining the medical profession's integrity, and preventing "discrimination on the basis of race, sex, or disability." *Dobbs*, 142 S. Ct. at 2284.

Incidental burden. GBP again claims that the challenged laws "preclude" the use of mifepristone and "ban[] an article of commerce." Compl. ¶ 104. Not so. West Virginia law regulates only primary conduct—that of aborting an unborn child—and leaves mifepristone untouched for other purposes, such as treating cancer or Cushing disease, as well as for any legal abortion within one of the Act's exceptions, including medical emergencies, rape, and incest. GBP is more honest where it describes the burden as "preventing GenBioPro from developing a market for its product." Compl. ¶ 107. However, the challenged laws do not "prevent" GBP from any commercial activity of GBP, including the marketing, sale, or distribution of its products; rather, these statutes target several aspects of regulating abortion as explained throughout this brief. But any incidental business development challenges in West Virginia resulting from these statutes do not impose a significant burden on interstate commerce. *Johnson v. Cnty. of Horry, S.C.*, 360 Fed.Appx 466, 472 n.7 (4th Cir. 2010) (shrinking the market for one or two highly specialized companies imposes no "significant practical burden upon interstate trade").

The burden does not clearly outweigh benefits. Given that West Virginia's laws advance legitimate state interests and impose only an incidental burden on interstate commerce, GBP bears the burden of proving that the burden imposed is "clearly excessive" relative to the benefits. *Hazel*, 813 F.3d at 155. This it cannot do. The incidental effect on interstate commerce does not remotely outweigh the many interests protected by West Virginia's challenged laws. Consider, for example, just one: the interest in preserving human life. It is within the Legislature's prerogative to determine that the most vulnerable human lives among us are incalculably important and worth protecting—and the preservation of life cannot be matched by other interests, be they public or private.

Second, "Dormant Commerce Clause restrictions apply only when Congress has not exercised its Commerce Clause power to regulate the matter at issue." *Tenn. Wine & Spirits Retailers Ass'n v. Thomas*, 139 S. Ct. 2449, 2465 (2019). Here, Congress *has* used that power to regulate the issue of abortifacients in interstate commerce, specifically making it illegal to send such materials in the mails. *See* 18 U.S.C. §§ 1461–1462. Thus, normal Dormant Commerce Clause restrictions are not apropos in the first place. To the contrary, because "Congress has proscribed [this] interstate commerce," a state law may "discriminate or burden that commerce" so long as it does not conflict with Congress's objectives. *Pic-A-State PA, Inc. v. Pennsylvania.*, 42 F.3d 175, 179 (3d Cir. 1994) (citing *California v. Zook*, 336 U.S. 725, 733 (1949)). West Virginia's challenged laws, though, neither discriminate nor truly burden commerce as explained above. Even if they did, such consequences would complement Congress's own handiwork and, thus, fail to violate the Commerce Clause. For this and the other reasons above, GenBioPro's Commerce Clause claims should be dismissed.

CONCLUSION

For the reasons set forth herein, Defendant Patrick Morrisey, in his official capacity as the Attorney General of the State of West Virginia, requests his Motion to Dismiss this matter be granted.

Respectfully submitted,

By counsel,

PATRICK MORRISEY
West Virginia Attorney General

/s/ *Curtis R. A. Capehart*
Douglas P. Buffington II (WV Bar # 8157)
Chief Deputy Attorney General
Curtis R.A. Capehart (WV Bar # 9876)
Deputy Attorney General
OFFICE OF THE WEST VIRGINIA ATTORNEY GENERAL
State Capitol Complex
1900 Kanawha Blvd. E, Building 1, Room E-26
Charleston, WV 25305-0220
Telephone: (304) 558-2021
Facsimile: (304) 558-0140
Email: Curtis.R.A.Capehart@wvago.gov

Denise M. Harle *
ALLIANCE DEFENDING FREEDOM
1000 Hurricane Shoals Rd. NE, Ste. D-1100
Lawrenceville, GA 30043
Tel.: (770) 339-0774
Fax: (770) 339-6744
dharle@adflegal.org

Erin M. Hawley *
ALLIANCE DEFENDING FREEDOM
440 First Street NW, Ste. 600
Washington, DC 20001
Tel.: (202) 393-8690
Fax: (202) 347-3622
ehawley@adflegal.org

* Visiting Attorneys (visiting attorney fees paid to West Virginia State Bar; Statements of Visiting Attorneys forthcoming)

Counsel for Defendant, Patrick Morrisey, in his official capacity as Attorney General of the State of West Virginia

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

***Plaintiff*,**

v. **Civil Action No. 3:23-cv-00058**

MARK A. SORSAIA, in his official capacity, AND PATRICK MORRISEY, in his official capacity, **Hon. Robert C. Chambers**

Defendants.

CERTIFICATE OF SERVICE

I hereby certify that, on this 21st day of February, I electronically filed the foregoing "Memorandum in Support of Motion to Dismiss" with the Clerk of Court and all parties using the CM/ECF System.

/s/ Curtis R. A. Capehart
Curtis R. A. Capehart
Deputy Attorney General

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

HUNTINGTON DIVISION

GENBIOPRO, INC.,

Plaintiff,

v. CIVIL ACTION NO. 3:23-0058

MARK A. SORSAIA, in his official capacity as Prosecuting Attorney of Putnam County and PATRICK MORRISEY, in his official capacity as Attorney General of West Virginia,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending before the Court is Defendant Mark A. Sorsaia's Rule 12(b)(1) and Rule 12(b)(6) Motion to Dismiss for Failure to State a Claim (ECF No. 17) and Defendant Patrick Morrisey's Motion to Dismiss (ECF No. 19). For the following reasons, the Motions are **DENIED** as to their arguments concerning standing. The Court holds in abeyance the remainder of the Motions.

I. BACKGROUND

Plaintiff GenBioPro, Inc. ("GenBioPro") is the only United States manufacturer of generic mifepristone. Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 1, ECF No. 35. Mifepristone is a Food and Drug Administration ("FDA") approved and regulated medication which is commonly prescribed as step one in a two-step medication abortion regimen. Compl. ¶ 2, ECF No. 1. Mifepristone and misoprostol—the other medication abortion drug—are Plaintiff's "sole source

of revenue." *Id*. ¶ 23. Mifepristone has been approved for nationwide use and sale by the FDA, and GenBioPro sells the drug throughout a national market. *Id*. ¶ 77.

On June 24, 2022, the Supreme Court decided *Dobbs v. Jackson Women's Health Organization*, reversing *Roe v. Wade*[1] and "return[ing] the issue of abortion to the people and their elected representatives." 142 S. Ct. 2228, 2279 (2022). Following this grant of authority, West Virginia passed the Unborn Child Protection Act ("UCPA") in September 2022. W. Va. Code § 16-2R-1 *et seq*. The act of performing, inducing, or attempting to perform or induce an abortion is now illegal in the state, subject to a limited series of exceptions.[2] W. Va. Code § 16-2R-3. This expressly includes abortions performed or induced via "medicine" or "drug." W. Va. Code § 16-2R-2. The UCPA defines the prohibited "attempt to perform or induce an abortion" as "an act or the omission of an act that, under the circumstances as the person so acting or omitting to act believes them to be, constitutes a substantial step in a course of conduct intended to culminate in an abortion." *Id*. If a licensed medical professional "knowingly and willfully performs, induces, or attempts to perform or induce an abortion" with the intent to violate the UCPA, "the licensing board shall revoke medical professional's license." W. Va. Code § 16-

[1] 410 U.S. 113 (1973).

[2] Under the UCPA, "[a]n abortion may not be performed or induced or be attempted to be performed or induced unless in the reasonable medical judgment of a licensed medical professional: (1) The embryo or fetus is nonviable; (2) The pregnancy is ectopic; or (3) A medical emergency exists." W. Va. Code § 16-2R-3(a). This prohibition does not apply "to an adult within the first 8 weeks of pregnancy if the pregnancy is the result of sexual assault . . . or incest" and the patient has taken steps to report the assault or incest to law enforcement. W. Va. Code § 16-2R-3(b). Likewise, the prohibition does not apply to "a minor or an incompetent or incapacitated adult within the first 14 weeks of pregnancy if the pregnancy is the result of sexual assault … or incest" and either the patient has taken steps to report the assault or incest to law enforcement or has received medical treatment for the same. W. Va. Code § 16-2R-3(c).

2R-7. If a formerly licensed medical professional or any other person "knowingly and willfully performs, induces, or attempts to perform or induce an abortion," they are guilty of a felony and subject to imprisonment for "not less than three nor more than 10 years." W. Va. Code § 61-2-8(a), (b).

Prior to the decision in *Dobbs* and the passage of the UCPA, West Virginia had provisions in place which Plaintiff asserts greatly limited the prescription and sale of mifepristone. Compl. ¶¶ 87-88. These restrictions required a waiting period and counseling before obtaining an abortion. W. Va. Code § 16-2I-2. The UCPA provides that this restriction has "no effect" while the UCPA is in force but would "become immediately effective" again should the UCPA "be judicially determined to be unconstitutional." W. Va. Code § 16-2R-9. Further pre-UCPA provisions continue to prohibit providers from prescribing medication abortion drugs via telemedicine. W. Va. Code §§ 30-3-13a(g)(5); 30-1-26(b)(9).

In contrast, the FDA has continually eased restrictions on access to mifepristone. The FDA is tasked with promulgating regulations concerning the approval of prescription medications for sale under the Food, Drug, and Cosmetic Act ("FDCA"). 21 U.S.C. § 393(b)(1). Under regulations known as "Subpart H," the FDA approves drugs which treat "serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments" subject to "restrictions to assure safe use." 21 C.F.R. §§ 314.500, 314.520; Compl. ¶ 36. According to the Complaint, in 2000, Danco Laboratories, LLC's Mifeprex—name-brand mifepristone—was approved under the Subpart H regulatory scheme, which imposed certain restrictions on prescription and administration of the drug to assure safe use. Compl. ¶¶ 38-39. In 2007, Congress enacted the Food and Drug Administration Amendments Act ("FDAAA"), requiring that drugs formerly approved under Subpart H be re-approved under a new regulatory scheme, entitled the

Risk Evaluation and Mitigation Strategy ("REMS"). *See* 21 U.S.C. §§ 355-1(a), (g)(4)(B), (h); Compl. ¶ 41. If the FDA determines that a drug may cause an "adverse drug experience," then the agency must design and implement a REMS. § 355-1(a), (b)(1). However, any restrictions imposed under the regulatory scheme must "not be unduly burdensome on patient access to the drug." § 355-1(f)(2)(C). The FDA must reassess a drug's REMS periodically. § 355-1(d).

Following the passage of the FDAAA and the implementation of the REMS schema, the manufacturer of Mifeprex proposed a REMS for their product to the FDA. Compl. ¶ 55. The FDA approved the proposed REMS in 2011. *Id*. The 2011 REMS[3] required that Mifeprex only be prescribed by certified physicians, dispensed in certain healthcare facilities, and taken in the provider's clinic. *Id*. ¶ 56. In 2016, the FDA revised the Mifeprex REMS,[4] increasing the gestational age through which the drug is indicated, expanding those who could be certified to prescribe Mifeprex from "physicians" to "healthcare providers," and reducing the number of required patient visits to their healthcare providers. *Id*. ¶ 58. In April 2019, the FDA approved GenBioPro's generic version of mifepristone, subject to the same REMS as Mifeprex.[5]

[3] U.S. Food & Drug Admin., NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg, Risk Evaluation and Mitigation Strategy (REMS) (June 2011), https://www.fda.gov/media/164648/download.

[4] U.S. Food & Drug Admin., NDA 020687 MIFEPREX (mifepristone) Tablets, 200 mg, Risk Evaluation and Mitigation Strategy (REMS) (Mar. 2016), https://www.fda.gov/media/164649/download.

[5] U.S. Food & Drug Admin., Mifepristone Tablets, 200 mg, Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200mg (Apr. 2019), https://www.fda.gov/media/164650/download.

Id. ¶¶ 60-61. On January 3, 2023,[6] the FDA promulgated a new REMS[7] for mifepristone which no longer limits dispensation of the drug to healthcare settings, thereby allowing patients to receive the medication either by mail or from certified pharmacies. *Id*. ¶ 66.

Plaintiff filed suit in this Court on January 25, 2023, alleging that the UCPA and prior restrictions violate the Supremacy and Commerce Clauses by limiting the sale of mifepristone in West Virginia. Prosecuting Attorney of Putnam County Mark Sorsaia and Attorney General of West Virginia Patrick Morrisey were named as defendants in their official capacities. Both Defendants have filed motions to dismiss. ECF Nos. 17 & 19. Each Defendant disputes GenBioPro's standing, as well as Plaintiff's interpretation of the Supremacy and Commerce Clauses. The Court heard oral argument on the issue of standing on April 24, 2023, and that issue is now ripe for adjudication.

II. LEGAL STANDARD

Article III of the United States Constitution limits the jurisdiction of federal courts to "cases" and "controversies." U.S. Const. art. III, § 2. The Supreme Court has interpreted this as a

[6] The Court notes that while the REMS was most recently updated in March 2023 "to add space to allow for additional contact information on the forms" and "correct a typographical error," the last significant modification was in January 2023. *See Update History*, Mifepristone, Shared System REMS, U.S. Food & Drug Admin.,, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390 (last accessed Apr. 27, 2023).

[7] U.S. Food & Drug Admin., Mifepristone Tablets, 200 mg, Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200mg (Mar. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_REMS_Full.pdf [hereinafter 2023 REMS].

requirement that plaintiffs demonstrate an "irreducible minimum" to establish standing: (1) an injury in fact, (2) which is fairly traceable to the allegedly offensive conduct, and (3) which is likely to be redressed by a favorable decision from the court. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992). "[E]ach element [of standing] must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation." *Id*. at 561. "A defendant may challenge standing at the motion-to-dismiss stage in one of two ways: facially or factually." *Wikimedia Foundation v. Nat'l Sec. Agency*, 857 F.3d 193, 208 (4th Cir. 2017) (quoting *Beck v. McDonald*, 848 F.3d 262, 270 (4th Cir. 2017)) (internal brackets omitted).

A "facial" challenge questions whether the allegations in the complaint are sufficient to sustain the court's jurisdiction. *Thigpen v. United States*, 800 F.2d 393, 401 n.15 (4th Cir. 1986), *rejected on other grounds*, *Sheridan v. United States*, 487 U.S. 392 (1988). If a "facial" challenge is made, the court must accept the allegations in the complaint as true and decide if the complaint is sufficient to confer subject matter jurisdiction. *Id*. On the other hand, a "factual" challenge contests the truthfulness of the factual allegations in the complaint upon which subject matter jurisdiction is based. In this situation, a "district court is to regard the pleadings' allegations as mere evidence on the issue and may consider evidence outside the pleadings without converting the proceeding to one for summary judgment." *Richmond, Fredericksburg & Potomac R.R. Co. v. United States*, 945 F.2d 765, 768 (4th Cir. 1991) (citing *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982); *Trentacosta v. Frontier Pac. Aircraft Indus.*, 813 F.2d 1553, 1558 (9th Cir. 1987)).

To survive a motion to dismiss, a complaint must contain "a short and plain statement of the claim showing [the plaintiff] is entitled to relief." Fed. R. Civ. P. 8(a)(2). While the facts alleged in the complaint need not be probable, the statement must contain "enough facts to state a

claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim has facial plausibility when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). In considering the plausibility of a plaintiff's claim, the Court accepts all well-pleaded factual allegations in the complaint as true. *Id.* Still, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*. (citation omitted).

Determining whether a complaint states a plausible claim is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id*. at 679. If the court finds from its analysis that "the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id*. (quoting, in part, Fed. R. Civ. P. 8(a)(2)). Nonetheless, a plaintiff need not show that success is probable to withstand a motion to dismiss. *Twombly*, 550 U.S. at 556 ("[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely.").

III. DISCUSSION

In his Memorandum of Law in Support of his Motion to Dismiss, Defendant Morrisey argues that Plaintiff GenBioPro lacks Article III standing to pursue its claims, contesting GenBioPro's asserted injury in fact and the alleged redressability of that injury. *See* Mem. in Supp. of Mot. to Dismiss at 6-8, ECF No. 20. Defendant Sorsaia has raised similar arguments in his Motion to Dismiss, and additionally asserts that the injury GenBioPro has raised cannot be traced to his

actions. Mem. of Law in Supp. of Def. Sorsaia's Mot. to Dismiss at 3-4, ECF No. 18. For the following reasons, the Court **DENIES** both Motions as to standing.

A. Injury in Fact

Injuries in fact must be "concrete and particularized" and "actual or imminent" rather than "conjectural or hypothetical." *Lujan*, 504 U.S. at 560. For an injury to be "particularized" it "must affect the plaintiff in a personal and individual way." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339 (2016). The Supreme Court has also characterized this requirement as not "undifferentiated," *United States v. Richardson*, 418 U.S. 166, 177 (1974) and "distinct," *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990). For an injury to be "concrete" it must be "de facto," or "real" rather than "abstract"—though not necessarily "tangible." *Spokeo*, 578 U.S. at 340; *see Friends of the Earth v. Laidlaw Environmental Servs., Inc.*, 528 U.S. 167, 181-84 (2000) (involving recreational and aesthetic injuries). In contrast, an injury is not "actual or imminent" when it relies upon so-called "some day" intentions which are too indefinite to confer standing. *Lujan*, 504 U.S. at 564; *Doe v. Obama*, 631 F.3d 157, 162-63 (4th Cir. 2011).

Defendant Morrisey argues that GenBioPro's alleged injury is neither particularized nor concrete, as GenBioPro does not allege "that it has ever sold [medication] abortion drugs in West Virginia, nor does it allege any specific plan to do so." Def. Morrisey's Mem. in Supp. of Mot. to Dismiss at 7. Rather, GenBioPro alleges an injury premised upon its lessened "opportunity and ability to market, promote, and sell" its product within the state, leading to "lost sales, customers, and revenue." Compl. ¶¶ 15, 79. Defendant Morrisey argues this is insufficient, likening GenBioPro's asserted injuries to the insufficient "some day" intentions in *Lujan*. Def. Morrisey's Mem. in Supp. of Mot. to Dismiss at 7. In Response, GenBioPro argues that its injuries are

appropriately alleged economic harm, as well as credibly threatened enforcement of the UCPA against itself or its vendees. Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 3-5. The Court will first consider the parties' arguments as to the alleged economic injury.

"[F]inancial harm is a classic and paradigmatic form of injury in fact." *Air Evac EMS, Inc. v. Cheatham*, 910 F.3d 751, 760 (4th Cir. 2018) (quoting *Cottrell v. Alcon Labs.*, 874 F.3d 154, 163 (3d Cir. 2017)); *see also Adkins v. Rumsfeld*, 464 F.3d 456, 465 (4th Cir. 2006), *cert. denied*, 127 S. Ct. 2972 (2007) (finding an injury which "allegedly inflicts a direct economic harm upon [the plaintiff] is concrete and not hypothetical."). "[W]here a plaintiff alleges financial harm, standing is often assumed without discussion." *Cottrell*, 874 F.3d at 163 (internal quotation omitted). "Any monetary loss suffered by the plaintiff satisfies the injury-in-fact element; even a small financial loss suffices." *Id*. (quoting *Carter v. HealthPort Techs., LLC*, 822 F.3d 47, 55 (2d Cir. 2016)). Applying this principal, the Supreme Court has found that physicians who performed abortions had standing to challenge restrictions on Medicaid payment for abortions, as fewer reimbursed abortions would lead to a loss in physician revenue. *Singleton v. Wulff*, 428 U.S. 106, 113 (1976); *see also Reprod. Health Servs. v. Strange*, 3 F.4th 1240, 1251-52 (11th Cir. 2021) (finding physicians had standing to challenge restrictions on minor patients where less abortions on minors would lead to loss of revenue).

Both the Fourth Circuit and the Supreme Court have found that lost business opportunities are a form of economic injury. *Md. Shall Issue, Inc. v. Hogan*, 971 F.3d 199, 211 (4th Cir. 2020) (citing *Craig v. Boren*, 429 U.S. 190, 194 (1976)). In *Hogan*, the Fourth Circuit found that a firearms store had standing to challenge a state handgun license requirement, due to the business's allegations of lost sales. *Id*. In turn, *Craig* held that a beer vendor had standing to challenge a law limiting the sale of beer to adolescent men, where the vendor could either "heed the statutory

discrimination, thereby incurring a direct economic injury through the constriction of her buyers' market" or suffer potential "sanctions and perhaps loss of license." 429 U.S. at 194. GenBioPro reasons that it has suffered direct economic harm due to its loss of business opportunities to sell mifepristone within West Virginia, and therefore, it is akin to the handgun and beer vendor challenging laws limiting the sale of those goods. Pl.'s Opp'n. to Def. Morrisey's Mot. to Dismiss at 3.

Defendants do not dispute GenBioPro's business interest in selling mifepristone generally. Rather, they argue that because GenBioPro's complaint does not allege the company has ever sold in West Virginia prior to the passage of the UCPA, its claim that it wishes to enter the market now is purely speculative. Reply in Supp. of Mot. to Dismiss at 2-3, ECF No. 45. The Court interprets this as a facial challenge as to whether the allegations in the complaint are sufficient to sustain the court's jurisdiction. *See Thigpen*, 800 F.2d at 401 n.15. Defendant Morrisey emphasizes that the plaintiffs in *Hogan* and *Craig* had past sales in the market they argued was now restricted by statute. Reply in Supp. of Mot. to Dismiss at 2-3. At oral argument, Plaintiff underscored that other courts have found injuries based on market constriction where plaintiffs were not already operating in the targeted market, citing *Ezell v. City of Chicago*, 651 F.3d 684 (7th Cir. 2011), and *303 Creative LLC v. Elenis*, 6 F.4th 1160 (10th Cir. 2021). Upon consideration, the Court agrees that there is no per se requirement to show past sales in order to demonstrate economic injury caused by statutes which constrict potential markets. *See Ezell*, 651 F.3d at 692, 696 (granting a national firing range vendor standing to challenge state firing range restrictions where they merely expressed a desire to open a firing range in Chicago); *303 Creative*, 6 F.4th at 1172 ("Although Appellants have not yet offered wedding website services" their past general website services and intent to offer wedding websites demonstrated standing to challenge statutory restrictions). Absent

any such per se requirement of past presence in the market, the Court applies "its judicial experience and common sense" to determine whether the Complaint plausibly alleges an intent to sell in West Virginia which has been constricted by the challenged statutes. *See Iqbal*, 556 U.S. at 679.

GenBioPro is a well-established manufacturer of a nationally distributed and federally approved product. Compl. ¶ 2. The company's only revenue producing products are medication abortion drugs. *Id*. ¶ 23. Plaintiff attests that it spent nearly a decade working to attain FDA approval for its generic mifepristone. *Id*. ¶¶ 2, 60. GenBioPro's FDA approval allows it to sell mifepristone nationwide. *Id*. ¶ 77. Since Plaintiff received approval from the FDA to sell generic mifepristone, it has sold approximately 850,000 units of the drug. *Id*. ¶ 3. Accordingly, Plaintiff has demonstrated how any constriction of the market for mifepristone would affect it in a particularized manner. *See Spokeo*, 578 U.S. at 339 (discussing particularization of injuries).

Furthermore, the Complaint provides evidence of the growing market for mifepristone, which now accounts for more than half of abortions in the United States. *Id*. ¶ 76. Plaintiff asserts that several nationwide pharmacy chains—some of which have locations in Putnam County—have evinced a desire to sell mifepristone but are prevented from doing so by West Virginia's statutes and Defendants' threatened legal action. *Id*. ¶¶ 75, 78, 80. While mifepristone is approved by the FDA for medication abortion up to ten weeks gestation, West Virginia's UCPA limits "medicine" abortion to an extremely narrow set of circumstances. *See id*. ¶ 83; W. Va. Code § 16-2R-3. The prior restrictions on prescription of mifepristone via telemedicine likewise conflict with the REMS. *See* Compl. ¶¶ 66, 86, 88; W. Va. Code §§ 30-3-13a(g)(5); 30-1-26(b)(9). The Court concludes that there is nothing "conjectural or hypothetical" about GenBioPro's affirmations that it would be selling its product to a wider market in West Virginia were it not for the UCPA and prior

restrictions. *See Spokeo*, 578 U.S. at 339. Accordingly, the Court finds that GenBioPro's Complaint plausibly alleges a sufficiently concrete intent to access the market in West Virginia, which arguably is stymied by the UCPA and prior restrictions.

GenBioPro has plausibly asserted a sufficiently concrete and particularized injury in fact. As the Court has found that GenBioPro has plausibly alleged injury in fact based on economic harms, it need not determine whether the UCPA's provisions are sufficiently vague to subject Plaintiff to potential criminal liability.

B. Redressability

It is insufficient to show merely that Plaintiff has been injured; that injury must be traceable to Defendants and redressable by the relief requested from the Court. *Lujan*, 504 U.S. at 560-61. Here, the relief requested by GenBioPro is a declaratory judgment that both the UCPA and the prior restrictions are invalid under the Constitution. Compl. at 32. Defendants have argued that Plaintiff's injury would not be redressed by this relief, as (1) redressability is impermissibly dependent on the third-party action of "medical professionals," and (2) the Comstock Act bars relief. Def. Morrisey's Mem. in Supp. of Mot. to Dismiss at 7-8. Further, Defendant Morrisey asserts that the alleged injuries caused by the pre-UCPA restrictions on dispensation of mifepristone cannot be redressable, as those restrictions are not currently operative. *Id.* at 8. In rebuttal, Plaintiff reiterates that if this Court were to find West Virginia's statutes to be unconstitutional, then the statutory restrictions on the market for their products would be eased. Pl.'s Opp'n. to Def. Morrisey's Mot. to Dismiss at 5-7.

In determining whether standing exists, "[t]he relevant inquiry is whether … the plaintiff has shown an injury to himself that is likely to be redressed by a favorable decision." *Simon v. E. Ky.*

Welfare Rights Org., 426 U.S. 26, 38 (1976). However, redressability does not require that the injury be completely ameliorated. *See Massachusetts v. EPA*, 549 U.S. 497, 526 (2007).

a. Alleged Dependence on Third-Party Action

Defendant Morrisey argues that Plaintiff's injury is not redressable by the relief requested, as invalidation of the statutes does not necessarily entail that "medical professionals" will prescribe or purchase mifepristone from GenBioPro. Therefore, he argues the relief requested is impermissibly dependent on third-party action. Def. Morrisey's Mem. in Supp. of Mot. to Dismiss at 7-8.

The Court disagrees. None of the cases in which doctors, contraceptive providers, or other vendors were found by the Supreme Court to have standing found that relief was impermissibly premised on third-party customer sales. *See, e.g.*, *Singleton*, 428 U.S. at 113 (finding that doctors providing abortion care had standing where they would suffer economic loss due to restrictions on abortion); *Carey v. Population Servs. Int'l*, 431 U.S. 678, 682–84 (1977) (finding contraceptive vendor had standing to challenge restriction on contraceptive sales); *Craig*, 429 U.S. at 194 (finding beer vendor had standing to challenge restriction on beer customers). Just as the Supreme Court has in the past assumed that people will continue to seek beer, contraceptives, and abortion, the Court finds here that it is reasonable to assume pharmacies and doctors will continue to prescribe and purchase abortion medication. This inference is supported by the fact that medication abortion is the most common form of abortion in the United States. Compl. ¶ 76. Furthermore, the Complaint alleges that pharmacies with locations in West Virginia have stated they would sell mifepristone, absent the statutory restrictions. *Id*. ¶ 78. At the motion to dismiss stage, the Court accepts these factual allegations as true. *See Iqbal*, 556 U.S. at 678.

Simply put, the Court finds the argument that no medical practitioner or pharmacy in the state of West Virginia would ever prescribe or sell mifepristone to be facially implausible. More abstractly, the underlying injury asserted by Plaintiff is constriction of the market it sells within, and the relief requested would redress that market constriction—even if every "medical professional" in the state declined to buy from Plaintiff, it would still have an increased opportunity to "market its product in West Virginia." *See* Compl. ¶ 77. Accordingly, the Court rejects Defendant Morrisey's argument.

b. The Comstock Act

Next, Defendant Morrisey argues that even if the Court were to grant the relief requested, Plaintiff's business would still be illegal under the Comstock Act, thereby negating redressability. Def. Morrisey's Mem. in Supp. of Mot. to Dismiss at 7-8. The Court finds that this argument is without merit.

The Comstock Act of 1873 declares that "[e]very article or thing designed, adapted, or intended for producing abortion," as well as "[e]very article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion," is "nonmailable matter" that the United States Postal Service ("USPS") may not lawfully deliver. 18 U.S.C. § 1461. While the plain language of the statute arguably encompasses GenBioPro's business model, the Comstock Act is currently understood to apply only to use of the mails in an illegal manner. Courts have held this consistently since 1915. *See Bours v. United States*, 229 F. 960 (7th Cir. 1915); *Davis v. United States*, 62 F.2d 473 (6th Cir. 1933); *United States v. One Package*, 86 F.2d 737 (2d Cir. 1936); *Consumers Union of United States, Inc. v. Walker*, 145 F.2d 33 (D.C. Cir. 1944). The Department of Justice's current

enforcement interpretation concurs. Dept. of Justice, Application of the Comstock Act to the Mailing of Prescription Drugs that Can Be Used for Abortions, Mem. Op. for the Gen. Couns. USPS (Dec. 23, 2022).

While Defendant Morrisey has obliquely threatened legal action against pharmacies willing to distribute mifepristone in West Virginia, he does not have the authority to enforce federal law. *See* Compl. ¶ 75. To reiterate, the entity with that enforcement authority—the Department of Justice—has stated that it will not enforce the Comstock Act against legal vendors of mifepristone. Dept. of Justice, Application of the Comstock Act to the Mailing of Prescription Drugs that Can Be Used for Abortions, Mem. Op. for the Gen. Couns. USPS (Dec. 23, 2022). Accordingly, this Court declines to find that a widely abrogated 19th century statute which the federal government will not enforce bars redressability here.

c. Redressability as to the Prior Restrictions

Finally, Defendant Morrisey argues that Plaintiff cannot challenge provisions which are not currently in effect, i.e., the restrictions on prescription of mifepristone extant prior to the passage of the UCPA. Def. Morrisey's Mem. in Supp. of Mot. to Dismiss at 8. In support, Defendant Morrisey cites *California v. Texas* for the proposition that "[t]o find standing … to attack an unenforceable statutory provision would allow a federal court to issue what would amount to 'an advisory opinion without the possibility of any judicial relief.'" 141 S. Ct. 2104, 2116 (2021) (internal citation omitted). Plaintiff's Response emphasizes that *California v. Texas* dealt with a "toothless law" that had "no means of enforcement," while the provisions here would spring back into effect were the Court to declare the UPCA unconstitutional. Pl.'s Opp'n. to Def. Morrisey's Mot. to Dismiss at 7.

The Court agrees with Plaintiff. The prior provisions were superseded by the UCPA,[8] which suspends their enforceability so long as the UCPA is in effect. W. Va. Code § 16-2R-9. However, the UCPA includes a provision that should it be found unconstitutional the older provisions would once again become enforceable. *Id*. Had GenBioPro challenged the prior provisions without challenging the UCPA, it may not have had standing. But as Plaintiff has challenged the UCPA, it also may challenge the provisions which would spring back into enforceability if this Court were to find the UCPA unconstitutional. Of course, if the Court were to find that the statute is constitutional, it would not consider GenBioPro's challenges to the other provisions.

Accordingly, the Court finds that GenBioPro's economic injuries are traceable to the statutes complained of and would be redressed by the relief requested from the Court.

C. Traceability as to Defendant Sorsaia

While the Court has found GenBioPro has standing as to Defendant Morrisey, "the standing inquiry must be evaluated separately as to each defendant." *Disability Rights S.C. v. McMaster*, 24 F.4th 893, 901-02 (4th Cir. 2022) (citing *Bostic v. Schaefer*, 760 F.3d 352, 370–71 (4th Cir. 2014)).

As discussed above, "traceability" is one the three "irreducible" prongs of Article III standing. *Lujan*, 504 U.S. at 560-61. A plaintiff's injury satisfies the traceability element of standing when there is "a causal connection between the injury and the [defendant's] conduct complained of by the plaintiff." *Air Evac*, 910 F.3d at 760 (internal quotation marks omitted). "While the defendant's

[8] The Court notes that West Virginia Code § 30-3-13a(g)(5) and § 30-1-26(b)(9) remain in effect. Accordingly, the analysis in this section is directed only towards GenBioPro's challenge as to West Virginia Code § 16-2I-2.

conduct need not be the last link in the causal chain, the plaintiff must be able to demonstrate that the alleged harm was caused by the defendant, as opposed to the 'independent action of some third party not before the court.'" *Id.* at 760 (quoting *Frank Krasner Enters., Ltd. v. Montgomery Cnty.*, 401 F.3d 230, 234 (4th Cir. 2005)). Further, "an injury resulting from the application or threatened application of an unlawful enactment remains fairly traceable to such application." *Fed. Election Comm'n. v. Cruz*, 142 S. Ct. 1638, 1647 (2022).

Defendant Sorsaia argues that GenBioPro lacks standing as to him as a defendant, as the injury Plaintiff complains of cannot be traced to his actions or inaction. Mem. of Law in Supp. of Def. Sorsaia's Mot. to Dismiss at 4. The Fourth Circuit addressed a similar argument in *Disability Rights South Carolina v. McMaster*. 24 F.4th at 901-02. In *McMaster*, the Appeals Court held that mere public endorsement of a statute by a state official was insufficient to demonstrate traceability, where the defendant governor did not have the authority to enforce the statute. *Id*. Rather, *McMaster* held that "[t]o establish standing, '[a] plaintiff who challenges a statute must demonstrate a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement.'" *Id*. at 902 (quoting *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979)). In other words, "[a] controversy exists not because the state official is himself a source of injury but because the official represents the state whose statute is being challenged as the source of injury." *Mobil Oil Corp. v. Atty. Gen. of Va.*, 940 F.2d 73, 76 n.2 (4th Cir. 1991) (quoting *Wilson v. Stocker*, 819 F.2d 943, 947 (10th Cir. 1987)). But "[w]hen a defendant has no role in enforcing the law at issue, it follows that the plaintiff's injury allegedly caused by that law is not traceable to the defendant." *McMaster*, 24 F.4th at 901-02.

The Court has found that the source of GenBioPro's alleged injury is the UCPA and prior restrictions on abortion in the state. As the Prosecuting Attorney of Putnam County, Defendant

Sorsaia is charged with enforcing the UCPA's criminal penalties, and the Complaint plausibly asserts that he has indicated that he will enforce the UCPA. W. Va. Code § 7-4-1(a); Compl. ¶ 24. GenBioPro has alleged an intent to distribute its product within the state and to specific pharmacies within the county. Compl. ¶ 78. Unlike the governor in *McMaster*, therefore, the statute challenged as the source of GenBioPro's alleged injury within Putnam County is traceable to the enforcement authority of Defendant Sorsaia.

Accordingly, Defendant Sorsaia's Motion is **DENIED** as to the issue of standing.

D. Third-Party Standing

GenBioPro argues that it may assert the rights of third parties to whom it wishes to sell mifepristone within West Virginia. Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 7-8; Pl.'s Opp'n to Def. Sorsaia's Mot. to Dismiss at 12-14. Defendant Morrisey counters that "in order to assert the interests of a third party, a vendor plaintiff must first satisfy the requirements of Article III standing itself." Reply in Supp. of Mot. to Dismiss at 3 (citing *Hogan*, 971 F.3d at 214-15). While the Court agrees with Defendant Morrisey's interpretation of *Hogan* and related cases, it has already found that Plaintiff has satisfied the requirements of Article III standing as to itself, above. While Plaintiff raised the same argument as to Defendant Sorsaia, he neglected to file a Reply. Therefore, the Court will consider whether Plaintiff has met the requirements to assert third-party standing on behalf of its vendees.

A "plaintiff generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." *Warth v. Seldin*, 422 U.S. 490, 499 (1975); *see Hogan*, 971 F.3d at 214. This rule is meant to ensure that parties appearing before the court have "the appropriate incentive to challenge (or not challenge) governmental action and to do so

with the necessary zeal and appropriate presentation." *Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004). And yet, the Supreme Court has found circumstances in which plaintiffs may have standing to assert the rights of others. *See id*. at 129-30.

One widely recognized ground for third-party standing is the vendor-vendee relationship, where the vendor independently has established its own standing. *See Craig*, 429 U.S. at 195 ("As a vendor with standing to challenge the lawfulness of [the relevant statutes], appellant [] is entitled to assert those concomitant rights of third parties that would be 'diluted or adversely affected' should her constitutional challenge fail and the statutes remain in force."). "[V]endors and those in like positions have been uniformly permitted to resist efforts at restricting their operations by acting as advocates of the rights of third parties who seek access to their market or function." *Id*.; *see also Carey*, 431 U.S. at 682–84 (granting third-party standing to a nationwide mail-order contraceptive vendor to challenge a state prohibition on contraceptive sales by asserting vendee right to privacy); *Eisenstadt v. Baird*, 405 U.S. 438, 443-446 (1972) (granting third-party standing to plaintiff prosecuted for illegal distribution of contraceptives to assert equal protection rights of unmarried persons denied access to contraceptives). "Courts have invariably found that a vendor has a sufficiently close relationship with its customers when a challenged statute prevents that entity from transacting business with them." *Hogan*, 971 F.3d at 216 (citing *Craig*, 429 U.S. at 192–97; *Lepelletier v. F.D.I.C.*, 164 F.3d 37, 43–44 (D.C. Cir. 1999)). Furthermore, the Fourth Circuit has held that "a vendor has third-party standing to pursue claims on behalf of its customers, regardless of whether a vendor's customers are hindered in bringing their own claims." *Id*. at 216 (collecting cases).

Here, GenBioPro is a vendor of mifepristone. Compl. ¶ 3. Under the current REMS, its customers include certified healthcare providers and pharmacies nationwide. *See id*. ¶¶ 66, 71;

2023 REMS. Plaintiff has plausibly alleged an intention to sell to this group of vendees in West Virginia. *See id*. ¶¶ 78-79. The Court has held above that GenBioPro has plausibly alleged that the UCPA restricts its sales to these vendees in the state and that this restriction is sufficient to constitute an economic injury in fact. Accordingly, the Court holds that GenBioPro may assert the third-party rights of the certified healthcare providers and pharmacies who seek access to its market but are prevented by the UCPA from transacting business with GenBioPro.

GenBioPro wishes to assert its customers' interests in not being subjected to criminal penalties due to West Virginia's enforcement of allegedly unconstitutional statutory provisions. Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 7-8; Pl.'s Opp'n to Def. Sorsaia's Mot. to Dismiss at 6-8, 13. Where no criminal enforcement action has been initiated, "a plaintiff satisfies the injury-in-fact requirement where he alleges 'an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder.'" *Susan B. Anthony List v. Dreihaus*, 573 U.S. 149, 159 (2014) (quoting *Babbitt*, 442 U.S. at 298). Where such a credible threat of enforcement exists, plaintiffs "should not be required to await and undergo a criminal prosecution as the sole means of seeking relief." *Babbitt*, 442 U.S. at 298. However, where the government has "disavowed enforcement," there is no credible threat of prosecution. *See Susan B. Anthony List*, 573 U.S. at 163; *Holder v. Humanitarian Law Project*, 561 U.S. 1, 16 (2010) (emphasizing that the government did not disavow future enforcement of the challenged statute).

GenBioPro has alleged that West Virginia's limitations on the sale of mifepristone violate the Supremacy and Commerce Clauses of the Constitution. Compl. at 28-32. The Court finds this sufficient to satisfy the alleged "intention to engage in a course of conduct arguably affected with a constitutional interest." *See Susan B. Anthony List*, 573 U.S. at 159. While the Court has declined

to determine whether GenBioPro itself could be subject to criminal liability pursuant to the UCPA, it is more than arguable that at least some of the pharmacies and medical personnel who could distribute mifepristone under the 2023 REMS also could be prosecuted for that distribution under West Virginia law. GenBioPro's vendees include non-physicians and pharmacies, who can be certified to distribute mifepristone under the current REMS. *See* Compl. ¶¶ 58, 71; 2023 REMS. The Complaint alleges that national pharmacy chains with locations in Putnam County, West Virginia have expressed a desire to sell mifepristone. *Id*. ¶ 78. Accordingly, as County Prosecutor for Putnam County and Attorney General of West Virginia, Defendants could prosecute GenBioPro's customers under § 61-2-8(a). Further, rather than "disavowing enforcement," both Defendants have affirmatively expressed that they will enforce the relevant criminal provisions. *Id*. ¶¶ 24, 75.

At oral argument, Defendant Sorsaia underscored that West Virginia's criminal penalties for performing illegal abortions do not apply to "licensed medical professionals," who he implied are the majority of GenBioPro's customers. "Licensed medical professionals" who would violate the UCPA by prescribing mifepristone for abortion care outside of the limited exceptions would only be subject to licensure revocation, rather than criminal prosecution. W. Va. Code § 16-2R-7. The UCPA defines "licensed medical professional" as a person licensed under either West Virginia Code § 30-3-1 *et seq.* or § 30-14-1 *et seq*., which govern licensure of the practice of medicine, surgery, podiatry, and osteopathic medicine or surgery for physicians and physicians' assistants. Therefore, registered professional nurses and nurse practitioners are not "licensed medical professionals" for the purposes of the UCPA, as they are subject to different statutory schemes under West Virginia Code § 30-7-1, *et seq*. and § 30-7A-1, *et seq*. Nor would pharmacists or pharmacies be considered "licensed medical professionals," as they are governed by West Virginia

Code § 30-5-1, *et seq*. *See also* W. Va. Code § 30-5-22 (outlining registration requirements for pharmacies). Accordingly, registered professional nurses, nurse practitioners, pharmacists, and pharmacies who could be certified under the mifepristone REMS would be subject to the criminal penalties of § 61-2-8(a), rather than the license revocation of § 16-2R-7, were they to violate § 16-2R-3.

Therefore, the Court finds that GenBioPro has plausibly alleged that its vendees have suffered an injury in fact sufficient for Article III standing in the form of a credible threat of enforcement, and that GenBioPro may assert the third-party rights of its vendees, due do its independent standing and its relationship with them as a vendor.

IV. CONCLUSION

For the forgoing reasons, the Court concludes that Plaintiff has sufficiently alleged Article III standing for this Court to hear the instant case or controversy. Accordingly, the Court **DENIES** each Motion to Dismiss in part and holds in abeyance the remainder of the Motions. The Court **DIRECTS** that counsel to appear in person on **May 23, 2023,** at **1:30 p.m.** to argue the remaining issues raised in the Motions.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented parties.

ENTER: May 2, 2023

ROBERT C. CHAMBERS
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

HUNTINGTON DIVISION

GENBIOPRO, INC.,

Plaintiff,

v. CIVIL ACTION NO. 3:23-0058

MARK A. SORSAIA, in his official capacity as Prosecuting Attorney of Putnam County and PATRICK MORRISEY, in his official capacity as Attorney General of West Virginia,

Defendants.

ORDER

In consideration of the Supreme Court's opinion in *National Pork Producers Council v. Ross*, No. 21–468, — S. Ct. — (2023), the Court **DIRECTS** the parties to file supplemental briefing by **Friday, May 19, 2023**. The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented parties.

ENTER: May 11, 2023

ROBERT C. CHAMBERS
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,	CIVIL ACTION NUMBER 3:23-cv-00058
Plaintiff,	
-vs-	
MARK A. SORSAIA, in his official capacity as Prosecuting Attorney of Putnam County and PATRICK MORRISEY, in his official capacity as Attorney General of West Virginia,	
Defendants.	

MOTION HEARING
BEFORE THE HONORABLE ROBERT C. CHAMBERS,
UNITED STATES DISTRICT JUDGE
MONDAY, APRIL 24, 2023

Proceedings recorded by mechanical stenography, transcript produced by computer.

CATHERINE SCHUTTE-STANT, RDR, CRR
Federal Official Court Reporter
300 Virginia Street, East
Charleston, WV 25301

APPEARANCES:

For the Plaintiff:

ANTHONY J. MAJESTRO, ESQUIRE
Powell & Majestro
Suite P-1200
405 Capitol Street
Charleston, WV 25301

DAVID C. FREDERICK, ESQUIRE
Kellogg Hansen Todd Figel & Frederick
Suite 400
1615 M Street, NW
Washington, D.C. 20036

For the Defendant Mark A. Sorsaia:

JENNIFER SCRAGG KARR, ESQUIRE
Putnam County Judicial Building
12093 Winfield Road
Winfield, WV 25213

For the Defendant Patrick Morrisey:

CURTIS R. CAPEHART, ESQUIRE
West Virginia Attorney General's Office
Building 1, Room 26e
1900 Kanawha Boulevard, East
Charleston, WV 25305

(The following proceedings were held before the Honorable Robert C. Chambers, United States District Judge, in the case of *GenBioPro, Inc., versus Mark A. Sorsaia,* in his capacity as Prosecuting Attorney of Putnam County, et. al., on April 24, 2023, at Huntington, West Virginia, beginning at 2:02 p.m.)

COURT SECURITY OFFICER: All rise.

THE COURT: Good afternoon.

Before we start the proceeding, I'm advised that we have a number of individuals who are participating by listening by telephone, so I want to instruct them that they are reminded that there is a general prohibition against any sort of recording or rebroadcasting of court proceedings. A violation of that prohibition could result in sanctions. So please make sure that you abide by that requirement.

I'm also advised they've already been instructed to mute their devices, so hopefully that will continue throughout.

So I appreciate counsel quickly making themselves available for this hearing after the Court contacted you.

I've done an order which explains that I'm limiting this hearing to a discussion of the standing issues presented by the plaintiff's complaint.

Obviously, it's a necessary part of the Court's deliberation over the pending motions to determine that

there is adequate standing as to both of the defendants, and it's a threshold requirement. So I felt it appropriate to have a separate -- and hopefully successfully quickly resolving this one way or the other in doing this as a first step. And consequently, I asked plaintiffs to be prepared to first outline, since plaintiff has the burden of establishing standing, the basis in the Complaint for standing, and then to respond to the arguments that you've seen raised by the defendant.

So who is presenting on behalf of the plaintiff?

MR. MAJESTRO: Your Honor, Anthony Majestro for the plaintiff. I would like to introduce David Fredrick from Kellogg Hansen in Washington, D.C., who will be handling the argument for the plaintiffs.

THE COURT: All right. Thank you.

Welcome, Mr. Frederick.

MR. FREDERICK: Your Honor, is it all right that I speak from here?

THE COURT: It is. I'm going to ask all of you to use the microphones whenever possible. The acoustics in this courtroom aren't particularly good, and the court reporter is using a recording and -- using headphones to hear through the system, and so it is necessary for you to use the microphones.

With that, go ahead.

MR. FREDERICK: Thank you, Your Honor.

David Frederick for plaintiff, GenBioPro.

We brought this case to challenge West Virginia's Criminal Abortion Ban and associated restrictions under two theories. The Ban is preempted by the Food and Drug Administration Amendments Act of 2007, the FDAAA, and the associated FDA rules and statutes, and it breaches the Commerce Clause of the U.S. Constitution.

The Ban seeks to override the FDA's approval of mifepristone for its indicated use in the early termination of pregnancy.

You've directed us to address standing. And that's what I'd like to focus on in my presentation today.

The tests for standing is three-fold: injury in fact, sufficient causal connection for the injury; and the conduct complained of; and the likelihood that the injury will be redressed by a favorable decision.

Now, I want to address the pleading standard for standing because we are here on a motion to dismiss. And the Supreme Court said in the *Susan B. Anthony* case the test for standing and the pleading requirements for standing depend on the level at which the challenge is being made.

Because we are at the motion to dismiss stage, the normal pleadings' standard for a motion to dismiss apply, which means that we are charged with pleading plausibly that

we have standing.

Now, we understand and appreciate, Your Honor, that at summary judgment we will be called upon to present proof that would support the allegations made in the Complaint. And we are prepared to do so. And if asked by the Court, I can outline some of those proofs that we would expect to be presenting.

But for purposes of this argument, we believe we have plausibly pleaded standing, because we plausibly pleaded that we are injured by the state's ban, that it is causally connected to the statements made by the attorney general and the Putnam prosecutor, and that a favorable decision by you declaring the state's ban and associated restrictions to be unconstitutional under the Supremacy Clause and the dormant Commerce Clause would redress the harm that we suffer.

So with that, let me just start by saying that the generic form of mifepristone is GenBioPro's principal product, and it sells throughout the United States, as we pleaded in the Complaint. We seek to sell in West Virginia -- or seek to have distributed for sale because GenBioPro is not a direct seller -- but through pharmacies, telemedicine providers, mail health, pharmacies, et cetera, and other distributors; and is precluded by doing so by the statute enacted by the West Virginia legislature.

So the very first point is economic harm.

The Fourth Circuit has called this, quote, the paradigmatic form of an injury to confer standing. That's the *Maryland Shall Issue* case decided by the Fourth Circuit in 2020, and it quotes a decision out of this court, *Air Evac EMS*. That was a case involving interplay with health providers.

Now, the attorney general admits that the Ban causes harm to GenBioPro's, quote, bottom line. And that ought to be enough at the pleading stage for us plausibly to show economic injury, that one concession there.

As the Fourth Circuit held in *Maryland Shall Issue*, even a small amount of loss of money is ordinarily an injury. And like a gun owner in *Maryland Shall Issue* and the beer vendor in the Supreme Court case of *Craig versus Boren*, GenBioPro has lost business opportunities as a result of West Virginia's unconstitutional laws.

THE COURT: Here's the rub -- and this is what I think the defendant points to -- GenBioPro does not allege in the Complaint that they've had any past sales.

As I understand it, you've been in the business since about 2019?

MR. FREDERICK: That's correct.

THE COURT: And so -- and you say that it's a nationwide business. Fair enough. But you didn't allege that you were already selling or already even taking steps

to certify doctors or pharmacies under the more recent REMS.

So when I looked at these cases, frankly, the first thing that occurred to me is that these other plaintiffs who you -- in the cases you noted were established as already doing business and already had direct sales to their customers in the states where they brought the cases and were asserting standing.

And defendant argues that you've only stated a generalized intention to do business in West Virginia and/or other states, but you haven't actually done business in West Virginia.

So do these cases not require something more than just an intention to engage in the business at some point?

MR. FREDERICK: They do not. There is not a single case on point that they have cited that requires past sales.

THE COURT: Are there any cases that you've come across where a similarly situated plaintiff sought standing based on economic harm where they didn't already have past sales or an existing customer relationship within the targeted state?

MR. FREDERICK: Yes. The Fourth Circuit cited a case out of the Seventh Circuit called *Ezell*. And if I -- it's called *Ezell versus the City of Chicago*. That was a case involving firing range practice areas.

The company was one that said in the reported decision, we sell throughout the United States, and we have intent to create a firing range in the City of Chicago. Because of the ordinance passed by the City of Chicago, the firing range facility operator was not able to provide a firing range facility. It obviously had not done any business in the City of Chicago. It wanted to do business. And but for the existence of the ordinance banning the firing range facility, it would have been permitted to do so.

The Seventh Circuit said there is standing to bring the challenge under the Constitution. That was a Second Amendment case.

But the Seventh Circuit said that there was standing because there was economic harm due to the loss of prospective sales. That case was cited with approval in *Maryland Shall Issue*. *Maryland Shall Issue* was a case involving those sales at the time to young people who didn't have the license that was required by the state. So these were all prospective sales that were being complained of.

THE COURT: But they were already in the state, doing business and making sales?

MR. FREDERICK: Yes, Your Honor. And if -- I would say it's not a pleading requirement. Because the pleading requirement is that there be a loss potential for sales.

We can establish evidence, if put to the proof, that there have been past sales by GenBioPro of mifepristone in West Virginia. We didn't think it was necessary to plead that.

We would urge you to not require us to go through the mechanics of amending the Complaint. We can provide evidence of that, if necessary, at cross-motions for summary judgment.

THE COURT: I wish you had said that when you saw their initial attack -- and I don't -- by saying I wish you had, I'm not criticizing you, I just think if you -- I think it's really clear if you would have alleged that you were already conducting transactions -- and I'm not saying you're wrong. I'm still pondering all this. And I understand your position and why you would take the position that you don't need to allege nor even have had past sales.

MR. FREDERICK: There is also a Tenth Circuit case called *303 Creative*. And in that case, the website designer had not yet started to make websites that would be -- that would implicate questions about same-sex marriage. There was only a prospective creation of the website there.

And let me explain to you exactly why it shouldn't matter in this particular case.

West Virginia enacted its Criminal Abortion Ban in September of 2022. To our knowledge, people complied with

that and have not had any sales in that time period.

In January of 2023, the FDA promulgated new risk mitigation strategies. These are REMS.

THE COURT: Right.

MR. FREDERICK: That is the name for them. And these REMS provided for telemedicine, for mail order provision of mifepristone. And so the direct collision occurred. And so if you would suppose that there had been an abortion ban throughout this entire period, it would be odd to think that the plaintiff can only get standing by showing violation of the law through sales that would be in conflict with the state law.

GenBioPro is a law-abiding company and is seeking through legal means to come up with the appropriate answer.

And so if you think about the logic of their position, it actually doesn't make sense, because it would mean that a state could act unconstitutionally to constrict an out-of-state distributor's products. And then if the federal government changed the rules that would have enabled that product to be distributed for sale in a state, under their theory of standing, there is no standing because there was no prior sale.

And so I think that if you think about it from a logical perspective, it can't be a pleading standard.

If you look at *Craig versus Boren*, *Maryland Shall*

Issue, the *Ezell* case, there was no -- there was no prior sale to the target audience. It can't be a pleading requirement.

But if you think that we need to provide evidence to that effect, we can show some evidence of past sales in prior periods.

So if that's the only issue that's hanging you up about standing, I hope I've adequately --

THE COURT: Well, I appreciate -- and you have responded to my questions, but I'm not going to say that's the only issue hanging me up.

I reserve the right to review all of this and make a ruling based upon all of it. But you've certainly explained your injury in fact theory. And I understand when I looked at these cases, one of the things that occurred to me, especially in the context of the defendants' argument, was that even though you had been in the business in 2019 -- and I understand that the recent REMS changed the landscape considerably, and would have expanded the possibility of business -- as you've acknowledged, it's a pleading stage standard. But the Court can't just accept a conclusory statement that we have standing because we have an injury in fact. You have to demonstrate, plausibly allege what that is. And I appreciate your answering those questions for me here today.

MR. FREDERICK: All right. And I can point you to the paragraphs of the Complaint that we think adequately --

THE COURT: Why don't we do that, just to make sure we are on the same page as we go through this.

MR. FREDERICK: Sure. So paragraph 3 pleads that the company provides medication abortion, and that is a form of ending pregnancy that is used now in more than half of all instances in the United States.

Paragraph 11 explains that the Ban constricts the market for mifepristone.

Paragraph 74 explains that the West Virginia sales Ban constricts West Virginia sales.

Paragraphs 78 through 80 explain how pharmacies, both brick and mortar pharmacies like Walgreens and CVS, and a mail order pharmacy known as HoneyBee, would provide mifepristone to persons here in the state.

And paragraph 110 alleges that there's a constriction of the market.

We think those -- we easily satisfy plausibility.

THE COURT: Right. And, as I recall, you explicitly alleged in one of those paragraphs that the big pharmacies had publicly stated an intention at some point to distribute the drugs.

Is that correct?

MR. FREDERICK: That's correct.

THE COURT: And I guess that since -- maybe not so clear, as I understand it, and -- but it's not part of the pleadings -- one or more of these pharmacies have now indicated some hesitation about getting into the distribution of mifepristone in those states where attorney generals have said that there should -- that the Ban should prohibit it.

MR. FREDERICK: That brings me to third-party enforcement, because the attorney general here has signed one of those letters that threaten Walgreens, one of the pharmacies that said it would comply with the 2023 REMS to provide mifepristone in its pharmacy.

And in the February 1 letter that the attorney general cosigned with the Attorney General of Kansas, threatened Walgreens with a civil RICO action.

And that threat, we think, brings four square in the third-party enforcement doctrine of standing.

THE COURT: Before we get to that, let's cover the other bases.

You've acknowledged injury in fact, traceability, and redressability. So let's not get into the local prosecutor and the pre-enforcement issue raised there.

Tell me what your response is to the defendants' arguments about traceability and redressability with respect to your injury in fact based standing as a -- for economic

loss.

MR. FREDERICK: Sure. Let me start with traceability.

Both of the defendants have the authority to enforce the law in West Virginia, and neither have disavowed an enforcement intent relating to the Ban.

Under the *Susan B. Anthony* case, that is sufficient for justiciability in terms of traceability where the government has not disavowed enforcement of the unconstitutional law.

We cite other cases in our opposition briefs at 7 and 4, that I think well explained the principal here.

The defendants' commitment to enforcing an unconstitutional law is causing West Virginians not to purchase or prescribe GenBioPro's product. And that's sufficient for traceability.

The *303 Creative* case is on point for this, where the Court said an injury in fact is fairly traceable to a defendant if the defendant is charged with the responsibility to enforce the statute.

And in the Fourth Circuit, the *Libertarian Party* case says that traceability only requires the defendants have, quote, "some part" in causing plaintiff's harm.

Now, as the sequence that you described, which will play itself out in pleading and, in fact, the statements of enforcement by the defendants have chilled the market for

GenBioPro's product. That's sufficient to show the traceability necessary for standing purposes to challenge the unconstitutionality.

THE COURT: I take it that the enforcement you're talking about, primarily, is enforcement of the so-called Unborn Child Act, the Ban -- abortion prohibition, the most recent of the acts by the state legislature. And as I read it, it certainly greatly restricts when any abortion can be performed within the state. It requires, of course, that it be by a medical provider. And that in combination with the earlier statute, which literally criminalizes an illegal abortion, you're really talking about enforcement, both in terms of exposure to a criminal charge, as well as exposure to a licensing revocation or suspension with regard to any doctor or pharmacy.

MR. FREDERICK: That's correct. And even GenBioPro itself, even though it is an out-of-state distributor of mifepristone, falls within an overly broad and vague definition of an attempt to perform or induce an abortion. The definition under state code 16-2R-2 says that abortion means -- that an attempt to perform or induce means an act that constitutes a substantial step in the course of conduct intended to culminate in an abortion.

THE COURT: Almost a state Comstock Act.

MR. FREDERICK: Well, it was -- you know, we can

talk about the Comstock Act in due course, but I just want to start with the definition, which actually leads directly one to think that it could conceivably encompass through its vagueness a company like GenBioPro.

So I think that for these reasons, the traceability goes right back to the statute and goes right back to the activities that GenBioPro is seeking through its distribution of mifepristone in West Virginia.

Now, as to redressability, we've asked for declaratory judgment that the law is unconstitutional. The pharmacies that we cited in our Complaint said that in those states where it is not illegal, they would distribute the product in their pharmacies. We think that's sufficient for redressability.

The laws that have been enforced by the defendants have caused the injury from preventing the sale of the product in the state. So we think we meet each of the elements of standing just as a direct entity by GenBioPro itself.

We think it also satisfies third-party standing, because the providers that you mentioned who face the harm and risk of possible enforcement against them are within the zone protectable by a vendor.

Craig versus Boren established that principle almost 50 years ago when the gentleman who wanted to buy 3.2 beer underage eventually got older than the age prescribed by the

statute, but the Supreme Court said that the seller of the 3.2 beer was able to assert third-party standing on behalf of those whose equal protection rights were being bridged by the Oklahoma statute there.

So we think that there is adequate grounds for both the third-party standing, the threat of enforcement provides adequate standing, and the ability of the vendor here in a better position actually because of hindrances, the cost of litigation, the expense, the difficulty of litigation for individuals, to say nothing of, you know, the concerns with making our product available for sale in the state, I think adequately satisfies all of the relevant standing requirements.

THE COURT: And then with respect to threat of enforcement as a basis to hold in the county prosecutor, it is because the county prosecutor could seek criminal enforcement against your customers, but you argue, even against GenBioPro?

MR. FREDERICK: Well, that -- I'm not inviting that, Your Honor.

THE COURT: Right.

MR. FREDERICK: I'm saying that the vagueness of the statute raises the specter of that, and that is sufficient for standing.

The fact that there are Walgreens stores and pharmacies

in the Putnam County area that are potentially subject to prosecution is sufficient for the threat of enforcement aspect of standing. And -- and it is a real thing, based on the circumstances that I've laid out, that we can make it a full or factual presentation at summary judgment if the Court views the pleading plausible now is sufficient, which we think that the Court should.

THE COURT: All right. Thank you.

MR. FREDERICK: I've got nothing further on standing, unless there are questions that you have. I'd like to save some time for rebuttal, if I might.

THE COURT: Oh, you will. That's fine.

All right.

MR. CAPEHART: Thank you, Your Honor.

I just want to make sure everyone can hear. Is the microphone picking up well?

(Pause.)

THE COURT: I'm sorry. Go ahead.

MR. CAPEHART: Not a problem, Your Honor.

First of all, I just want to take a moment to clarify a couple of things, and especially about how the Unborn Child Protection Act works, especially following some of the concerns about the definition of abortion, because I'm not sure -- I'm not reading it maybe the way that counsel is over here.

Looking at it, an abortion means the use of any instrument, medicine, drug, or any other substance or device with the intent to terminate a pregnancy of a patient known to be pregnant, and with an intent to cause the death and expulsion or removal of an embryo or fetus.

It also goes on to clarify what the definition does not mean. I'm not sure I've seen anything from there that leads me to believe that anyone would ever try to look at the manufacturer of an abortion drug and the shipment or sale of that abortion drug in West Virginia as somehow something to be controlled or to be looked at as an abortion.

THE COURT: It wouldn't be the use of the medicine?

MR. CAPEHART: The use of the medicine would be, but the manufacturer, absolutely not.

THE COURT: Well, okay. I mean, here, you're talking about the manufacture and distribution through the sale.

MR. CAPEHART: Correct.

THE COURT: I take it that at this point neither the attorney general nor the prosecutor have announced any policy response to that argument and disavowed any possibility of bringing a criminal prosecution against the maker of the drug. And I say that in the context, frankly, of you raising the Comstock Act as a possible violation.

It's federal law. It's not enforceable by you guys, but you've raised that as a possible consequence of the manufacturer's decision to produce or to manufacture and sell in the state, and thereby transport over interstate commerce.

So it really -- I appreciate what you're saying, but I -- I don't think I could find that as a persuasive declaration that there is no exposure to criminal prosecution.

MR. CAPEHART: Well, and I appreciate the opportunity here on the record to clarify some of these things, because I think there has been a bit of a misapprehension as to exactly what the purpose of the statute is. And I can't speak to what a prosecuting attorney would do as the principal prosecuting arm of the state government vis-a-vis the criminal code, 61-2-8. That's the prosecutor's decision. I'll let the prosecutor's office speak to that.

But in terms of our read of what the Unborn Child Protection Act was about, it's all about the regulation of the practice of abortion, and also of the practice of medicine as it relates thereto. It's limiting only that practice to those persons identified within the statute as being capable of performing legal abortions that may continue and may happen within the bounds of the Unborn

Child Protection Act, which there certainly are some.

THE COURT: Even if that is the case, does that really change the Court's analysis? The plaintiffs have asserted that they have third-party standing on behalf of their putative customers, and those are the people that are clearly exposed to criminal prosecution if they use the plaintiff's product to perform an abortion.

MR. CAPEHART: Not to step on the prosecutor's toes, but my reading of the criminal statute of 61-2-8 is to clarify that those persons who are not identified within the Unborn Child Protection Act as being permitted to perform abortions are creating -- excuse me -- are performing a criminal act to induce or perform an abortion.

That clarifies that only those persons identified in the Unborn Child Protection Act may ever be the group of persons who could conduct a legal abortion. Anyone else, potentially, is subject to criminal prosecution.

THE COURT: Well, maybe I'm missing something here.

So the state's criminal statute criminalizes abortions performed other than those that are narrowly permitted under the statute.

MR. CAPEHART: Correct.

THE COURT: So the plaintiffs are arguing that that narrow permission for abortion under the West Virginia

statute, and particularly the most recent one, effectively limits when their product can be used by a medical provider in West Virginia to perform an abortion. And so I -- it's clear to me then that the doctors and/or pharmacies who use -- who purchase and use mifepristone in a way that's outside of the West Virginia statute are clearly subject to criminal prosecution.

What am I missing?

MR. CAPEHART: You're saying that if someone were to perform a purely elective abortion, which the Unborn Child Protection Act does not permit, that would be an act outside of the law, that those are no longer legal in West Virginia.

THE COURT: Right.

MR. CAPEHART: And anyone who wants to perform one of those violates the Unborn Child Protection Act, and then similarly would be subject to some kind of criminal prosecution. But that's about the practice of abortion.

That's not about this manufacturer or their product or how someone utilizes their product. Their product is utilized perfectly legally. And as I read it, I don't see how use of their product subjects them to liability any more than the use of the Louisville Slugger crime subjects --

THE COURT: Well, I believe the whole point of their lawsuit is that under the Commerce Clause and the

Supremacy Clause the statute you're defending constricts when their products can be used. And so I don't think we're -- maybe we are just not connecting with each other.

But it seems pretty clear to me that their claims are that because of the restrictive market for their product created by West Virginia's strict abortion laws violates -- results in a violation of the Commerce Clause and the Supremacy Clause.

We're going to argue later, obviously, about whether it does and all that, but those are the two claims that they've raised, and very clearly they're arguing -- they're claiming that you have constricted the market for their product and that's caused them economic injury, and so they have standing to bring the claims because of their own economic injury. And, obviously, bringing -- a vendor can bring claims under the Commerce or Supremacy Clause where they most likely are here.

And so, I mean, maybe I'm missing something that you're saying and I'm just not able to hear it right.

But pretty clearly, it seems to me, they have claimed injury in fact to bring these claims based upon those circumstances. And the threat of prosecution arises because the attorney general and/or the county prosecutor can prosecute their customers for criminal violations for the use of their product in performing an abortion that's

outside of the restrictions that the state has imposed.

MR. CAPEHART: I guess we just never looked at that, subjecting them to any kind of criminality.

THE COURT: Well, there's two things to think about here. One is that -- whether they have standing or not is not dependent upon the cause of action they raise.

Clearly, the Court says that standing is determined based -- it is a constitutional requirement that has to be met in order to consider a party -- a party who can properly raise whatever claims they might have. And so they don't have to have standing just based upon -- they don't have to prove their economic injury results from a Commerce Clause or a Supremacy Clause violation.

Standing is determined, whether they have a sufficient interest to be recognized by a court as a proper party to bring whatever claims they have.

And so here, that's obviously what they are claiming, that they have an economic loss.

And I don't think you all dispute the economic loss, or do you? I mean, is that what you're saying now?

MR. CAPEHART: No. I think to the extent that -- that one would state that there may be fewer abortions after the passing of the statute as compared to before, it's entirely possible. I don't know that. I haven't seen any data on that.

THE COURT: Well, irrespective of -- irrespective of how many abortions are performed, whether it's up or down, their claim is that their product will not be able to be used to the, I guess, sort of the full extent that it's designed to be used, because of the restrictions the state imposes.

So that's their injury in fact is the economic loss from not being able to market and sell their product as extensively as they otherwise could, given the FDA approval.

MR. CAPEHART: Well, and I guess on that point, Your Honor, we still believe that that's a bit of a speculative argument in the first place. And it's -- I appreciate some of the clarifications that counsel provided.

I don't know that we ever read any of those paragraphs of the Complaint to assert that there was affirmatively any sale in West Virginia.

THE COURT: Well, I agree. It's kind of where we started. They did not allege that they have had any past sales.

Now, they say that they have, and they could, but we are not to that point.

Based purely upon their pleading, they did not claim that they had already had sales. I don't think they even claimed -- in West Virginia -- I don't think they even claimed that they had any sort of a contractual or similar

relationship with any doctor or pharmacy.

But what they have clearly alleged is that they have been in the business of making this generic for three years, and they have sold it widely across the United States. And they have even claimed that specifically under the latest REMS -- R-E-M-S -- they could have, and they could distribute through a pharmacy, and that they specifically alleged one or more of these big chains announced that they were going to distribute the drug.

And so I agree they haven't alleged what I examined Mr. Frederick about, past sales, or even a current existing operation of sales within the state, but they've alleged something different.

And so the question is is that enough?

MR. CAPEHART: And we have, obviously, taken the position, Your Honor, that, no, it's not.

The fact that a market participant can come to a market that it's never been a part of and allege that its share of the market or its customer base in a market that it's never been present in has been somehow constricted, even though they've never had a share of that market, seems like a bridge too far. Especially, you know, as we've been saying, I see no reason to believe that there actually have been sales.

In fact, it would be a bit of a concern, perhaps,

because the manufacturer BioPro lacks the manufacturer's license required by the Board of Pharmacy to send their materials into West Virginia. That's wholly lacking. So that would be a violation of West Virginia law.

I don't know that that's --

THE COURT: I don't mind telling you, when I went through all this and at that point decided that I wanted to have a hearing on it to get full argument out here, one of my concerns about the injury in fact allegations of the plaintiff is whether or not it fell somehow on that side of the continuum towards like *Lujan* and those cases, where the Court talked about people -- plaintiffs can't just sort of speculate that they are going to do something that would give them standing.

And the Court has been, I guess, fairly clear and consistent that generalized grievances argue that you can't just come in and say, well, I'm one of the many people who object to this. I don't like this policy.

That's not enough to give standing. Taxpayers don't automatically have standing to challenge every spending decision.

And so here, my dilemma was looking at, you know, sort of the continuum of conduct that might fall within the economic loss line. Have they crossed that threshold from being sort of speculative and generalized intent to do

something, like conduct sales, or -- or do they meet the test because of what they've done.

And, you know, I'm not going to -- I'm not going to decide this sitting up here on the bench today. I never feel comfortable doing that. But, to be honest with you, because I want you to be able to respond, the closer we've gotten to this hearing, the more inclined I am to conclude that there is injury in fact; that they don't have to have that level of contact and sales within the state that they might have to have for some other purpose; for instance, to be conducting business for personal jurisdiction or something like that.

Here, this company has been making this generic for three years. They've alleged that they sell it nationwide.

Clearly, under the REMS, they've got a new sort of class of customers in that pharmacies can deal with this directly. And they've also got, under the FDA approvals, an increased sort of possibility of business because doctors could do it through telemedicine and other things like that.

And so, you know, those don't seem -- it doesn't seem that GenBioPro is just some pharmaceutical company that wants to get into the business and is coming to West Virginia to challenge restrictive laws.

They are in the business. And it sounds like they've been performing business activities consistent with their

claims. And the claims are not simply conclusory; they're plausible claims that pharmacies located throughout West Virginia, including Putnam County, have indicated an intention -- or at least they had at the time of the suit -- to be involved in the distribution, and that this is a drug that is becoming more widely-accepted, and is now, as I think they allege -- and I think I probably read this somewhere in the papers, too -- it is the predominant form of medical abortions. That using a -- this drug is more common than not when it comes to performing a lawful abortion.

So all of that seems to me to start tipping in the balance much more towards the plaintiff and a finding that this is not a generalized grievance, this is not a speculative economic loss, that this is something pretty direct.

MR. CAPEHART: I think our position has always been that it looks speculative and somewhat remote. And given the fact, as you said, they received generic approval in 2019 from FDA, yet have never -- as far as we know from the pleadings or from some other records -- had any access to West Virginia or availed themselves of it.

So they've been doing it for four years and never been here before. Now they're here, still with zero contacts, from everything that we can see. That looks very, very

speculative. And if that there is some sort of intent desire, hardened goal to be into the West Virginia market, when that's never been present before or evident in many ways, again, by the fact that they do not have the single manufacturer's license that every manufacturer is required to have when sending their drug products to West Virginia, that's a pretty easy get. And lacking even that after four months of litigation doesn't speak to me as though someone who is really trying to get into the market.

THE COURT: All right. I appreciate that.

Thank you.

What else do you want to say?

Well, let me ask you this -- I didn't want to interrupt you.

Mr. Frederick cited a couple cases, a Seventh Circuit case, and then another one, where there were not direct sales in the targeted state at or before the time of the lawsuit being filed. So --

MR. CAPEHART: I'm afraid I don't have absolute command of those right in front of my mind, Your Honor. But, if I recall correctly, it's still involved with an outright total ban of the some type of activity I think was the --

THE COURT: The gun range case?

MR. CAPEHART: The firing range case, yes. Which

is obviously not the case here. There is nothing in West Virginia law that serves as any impediment to a drug manufacturer coming in, marketing and selling it, except the licensure through the boards of pharmacy and whatnot.

THE COURT: In the *Maryland Shall Issue* case and in the *Craig v Boren*, these were businesses that had a whole lot more sales going on than just the sales that were affected by the state's restrictions that were being challenged.

MR. CAPEHART: And they were active in the marketplace prior to the change in code, which is obviously not the case here.

THE COURT: Okay. Anything else you want to bring up on traceability or redressability with respect to GenBioPro standing?

MR. CAPEHART: No. I think we've touched on a lot of the things that I was going to try and get into, Your Honor.

THE COURT: Do you want to address separately third-party standing?

MR. CAPEHART: In terms of redressability? In terms of --

THE COURT: Well, with any of these things, I guess. I mean, as I understand the law, if a party has standing, they may also seek third-party standing where they

stand in the shoes of some other personal entity and be able to bring -- they would have standing to bring claims consistent with what those claims would be here.

And GenBioPro is arguing that it has third-party standing on behalf of pharmacies and doctors that would otherwise -- it would be their customers if these restrictions were found to be -- determined to be unconstitutional.

MR. CAPEHART: Well, and I think in regard to pharmacies, again, as I was saying earlier, I don't see how pharmacies are implicated by the statutes that are being challenged. It's about the practice of medicine, and also about the criminality of the act of performing an illegal abortion under state law.

The pharmacies don't deal with that. They are simply in the process -- they exist to dispense medications per prescriptions by doctors, which is something that a pharmacy -- and, obviously, talking about mifepristone -- one would have to be properly trained and have the proper certification under the REMS so that they could dispense it in the first place.

And I may be wrong, but I'm not sure that there is actually one in West Virginia. I think HoneyBee is a mail-order pharmacy that is outside West Virginia that wants to ship them here. But I don't believe there is a physical

pharmacy in West Virginia that has been certified by GenBioPro to dispense their medications.

Again, we don't see how pharmacies are directly implicated or regulated by any of the statutes in play. The physicians are, but the physicians are through the practice of medicine. That's wholly bound to the state to decide. That's made that pretty clear.

THE COURT: All right. Okay. Anything else?

MR. CAPEHART: Not at this time.

THE COURT: All right.

MS. SCRAGG KARR: Thank you, Your Honor.

Jennifer Scragg Karr, representing Mark Sorsaia, the prosecuting attorney.

THE COURT: Tell me his name again. I have met him and I've heard his name for years, but -- well, I've read it for years. I don't hear it very often.

MS. SCRAGG KARR: It is Sorsaia.

THE COURT: Sorsaia, all right. All right, thank you.

MS. SCRAGG KARR: And so I will just discuss why you should dismiss this claim against Mark Sorsaia. And that is because, as the prosecuting attorney, he is only in the business of prosecuting crimes. And this plaintiff doesn't have a stake in the controversy of prosecuting crimes, because when you look at what is a crime under our

new state law, the legislature enacted the Chapter 16, Section 2R. And when you look at that, the only thing that is an actual crime, when it comes to abortion, is under 61-2-8.

And when you read the criminal statute, it actually exempts a licensed medical professional, and it exempts a pregnant female who is having --

So as it relates to this plaintiff, the plaintiff would be dispensing a pill pursuant to a licensed medical professional requesting it, giving a prescription, and the pharmacist filling it. So because the doctor and the pharmacist are licensed medical professionals, we as a prosecutor could not prosecute them for a crime.

THE COURT: But if they -- if, in all of those circumstances, they were a licensed medical provider, they got the drug from a licensed pharmacy that was manufactured by the plaintiff, if they performed an abortion using that drug, and that abortion was outside the restrictions that the State of West Virginia imposed in both of these Acts, but, in particular, the more recent more restrictive Act, they would be subject -- that provider would be subject to prosecution for a crime.

MS. SCRAGG KARR: No, because they are exempt. Under the statute, it says, any person other than a licensed medical professional, as defined in 16-2R-2 -- which talks

about how they have to be licensed in West Virginia -- who would then do a -- knowingly and willfully perform, induce, or attempt to perform an abortion.

So it's any person other than that licensed medical professional.

So I think in this case what the plaintiff is probably looking at is the medical professional would be at -- have the potential to have their license revoked if they prescribed this pill in violation of the code section.

THE COURT: But you think that's the only penalty that a licensed provider would be subject to if they performed an abortion at 18 weeks, using mifepristone? And I know that's outside of the time they said.

MS. SCRAGG KARR: That's correct. That's how I read the statute. So by having that licensed medical -- the medical license would prevent them from being prosecuted.

THE COURT: Okay. Thank you.

(An off-the-record discussion was held between the Court and law clerk.)

THE COURT: All right. And my clerk is reminding me that the penalty section provides that on the first instance of a violation, they can be sanctioned on their license, but if they did it again, a second one, they'd be subject to criminal penalties.

MS. SCRAGG KARR: Well, actually what it says at

subsection (b) of that 61-2-8, and that says, a person who was formerly a licensed medical professional.

Then -- and so, still again, they would be a person who no longer was a licensed medical professional. So regardless of how many abortions the medical professional would have authorized or conducted, it wouldn't matter under that code section.

I think what maybe your law clerk is thinking is once they would perform an illegal abortion or have one performed, then they would lose their license through a procedure of the code, and then once they lost that, if they did another one, they could be prosecuted. That would be true. They would no longer be a medical professional.

THE COURT: All right. Thank you for clarifying that.

All right, anything else?

MS. SCRAGG KARR: No, Your Honor.

THE COURT: I'll give you've a few minutes for rebuttal.

MR. FREDERICK: Let me start with the prosecutor, because the prosecutor has not disavowed an intent to enforce the statute. And that failure to disavow is particularly critical for pharmacies, which are not exempt from the statute, or nurse practitioners, who are not exempt from the statute, and who, under the FDA guidance, are able

to provide mifepristone to pregnant women.

And so however much today's argument might focus on doctors, it doesn't address an issue that goes to standing under the third-party doctrine, under pre-enforcement challenges, which they don't acknowledge.

We are allowed to bring a pre-enforcement challenge to the law under the *Susan B. Anthony* case. And by the plain terms of the state statute, it encompasses people that are protected by the FDA 2023 REMS.

The Ban includes criminal penalties for pharmacies at 61-2-8, which we cited in our opposition to the prosecutor's motion at 11, pharmacists are not licensed medical professionals within the meaning of the statute. And because they face criminal penalties, I think that the prosecutor really, respectfully, has to stay in the case. There is not a way to avoid that, given past statements about intending to enforce the statute as it is written.

With respect to the attorney general, I'm perplexed by the argument made today, frankly, because what the attorney general seems to be saying is that we can -- we can go after all the people who create the market for mifepristone, the doctors, the pharmacists, the nurse practitioners and everybody else, and it doesn't matter that it constricts your economic losses. Somehow the maker of the drug and the distributor in the state of the drug doesn't have standing

to say the state law is unconstitutional.

That doesn't make any sense.

And the fact that the *Ezell* case is pretty much on point -- and let me give you the citation. It is 62 F.3d at 692, Your Honor -- says that the firing range facility operator intended to create a facility in Chicago. It didn't have one at the time. It was doing them throughout the nation.

So it simply can't be the case that someone seeking to do business in a location but for a constitutional prohibition lacks standing in order to challenge the unconstitutionality of the statute.

I'm happy to address any of the other issues, but I don't think there is a serious argument here today that we lack standing to challenge the West Virginia statute.

And I look forward to the Court's decision and the opportunity to litigate the merits further.

THE COURT: All right. Thank you.

So you can take your seat.

Here's my plan. I would decide this within the next few days. I'll get started today. And within the next several days, I'll make a decision. And if I think I can get an opinion written on it within a few more days, like the next week or 10 days, you'll just hear -- you'll get all that at once, one way or the other.

If I think it's going to take me much longer than that, for some reason, then I might short-order just saying that we have found or not found standing and an opinion will follow.

A lot of it just depends on what else comes into the Court that I've got to address between now and then, but my plan would be to decide this pretty quickly.

If I decide there is standing, then what I would hope to do is -- if I cannot get too distracted by other cases -- to spend enough time on the other issues that are raised in the motion to dismiss, so that I can have a meaningful argument session with you again. And I'm really hoping I can do that within the next month.

My plan would be to try to -- if I can get up to speed on it -- bring you in some time in the middle, latter part of May and let you do oral argument on the remaining issues. And then be prepared to submit it and try to get it decided as quickly as I can at that point. Okay?

As much as I can do. All right.

Thank you all for your appearance today and your argument. I appreciate it.

(Proceedings concluded at 2:55 p.m.)

CERTIFICATE OF OFFICIAL REPORTER

I, Catherine Schutte-Stant, Federal Official Realtime Court Reporter, in and for the United States District Court for the Southern District of West Virginia, do hereby certify that, pursuant to Section 753, Title 28, United States Code, the foregoing is a true and correct transcript of the stenographically reported proceedings held in the above-entitled matter and that the transcript page format is in conformance with the regulations of the Judicial Conference of the United States.

s/Catherine Schutte-Stant, RDR, CRR

_____ May 17, 2023

Catherine Schutte-Stant, RDR, CRR
Federal Official Court Reporter

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

Plaintiff,

v.

MARK A. SORSAIA, ***in his official capacity as Prosecuting Attorney of Putnam County*** **AND PATRICK MORRISEY,** ***in his official capacity as Attorney General of West Virginia,***

Defendants.

Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)

PLAINTIFF GENBIOPRO'S SUPPLEMENTAL BRIEF REGARDING *NATIONAL PORK PRODUCERS COUNCIL v. ROSS*

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

INTRODUCTION

The Supreme Court's decision in *National Pork Producers Council v. Ross* reaffirmed the Court's 50-year-old balancing test for dormant Commerce Clause claims: when a nondiscriminatory state law places a burden on interstate commerce that clearly exceeds its local benefits, that law violates the Commerce Clause. No. 21–468, — S. Ct. — , 2023 WL 3356528, at *18 (U.S. May 11, 2023) (Roberts, C.J., concurring in part and dissenting in part); *id.* at *17 (Sotomayor, J., concurring in part). A six-Justice majority held courts should apply this undue burden test, first articulated in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970), even when doing so requires them to "weigh disparate burdens and benefits," such as asserted moral interests and interference with interstate commerce. *National Pork*, 2023 WL 3356528, at *17 (Sotomayor, J., concurring in part); *see id.* at *19 (Roberts, C.J., concurring in part and dissenting in part).

The same majority agreed that *Pike*'s balancing test applies not just when traditional instrumentalities of commerce, like trains, are at issue, but whenever a state statute interferes with interstate commerce. *Id.* at *17 (Sotomayor, J., concurring in part); *id.* at *19 (Roberts, C.J., concurring in part and dissenting in part). The burdens on interstate commerce are particularly salient in "area[s] presenting a strong interest in 'national uniformity.'" *Id.* at *20 (Roberts, C.J., concurring in part and dissenting in part) (quoting *General Motors Corp. v. Tracy*, 519 U.S. 278, 298 n.12 (1997); *see id.* at *17 (Sotomayor, J., concurring in part) (same).

Under the framework affirmed in *National Pork*, West Virginia's Unborn Child Protection Act, W. Va. Code § 16-2R-1 *et seq.*, and associated penalties, *id.* § 61-2-8 (collectively, the "Criminal Abortion Ban" or "Ban"), and abortion restrictions[1] violate the

[1] W. Va. Code §§ 16-2I-2 (requiring waiting period and counseling before an abortion procedure), 30-1-26(b)(9) (prohibiting providers from prescribing mifepristone via

Commerce Clause. These laws impose a severe burden on interstate commerce by functionally banning an article of commerce—mifepristone. The laws impede the flow of commerce into and around West Virginia, disrupting the market for a drug that Congress subjected to nationally uniform federal regulation. And the laws impose "derivative harms" cognizable under the Commerce Clause by depriving West Virginians of access to an essential healthcare product. *National Pork*, 2023 WL 3356528, at *20 (Roberts, C.J., concurring in part and dissenting in part). These direct burdens on interstate commerce and derivative harms outweigh the State's alleged interest in passing the Ban and Restrictions.

ARGUMENT

I. AS SIX JUSTICES AGREED IN *NATIONAL PORK*, A LAW THAT UNDULY BURDENS INTERSTATE COMMERCE, SUCH AS WEST VIRGINIA'S, VIOLATES THE COMMERCE CLAUSE

The Commerce Clause "confer[s] a 'right' to engage in interstate trade free from restrictive state regulation." *Dennis v. Higgins*, 498 U.S. 439, 448 (1991). In *National Pork*, a majority of the Supreme Court reaffirmed the rule, set forth in *Pike*, that when the "burden imposed on [interstate] commerce" by a state law "is clearly excessive in relation to the putative local benefits," the law violates the Commerce Clause. *National Pork*, 2023 WL 3356528, at *16 (Sotomayor, J., concurring in part) (quoting *Pike*, 397 U.S. at 142); *see id*. (rejecting any "fundamental reworking" of the *Pike* "doctrine"); *id.* at *18 (Roberts, C.J., concurring in part and dissenting in part) ("Today's majority does not pull the plug [on *Pike*'s balancing test].").

All Justices recognized that the Court has invalidated laws under the Commerce Clause in cases implicating the "arteries" and "instrumentalities" of commerce, such as interstate transportation. *Id.* at *11 n.2 (majority opinion.); *id.* at *17 (Sotomayor, J., concurring in part);

---

telemedicine), 30-3-13a(g)(5) (providing for rule banning prescribing mifepristone via telemedicine) (collectively, the "Restrictions").

id. at *18-19 (Roberts, C.J., concurring in part and dissenting in part). A six-Justice majority confirmed that a state law regulating products other than the traditional instrumentalities of commerce, such as the cantaloupe packaging at issue in *Pike*, may likewise violate the Commerce Clause if the burdens the law places on interstate commerce clearly exceed its local benefits. *Id.* at *17 (Sotomayor, J., concurring in part); *id.* at *19 (Roberts, C.J., concurring in part and dissenting in part). A state law may fail *Pike*'s balancing test, too, when it interferes in an arena requiring nationally uniform regulation at the federal level. *Id.* at *20 (Roberts, C.J., concurring in part and dissenting in part); *id.* at *17 (Sotomayor, J., concurring in part).

West Virginia's Ban and Restrictions fail this test. First, they regulate "in an area where there is a compelling need for national uniformity," *Yamaha Motor Corp., U.S.A. v. Jim's Motorcycle, Inc.*, 401 F.3d 560, 572 (4th Cir. 2005): the "health care delivery system" for drugs subject to a Risk Evaluation and Mitigation Strategy ("REMS"), 21 U.S.C. § 355-1(f)(2)(D). Congress subjected this small subset of drugs to the comprehensive postmarket regulatory regime it established in the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. No. 110-85, 121 Stat. 823, which requires the drugs to move through interstate commerce. *See*, *e.g.*, *id.* § 505-1(f)(2)(D)(ii), 121 Stat. at 930 (requiring that any restrictions "be designed to be compatible with established distribution, procurement, and dispensing systems for drugs"); *id.* § 505-1(f)(5)(B)(ii), (iii), 121 Stat. at 931 (requiring that any restrictions not "unduly burden[] . . . patient access to the drug" and "minimize the burden on the health care delivery system"). This regime dictates in detail how such drugs move through interstate commerce, from packaging to distribution to dispensing. *See* Compl. ¶¶ 48-50; *see also* Plaintiff's Opposition to Defendant Patrick Morrisey's Motion to Dismiss at 23-24 (Mar. 17, 2023) ("Opp. to Morrisey MTD"), Dkt. 35; Letter from Patrizia A. Cavazzoni, Dir., U.S.

Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., to Donna J. Harrison, Exec. Dir., Am. Ass'n of Pro-Life Obstetricians & Gynecologists, & Quentin L. Van Meter, President, Am. Coll. of Pediatricians at 6 (Dec. 16, 2021) (explaining FDA's determination that allowing mifepristone to be dispensed by mail "will render the REMS less burdensome to healthcare providers and patients"), https://www.regulations.gov/document/FDA-2019-P-1534-0016.

Second, West Virginia's laws do not incidentally regulate interstate commerce in this arena; they impose a total ban by forbidding mifepristone in almost all circumstances for its indicated use. Courts have long recognized that product bans work a severe burden on interstate commerce. *See Schollenberger v. Pennsylvania*, 171 U.S. 1, 12 (1898). Finally, besides burdening "integral healthcare distribution mechanisms," such as drug manufacturers, nationwide pharmacies, and online pharmacies, Compl. ¶ 78, the Ban and Restrictions inflict serious "derivative harms," *National Pork*, 2023 WL 3356528, at *20 (Roberts, C.J., concurring in part and dissenting in part), depriving patients of access to FDA-approved, lifesaving healthcare that Congress prioritized for "patient access" nationwide, 21 U.S.C. § 355-1(f)(2)(C). GenBioPro alleges these harms to interstate commerce and derivative harms. *See* Compl. ¶¶ 1, 15-17, 39, 78-79, 104, 106-110.

A. A Six-Justice Majority Voted To Retain *Pike*'s Balancing Test And Confirmed That The Test Applies To Statutes Like West Virginia's

When a state "statute regulates even-handedly to effectuate a legitimate local public interest," the *Pike* balancing test asks judges to determine whether the "burden" the law imposes on interstate commerce "is clearly excessive" in relation to the law's "putative local benefits." *National Pork*, 2023 WL 3356528, at *16 (Sotomayor, J., concurring in part) (quoting *Pike*, 397 U.S. at 142). If the law's burden outweighs its benefits, the law violates the Commerce Clause.

On May 11, 2023, the Supreme Court unanimously reaffirmed that *Pike*'s balancing of the burden on interstate commerce in relation to local benefits remains the operative test for evaluating whether a state law violates the Commerce Clause.[2] Six Justices would apply *Pike* to cases like this one, where the law does not discriminate in pricing and requires the court to balance burdens on interstate commerce and noneconomic interests. Chief Justice Roberts, writing for four Justices, stated that the *Pike* analysis "reflects the basic concern of our Commerce Clause jurisprudence that there be 'free private trade in the national marketplace.'" *Id.* at *18 (Roberts, C.J., concurring in part and dissenting in part, joined by Alito, Kavanaugh & and Jackson, JJ.) (quoting *Tracy*, 519 U.S. at 287). He emphasized that *Pike* protects "a national 'common market'" and that courts can readily apply its framework, as they have for 50 years. *Id.* at *18-19 (quoting *Hunt v. Washington State Apple Advert. Comm'n*, 432 U.S. 333, 350 (1977)).

Justice Sotomayor, joined by Justice Kagan, echoed Chief Justice Roberts's confidence in judges' ability to conduct *Pike* balancing, including when they must balance "economic burdens against noneconomic benefits." *Id.* at *17 (Sotomayor, J., concurring in part and holding that judges are "up to the task that *Pike* prescribes"). She observed that "courts generally are able to weigh disparate burdens and benefits against each other, and . . . they are called on to do so in

[2] All Justices analyzed the pork producers' claim under *Pike*; they disagreed only on the outcome of the undue burden test (or whether the Court could conduct the test at all) on the facts alleged in the operative complaint. Justice Gorsuch, writing in Part IV.A for the majority, acknowledged that "even nondiscriminatory burdens" a statute places on interstate commerce may fail under *Pike*. *National Pork*, 2023 WL 3356528, at *11 (majority opinion) (quoting *Department of Revenue of Ky. v. Davis*, 553 U.S. 328, 353 (2008)). But Justices Gorsuch, Thomas, and Barrett would hold that *Pike*'s balancing is "a task no court is equipped to undertake" when "[t]he competing goods are incommensurable," as with moral and health interests (animal welfare) versus dollars and cents (burden on pork producers). *Id.* at *13. Theirs is the minority view.

other areas of the law with some frequency." *Id.* But applying that test, these two Justices concluded that the pork producers' Commerce Clause claim foundered because they "fail[ed] to allege a substantial burden on interstate commerce"—"a threshold requirement" of *Pike*. *Id.* at *16.

Chief Justice Roberts and Justices Alito, Kagan, Sotomayor, Kavanaugh, and Jackson thus make up a majority of the Court holding that the *Pike* framework governs Commerce Clause challenges to laws that do not discriminate against out-of-state commerce, including those requiring judges to balance burdens on commerce with states' asserted noneconomic interests. This six-Justice majority reaffirmed the Court's long history of balancing disparate burdens and benefits in cases that implicate constitutional rights. *See id.* at *19 (Roberts, C.J., concurring in part and dissenting in part) (discussing cases). For example, Chief Justice Roberts explained that the Court has weighed "the purpose to keep the streets clean and of good appearance" against the "the constitutional protection of the freedom of speech and press," *Schneider v. New Jersey (Town of Irvington)*, 308 U.S. 147, 162 (1939), and an individual's Fourth Amendment interests in "privacy and security" against society's interests in surgically removing a bullet from a suspect's chest for evidentiary purposes, *Winston v. Lee*, 470 U.S. 753, 760 (1985); *see National Pork*, 2023 WL 3356528, at *19 (Roberts, C.J., concurring in part and dissenting in part). As the Chief Justice explained, "sometimes there is no avoiding the need to weigh seemingly incommensurable values." *National Pork*, 2023 WL 3356528, at *19 (Roberts, C.J., concurring in part and dissenting in part).

The same six-Justice majority agreed that a state law need not discriminate against out-of-state companies or burden traditional "arteries of commerce," like trucks and trains, to violate the Commerce Clause. *Id.* at *17 (Sotomayor, J., concurring in part); *see id.* at *19 (Roberts,

C.J., concurring in part and dissenting in part) ("As a majority of the Court agrees, *Pike* extends beyond laws either concerning discrimination or governing interstate transportation."). Both opinions composing the majority cited *Edgar v. MITE Corp.*, 457 U.S. 624, 643-46 (1982), in which the Court held that an Illinois law requiring state approval for shareholder tender offers placed a "substantial" burden on interstate commerce that outweighed the state's asserted interests in protecting securities holders. *National Pork*, 2023 WL 3356528, at *19 (Roberts, C.J., concurring in part and dissenting in part); *see id.* at *17 (Sotomayor, J., concurring in part). This approach reaffirmed precedent "leav[ing] the courtroom door open to plaintiffs invoking the rule in *Pike*, that even nondiscriminatory burdens on commerce may be struck down on a showing that those burdens clearly outweigh the benefits of a state or local practice." *Department of Revenue of Ky. v. Davis*, 553 U.S. 328, 353 (2008); *see also United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 346 (2007) (plurality opinion) (*Pike* applies to "a nondiscriminatory statute like this one").

B. *National Pork* Confirms That West Virginia's Ban And Restrictions Violate The Commerce Clause

The Ban and Restrictions fail *Pike*'s balancing test for three reasons: (1) they intrude on an area in which Congress requires nationally uniform regulation; (2) they functionally ban a product for its indicated use; and (3) they inflict "derivative harms" by imperiling the health and safety of pregnant West Virginians and the national market for medications. That result is even clearer after *National Pork*.

1. *National Pork* Confirmed That Laws Burdening A Market Requiring National Uniformity, As Congress Established For REMS Drugs, Violate The Commerce Clause

All members of the Supreme Court held in *National Pork* that state laws may conflict with the Commerce Clause if they impose an excessive burden in an area requiring "national

uniformity." *National Pork*, 2023 WL 3356528, at *20 (Roberts, C.J., concurring in part and dissenting in part) (quoting *Tracy*, 519 U.S. at 298 n.12); *id.* at *11 n.2 (majority opinion) (recognizing that the Commerce Clause can invalidate state regulation "when a lack of national uniformity would impede the *flow* of interstate goods"). If a statute serves a legitimate local interest, courts must balance that interest against the inherent burden created by regulating "in an area where there is a compelling need for national uniformity." *Yamaha*, 401 F.3d at 572. A state law thus may fail *Pike*'s balancing test when it "adversely affect[s] interstate commerce by subjecting activities to inconsistent regulations." *CTS Corp. v. Dynamics Corp.*, 481 U.S. 69, 88 (1987).

West Virginia's laws burden "interstate commerce involving prescription drugs" subject to federal postmarket restrictions. *Association for Accessible Meds. v. Frosh*, 887 F.3d 664, 669-70 (4th Cir. 2018) (cited in *National Pork*, 2023 WL 3356528, at *9 (majority opinion)). The Ban and Restrictions impose "burden[s] on the health care delivery system" for these drugs in contravention of Congress's mandate to reduce such burdens. *See* 21 U.S.C. § 355-1(f)(2)(D). They thereby cause "economic harms to the interstate market" that have "*market-wide* consequences." *National Pork*, 2023 WL 3356528, at *19-20 (Roberts, C.J., concurring in part and dissenting in part).

West Virginia's Ban and Restrictions go far beyond regulating the cantaloupe at issue in *Pike* or the sows in *National Pork*. They burden a market that Congress designated for national uniformity in regulation, bringing them into the heartland of the Commerce Clause. By regulating how mifepristone may be provided, dispensed, and prescribed, West Virginia's laws affect the very "*flow*" of commerce for mifepristone. *Id.* at *11 n.2 (majority opinion) (quoting, with emphasis, *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 128 (1978)).

In *National Pork*, the negative effects on commerce the producers identified focused primarily on the fact that California's law would require out-of-state pork producers to comply in order to maintain their business because of the interconnected nature of the national pork market, "mak[ing] pork production more expensive nationwide." *National Pork Producers Council v. Ross*, 6 F.4th 1021, 1033 (9th Cir. 2021), *aff'd*, No. 21-468, 2023 WL 3356528 (U.S. May 11, 2023). But as the district court found, and the Supreme Court affirmed, the producers "fail[ed] to make a plausible allegation that the pork production industry is of such national concern that it is analogous to taxation or interstate travel, where uniform rules are crucial." *Id*. at 1031. The key burden, in other words, was "the cost of compliance" with the statute. *Id.* at 1033. That is not true here. Drugs like mifepristone that treat serious medical conditions, and that FDA and Congress approved for distribution nationwide, are matters of national importance. Preventing patients from accessing those drugs threatens their lives and wellbeing, not just their pocketbooks.

Congress specifically required uniform federal regulation that is not "unduly burdensome on patient access" to REMS medications. 21 U.S.C. § 355-1(f)(2)(C). It required such regulation to "minimize the burden" on a key instrumentality of interstate commerce: "the health care delivery system." *Id.* § 355-1(f)(2)(D). In the 2007 amendments to the Federal Food, Drug, and Cosmetic Act, Congress mandated that FDA alone may control how drugs subject to postmarket restrictions move through the interstate market from manufacturer to patient. *See generally* FDAAA § 505-1(f), 121 Stat. at 930-31 (codified at 21 U.S.C. § 355-1(f)); Opp. to Morrisey MTD at 10-11 & n.7.

Congress required FDA to work with drug sponsors like GenBioPro to develop and implement REMS incorporating drugs' distribution schemes. The first REMS governing

Mifeprex (branded mifepristone) included regulations governing how the manufacturer should distribute the drug, including to whom it could be shipped, as has every REMS since. *See* U.S. Food & Drug Admin., *2011 Mifeprex (Mifepristone) REMS*, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2011-06-08_Full.pdf (last visited May 19, 2023). FDA can impose only restrictions that comply with Congress's directive "to minimize the burden on the health care delivery system," taking into account compatibility with "established distribution, procurement, and dispensing system for drugs," and those restrictions must not be "unduly burdensome on patient access to the drug." 21 U.S.C. § 355-1(f)(2)(C), (D). In requiring REMS drugs to be accessible via "the health care delivery system," Congress expressed its intent that these drugs be available in, and flow through, channels of interstate commerce. West Virginia's Ban and Restrictions contravene that intent by burdening the flow of mifepristone into and around the State.

Because Congress mandated a uniform system of regulation that minimizes the burden on the nationwide "health care delivery system" for REMS drugs, including mifepristone, GenBioPro's Commerce Clause claim is stronger than that of the plaintiffs in *National Pork*. The "people's . . . elected representatives" (Congress) have spoken. *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2243 (2022). They provided in the FDAAA that REMS drugs must be accessible to patients and regulation must minimize burdens on the interstate "health care delivery system" for these drugs. *See* 21 U.S.C. § 355-1(f)(2)(D), (5)(A)(ii), (5)(B)(iii). States regulating REMS drugs in different ways, creating multiple markets with different rules and restrictions deviating from FDA's considered judgment about safe use and access, is the very "economic Balkanization" the Framers ratified the Commerce Clause to prevent. *Hughes v. Oklahoma*, 441 U.S. 322, 325-26 (1979).

2. West Virginia's Laws Ban Mifepristone And Thereby Impose A Severe Burden On Interstate Commerce

A complete product ban imposes a particularly severe burden on interstate commerce, as the Supreme Court recognized more than a century ago. *Schollenberger*, 171 U.S. at 12. The Ban and Restrictions violate the Commerce Clause for this reason, too. In the years since *Schollenberger*, some courts have allowed states to prohibit importation of nonessential goods like foie gras, shark fins, or, as Justice Gorsuch highlighted, horsemeat. *E.g.*, *Cavel Int'l, Inc. v. Madigan*, 500 F.3d 551 (7th Cir. 2007) (horsemeat); *see National Pork*, 2023 WL 3356528, at *15 (majority opinion) (identifying fireworks, horsemeat, and plastic bags as consumer products states may ban).

These limited exceptions to *Schollenberger* have three things in common: (1) the products involved are not necessities (*never* FDA-approved drugs that address serious medical conditions), (2) they often cause severe harms or offer little public benefit, and (3) Congress did not subject these items to an integrated, and inherently national, system (here, for delivery of drugs and provision of medical services), much less limit "burdens" on that system. Horsemeat and shark fins fit those three criteria. Mifepristone fits none. No court has upheld a state ban of an FDA-approved medication essential for healthcare.

West Virginia's Ban is, in fact, a "Ban." The Putnam Prosecuting Attorney admits as much. *See* Defendant Mark Sorsaia's Rule 12(b)(1) and Rule 12(b)(6) Motion to Dismiss at 2 (Feb. 16, 2023), Dkt. 17. The Attorney General ("WVAG") responds to GenBioPro's allegations by denying that West Virginia has "banned mifepristone at all." Reply in Support of Motion to Dismiss at 10 (Mar. 31, 2023) ("WVAG Reply"), Dkt. 45. He cites the fact that West Virginia does not attempt to regulate "off-label" use of mifepristone for conditions other than its FDA indication of termination of early abortion, and points to the Ban's limited exceptions. *Id.*

Whether these exceptions allow mifepristone to be sold and used in practice, and whether the possibility of off-label use saves the Ban from being a ban, are issues appropriately addressed on summary judgment. Hypothetical availability of "off-label" use does not mitigate the severe burden on its sales of mifepristone for its indicated use, or on the interstate commerce instrumentalities (pharmacies, telehealth) that deliver the drug.

3. West Virginia's Laws Impose Derivative Harms That Are Cognizable Burdens Under *Pike*—Including Harm to Health And Safety

National Pork also undercuts the WVAG's unsupported assertion that courts applying *Pike*'s balancing test cannot consider "noncommercial burdens allegedly imposed on third parties," such as the burden GenBioPro alleges the Ban imposes on "West Virginians' right to access lifesaving, safe, and necessary healthcare." WVAG Reply at 10-11. Six Justices squarely rejected that argument in *National Pork*. As the Chief Justice explained, the "derivative harms" the Court has "long considered in this context" are cognizable burdens, "even if those burdens may be difficult to quantify." *National Pork*, 2023 WL 3356528, at *20 (Roberts, C.J., concurring in part and dissenting in part) (citing *Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662, 674 (1981) (plurality opinion), and *Raymond Motor Transp., Inc. v. Rice*, 434 U.S. 429, 445 & n.21 (1978)).

Courts applying *Pike* routinely consider a challenged law's effect on third parties and the public. *See*, *e.g.*, *Kassel*, 450 U.S. at 674 (noting the significance of the fact that the challenged "law may aggravate . . . the problem of highway accidents" in describing the burden on interstate commerce); *Bibb v. Navajo Freight Lines, Inc.*, 359 U.S. 520, 527-28 (1959) (invalidating state regulation that caused derivative harms, including physical danger, delays, and significant labor time).

Here, West Virginia's laws bring about "derivative harms" to pregnant West Virginians by depriving them of essential medicine. *National Pork*, 2023 WL 3356528, at *20 (Roberts, C.J., concurring in part and dissenting in part). That deprivation endangers West Virginians' health and their lives: according to FDA and the U.S. Department of Health and Human Services ("HHS"), "pregnancy itself entails a significantly higher risk of serious adverse events [than medication abortion], including a death rate 14 times higher than that associated with legal abortion." Brief for Fed. Appellants at 42, *Alliance for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 26, 2023), Dkt. 222. Such harms are a cognizable component of the Commerce Clause analysis. *National Pork*, 2023 WL 3356528, at *21 (Roberts, C.J., concurring in part and dissenting in part) (listing "worse health outcomes," the spread of pathogens, and "consequential threats to animal welfare" among the relevant alleged harms) (brackets omitted).

The Ban and Restrictions functionally prevent West Virginians from accessing mifepristone for its indicated use, even though Congress tasked FDA with ensuring all Americans could access this drug for medication abortion. *See* Opp. to Morrisey MTD at 8-9; Brief of Food and Drug Law and Health Law Scholars as Amici Curiae in Support of Plaintiff's Opposition to Defendants' Motions to Dismiss at 8 & n.6 (Mar. 27, 2023), Dkt. 44 ("Congress was well aware that the 'deemed to have in effect' language [in the FDAAA] would sweep mifepristone into this new statutory scheme [and subject the drug to a REMS].").

Aside from the harms the Ban and Restrictions cause pregnant people in West Virginia, these laws (and others like them) upend the national market for drugs. Manufacturers will hesitate to invest in developing drugs that they anticipate requiring a REMS when those drugs implicate salient political issues, based on concerns that states could close the doors of their markets. *See* Opp. to Morrisey MTD at 25; Compl. ¶ 17. The Commerce Clause ensures that

anyone who wants to manufacture a product in the United States "be encouraged to produce by the certainty that he will have free access to every market in the Nation." *National Pork*, 2023 WL 3356528, at *18 (Roberts, C.J., concurring in part and dissenting in part) (quoting *H. P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 539 (1949)). States regulating REMS drugs in different ways, creating separate markets, is the kind of economic fracturing the Framers ratified the Commerce Clause to prevent. *See Hughes*, 441 U.S. at 325-26.

West Virginia's interest in "unborn lives"—the only state interest mentioned in the statute, W. Va. Code § 16-2R-1—cannot overcome the burdens its Ban works on the interstate "health care delivery system" for mifepristone and on "access" to necessary healthcare for pregnant patients. *See* pp. 8-10, *supra*. Moreover, the REMS statute specifically requires the Secretary of HHS to consider the "seriousness" of patients' "conditions" and the "expected benefit" to them in developing regulations on REMS drugs, thereby prioritizing the health of the patient in providing access to these medications. 21 U.S.C. § 355-1(a)(1)(A)-(E); *accord id.* § 355-1(f)(2)(C)(i) (requiring FDA, in imposing elements to assure safe use that are not "unduly burdensome on patient access to the drug," to consider, among other factors, "patients with serious or life-threatening . . . conditions"). The State's asserted interest cannot eclipse this congressional mandate. And it cannot outweigh Congress's judgment that mifepristone must be accessible via interstate commerce. *See* pp. 9-10, *supra*.

II. *NATIONAL PORK* LIMITS EXTRATERRITORIAL REGULATION CLAIMS TO PRICING STATUTES

The plaintiffs in *National Pork* advanced an extraterritorial regulation theory premised on the idea that California's pork rules impermissibly regulated out-of-state activities because the interconnected nature of the pork industry forces even non-California hog farmers to comply with California's law. *See National Pork*, 2023 WL 3356528, at *6 (majority opinion); *see also*

National Pork, 6 F.4th at 1028. The Supreme Court unanimously rejected this argument and limited dormant Commerce Clause claims premised on extraterritorial regulation to statutes that discriminate against interstate commerce by tying in-state prices to out-of-state prices. *National Pork*, 2023 WL 3356528, at *9 (majority opinion). The Justices clarified that extraterritorial regulation claims based on *Healy v. Beer Institute*, 491 U.S. 324 (1989), and related cases must involve some element of "purposeful discrimination against out-of-state economic interests" linked to prices. *National Pork*, 2023 WL 3356528, at *8 (majority opinion).

West Virginia's Ban and Restrictions are not price control or price affirmation statutes. GenBioPro therefore will not advance extraterritorial-regulation arguments.

CONCLUSION

The Supreme Court's decision in *National Pork* strengthens GenBioPro's Commerce Clause claim premised on the undue burden West Virginia's laws impose on interstate commerce and the nationwide healthcare delivery system. For the foregoing reasons and those in GenBioPro's Opposition to the Attorney General's Motion to Dismiss, the Court should deny Defendants' motions to dismiss.

Dated: May 19, 2023

Respectfully submitted,

/s/ *Anthony J. Majestro*

Anthony J. Majestro
WV Bar No. 5165
Christina L. Smith
W. Va. Bar No. 7509
POWELL & MAJESTRO P.L.L.C.
405 Capitol Street
Suite P-1200
Charleston, WV 25301
Tel: (304) 346-2889
amajestro@powellmajestro.com
csmith@powellmajestro.com

David C. Frederick*
Ariela M. Migdal*
Eliana Margo Pfeffer*
Mary Charlotte Y. Carroll*
KELLOGG, HANSEN, TODD,
FIGEL & FREDERICK, P.L.L.C.
1615 M Street, N.W., Suite 400
Washington, D.C. 20036
Tel: (202) 326-7900
dfrederick@kellogghansen.com
amigdal@kellogghansen.com
epfeffer@kellogghansen.com
mcarroll@kellogghansen.com

Skye L. Perryman*
Kristen Miller*
DEMOCRACY FORWARD FOUNDATION
P.O. Box 34553
Washington, D.C. 20043
Tel: (202) 448-9090
sperryman@democracyforward.org
kmiller@democracyforward.org

John P. Elwood*
Daphne O'Connor*
Robert J. Katerberg*
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, N.W.
Washington, D.C. 20001
john.elwood@arnoldporter.com
daphne.oconnor@arnoldporter.com
robert.katerberg@arnoldporter.com

*admitted pro hac vice

Counsel for Plaintiff GenBioPro, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

***Plaintiff*,**

v.

MARK A. SORSAIA*, in his official capacity as Prosecuting Attorney of Putnam County* AND PATRICK MORRISEY, *in his official capacity as Attorney General of West Virginia*,

Defendants.

Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)

CERTIFICATE OF SERVICE

I, the undersigned, counsel for Plaintiff, GenBioPro, Inc., do hereby certify that on May 19, 2023, I electronically filed and served the foregoing **PLAINTIFF GENBIOPRO'S SUPPLEMENTAL BRIEF REGARDING *NATIONAL PORK PRODUCERS COUNCIL v. ROSS*** with the Clerk of the Court and all parties using the CM/ECF system.

Respectfully submitted,

/s/ *Anthony J. Majestro*

Anthony J. Majestro
WV Bar No. 5165
Christina L. Smith
W. Va. Bar No. 7509
POWELL & MAJESTRO P.L.L.C.
405 Capitol Street
Suite P-1200
Charleston, WV 25301
Tel: (304) 346-2889
amajestro@powellmajestro.com
csmith@powellmajestro.com

Counsel for Plaintiff GenBioPro, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

Plaintiff,

v.

MARK A. SORSAIA, in his official capacity, AND PATRICK MORRISEY, in his official capacity,

Defendants.

Civil Action No. 3:23-cv-00058

Hon. Robert C. Chambers

DEFENDANTS' SUPPLEMENTAL BRIEFING IN LIGHT OF *NATIONAL PORK PRODUCERS COUNCIL V. ROSS*, NO. 21-468, — S. CT. — (2023)

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

INTRODUCTION

GenBioPro's Commerce Clause claim[1] boils down to this: the challenged laws negatively affect its bottom line because it cannot market its products within West Virginia. The Supreme Court's decision in *National Pork Producers Council v. Ross*, __ S. Ct. __, No. 21-468, 2023 WL 3356528 (U.S. May 11, 2023), clarifies that allegation does *not* present a Commerce Clause problem.

In *National Pork Producers*, the Court addressed a California statute that banned "the in-state sale of certain pork products derived from breeding pigs confined in stalls so small they cannot lie down, stand up, or turn around." *Id.* at *4. The Pork Producers challenged that law, "arguing that the law unconstitutionally interferes with their preferred way of doing business in violation of th[e] Court's dormant Commerce Clause precedents." *Id.* "Both the district court and court of appeals dismissed the producers' complaint for failing to state a claim." *Id.* The Supreme Court affirmed, explaining that "[c]ompanies that choose to sell products in various States must normally comply with the laws of those various States." *Id.* at *5. For the same reason, GenBioPro must comply with the laws of West Virginia if it wishes to market its product there, and its dormant Commerce Claim should be dismissed.

ARGUMENT

GenBioPro argued in its opposition to Defendant Morrisey's motion to dismiss that the challenged laws "violate the [Commerce] Clause by imposing an undue

[1] GenBioPro also asserts a preemption claim under the Supremacy Clause. *National Pork Producers* does not address preemption and therefore, has no impact on that claim, which was fully addressed in Defendant Morrisey's opening brief and reply in support of his motion to dismiss.

burden on interstate commerce, by regulating extraterritorially, and by functionally banning an article of commerce." Pl.'s Opp'n 23, ECF No. 35. Each of these arguments fails under *National Pork Producers*.

I. The Commerce Clause does not prohibit extraterritorial regulation by a State absent purposeful discrimination against out-of-state economic interests.

GenBioPro argues that the challenged laws violate the Commerce Clause because they "have the 'practical effect' of regulating extraterritorially." Pl.'s Opp'n 26. In *National Pork Producers*, the Supreme Court unanimously disavowed an "'almost *per se*' rule against laws with extraterritorial effects." *Nat'l Pork Producers Council v. Ross*, No. 21-468, 2023 WL 3356528, at *15 n.4 (U.S. May 11, 2023). If extraterritoriality has any relevance to the Commerce Clause at all, it is a non-dispositive factor that may be considered as part of the balancing test of *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970). *Compare Nat'l Pork Producers*, 2023 WL 3356528, at *12–13 (plurality) (holding that a plaintiff cannot allege a claim under *Pike* absent evidence of discrimination, regardless of extraterritorial effects), *with id.* at 21 (Roberts, C.J., concurring in part and dissenting in part) (arguing that extraterritorial effects are relevant but not dispositive under *Pike*). Therefore, GenBioPro's independent extraterritoriality claim must fail as a matter of law.

II. The Commerce Clause does not prohibit a State from banning an article of commerce.

Relying on a single case from 1898, GenBioPro argues that the challenged laws violate the Commerce Clause because they ban an article of commerce. Pl.'s Opp'n 27 (citing *Schollenberger v. Pennsylvania*, 171 U.S. 1, 12 (1898)). But the plurality opinion in *National Pork Producers* criticizes the dissent's proposed rule because it

could "require any consumer good available for sale in one State to be made available in every State." *Nat'l Pork Producers*, 2023 WL 3356528, at *15 (plurality). The plurality does not even mention *Schollenberger* and cites State laws banning ordinary consumer goods "ranging from fireworks . . . to single-use plastic grocery bags." *Id.* Critically, the dissent responds not by citing some *per se* rule against banning particular articles of commerce, but by explaining that the dissent's proposed rule applies only where a challenged law requires "compliance even by producers who do not wish to sell in the regulated market." *Id.* at *21 (Roberts, C.J., concurring in part and dissenting in part). None of the other Justices so much as mention a rule against States banning articles of commerce within their own borders.

Regardless, the challenged laws do *not* ban mifepristone within West Virginia's borders, but instead allow for the use of mifepristone for exceptional circumstances when an abortion can be performed legally, such as "within the first 8 weeks of pregnancy if the pregnancy is the result of sexual assault," W. Va. Code § 16-2R-3(b), so long as the doctor does not prescribe mifepristone by telemedicine, *id.* § 30-3-13a(g)(5). Thus, GenBioPro's argument that the challenged laws violate the Commerce Clause by banning an article of commerce fails as a matter of law.

III. The challenged laws do not violate the *Pike* balancing test.

Finally, GenBioPro argues that the challenged laws unduly burden interstate commerce under *Pike*. Pl.'s Opp'n 23. The Justices in *National Pork Producers* appear to disagree about whether *Pike* remains good law and, if it does, how it should be applied. A majority of the Court "agree[d] that heartland *Pike* cases seek to smoke out purposeful discrimination in state laws (as illuminated by those laws' practical

effects) or seek to protect the instrumentalities of interstate transportation." *Nat'l Pork Producers*, 2023 WL 3356528, at *15 n.4. And a majority of the Court held that *Pike* does not cover laws like the California statute at issue in *National Pork Producers*. *Id.*

A three-Justice plurality of the Court rejected the idea that *Pike* "authoriz[es] judges to strike down duly enacted state laws regulating the in-state sale of ordinary consumer goods (like pork) based on nothing more than their own assessment of the relevant law's 'costs' and 'benefits.'" *Id.* at *12 (plurality).

A different four-Justice plurality posited that *Pike* requires a plaintiff to plead "facts leading, 'either logically or as a practical matter, to [the] conclusion that the State [was] discriminating against interstate commerce.'" *Id.* at *13 (plurality) (quoting *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 125 (1978)). Because the National Pork Producers failed to "plead facts 'plausibly' suggesting a substantial harm to interstate commerce," *Pike* balancing did not apply. *Id.* at *14; *accord id.* at *17 (Sotomayor, J., concurring in part).

The four partially dissenting Justices opined that "*Pike* extends beyond laws either concerning discrimination or governing interstate transportation." *Id.* at *19 (Roberts, C.J., concurring in part and dissenting in part). Two partially concurring Justices agreed but adopted a higher standard for alleging a substantial harm to interstate commerce. *Id.* at *17 (Sotomayor, J., concurring in part). And one Justice stated that while she agrees with two other Justices that balancing the benefits and burdens of a law is not a judicial endeavor, she "would permit petitioners to proceed

with their *Pike* claim"—like the partially dissenting Justices—if "the burdens and benefits were capable of judicial balancing." *Id.* at *18 (Barrett, J., concurring).

Justice Gorsuch claimed that "[a] majority [of the Court] rejects any effort to expand *Pike*'s domain" outside its "heartland" of "smok[ing] out purposeful discrimination" and "protect[ing] the instrumentalities of interstate transportation." *Id.* at *15 n.4 (plurality). Yet the Chief Justice asserted that "a majority of the Court agrees" that "*Pike* extends beyond laws either concerning discrimination or governing interstate transportation." *Id.* at *19 (Roberts, C.J., dissenting in part and concurring in part). And Justice Kavanaugh seems to think that Justice Gorsuch's opinion controls "for purposes of the Court's judgment as to the plaintiffs' *Pike* claim," *id.* at *22 (Kavanaugh, J., concurring in part and dissenting in part), but that the Chief Justice's opinion "reflects the majority view" on "whether to retain the *Pike* balancing test," *id.* at *24 n.3.

Fortunately, this Court need not discern which opinion controls to resolve this case because GenBioPro's Commerce Clause claims fail under all three formulations of *Pike*.

A. GenBioPro impermissibly asks this Court to engage in "freewheeling" balancing of the challenged laws' "costs" and "benefits."

GenBioPro asks this Court to balance the State's interest in "protecting unborn lives" against "the burden on West Virginians' right to access lifesaving, safe, and necessary healthcare." Pl.'s Opp'n 25. This is precisely the sort of balancing that a majority of the Court rejected in *Dobbs* and that a three-Justice plurality of the Court rejects in *National Pork Producers*. In *Dobbs*, the Court held that courts must not

engage in "freewheeling judicial policymaking" under the Fourteenth Amendment (or the Constitution generally) to "weigh th[e] [important policy] arguments" concerning "how abortion may be regulated to the States," and that the issue of abortion should be left to "the people and their elected representatives." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2242, 2248, 2259 (2022).

In *National Pork Producers*, the three-Justice plurality reaffirmed that courts also may not exercise "freewheeling power" to "strike down duly enacted state laws . . . based on nothing more than their own assessment of the relevant law's 'costs' and 'benefits'" under the Commerce Clause. 2023 WL 3356528, at *12 (plurality). As in *Dobbs*, the *National Pork Producers* plurality explains that "[i]n a functioning democracy, policy choices like these usually belong to the people and their elected representatives" who are "entitled to weigh the relevant 'political and economic' costs and benefits for themselves . . . and 'try novel social and economic experiments' if they wish." *Id.* at *13 (internal citations omitted).

Regardless, "noneconomic interests," such as the "putative harms" to West Virginia women seeking abortions, are not "freestanding harms cognizable under the dormant Commerce Clause." *Id.* at *15. As explained below, *see infra* Parts III.B and III.C, the only economic harm that GenBioPro alleges is damage to its own bottom line. But that is precisely the sort of weighing of "economic costs (to some) against noneconomic benefits (to others)" that the plurality says is "insusceptible to resolution by reference to any juridical principle." *Id.* at *12. Consequently,

GenBioPro has failed to plead a claim under the three-Justice plurality's formulation of *Pike*.

B. Even if *Pike* applied, the challenged laws pass muster under the version of the *Pike* balancing test articulated in Part IV.C of Justice Gorsuch's opinion.

Pike balancing does not apply here because GenBioPro does not allege a burden in interstate commerce, let alone a substantial one. A four-Justice plurality in *National Pork Producers* held that "*Pike* requires a plaintiff to plead facts plausibly showing that a challenged law imposes 'substantial burdens' on interstate commerce *before* a court may assess the law's competing benefits or weigh the two sides against each other." *Id.* at *13. If, as the plurality held, the National Pork Producers' complaint "fail[ed] to clear even that bar," *id.*, then GenBioPro's complaint is plainly insufficient to state a Commerce Clause claim because it alleges *no* burden on interstate commerce at all.

The plurality further held that *Pike* requires a plaintiff "to plead facts leading, 'either logically or as a practical matter, to [the] conclusion that the State [was] discriminating against interstate commerce.'" *Id.* at *13 (plurality) (quoting *Exxon Corp.*, 437 U.S. at 125). Relying on *Exxon Corp.*, the plurality explained that a "change [in] the market structure" resulting from the law is insufficient absent discrimination.

Even if the *Pike* balancing test applied, GenBioPro has failed to meet it. Nothing in GenBioPro's complaint alleges discrimination against interstate commerce. West Virginia seeks to prevent all abortions except in very limited circumstances, W. Va. Code § 16-2R-3(a), regardless of where the abortion-inducing

drug is produced or whether an abortion-inducing drug (as opposed to a surgical procedure) is used at all. And for those abortions that fall under the statute's exceptions, West Virginia's telemedicine requirements have no relation to whether the abortion-inducing drug was produced out-of-state. *See id.* §30-3-13a(g)(5).[2]

Instead, GenBioPro alleges that the challenged laws "prevent[] GenBioPro from developing a market for its product, mifepristone, in West Virginia" and "force[s] [West Virginia] patients to fulfill waiting period and counseling requirements before accessing mifepristone." Compl. ¶¶ 107, 108, ECF No. 1. In other words, GenBioPro merely alleges a burden on *its own sales within West Virginia* and *on consumers within West Virginia*. But the plurality is clear that "no one thinks that costs ultimately borne by in-state consumers thanks to a law they adopted counts as a cognizable harm under [the Court's] dormant Commerce Clause precedents." *Nat'l Pork Producers*, 2023 WL 3356528, at *14. Therefore, GenBioPro has failed to state a claim under the four-Justice plurality's formulation of *Pike*.

C. The challenged laws also pass muster under the version of the *Pike* balancing test articulated in Chief Justice Roberts's dissent.

The four partially dissenting Justices opined that *Pike* concerns *economic* harms to the *interstate* market. *Id.* at *19 (Roberts, C.J., concurring in part and dissenting in part). The alleged harms must be broad, "market-wide *consequences*;" mere "compliance costs" are insufficient for a Commerce Clause violation. *Id.* (emphasis by the Court). Critically, these harms must be *economic*; noneconomic

[2] This also holds true for the informed consent provisions challenged by GenBioPro, which are currently ineffective. *See* W. Va. Code § 16-2I-2.

harms are not relevant to the Commerce Clause. *Id.* at *20. "[S]weeping extraterritorial effects" are relevant, but not dispositive, under *Pike*. *Id.* at *21.

GenBioPro fails to allege facts sufficient to meet even the dissent's lower bar. GenBioPro has alleged *no* harms, economic or otherwise, outside of West Virginia. The *National Pork Producers* dissent relied on "compliance even by producers who do not wish to sell in the regulated market," "industry-wide harms," and "pervasive changes to the pork production industry nationwide" to argue that the California law violated the Commerce Clause. *Id.* at *21–22.

In contrast, GenBioPro clearly wishes to market its product in West Virginia, Compl. ¶ 107, and it alleges no harms to the abortion industry (or abortion patients) outside West Virginia. Nor does GenBioPro allege any changes to its own business model as a result of the challenged laws. In its opposition to Defendant Morrisey's motion to dismiss, GenBioPro argues that "manufacturers will face increased regulatory costs and unresolvable complexity with deleterious effects throughout the national healthcare delivery system and the pharmaceutical market." Pl.'s Opp'n 25. In support of this argument, GenBioPro cites paragraph 17 of its complaint. *Id.* But paragraph 17 merely restates GenBioPro's preemption argument that the Challenged Laws conflict with FDA regulations. Compl. ¶ 17. Nowhere in the complaint does GenBioPro allege the type of "industry-wide harm" that the *National Pork Producers* dissent would require.

The challenged laws do not require GenBioPro to change its chemical formula, its production methods, or even the conditions of its workers. In fact, the challenged

laws do not regulate GenBioPro or its competitors at all; the laws regulate abortion *providers*, not manufacturers of products that may be used to perform an abortion. *See* W. Va. Code §§ 16-2R-3(a) ("An abortion may not be performed or induced . . . unless in the reasonable medical judgment of a *licensed medical professional* . . . ." (emphasis added); 16-2R-3(g) ("An abortion performed or induced . . . shall be performed by a *licensed medical professional* who has West Virginia hospital privileges." (emphasis added)); 16-2I-2(a) (requiring that informed consent information be given to the abortion patient "*by the physician* or the *licensed medical professional* to whom the responsibility has been delegated by the physician who is to perform the abortion" (emphasis added)); 30-3-13a(g)(5) (providing that "[a] *physician or health care provider* may not prescribe any drug with the intent of causing an abortion" over telemedicine (emphasis added)). Nor do the challenged laws regulate manufacturers indirectly by requiring providers to only prescribe drugs from manufacturers who follow certain constraints. Therefore, GenBioPro has failed to state a claim under the dissent's formulation of *Pike*.

* * *

A majority of the Supreme Court held in *National Pork Producers* that "'extreme caution' is warranted before a court deploys [its] implied authority" under the dormant Commerce Clause. *Nat'l Pork Producers*, 2023 WL 3356528, at *16 (quoting *General Motors Corp. v. Tracy*, 519 U.S. 278, 310 (1997)). The Court further explained that "[p]reventing state officials from enforcing a democratically adopted state law in the name of the dormant Commerce Clause is a matter of 'extreme

delicacy,' something courts should do only 'where the infraction is clear.'" *Id.* (quoting *Conway v. Taylor's Executor*, 1 Black 603, 634 (1862)). Here, GenBioPro has alleged nothing more than harm to its own bottom line because it claims it can no longer market its product in West Virginia. That allegation does not present a dormant Commerce Clause problem under *any* understanding of the Court's decision.

CONCLUSION

For the foregoing reasons, this Court should grant Defendant Morrisey's motion to dismiss for failure to state a claim under the Commerce Clause.

Respectfully submitted,

PATRICK MORRISEY
West Virginia Attorney General

/s/ Curtis R. A. Capehart
Douglas P. Buffington, II (WV Bar No. 8157)
Chief Deputy Attorney General
Curtis R. A. Capehart (WV Bar No. 9876)
Deputy Attorney General
OFFICE OF THE ATTORNEY GENERAL
State Capitol Complex
1900 Kanawha Boulevard E,
Building 1, Room E-26
Charleston, WV 25305-0220
Tel.: (304) 558-2021
Fax: (304) 558-0140
curtis.r.a.capehart@wvago.gov

Denise M. Harle*
ALLIANCE DEFENDING FREEDOM
1000 Hurricane Shoals Rd. NE, Ste. D-1100
Lawrenceville, GA 30043
Tel.: (770) 339-0774
Fax: (770) 339-6744
dharle@adflegal.org

Erin M. Hawley*
ALLIANCE DEFENDING FREEDOM
440 First Street NW, Ste. 600
Washington, DC 20001
Tel.: (202) 393-8690
Fax: (202) 347-3622
ehawley@adflegal.org

**visiting attorney*

Counsel for Defendant Patrick Morrisey, in his official capacity as Attorney General of the State of West Virginia

MARK A. SORSAIA
Prosecuting Attorney

/s/ Jennifer Scragg Karr (by permission)
Jennifer Scragg Karr (WV Bar No. 8051)
Assistant Prosecuting Attorney
Putnam County Judicial Building
12093 Winfield Road
Winfield, WV 25213
Tel.: (304) 586-0205
Fax: (304) 586-0269
jkarr@putnamwv.org

Counsel for Defendant Mark A. Sorsaia, in his official capacity as Prosecuting Attorney of Putnam County

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

HUNTINGTON DIVISION

GENBIOPRO, INC.,

Plaintiff,

v.

MARK A. SORSAIA, in his official capacity, AND PATRICK MORRISEY, in his official capacity,

Defendants.

Civil Action No. 3:23-cv-00058

Hon. Robert C. Chambers

CERTIFICATE OF SERVICE

I hereby certify that, on this 19th day of May, 2023, I electronically filed the foregoing Supplemental Brief with the Clerk of Court and all parties using the CM/ECF System.

/s/ Curtis R. A. Capehart
Curtis R. A. Capehart
Deputy Attorney General

IN THE UNITED STATES DISTRICT COURT FOR THE

SOUTHERN DISTRICT OF WEST VIRGINIA, HUNTINGTON DIVISION

BEFORE THE HONORABLE ROBERT C. CHAMBERS, JUDGE

---o0o---

GENBIOPRO, INC.,
Plaintiff,
vs. No. 3:23-cv-00058

MARK A. SORSAIA, in his official capacity as Prosecuting Attorney of Putnam County, and PATRICK MORRISEY, in his official capacity as Attorney General of West Virginia,
Defendants.
_____/

REPORTER'S TRANSCRIPT OF PROCEEDINGS

MOTION HEARING

TUESDAY, MAY 23, 2023, 1:30 P.M.

---o0o---

For the Plaintiff: POWELL & MAJESTRO
Suite P-1200
405 Capitol Street
Charleston, West Virginia 25301
BY: ANTHONY J. MAJESTRO
and ARIELA M. MIGDAL
and CHRISTINA L. SMITH

KELLOGG, HANSEN, TODD, FIGEL & FREDERICK
Suite 400
1615 M Street, N.W.
Washington, D.C. 20036
BY: DAVID C. FREDERICK
and MARY CHARLOTTE CARROLL

(Appearances continued next page...)

Reported by: KATHY L. SWINHART, CSR
Official Court Reporter
(304) 528-2244

Proceedings reported by mechanical stenography, transcript produced by computer-aided transcription.

APPEARANCES (Continued)

For Defendant MARK A. SORSAIA:

PUTNAM COUNTY JUDICIAL BUILDING
12093 Winfield Road
Winfield, West Virginia 25219
BY: JENNIFER SCRAGG KARR
Assistant Prosecuting Attorney

For Defendant PATRICK MORRISEY:

WEST VIRGINIA ATTORNEY GENERAL'S OFFICE
Building 1, Room 26e
1900 Kanawha Boulevard, East
Charleston, West Virginia 25219
BY: CURTIS R. CAPEHART
Deputy Attorney General

ALLIANCE DEFENDING FREEDOM
Suite 600
440 First Street, N.W.
Washington, D.C. 20001
BY: ERIN MORROW HAWLEY

HUNTINGTON, WEST VIRGINIA

TUESDAY, MAY 23, 2023, 1:23 P.M.

---o0o---

THE COURT: Good afternoon.

MR. MAJESTRO: Good afternoon, Your Honor.

MR. FREDERICK: Good afternoon, Your Honor.

THE COURT: All right. We're here today for the Court to hear arguments on the remaining issues and motion to dismiss. So who is going to be presenting on the defense side?

MS. HAWLEY: Your Honor, Erin Hawley for West Virginia.

THE COURT: All right. Are you ready?

MS. HAWLEY: Yes, ma'am -- or yes, sir.

THE COURT: All right. Go ahead.

MS. HAWLEY: Sorry.

May it please the Court. Erin Hawley for defendant West Virginia.

GenBioPro makes the counterintuitive argument that the FDA's imposition of additional safeguards on especially dangerous drugs means that states cannot also help regulate the safety of those drugs, even though the Supreme Court has called this an area of historical and especially local concern. This means that the graver the risk from a drug, drugs like opioids and chemical abortion, the less states can

do to protect their citizens.

GenBioPro's three preemption claims fail. First each of them fails to overcome the presumption against preemption. Congress does cavalierly preempt state law particularly where, as we discussed, states have traditionally regulated.

As for field preemption, Your Honor, under Fourth Circuit precedent, field preemption is not available, whereas here there is an express preemption clause -- or, excuse me -- an express savings clause.

I'm sorry, Your Honor.

In addition, Your Honor, field preemption is impossible in this case to rebut because it cannot rebut the presumption against preemption as the Supreme Court found in *Wyeth*. In that case, also involving the FDCA, also involving regulation of the pharmaceutical market, the Court noted that this is precisely an area of historic state concern, and, therefore, field preemption was impossible. In fact, *Wyeth* is a case didn't even argue for field preemption.

With respect to conflict preemption, there are two sorts of preemption that GenBioPro alleges. First, GenBioPro speaks about impossibility preemption. But impossibility preemption, Your Honor, applies when it is literally impossible, not possibly impossible, but literally impossible to comply with both federal and state law. This applies in a situation like *PLIVA* or like *Bartlett*, where it was impossible

for the drug manufacturer to comply with FDA's label while having a contrary state label. The requirements did not overlap; they contradicted. It was physically impossible for the drug manufacturers to do that.

That is not the case here. I'm aware of no case, and I don't believe plaintiffs cite one, Your Honor, where a court has found impossibility preemption in a situation like this, where the different regulations, the different statutes act on different entities.

THE COURT: Act on different --

MS. HAWLEY: Different entities.

So the FDA here, of course, regulates drug manufacturers, the drug sponsors. In contrast, West Virginia is regulating abortion, and it acts on abortion providers, so completely different entities. I think there is no logical way to say that it is impossible for GenBioPro to comply with both federal and state law.

So that leaves us, Your Honor, with the third bucket of preemption, and that's the sort of purpose preemption or the idea that West Virginia's laws here frustrate the purpose of Congress in the FDCA. Again, we have that clear presumption against preemption. In fact, it applies with special force in this area. As the Supreme Court has noted, even Justice Stevens acknowledged that when you're looking at this sort of preemption, we want to be careful to tailor our

preemption analysis to the text of the statutes rather than to do a deep dive into purpose.

Here, we don't have to dive very far for purpose at all. The FDCA plainly says that its purpose is to protect the safety of consumers as well as to make sure that drugs are efficacious. So --

THE COURT: Well, but in the additional act, the agency was charged with addressing accessibility, too, which admittedly is different from the FDA review undertaken before.

MS. HAWLEY: I think that's a great point, Your Honor, and GenBioPro's brief points out that it is relying exclusively, as you suggest, on the 2007 amendments, the REMS statute which is codified at Section 355-1. But when you look closely at that statute, Your Honor, the very title is 355-1(f), and it says that the REMS provision is allowed to assure safe access, which GenBioPro focuses on, but it leaves off the second part of that title, which is the drugs that would not otherwise be available.

So I think when you look at Section 355-1, what you see is that this provision, too, is all about approval. The FDA is approving drugs that are especially dangerous. The FDA cannot use this section unless it finds that these drugs have severe and known consequences, severe adverse events like hospitalization and death, so we're talking about a narrow category of drugs that are particularly dangerous. And in

that narrow category, the FDCA -- these amendments instruct the FDA to look at patient access, but only in terms of its own regulations on that access.

So if you look at Section 355-1(f)(2), it says assuring access and minimizing burden. That's something that GenBioPro highlights, but then it goes on "such elements to assure safe use under paragraph (1)," so referring back to those REMS provisions. So I think it's clear from the structure, as well as the text of 355-1, what Congress did in those amendments is to say, when you have these really dangerous drugs, we're going to put additional restrictions on them. We realize some people might need them, so, FDA, don't go overboard, don't put restrictions on that aren't necessary. We still want people to get them. But it in no way suggested that complimentary state regulations would be preempted. That would be contrary to the entire history of the FDCA.

As my esteemed colleague on the other side argued successfully in the *Wyeth v. Levine* case, the FDCA has long set a federal floor. It has never been interpreted to set a federal ceiling. The Supreme Court in *Wyeth* called that sort of an astounding idea, that the FDCA might do that. And especially coupled with the presumption against preemption, I don't think you can get that access purpose out of Section 355.

THE COURT: Isn't it significant that at the time

Congress passed this act, that abortion was a constitutionally protected right, and so in every state there was already the availability of abortion? And isn't the clearing accessibility as one of three things that the agency has to look at, doesn't that give it significance for the discussion we're having today?

MS. HAWLEY: I don't think so, Your Honor, especially when we look at the congressional history here.

The 2007 amendments were a reaction to the Vioxx controversy. The Vioxx controversy involved a very popular drug that turned out to be quite dangerous. It increased risk of stroke and heart disease, essentially about doubled it. So Congress -- the public was upset about this. In the 2007 amendments, Congress strengthened the FDA's authority make sure drugs are safe.

But that statute, Your Honor, was passed, signed by the first President Bush. It passed the House overwhelmingly, 400 and some to a handful, and it passed the Senate by unanimous consent. I don't think you can read from that a congressional direction that abortion should be available everywhere.

THE COURT: Okay. So in *Wyeth*, we know that the Court focused on the fact that, at common law, there were remedies for defective products, and the Court found that that was not preempted by the terms of the FDA. And all that focus was on

labeling, and it seems to me the cases that have come up since generally have been cases involving labeling more than anything else.

So does the State claim that its abortion ban here is based upon its determination that this is not a safe drug?

MS. HAWLEY: No, Your Honor.

The State here is not taking issue -- it's the subject of other litigation --

THE COURT: Okay. So it does seem to me, then, there's a pretty good argument that with regard to safety and efficacy, the FDA decision is preempted; that that is what the agency is charged with doing. There's a long history of this agency being responsible for making determinations about pharmaceuticals, what's approved, what's not approved, I mean, for a hundred years, I guess more now.

So at least are those things not preempted?

MS. HAWLEY: So I think that's correct, Your Honor, but how the Supreme Court in *Wyeth* and in *PLIVA* and *Bartlett* as well, found this to operate is that the FDCA has always operated with complimentary state regulation.

Since it was passed in 1906, Congress has worked to ensure state regulation and even state tort laws --

THE COURT: Well, I think I agree with that. And it seemed to me in *Wyeth*, the Court in particular reviewed the FDA requirements for when you can change labels and so

forth --

MS. HAWLEY: Yes.

THE COURT: -- and found because there is a mechanism --

MS. HAWLEY: Yes.

THE COURT: -- within the statute itself to allow for a label change as the drug is used and more information is gathered and so forth.

So here there is no claim by the State that this drug is not as safe or not as effective as the FDA determined. Why is it not then in conflict with the FDA's determination that this is a drug that ought to be accessible throughout the healthcare industry in the country?

MS. HAWLEY: So I think a couple of things there, Your Honor.

So I don't think it -- again, if we focus on Section 355-1, I don't think that gets us to an access mandate. I think when we're talking about Section 355, what Congress is saying is that these are dangerous drugs. They're like Vioxx, they're like opioids, and we want them to have additional restrictions.

THE COURT: And that's what the FDA was charged with determining.

MS. HAWLEY: Yes, Your Honor.

THE COURT: So you keep coming back to that as though

the State is somehow complimenting, adding to the FDA's decision about what is safe or effective, but that's not the purpose of this statutory bar on using the drug.

MS. HAWLEY: So I think that actually helps the State here, Your Honor.

If you look at -- and, again, we're talking about the bucket here of purpose preemption cases, and so there's --

THE COURT: I'm sorry. Of what?

MS. HAWLEY: Of purpose preemption, where it frustrates the purpose.

THE COURT: Right.

MS. HAWLEY: And so there's a series of three cases from the Supreme Court that I think really illustrate why what West Virginia had done here is not preempted.

The first one of those is *Virginia Uranium* mining. In that case, Congress had, of course, regulated extensively in the field of mining; it had regulated for health and safety. And what Virginia was allowed to do is say we're not going to allow mining. We realize that the federal regulations speak to what is permissible with milling, what is permissible with tailing, but the Supreme Court said Virginia was operating in a different purpose, Your Honor, and so the different purpose is key here.

It's important to note that West Virginia does have a different purpose. It's not disagreeing with safety and

efficacy. It's saying instead West Virginia citizens have determined that life is worthy of protection no matter how small.

If you look at the *Harris* case, this is the meat packing case, and what the Supreme Court said in that case was, California, you can't interfere with slaughter standards, you can't say stuff about non-ambulatory pigs, but what you can do is you can disallow horses from being slaughtered entirely.

Similarly in a case called *PG&E*, this involved nuclear regulation, nuclear safety, again an area in which Congress is heavily invested, a heavily regulated area. And the Supreme Court in *PG&E* said Congress could institute a moratorium on building. Even though Congress heavily regulated the design and safety, California could say, no, we're not going to build because that determination was an economic one.

Similarly here, West Virginia's determination is one about unborn life, about maternal health. It's different than FDA safety and efficacy. And for that reason, Your Honor, I think that this case fits squarely within that line of cases that say when a state regulates for a different purpose, it is entitled to do so, and it would be an affront to state sovereignty to read congressional -- the FDCA or the 2007 amendments to take away those validly enacted state laws.

So, Your Honor, to talk -- we've talked about field

preemption. We've talked about how express savings clauses, as we find in the FDCA, are incompatible with field. We've talked about --

THE REPORTER: I'm sorry, incompatible with field?

MS. HAWLEY: Field preemption, yes, ma'am. I will speak more slowly.

So we've got the conflict impossibility preemption. We just talked about purpose preemption.

And to look again at the text of Section 355-1, what that text says is that such elements, the elements for the REMS under paragraph (1) are not to be unduly burdensome. So, again, we're talking about what FDA can do, not about what states can do under their complimentary authority.

In fact, in *Wyeth*, the Supreme Court said that to find that the FDCA was both a ceiling and floor would be an untenable interpretation of congressional intent and an overbroad view of agency power to preempt.

Again, we talked about the different purposes here, and how the West Virginia law being aimed at unborn life is something that is completely different from the FDA's prerogative, as Your Honor noted, in determining whether something is safe and effective. I would note, Your Honor, that that also distinguishes the *Zogenix* case from the District of Massachusetts. In that case, Massachusetts had determined that a particular opioid was unsafe. It had

directly disagreed with the FDA's safety determination.

Here, West Virginia is doing something completely different. What West Virginia is doing is saying we think -- that we want to protect unborn life and maternal health in this way. We're not disagreeing that mifepristone does what it says, we're not disagreeing in this lawsuit about its safety, but we're still entitled to protect life under the State's health and safety authority.

In addition, Your Honor, I think the presumption against preemption is particularly powerful here. My friends on the other side try to say that the presumption against preemption doesn't apply because this is an area of pharmaceuticals in which the federal government has long regulated. That is for sure true, the federal government has long regulated in the pharmaceutical field, but, again, *Wyeth* firmly forecloses GenBioPro's argument.

At footnote 3, *Wyeth* says rejecting an argument -- it rejects the argument that the presence of federal regulation means that there is not an inherent state authority to regulate for health and safety. It says that that misunderstands the argument. It says that the presumption against preemption is built upon the idea that Congress respects states in our federal system, and as a result -- and this is a quote -- the presumption "does not rely on the absence of federal regulation."

So *Wyeth* clearly said in this precise context that the presumption against preemption applies because states have historically regulated on health and safety matters. Indeed, there's nothing really more local than health and safety matters like the West Virginia statute at issue here.

With respect to the Commerce Clause claim, Your Honor, when we look at that claim, GenBioPro has conceded under the *Pork Producers* case their extraterritorial argument doesn't -- doesn't work. So that's putting to one side. GenBioPro also argues that the West Virginia laws here are an abortion ban. That's incorrect factually and also irrelevant legally.

As a factual matter, Your Honor, as we discussed, the purpose here is not to ban mifepristone. The statute that passed the West Virginia Legislature says nothing about mifepristone or about any other drug at all. What it does is it says that, in West Virginia, subject to certain exceptions like emergency situations, incest, rape, those sorts of things, that providers are not allowed to perform abortions and take the unborn life of a child. So it does not operate at all in the -- on mifepristone, is not an abortion -- or, excuse me -- is not a ban on mifepristone. Instead, it regulates abortion --

THE COURT: Well, the plaintiff characterizes it as a functional ban because the restrictions so great. I mean, I think you noted them, there are very limited exceptions of the

West Virginia Act. So is that not a functional ban?

MS. HAWLEY: So I think two things, Your Honor. A, it has nothing to do with mifepristone any more than it has to do with scalpels or masks or other things that might be used in an abortion. What West Virginia law is concerned about is with preventing the primary conduct of abortion, not with any particular drug. So I think it's incorrect to call this a ban on mifepristone. That is just not accurate.

Your Honor's correct that there are limited exceptions, but the availability of limited exceptions does mean that this is not a ban even on all abortions.

THE COURT: I think you all argued in your briefing that there was still the possible use of mifepristone in West Virginia as an off-label use, but it strikes me that that's really kind of immaterial to all of this.

The preemption argument is premised upon what the FDA has said is an allowable use and circumstances for its use consistent with the label essentially, and so it doesn't seem to me being able to use it off-label somehow alleviates what would otherwise be -- perhaps as they've argued, stand as an obstacle to the federal accessibility decision.

MS. HAWLEY: So I think, Your Honor, that that actually highlights why the purposes are different here. The fact that the West Virginia law does have exceptions -- it has exceptions for saving the life of the mother, for medical

emergencies, for fetal abnormalities that are quite severe, for rape and for incest. And in all of those situations, West Virginia allows mifepristone to be used if it's medically appropriate. So I think these exceptions show affirmatively that West Virginia is not questioning the safety or efficacy.

THE COURT: You know, as a sort of -- this is almost like a footnote to our discussion, but as my law clerks and I have gone through this, we know that West Virginia passed an earlier act. It is in essence suspended pending --

MS. HAWLEY: Yes, Your Honor.

THE COURT: -- determinations as to whether or not this act is constitutional. And if this act is deemed to be unconstitutional, then these prior provisions go in.

But as we've looked at it, it seems to us that the restriction on telemedicine, using telemedicine for this purpose, for this type of prescription, it is not sidelined by the current statute and that it might still be in effect.

Is that your understanding? Or have you thought about this aspect of it? Am I being clear about what I'm trying to say?

MS. HAWLEY: Yes, Your Honor.

I think that's correct in the instances in which the exception would apply. I think there would still be the requirement under West Virginia law for an in-person visit, and this, again, highlights how West Virginia law aids and

comes alongside federal law.

Without an in-person visit, a physician is not able to diagnose ectopic pregnancy, which could cost a woman her life, is not able to diagnose gestational age, and these sorts of in-person visits were once required by the FDA. Under the FDCA structure, they've clearly allowed states to supplement or compliment these. So I think this is an example of how West Virginia's laws, not UCPA, but the other laws are complimenting FDA's purpose, ultimate purpose in making sure that consumers are safe.

THE COURT: But it does seem that upholding the telemedicine restriction would pose an obstacle to the federal determination by the FDA that a telemedicine visit is sufficient to allow for this -- for a prescription.

MS. HAWLEY: I don't think so, Your Honor.

If you look back through the history of FDCA litigation, there are countless examples, like with the practice of law, where courts have allowed -- they found that the province, the regulation of medicine is something that is especially -- delegated especially to the province of state legislatures.

So, for example, even during the *Roe* regime, we had all sorts of things like informed consent, we had waiting periods, we had those sorts of restrictions on abortion even when there was a fundamental right to it under Supreme Court

law. The states were allowed to do that because it complimented FDA's safety and efficacy guidelines. It's not contrary to it, but built upon it.

Again, this goes back to the federal floor or the federal ceiling, and the Supreme Court was really clear in *Wyeth* that the FDCA sets a federal floor.

And I think as hard as you try, especially when coupled with the presumption against preemption, you just cannot get a right to access out of Section 355-1.

And to think just a bit about what that might mean in this and future cases, if REMS provisions mean that there's a right of access, that presumably would mean that GenBioPro must sell its drugs in every state. There's not a lot of evidence that it sold it here at all.

THE COURT: I don't know why it means that. It seems to me that one could easily say that's a matter for the private marketplace to determine. What the preemption would do is say states can't prohibit, which is pretty different than saying that preemption compels a producer to be in a market.

I agree, I don't think any court has ever said that. What we're talking about, though, is whether the state can prevent entry into the market.

MS. HAWLEY: But the core right of access, I think, is the same thing. As various commentators, even proabortion

commentators have noted, that when -- or at least to have access at a reasonable price, you know, the FDA has never said that these particular drugs need to be available at a price that most women can afford. But yet that would be directly tied to access as well, I believe, Your Honor.

In addition, if we think about Section 355-1, and if we're going to carve out from that provision a right of access that's unique to REMS, as my colleagues on the other side say, they tried to say it's state tort law, and that makes sense in this case because their client GenBioPro only has one drug, it only manufactures mifepristone. However, Your Honor, I don't think it's possible to say there is both a right to access and state tort law still exists.

Wyeth is clear -- I understand why the other side does this. *Wyeth* is clear that Congress viewed state tort law as a compliment. Otherwise there is absolutely no remedy for individuals who are harmed by these admittedly dangerous drugs.

But I don't think you can have your cake and eat it, too. I don't think you could say, states, you can't regulate notwithstanding the presumption of preemption, but we're also going to allow state tort law because we need some remedy when women or others are grievously injured. And the other side, I'm not sure how they can say that one exists and not the other, Your Honor.

THE COURT: All right.

MS. HAWLEY: So to come back to the Commerce Clause, there is no extraterritoriality after *Pork Producers*.

GenBioPro also talks, Your Honor, about a ban. As we've talked about it, I don't think it's a ban on mifepristone at least. Even if it's a functional ban on abortion, again we have serious exceptions in the statute, but it is not a ban on mifepristone.

In addition, as I mentioned before, I think even that fact, if it were true, would be legally irrelevant. Justice Gorsuch's opinion notes that all sorts of things are banned. Fireworks are banned. Shark fins are banned. Horse meat, as we've already talked about, is banned. And the fact that it is unavailable in a particular state does not trigger the dormant Commerce Clause.

As I believe Justice Roberts pointed out, if that were the case, that would mean that if something were available in one state, it would have to be available in every other state, which is an untenable interpretation of the dormant Commerce Clause. So there is not a per se rule against bans, so that doesn't work either.

So we're left with Pike balancing. My friends on the other side note that Justice Roberts' opinion controls. I'm not sure that that is correct. But, at a minimum, what we can get from *Pork Producers* is that five justices clearly found

that the allegations in that case did not rise to the level of a dormant Commerce Clause violation.

That is a case in which California went out of its way to change the way pork producers in every pork-producing state produced hogs intentionally. Chief Justice Roberts notes that this would have imposed $368 million worth of compliance costs on pork producers. Contrast it to this case, Your Honor, where we have no allegations of interstate effects, no allegations of interstate economic effects at all. If *Pork Producers* failed the dormant Commerce Clause, Pike balancing, so too does this case.

And just to respond to a couple of things my friends on the other side note, they talk about derivative harms to women in West Virginia. In the *Pork Producers* case, the Court notes that no one thinks that harms from in-state -- derivative harms to in-state persons who voted for that particular provision are a dormant Commerce Clause harm. That is because they're intrastate, not interstate.

Chief Justice Roberts, who in my colleagues' opinion think is controlling, says that before you get to Pike balancing, you have to first find that there are economic interstate harms. These simply don't exist here. They're not even really alleged.

My friends point to paragraph 17, but that paragraph does not point to interstate economic harms, Your Honor. So,

here, we don't even get to balancing the economic harm of GenBioPro to these other derivative harms. As the Chief Justice said, when we're talking about the dormant Commerce Clause, we're talking about interstate, and we're talking about economic, neither of which are present here.

Is there anything else I can do to convince you, Your Honor, that --

THE COURT: Well, your argument is well. Do you want to address the major questions claim as well? Or if there is more you want to say on the Commerce Clause, go ahead. I don't like to interrupt lawyers when they're giving their presentation.

MS. HAWLEY: No. No, absolutely, Your Honor.

So with respect to the major questions doctrine, I really think it comes into play particularly when we're talking about that third preemption bucket, that purpose preemption bucket. And if the FDCA, the 2007 amendments are interpreted as you said -- and they were passed when *Roe* was the law of the land, when abortion was legal. If they're interpreted to require nationwide abortion access up until 10 weeks gestational age, there is no question that that is a significant, moral, economic, political question.

There is hardly any --

THE COURT: I don't doubt the significance or the importance of the question, but when you compare it to the

tobacco case and the other cases, the *EPA* case in West Virginia, it strikes me it's really not even in the same ballpark.

In those cases, you had major regulatory programs built upon long-standing statutes that had not been applied or interpreted that way or comprehensive regulation of some important topic. And while this is an important topic, all the plaintiffs are arguing here is not that there is a minimum -- or not that there are limits on abortion laws generally but, rather, with respect to an abortion law that conflicts with the federal approval of mifepristone, those state laws have to yield.

And that's really different, it seems to me, than some comprehensive regulation of abortion as a result of FDA decisions. It looks to me like there is really no comparison between the scope of the regulatory action undertaken in those major question cases versus here where it's important, but pretty narrow, even in the context of the abortion debate.

MS. HAWLEY: But it's not narrow in its effect, Your Honor. To think about -- you know, we're talking about bans and not bans. The functional effect of FDA's decision here, if interpreted the way GenBioPro does, is to require nationwide abortion access up until 10 weeks of age.

As the states' amicus brief points out, the FDA, of course, also regulates scalpels and other sorts of medical

equipment that is involved in abortion. But in order for the FDA to have that sort of authority, A, Congress would have to give it to them, and, B, Congress would have to have it.

Do we think Congress has the ability to pass a nationwide abortion law requiring access in each and every state up until 10 weeks of gestational age? I think that's a really difficult question, Your Honor.

THE COURT: Well, I guess I'm troubled by characterizing this as being, you know, some sort of congressional act broadly requiring abortion to be available. It is always -- in this case, it is limited to the approved drug that has gone through this process. And I guess it strikes me as kind of ironic that you're arguing that interpreting the FDA statute as guaranteeing access up to 10 weeks through the use of this drug for termination across the board, that that is the functional equivalent of legalizing abortion everywhere. Well, I don't think it is.

But it seems to me it's kind of ironic that you're claiming that -- you object to their characterization of the mifepristone limitation as the functionally equivalent --

MS. HAWLEY: Your Honor, I was playing on that, that framework. That's -- yes, Your Honor. So I think here a couple of things.

First, even if you think the major questions doctrine doesn't apply here, I think *Wyeth* is clear that the

presumption against preemption does, and that still requires a clear statement.

I don't think that when you look at Section 355-1, we get a clear statement that Congress meant access, particularly when that means -- and I don't think there is -- if GenBioPro is correct, Your Honor, that means that every state's law that prohibits abortion before 10 weeks must fall. That's what preemption does. So, again, we can quibble and laugh about the semantics, but that means abortion will be legal up until 10 weeks in every single state.

I think we have to ask whether Congress has the power to do that. Under *City of Burney* I think that's a very open question. Then we have to ask did Congress give that authority to the FDA? If we're talking about the authority to mandate nationwide abortion access, then we are very much in the major -- or, excuse me -- the nondelegation doctrine question.

If Congress is giving an agency the authority to determine life and death, it has done so in the 2007 amendments without any guidance, Your Honor. There is no indication that the FDCA is allowed to even consider the unborn life or the other moral implications that even *Casey* acknowledged exist from the very earliest stages of pregnancy.

So I think, you know, A, does Congress have this power? Probably not. Did it delegate it to the FDA?

Probably not. And if it did, then we have a nondelegation problem because, even under *Gundy*, there's simply nothing approaching an intelligible principle.

Even putting all of that aside, Your Honor, we come back to the presumption against preemption, and it would require a clear statement in order to find that Congress meant the 2007 amendments to require access, you know, broad access to opioids, broad access to chemical abortion drugs, even though that means nationwide abortion, and I don't think when you look at Section 355 and you look at that test, and when it says such elements under section (1), I don't think it's talking about complimentary state regulations.

THE COURT: All right. Thank you.

MS. HAWLEY: Thank you, Your Honor.

THE COURT: All right. For plaintiff?

MR. FREDERICK: Thank you, Your Honor. May it please the Court. David Frederick for plaintiff GenBioPro.

Congressional intent is the touchstone of preemption under the Supremacy Clause. The Supreme Court has said that over and over, we do not decide cases on the basis of presumptions. We look at the words Congress enacted, and we determine whether or not what states are seeking to do conflicts with the words that Congress enacted.

Here, the defendants hardly say anything about the 2007 act that is at issue here, 355-1. They cite it once for

a passing reference in their reply brief. They hardly address the statutory construction arguments we have advanced at all. And today counsel offers a very interesting theory that, when you boil it down, doesn't add up. Because the theory that the State advances now is that notwithstanding that Congress knew mifepristone was one of 16 drugs that had been approved by the FDA under Subpart H when it enacted the 2007 act, and notwithstanding that Congress then told FDA for those drugs, go back to the sponsors, the makers of the drug and get updated risk management strategies for them, and the FDA did that.

Now, when Congress is giving specific directions to the FDA under a very comprehensive statute, it is really incumbent upon courts to evaluate what are the words that Congress enacted, and what are the implications. And what we're getting today is essentially an argument that you have to rely on a presumption against preemption in order to save a state statute that runs directly counter to Congress's words.

The words in the statute ensuring access most assuredly do not allow the State to not ensure access, and that's what the functional abortion ban does here. Counsel argues, well, there are these little exceptions here and there. But the point of the FDA's approval of mifepristone was to engage in the early termination of pregnancy by those patients who sought to do that.

THE COURT: If I look to the statute to discern what legislative intent was at the time, what's the significance of the fact that, at the time, there was a constitutional right to abortion that Congress could not control? It was not the author, it was a constitutional right. And so at the time this act passed, there was a right in every state to an abortion. And accessibility in that context doesn't mean guaranteeing that that right persists if the Court later determines that there is no such right, which is what's happened.

MR. FREDERICK: I think that the key language in the decision in the *Dobbs* decision, Your Honor, is returning the question of abortion to their elected representatives. The elected representatives here was Congress. When Congress enacted the REMS program in the 2007 act, it did so knowing that mifepristone affected the abortion right.

THE COURT: I understand that. I think what concerns me greatly about that statement is that we know at the time Congress understood the current law to guarantee a right to abortion in every state. So it's hard to read into that 2007 act an intent by Congress, in adding accessibility language to the statute, to be in effect legislatively guaranteeing that right that was determined by the Court to be a constitutional right.

MR. FREDERICK: And I think if you go back to first

principles, Your Honor, when the Court decided *Roe*, there was no medication abortion. There have been obvious technological developments in the provision of medication since *Roe versus Wade* was decided. But the core question for you is, when Congress made its enactment, and it had a clear intent and effect on mifepristone, is that to be accorded the kind of respect under the Supremacy Clause that is required where a state law has a conflict, imposes a conflict with a provision of a federal statute entrusting a federal agency with making the access and safety determinations necessary for the provision of that medication?

And that, to me, is a fairly straightforward question that has not really been joined by the other side in this case. Because if you look at all the different things that Congress told the FDA to do, to come up with rules for mitigating strategies, and if in a certain limited class there needed to be additional elements for safe use, to enact those as well, there are a very small number of drugs for which that is true. Mifepristone happens to be one of them.

Now, my colleague argues that somehow because there are additional elements, that that somehow adds to the availability of the states to jump in and offer additional restrictions. To the contrary, I think it argues the opposite.

Because if you look through 355-1 where it has

monitoring, evaluation, periodic updating, there is no indication in the statute that Congress intended for 50 states to come up with their own rules regarding FDA-approved medications and force the FDA to somehow keep track of them.

My friend says there's no effect on the system, but in the very first paragraph of 355-1, there is the admonition by Congress to ensure access without undue burdens to the system. The system here is the healthcare delivery system.

And it has both preemption consequences and overlapping Commerce Clause consequences because medications made out of state is affecting interstate commerce. Health insurance is part of the system. It is generally driven by national carriers. Regional and national medical providers, part of the healthcare system. And so all of these elements are affected, and the question is whether the functional ban that is conceded today of this drug is interfering with that healthcare system.

We submitted and we alleged in the complaint, in paragraph 16 and 17 -- they've ignored 16 as alleging that the system is affected adversely by what the State is seeking to do here, and I would note that there is not really any limiting principle to their argument. So under their position, all 50 states can override an FDA expert judgment about the additional elements for safe use that would ensure access, and that would be okay under their scenario simply

because Congress didn't use the words "pregnancy termination" in the 2007 act. Well, Congress didn't use the words "polio" or "small pox" or "acne" in the 2007 act either. But under the logic of their position, if the states wanted to take extraordinary actions to address those conditions, it has the lawful authority under the Supremacy Clause to do so.

FDA rules have never operated in a situation where anybody can come in and countermand the expert judgment in that way. To be sure, there are labeling requirements, and my colleague spends a lot of time talking about *Wyeth versus Levine*, which I'm very happy to talk about, but I don't think that case is really on point here because we're not talking about a labeling challenge.

We're talking about a specialized set of rules under 355-1 that are intended to ensure access while not burdening -- creating such burdensome safety rules that that avoids access that Congress thought was important for this particular class of drugs.

THE COURT: As I recall, I think it was a year or two after this act, that Congress passed the medical device act, and they had explicit, express preemption language. Is that not of some significance here where you're saying that they intended this comprehensive REMS process for deciding safety, efficacy, and availability basically?

MR. FREDERICK: If I could offer this correction to

the chronology suggested by the Court.

The medical device amendments was enacted in the 1970s, and there was an express preemption provision as to certain aspects of the approval of the device. It didn't cover all devices. It depended on when they were in the various stream and whether or not devices that had been grandfathered in also would be subject to the express preemption provision.

And that's why in *Medtronic versus Lohr* -- I don't think that's a case cited by any of the parties, but there the Court did not find preemption regarding a certain class of drugs. Now it is true in *Riegel versus Medtronic*, and that's another case that I don't think has been cited here, the Court did find the application of express preemption to nullify the state lawsuit.

But I think this -- your question, Your Honor, points exactly to the right problem, which is, what are the words of Congress, and how do they apply in light of what a state is seeking to do? And our point here is that you cannot have ensuring access and not creating an undue burden on the healthcare system and a state's functional ban that today counsel has functionally conceded that's exactly what the State seeks to do. And those are not compatible, and that is why the preemption clause and the preemption provisions of the Constitution under the Supremacy Clause, we submit, governs

here.

THE COURT: Well, just while we're on the subject, just so I can keep things clear as I sit down and review all this to try to decide it, do you still maintain that field preemption applies?

MR. FREDERICK: Yes.

THE COURT: Tell me briefly how you get there.

MR. FREDERICK: Yes, let me explain the field preemption argument. And first let me help by explaining how the system is designed to work.

So there are a certain class of drugs that have these risk mitigation strategies, REMS. Only for a particular subset of those REMS-approved drugs are there special elements to assure safe use.

So you start with 20,000 drugs --

THE COURT: Uh-huh.

MR. FREDERICK: -- okay, that have been approved by the FDA and are on the market, a certain subclass have what are called REMS, and it is only within that subset of the REMS-approved drugs where the FDA has enacted these elements to assure safe use. They're sometimes called ETASU in the briefs, but that's what these are.

At the time of the enactment of the 2007 act, there were only 16 that had these elements to assure safe use. Mifepristone was one of them.

Now, if you track through the language of 355-1, what it says is that if the Secretary, here the FDA, determines that a REMS drug needs to have these elements to assure safe use, the Secretary shall impose these additional rules.

Why is that important? We cite the *Locke* case in our brief, and in the *Locke* case the Secretary of Transportation was charged under certain ports and waterways acts to deal with regulations concerning oil tankers. For some of them, Congress said it's permissive regulatory authority, the Secretary may issue certain regulations. As to those, the Supreme Court held, if the Secretary issues those rules and the State conflicts with them, conflict preemption applies.

But there was Title II of the port and waterways act, and in that title what Congress had said was that the Secretary shall issue regulations concerning certain topics, and they had to do with equipment design features of oil tankers and the like. And the rationale the Court explained was that when Congress mandates that the federal agency deal with certain specific rules, there is not room for states to come in and offer contrary rules. The field is preempted because Congress entrusted that particular field to the federal agency.

Our field preemption argument, Your Honor, is relatively modest. At present, there are only about 58 drugs that have both the REMS and these special elements to assure

safe use. And as to that specific category, what Congress said was that FDA shall do a whole range of balancing and determine whether or not its rules would provide safe access and not create undue burdens for the system.

So our argument on field preemption flows directly out of the words of the statute, Congress's intent to mandate that the FDA, with this very small category of drugs, have very specialized rules that were designed to balance access with safety. Now, why is that important? Because every year Congress provided in 355-1, FDA is supposed to update its rules.

Now, field preemption operates by saying states should not have a role in that field because it's too important to entrust for national uniformity purposes. It would be impossible for the FDA to update its rules periodically given how fast states are enacting various issues and laws with respect to various topics concerning the termination of pregnancy. And so it's logical to suppose that Congress intended for that field to be completely entrusted to the FDA in that very narrow category where there is both a REMS drug and drugs that are needed to assure safe use.

So our field preemption argument, Your Honor, is very narrow, it's highly specialized, but I think it applies when you track through the monitoring, the evaluation, the periodic updating, and all of the different things that Congress

required the FDA to do with respect to those elements to assure safe use.

If, however, you were not to agree with me about that field preemption theory, our conflict preemption theory I think is rock solid, and it is completely impossible to imagine Congress's words saying ensure access to this medication and a state saying not ensure access to the medication, and that's what is conceded today to be what the State is seeking to do.

THE COURT: I know we've bandied these terms about, functional bans and so forth, but it is a fact that even under the West Virginia statute, mifepristone can be sold and used in West Virginia for its intended purpose.

MR. FREDERICK: Well, only under highly specialized circumstances that go well beyond restrictions that are imposed by the FDA.

THE COURT: Well --

MR. FREDERICK: And so it is impossible to comply with the permissive regime authorized by the FDA for the safe use of the drug and those circumstances where they allege that mifepristone would be available to deal with certain exceptions under the state statute.

THE COURT: Yeah, honestly I have some difficulty agreeing that that's an impossibility factor. You're able to sell it to a point, just not as much as you would like or as

much as the label would allow, and that that constitutes impossibility.

And I admit, these are cases that I haven't finished reviewing and thinking about, but I don't know that I've seen a case where it seems to me there is a similar sort of foundation.

MR. FREDERICK: Let's take the average person who does not have a medical emergency or otherwise fit within the exception. Under federal law, that woman is able to take mifepristone under the FDA rules.

Under the State of Virginia's rules --

THE COURT: West Virginia.

MR. FREDERICK: I'm sorry. West Virginia, excuse me. I'm thinking about Virginia mining, which I do want to talk about in a minute.

Under West Virginia's rules, that person is not able to take the drug in that circumstance. It is impossible for her to comply in both the West Virginia scheme and what permissions are afforded to her under federal law. That is preemption. That is the classic form of preemption. You can call it impossibility, you can call it inconsistency, you can call it irreconcilable conflict. There are many words that the Supreme Court has used to describe preemption principles over the years, but I think that the bottom line is the same.

THE COURT: Okay.

MR. FREDERICK: Now, with respect to obstacle preemption, which is the concept my colleague spends most of her time arguing, there is no question that when Congress is providing FDA authority to regulate these drugs under particularized systems and rules do not apply to 99.9 percent of all the drugs, that they're seeking to interfere and create an obstacle with that system.

And so under obstacle preemption cases, and *Geier* is one that is, I think, pretty directly on point -- that has not been discussed today, but there the question is if the federal agency provides for an option, it can't be for the state to come in and interfere with that selection of what option the federal government made available. That was a case involving airbags and seatbelts, so I appreciate that its subject matter is different.

The point I want to stress, though, is that whether you look at this problem under any of these three theories of preemption, the bulk of the situations in which the West Virginia ban applies run afoul of the federal permission to allow usage of mifepristone.

Now, *Virginia Mining* was mentioned. I want to point out just one fact, that in that case there was no federal rule concerning mining, uranium mining on private land, and so the argument for preemption would have meant that there was no law available by any sovereign to address uranium mining. And

what Virginia had sought to do was to say, because there is no federal law here, the State can take action with respect to uranium mining on private land, and a majority of the Court said that is not preempted, that is afar afield from what we're talking about here.

Similarly, my colleague invokes the *Harris* case. That involved actually a holding by the Supreme Court of preemption. The Court there held that the Federal Meat Inspection Act preempted California law regarding slaughterhouses, so I'm not sure how that helps the State here in this case.

And then with respect to the *PG&E* case, the Court held that there were state statutes regulating economic aspects --

THE COURT: I have a note, though, on the slaughterhouse case, that the Court ultimately did say, though, the State could ban horse meat, it just couldn't regulate it in a way inconsistent with the federal regulation.

MR. FREDERICK: Well, it was dicta, and that was not -- there was no ban at issue in that particular case. I'm not sure how far the dicta gets you in a situation like what we're talking about here, where the express words of the statute are to ensure access. I would submit that that just doesn't help the State here.

And then with respect to *PG&E*, the states here obviously retain their traditional authority over economic

electric utilities, but that doesn't go to the question we have here, which is that there is no state role for FDA-approved drugs in these particular circumstances.

To be sure, as all members of the public can offer comments when the FDA is reconsidering its rules and periodically updating them, but the State can't override the FDA's determination what is necessary for an element to assure a safe use.

On the major questions doctrine, Congress gave FDA authority to regulate access to these REMS drugs so that it can review the scientific and underlying aspects of the restrictions, and it endorsed with its approval when it did that in 2007. That's in Section 909 of the act itself, the statutes at large version of the act.

And so I think that it's important to say that, unlike the *West Virginia versus EPA* case -- what the EPA was seeking to do was to create a nationwide rule regarding electric power generation and its climate consequences. What the FDA did here was exactly what Congress told it to do, take these drugs that are subject to the REMS that you have approved under Subpart H, continue to refine those rules; if they need to be periodically updated, do that, and make those rules uniform and applicable nationally. And to be told otherwise would be really to create enormous chaos.

And it's not just in the drug industry and the

distribution of drugs, but it's in health insurance, retraining for providers, the effects on interstate commerce regarding when particular drugs are available and when they are not.

And the State just simply refuses to acknowledge that in 355-1 itself, Congress said to do these rules in a way that do not unduly burden the system, the healthcare system, and that's exactly what this functional ban is trying to do.

Now, flipping over to the Commerce Clause, let me address the Pike balancing because that is what we are seeking to do here.

There are interstate effects for the reasons that I've just outlined, and the court -- the cases properly understood it's an effort by the State that will have burdensome effects on interstate commerce, not just in drug delivery, not just pharmacies, but in all manner of education for providers, for healthcare delivery, for insurance provision, and all of these aspects of the healthcare system are interstate in their dimensions.

And if you were to accept the State's argument here, you would be opening up exactly the kind of problem that Chief Justice Roberts noted in his separate opinion in *National Pork*, which is to take what should be a national common market and fragment it so that states are each issuing their own rules in a way that would alter the balances that are intended

to be struck by having national arguments.

Now, ultimately the State's argument boils down to the idea that 355-1 applies to most everything except for pregnancy termination, and that means that there is actually no limiting principle to what the State is arguing. Because if you create judicially an exception to the words of 351 to apply -- 355-1 to apply to all the drugs that have been approved by the FDA subject to this limited subset, you're inviting states to say, well, we think small pox is different, we think vaccines are different, we think that acne is different, we think that polio is different.

These are all drugs on the list of 16 that, when Congress enacted the 2007 act, it expressly incorporated and deemed them to have in effect REMS subject to the FDA's considered judgment.

And I would submit that I'm not aware of any case -- and I've argued many cases involving preemption -- that has been decided solely on the basis of a presumption against preemption. And the reason why is because the whole concept behind the presumption is to try to understand what did Congress mean in particular circumstances, what was the scope of its intent and effect on state law. But here, where the other side doesn't even talk about the statute that Congress enacted with any kind of detail, you can't simply, I would submit respectfully, decide, well, the presumption applies and

so, therefore, the State can do what it wants notwithstanding the enactment that Congress made.

Let me address the telemedicine question that you posed. We do think --

THE COURT: Before you do, let me ask you another question about *National Pork*. And I admit I've struggled with trying to figure out -- I appreciate the thoughtfulness with which each side briefed the issues, as it does seem clear to me from reading Judge Gorsuch's opinion that the Court agreed that Pike should still be applied.

But I'm troubled that throughout that part of his decision, which was joined by the other judges, it's clearly part of the majority, that he often, I think three or four times, made reference to the fact that, in his view, the states still had the authority to enact laws and regulations that pertain to health and welfare, things like that -- and I'm sorry I don't have the language right in front of me.

But, as I read it, he said *Pike* is still good law, but it doesn't go as far as maybe some would argue -- have been arguing. But that in any event, even when we examine *Pike*, we have a setting where states are still traditionally able to set laws and regulations pertaining to healthcare.

MR. FREDERICK: Your Honor, I think that the proper way to understand Justice Gorsuch's opinion is in context where I think six justices disagreed with his way of limiting

Pike balancing. And so there is a certain quality of the Supreme Court's *National Pork* decision which you have to kind of create a chart and then figure out which justice fits into which bucket.

The way we've outlined it in our brief, our supplemental brief is to try to explain that Pike balancing can apply and has applied in situations where you're comparing straight economic considerations with considerations that, on their face, do not appear to be economic.

But where the Chief Justice's opinion is particularly helpful for our side, we believe, is in dealing with what are called derivative harms. And that's where if you were to take the idea of safety as an extant value that you wanted to promote through a state law, there actually is an economic consequence.

And as we pointed out in our supplemental brief, to force a woman to carry to term is 14 times higher mortality rate than to have a safe termination of pregnancy. There are economic consequences to the medical care system, to the drug delivery system by having that forced pregnancy all the way to term, and those economic consequences do have interstate effects.

Now, it is true that in our complaint we didn't plead, you know, fully elaborately. What we said is that we believe that the State through the ban does have these interstate

effects. I think it's sufficient for pleading purposes, especially as amplified by the briefing and argument today. But for purposes of accepting our allegations to be true, I think we're at a stage here where we easily should be surmounting a motion to dismiss where the allegations in the complaint are assumed to be true.

And where you take that kind of derivative harm allegation and you do apply certain economic consequences to that kind of what is called a safety rationale, there are economic forces on both sides to balance. And if you were just talking about safety in one realm, you have to understand what those consequences might be.

THE COURT: All right. I interrupted you when you were talking about --

MR. FREDERICK: I just wanted to say on the telemedicine ban, we agree with Your Honor that that is still in effect, that West Virginia does ban and that this is a direct conflict -- we talk about this in paragraph 73(c) of our complaint, where the FDA specifically considered and rejected an in-person requirement. That we allege at paragraph 88 of our complaint.

And so when you look at the FDA's rejection of an in-person requirement, the State's ban on telemedicine, I think you are drawn to the conclusion that West Virginia says you can only do this in person whereas the federal government

has said that's not necessary, and that is a conflict directly.

THE COURT: All right.

MR. FREDERICK: If the Court has no further questions --

THE COURT: I do have one sort of general question, and that is, as you noted here, we're at a motion to dismiss stage. So in your view, if I deny this motion, what sort of discovery fact development do you believe will ensue?

MR. FREDERICK: Your Honor, the way we would envision the progress of the case is that, upon your denial of the motion to dismiss, the parties would confer. We believe that within 45 days we could offer cross motions for summary judgment that would be based on affidavits. I think the preemption arguments are law-based arguments, they are not fact-based arguments. We could probably do preemption just simply on the basis of what the legal requirements are.

I appreciate from Your Honor's standing ruling that there are facts that we would submit through affidavit to support our standing, and that by Commerce Clause argumentation, we would likely submit those through affidavits as well.

I don't think there is going to ultimately be questions where there are disputed issues of fact. We are certainly open to working with the State to try to develop an

undisputed statement of facts through affidavits that we would share and exchange in advance. But our hope is that if the motion to dismiss were denied, we could move with alacrity to develop what would be a case that would fully satisfy Your Honor's earlier ruling and the necessities.

We all appreciate this case is going to go up on appeal, and our objective would be to provide an ample record so that a ruling that would invalidate the State's criminal abortion ban would be sustained on appeal.

THE COURT: All right. Thank you.

All right. Ms. Hawley, do you want to reply?

MS. HAWLEY: Thank you, Your Honor. A couple of things here.

First, Your Honor, West Virginia in no way concedes that its state law that protects unborn children is in any way directed at mifepristone or the healthcare system.

West Virginia has been clear in its pleading, in its state law and argument today that what West Virginia law does is seek to protect unborn children, maternal health, things that *Dobbs* expressly said were within the province of states and their elected representatives. So in no way do we concede that West Virginia is trying to interfere with the healthcare system.

With respect to --

THE COURT: But the law is aimed only at doctors. It

doesn't make it a crime or other sanction for a woman who decides to have an abortion, does it?

MS. HAWLEY: Well, Your Honor, I think that's recognizing that the State believes there are two victims of abortion, both the unborn child and often the woman who obtains one. So I think the State is being cognizant that women are sometimes in difficult situations and instead of saying that, in these situations, we're not going to go after the woman who may be suffering or in a strait, but instead we're going to say that providers cannot provide that.

For that reason, Your Honor, I think the impossibility claim absolutely follows. There is no case that I'm aware, my counsel on the other side didn't cite any, in which impossibility preemption is found when it's -- when the parties regulated are different parties.

Counsel on the other side mentioned, you know, a woman might be able to have one federally, have an abortion but not have an abortion in West Virginia, but that is not how impossibility preemption works. It looked at whether in *Wyeth* the drug company's label was acceptable under federal law and under state law. Here, the drug company, GenBioPro, has no impossibility of complying both with federal and state law.

In addition, Your Honor, counsel for the opposing side talked a lot about chaos. But to be clear, were this Court to find that the REMS provision did preempt state law, that would

be a sea change. REMS provisions have been around since 2007. Complimentary to those REMS provisions, states have long required things like in-person visits.

If you're going to prescribe an opioid, it's not unusual for a state to say you need to do that in person so the doctor can explain the severe risks --

THE COURT: Are they covered by the --

MS. HAWLEY: They are, Your Honor. Yes, sir.

THE COURT: -- by the elements intended to ensure safe use as well?

MS. HAWLEY: I believe so, Your Honor. And so we're talking about drugs here that, again, are a particular narrow category of drugs that have a grave risk.

Counsel on the other side talked a lot about this statute, and that's exactly where Your Honor should focus. If we look at Section 355-1, again, we do think the presumption against preemption applies here precisely because it requires in this area that has traditionally been governed by the states for this Court to find a clear indication that Congress intended access. That is nowhere in that statute.

Section 355-1 does talk about access, but it talks about access with respect to what FDA itself may do. FDA may not unnecessarily impede access. It in no way suggests that states will be stripped of their traditional authority to compliment the FDCA and the FDA's authority, Your Honor.

Also, I think that one thing that's sort of striking and missing from our discussion here is the Biden Administration, HHS, the Department of Justice has been forthright in its pursuit of abortion availability to the extent that complies with law. But, Your Honor, the FDA is not here today. And on pages 16 and 17 of our brief, we cite FDA questions and answers that establish that the FDA has long recognized that state law does in fact control some of the things that are regulated by the REMS.

In particular, the FDA concedes that, whereas the REMS allow for nonphysician providers, the FDA tells providers go and check with your state. Your state might have other regulations that compliment these REMS, and you need to abide by them. I think the indication from the FDA here is that states are able to do what they've always been able to do under the FDCA, and that's to compliment.

Just a few words, Your Honor, on field preemption. I think rather than being a narrow argument, it's quite a broad argument to say that anytime Congress says shall to an agency, that means that any complimentary state law is preempted.

With respect -- *Locke* was a ports and waterways case. Here we're talking about health and safety, which is a traditional area of state concern, whereas ports, of course, are a traditional area of federal concern. So I don't think that case helps a lot. Nor does the shall language.

With respect to impossibility, we've talked about that. We've got different -- different actors here, so impossibility preemption doesn't apply.

And when you get to obstacle preemption, Your Honor, in my colleague on the other side's brief, they note that purpose doesn't matter, but that is not correct under Supreme Court law. If you look at *PG&E*, if you look at *Virginia Uranium* mining, if you look at *Harris*, all of those cases plainly say that when you're looking at the sort of purpose requirement for preemption, you can look at why the state did what it did.

When we look at West Virginia, what West Virginia did here was say we want to protect unborn life. We don't care how. We don't care if it's chemical abortion drugs. We're not messing with the healthcare system. We want to protect unborn life. And that really distinguishes the situation from *Geier*, Your Honor.

I think *Geier* is probably the outer bounds of this sort of purpose preemption doctrine. And what *Geier* specifically found was that the regulation there offered the manufacturers a choice among passive restraints, and state tort law came in and said, no, you have to have seatbelts. In that, there was a conflict that the Court found, almost a direct conflict, but one that certainly doesn't exist here where you had different purposes. You've got the federal

safety purpose, and you've got the state law protection for life purpose.

As Your Honor noted, *Harris* I think is very helpful here. It may be dicta, but in *Virginia*, the uranium mining case, the majority cited *Harris* for the proposition that slaughtering horses -- a ban on slaughtering horses would be permissible notwithstanding the nationwide regulation of slaughterhouses in general.

Similar for *Virginia Mining* and *PG&E*, those cases are really clear that when you have a state directed to a different purpose, as is West Virginia's law, that survives purpose preemption.

And just a few words, Your Honor, on Pike balancing. As you mentioned, it's kind of hard to dissect, you know, what garners a majority for what parts of the opinion, but were -- are clear that five justices found that the allegations in that case were insufficient under the dormant Commerce Clause. I think those allegations vastly outweigh the interstate economic effects that GenBioPro has alleged here.

As we mentioned, Chief Justice Roberts, my colleague on the other side relies a lot on his opinion. I'd encourage you to look at pages 20 through 22 of that opinion. On those pages, he expressly says that the harms must be economic, and they must be interstate. And he in no way carves out healthcare, Your Honor.

That would really flip federalism on its head to say an area, as in *Wyeth*, notes time and again -- or go back to *Jones v. Rath* or *Santa Fe Railroad*, or all of these cases in which the Supreme Court has noted that the state's traditional authority is to protect for health and safety, that would be flipped on its head if we could sort of say, well, this is a healthcare case, and so a dormant Commerce Clause could just run wild and preempt or undo all these sorts of state laws. So that would really be flipping on its head.

In summary, Your Honor, just to quote the Chief Justice, we really sort of need sweeping extraterritorial effects under Pike balancing, and those simply don't exist here.

THE COURT: All right. Thank you.

MS. HAWLEY: Thank you.

THE COURT: All right. Well, I appreciate your arguments. I'm going to take all this under advisement, of course.

I think when you were here arguing standing, I was able to tell you that I thought I would have a decision within a couple of weeks. I can tell you here, without question, it will not be in a couple of weeks, it will be considerably longer.

I'm actually going to be unavailable for a while in the next few weeks, but I'll be working on this periodically,

and I certainly hope to get to it with some dispatch. I appreciate how serious this issue is and how important it is to not just the litigants here, but to others as well, so I will give that considerable weight in trying to make time on my schedule to make sure that I address this as thoroughly as I can and as quickly as I can.

Is there anything else that you folks need to bring to my attention today?

MS. HAWLEY: No, Your Honor.

THE COURT: If not, again, thank you for your excellent briefing and your really high-quality presentations today. It's helpful, and I appreciate it.

If there is nothing else, we'll stand adjourned.

THE COURT SECURITY OFFICER: All rise. Court is now adjourned.

THE COURT: Thank you, folks.

MR. FREDERICK: Thank you, Your Honor.

MS. HAWLEY: Thank you, sir.

(Proceedings were concluded at 2:40 p.m.)

---o0o---

CERTIFICATION:

I, Kathy L. Swinhart, CSR, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter as reported on May 23, 2023.

May 30, 2023
DATE

/s/ Kathy L. Swinhart
KATHY L. SWINHART, CSR

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

HUNTINGTON DIVISION

GENBIOPRO, INC.,

Plaintiff,

v. CIVIL ACTION NO. 3:23-0058

MARK A. SORSAIA, in his official capacity as Prosecuting Attorney of Putnam County and PATRICK MORRISEY, in his official capacity as Attorney General of West Virginia,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending before the Court are Defendant Mark A. Sorsaia and Defendant Patrick Morrisey's Motions to Dismiss. ECF Nos. 17 & 19. For the following reasons, the Motions to Dismiss are **GRANTED**, in part, and **DENIED**, in part.

I. BACKGROUND

Plaintiff GenBioPro, Inc. ("GenBioPro") is the only United States manufacturer of generic mifepristone. Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 1, ECF No. 35. Mifepristone is a Food and Drug Administration ("FDA") approved and regulated medication which is commonly prescribed as step one in a two-step medication abortion regimen. Compl. ¶ 2, ECF No. 1. Mifepristone and misoprostol—the other medication abortion drug—are Plaintiff's "sole source of revenue." *Id*. ¶ 23. Mifepristone has been approved for nationwide use and sale by the FDA, and GenBioPro sells the drug throughout a national market. *Id*. ¶ 77.

On June 24, 2022, the Supreme Court decided *Dobbs v. Jackson Women's Health Organization*, reversing *Roe v. Wade*[1] and "return[ing] the issue of abortion to the people and their elected representatives." 142 S. Ct. 2228, 2279 (2022). Following this grant of authority, West Virginia passed the Unborn Child Protection Act ("UCPA") in September 2022. W. Va. Code § 16-2R-1 *et seq*. The act of performing, inducing, or attempting to perform or induce an abortion is now illegal in the State, subject to a limited series of exceptions.[2] W. Va. Code § 16-2R-3. The UCPA expressly includes abortions performed or induced via "medicine" or "drug." W. Va. Code § 16-2R-2. The Act defines the prohibited "attempt to perform or induce an abortion" as "an act or the omission of an act that, under the circumstances as the person so acting or omitting to act believes them to be, constitutes a substantial step in a course of conduct intended to culminate in an abortion." *Id*. If a licensed medical professional "knowingly and willfully performs, induces, or attempts to perform or induce an abortion" with the intent to violate the UCPA, "the licensing board shall revoke medical professional's license." W. Va. Code § 16-2R-7. If a formerly licensed medical professional or any other person "knowingly and willfully performs, induces, or attempts to perform or induce an abortion," they are guilty of a felony and subject to imprisonment for "not less than three nor more than 10 years." W. Va. Code § 61-2-8(a), (b).

[1] 410 U.S. 113 (1973).

[2] Under the UCPA, "[a]n abortion may not be performed or induced or be attempted to be performed or induced unless in the reasonable medical judgment of a licensed medical professional: (1) The embryo or fetus is nonviable; (2) The pregnancy is ectopic; or (3) A medical emergency exists." W. Va. Code § 16-2R-3(a). This prohibition does not apply "to an adult within the first 8 weeks of pregnancy if the pregnancy is the result of sexual assault . . . or incest" and the patient has taken steps to report the assault or incest to law enforcement. W. Va. Code § 16-2R-3(b). Likewise, the prohibition does not apply to "a minor or an incompetent or incapacitated adult within the first 14 weeks of pregnancy if the pregnancy is the result of sexual assault … or incest" and either the patient has taken steps to report the assault or incest to law enforcement or has received medical treatment for the same. W. Va. Code § 16-2R-3(c).

Prior to the decision in *Dobbs* and the passage of the UCPA, West Virginia had provisions in place which Plaintiff asserts greatly limited the prescription and sale of mifepristone. Compl. ¶¶ 87-88. These restrictions required a waiting period and counseling before obtaining an abortion. W. Va. Code § 16-2I-2. The UCPA provides that this restriction has no effect while the UCPA is in force but would "become immediately effective" again should the UCPA "be judicially determined to be unconstitutional." W. Va. Code § 16-2R-9. Further pre-UCPA provisions continue to prohibit providers from prescribing medication abortion drugs via telemedicine. W. Va. Code §§ 30-3-13a(g)(5); 30-1-26(b)(9).

In contrast, the FDA has continually eased restrictions on access to mifepristone. The FDA is tasked with promulgating regulations concerning the approval of prescription medications for sale under the Food, Drug, and Cosmetic Act ("FDCA"). 21 U.S.C. § 393(b)(1). Under regulations known as "Subpart H," the FDA approves drugs which treat "serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments" subject to "restrictions to assure safe use." 21 C.F.R. §§ 314.500, 314.520; Compl. ¶ 36. According to the Complaint, in 2000, Danco Laboratories, LLC's Mifeprex—name-brand mifepristone—was approved under the Subpart H regulatory scheme, which imposed certain restrictions on prescription and administration of the drug to assure safe use. Compl. ¶¶ 38-39. In 2007, Congress enacted the Food and Drug Administration Amendments Act ("FDAAA"), requiring that drugs formerly approved under Subpart H be re-approved under a new regulatory scheme, entitled the Risk Evaluation and Mitigation Strategy ("REMS"). *See* 21 U.S.C. §§ 355-1(a), (g)(4)(B), (h); Compl. ¶ 41. If the FDA determines that a drug may cause an "adverse drug experience," then the agency must design and implement a REMS. § 355-1(a), (b)(1). However, any restrictions imposed under the regulatory scheme must "not be unduly

burdensome on patient access to the drug." § 355-1(f)(2)(C). The FDA must reassess a drug's REMS periodically. § 355-1(d).

Following the passage of the FDAAA and the implementation of the REMS schema, the manufacturer of Mifeprex proposed a REMS for its product to the FDA. Compl. ¶ 55. The FDA approved the proposed REMS in 2011. *Id*. The 2011 REMS[3] allowed Mifeprex to be prescribed by certified physicians up to 49 days of pregnancy, dispensed in certain healthcare facilities, and taken in the provider's clinic. *Id*. ¶ 56. In 2016, the FDA revised the Mifeprex REMS,[4] increasing the gestational age through which the drug is indicated, expanding those who could be certified to prescribe Mifeprex from "physicians" to "healthcare providers," and reducing the number of required patient visits to their healthcare providers. *Id*. ¶ 58. In April 2019, the FDA approved GenBioPro's generic version of mifepristone, subject to the same REMS as Mifeprex.[5] *Id*. ¶¶ 60-61. In response to the COVID-19 pandemic two years later, the FDA announced it would stop enforcing the in-person dispensation requirement of the mifepristone REMS. *Id*. ¶ 62. On January 3, 2023,[6] the FDA promulgated a new REMS[7] for mifepristone which no longer limits dispensation of the drug to healthcare settings, thereby allowing patients to receive the

[3] U.S. Food & Drug Admin., NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg, Risk Evaluation and Mitigation Strategy (REMS) (June 2011), https://perma.cc/3S5M-WMQ6.
[4] U.S. Food & Drug Admin., NDA 020687 MIFEPREX (mifepristone) Tablets, 200 mg, Risk Evaluation and Mitigation Strategy (REMS) (Mar. 2016), https://perma.cc/KC6Z-NQUA.
[5] U.S. Food & Drug Admin., Mifepristone Tablets, 200 mg, Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200mg (Apr. 2019), https://perma.cc/2XSU-3HYT.
[6] The Court notes that while the REMS was most recently updated in March 2023 "to add space to allow for additional contact information on the forms" and "correct a typographical error," the last significant modification was in January 2023. *See Update History*, Mifepristone, Shared System REMS, U.S. Food & Drug Admin., https://perma.cc/RE9X-NUJF (last accessed Aug. 9, 2023).
[7] U.S. Food & Drug Admin., Mifepristone Tablets, 200 mg, Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200mg (Mar. 2023), https://perma.cc/224Y-KFLE [hereinafter 2023 REMS].

medication either by mail or from certified pharmacies and no longer requiring in-person visits to healthcare providers.[8] *Id*. ¶ 66.

The FDA made these changes to the REMS in response to overwhelming evidence of the safety and efficacy of mifepristone. *Id*. ¶ 38, 58-59, 62-64. Decades of usage of the drug—both in the United States and abroad—as well as a rigorous agency and pharmaceutical industry review process have demonstrated that the FDA may promulgate REMS allowing for increased access without risking patient safety. *See, e.g.*, U.S. Food & Drug Admin., *Questions & Answers on Mifepristone for Med. Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 4, 2023) (discussing safety and access determinations made by the agency), https://perma.cc/6TDS-F9FL (last accessed Aug. 9, 2023). As summarized by Food and Drug Law and Health Law Scholar *amici*, "mifepristone has been subject to more regulatory and congressional scrutiny than perhaps any other prescription drug." ECF No. 40-1, at 5. Each time the REMS were altered, the FDA "used an internal team of experts . . . to conduct medical, chemistry, pharmacology, statistical, clinical pharmacology, and biopharmaceutrics reviews of all data" in accordance with the FDCA and agency practice. *Id*. at 10. The result of this heightened scrutiny and extensive review is a REMS which unambiguously assures the safety of the drug without any additional safeguards

[8] On the eve of entry of this Opinion, the Fifth Circuit issued its decision affirming a stay of the 2016 REMS and the FDA's 2021 non-enforcement decision, later codified in the 2023 REMS. *All. for Hippocratic Med. v. FDA*, — F.4th —, 2023 WL 5266026 (5th Cir. Aug. 16, 2023). The Court has reviewed the Fifth Circuit decision and does not find its primary determinations to be persuasive. Nevertheless, the Court notes the direct effect of that decision on this case, as mifepristone is currently subject to the "conditions for use that existed in 2016" pending the litigation of *Alliance for Hippocratic Medicine*. *Id*. at *1-2. However, the Fifth Circuit noted that its "holding is subject to the prior order of the Supreme Court, which stayed the district court's order pending resolution of this appeal and disposition of any petition for writ of certiorari." *Id*. at * 4. Regardless, 2023 REMS remains law, and the Court will consider Plaintiff's claims as to those restrictions.

from the States. Defendants have not disputed the safety of the mifepristone REMS, nor could they.

Confronted with West Virginia's additional barriers to prescribing its product, Plaintiff filed suit in this Court on January 25, 2023, alleging that the UCPA and prior restrictions violate the Supremacy and Commerce Clauses by limiting the sale of mifepristone in West Virginia. Prosecuting Attorney of Putnam County Mark Sorsaia and Attorney General of West Virginia Patrick Morrisey were named as defendants in their official capacities. Both Defendants have filed motions to dismiss. ECF Nos. 17 & 19. Each Defendant disputes GenBioPro's standing, as well as Plaintiff's interpretation of the Supremacy and Commerce Clauses. The Court heard oral argument on the issue of standing on April 24, 2023, and subsequently issued a Memorandum Opinion and Order finding that Plaintiff had standing on behalf of itself and on behalf of third-party vendees. ECF No. 54. On May 23, 2023, the Court heard oral argument on the remainder of the Motions to Dismiss. Accordingly, the matter is now ripe for adjudication.

II. LEGAL STANDARD

To survive a motion to dismiss, a complaint must contain "a short and plain statement of the claim showing [the plaintiff] is entitled to relief." Fed. R. Civ. P. 8(a)(2). While the facts alleged in the complaint need not be probable, the statement must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim has facial plausibility when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). In considering the plausibility of a plaintiff's claim, the Court accepts all well-pleaded factual allegations in the complaint as true.

Id. Still, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*. (citation omitted).

Determining whether a complaint states a plausible claim is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id*. at 679. If the court finds from its analysis that "the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id*. (quoting, in part, Fed. R. Civ. P. 8(a)(2)). Nonetheless, a plaintiff need not show that success is probable to withstand a motion to dismiss. *Twombly*, 550 U.S. at 556 ("[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely.").

III. DISCUSSION

A. Major Questions Doctrine

In his Motion to Dismiss, Defendant Morrisey argues that this is a major questions case. Def. Morrisey's Mem. of Law in Supp. of Mot. to Dismiss at 8-10, ECF No. 20. The Supreme Court inaugurated the so-called "major questions doctrine" in *West Virginia v. EPA*, 142 S. Ct. 2587 (2022). "Under that doctrine's terms, administrative agencies must be able to point to clear congressional authorization when they claim the power to make decisions of vast economic and political significance." *Id*. at 2616 (Gorsuch, J., concurring) (cleaned up); *see also Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014) ("When an agency claims to discover in a long-extant statute an unheralded power to regulate a significant portion of the American economy, we typically greet its announcement with a measure of skepticism." (internal quotation omitted)). Relying on a concatenation of caselaw in which agencies were found to lack the

authority to regulate broadly under ambiguous delegation provisions, *West Virginia* invalidated the Environmental Protection Agency's interpretation of a broad provision in the Clean Air Act as granting the agency comprehensive authority to regulate national energy systems. 142 S. Ct. at 2610-14; *see also Biden v. Nebraska*, 143 S. Ct. 2355, 2374 (2023) ("[W]hile the major questions 'label' may be relatively recent, it refers to 'an identifiable body of law that has developed over a series of significant cases' spanning decades." (quoting *West Virginia*, 142 S. Ct. at 2609)). In doing so, *West Virginia* held that courts must "presume that Congress intends to make major policy decisions itself, not leave those decisions to agencies." 142 S. Ct. at 2609 (internal quotation omitted). As abortion is one such major policy decision, Defendant Morrisey argues that this Court must conclude Congress did not intend to delegate the authority to the FDA to decide access issues for mifepristone. *See* Def. Morrisey's Mem. of Law in Supp. of Mot. to Dismiss at 9.

The Court does not dispute the serious social, ethical, economic, and political issues implicated by abortion. There is no doubt that "terminating a pregnancy is an issue with 'profound moral and spiritual implications even at its earliest stage.'" Def. Morrisey's Mem. of Law in Supp. of Mot. to Dismiss at 9 (quoting *Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 850 (1992)) (cleaned up). And yet, the Court disagrees that either the FDA's promulgation of the mifepristone REMS or GenBioPro's arguments concerning those REMS implicate those major questions. The seminal major questions cases all involved novel agency interpretations of long-standing ambiguous regulatory provisions as major grants of authority to reconfigure large aspects of the economy. *See West Virginia*, 142 S. Ct. at 2602-04; *Air Utility*, 573 U.S. at 323-24; *Biden v. Nebraska*, 143 S. Ct. at 2373 (involving attempted broad student loan forgiveness under a limited grant of emergency loan waiver authority); *FDA v. Brown &*

Williamson Tobacco Corp., 529 U.S. 120, 160 (2000) (involving attempted regulation of cigarettes as "drug delivery devices").

In contrast, here the FDA is acting narrowly pursuant to an explicit grant of authority as to a single prescription medication—the FDAAA's express command that the FDA promulgate a REMS for Subpart H-approved drugs (including mifepristone), subject to certain delineated principles, including ensuring accessibility. FDAAA, Section 909(b)(1); 21 U.S.C. § 355-1(f)(2)(C). That is all; the FDA is not making any novel claims to any broader authority hidden within the FDCA or the FDAAA amendments. In other words, the FDA's mifepristone REMS simply does not "effect a fundamental revision of the statute, changing it from one sort of scheme of regulation into an entirely different kind." *Biden v. Nebraska*, 143 S. Ct. at 2373 (quoting *West Virginia*, 142 S. Ct. at 2612) (cleaned up). Instead, the promulgation of the REMS was a routine regulatory action.

Nor is GenBioPro claiming that either the FDCA or the FDAAA amendments contain previously unstated broad abortion authority. GenBioPro's preemption argument can be characterized as: (1) the FDAAA commanded the FDA to consider access in promulgating a REMS for mifepristone; (2) pursuant to that authority, the REMS the FDA promulgated determined a standard of accessibility for the drug; and (3) West Virginia's abortion laws conflict with this standard. *See* Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 8-19. The Court will consider the cognizability of this preemption argument separately, below. But regardless of its validity, GenBioPro's argument does not allege an elephant hidden in a mousehole.

Defendant Morrisey argues that the FDCA "does not so much as mention abortion." Def. Morrisey's Mem. in Supp. of Mot. To Dismiss at 9. True—but nor does it mention any other

specific procedure, device, cosmetic, or medication it instructs the FDA to regulate. *See, e.g.*, 21 U.S.C. § 321(h)(1) (defining "medical devices" the FDA may regulate without specifying any particular device). Defendant misunderstands the purpose and scope of the statutory grants of agency authority by demanding that Congress have listed every possible medical condition and procedure when it instructed the FDA to regulate prescription medicine generally. For example—imagine if Congress were forced to list every endangered species for the Endangered Species Act ("ESA") to grant the Fish and Wildlife Service ("FWS") authority to protect any specific at-risk organism. *See* 16 U.S.C. § 1531 *et seq*. Calling this a "major questions case" and demanding the FDA refrain from treating abortion medications on par with other medications under the FDCA would make just as much sense as demanding the FWS refrain from listing the snail darter as an endangered species under the ESA. *See Tennessee Valley Auth. v. Hill*, 437 U.S. 153 (1978). If Defendant wishes to bring a delegation challenge, he will have to find standing to bring another suit.

But, significantly, Congress *did* specify that drugs previously approved under Subpart H would be deemed in effect to have a REMS in the 2007 FDAAA amendments.[9] FDAAA, Section 909(b)(1). Shortly thereafter, the FDA issued a notice indicating that mifepristone was one of these previously approved drugs. Dept. Health & Human Servs., *Identification of Drug & Biological Prods. Deemed to Have Risk Evaluation & Mitigation Strategies for Purposes of the Food & Drug Admin. Amendments Act of 2007*, 73 Fed. Reg. 16313-01, 16313 (Mar. 27, 2008). The fact that Congress did not specify that mifepristone is to be used for abortion when it incorporated the drug into the REMS scheme is of no more import than its lack of specification

[9] This is not a case where the regulatory agency relied upon an implied grant of authority. This list consisted of only 17 previously approved drugs and Congress undoubtedly knew that one, mifepristone, was used only for medication abortion.

as to isotretinoin's usage as an acne medication. *See id*. Each medicine listed in the FDA's 2008 Notice was approved for an indicated use via Subpart H, and Congress stated that those approvals were to be carried over into the new REMS schema (subject to eventual FDA re-evaluation). An order to regulate an express list of prescription medicines under a second list of articulated criteria is about as granular a grant of authority as Congress ever gives an agency.

Accordingly, the Court finds that this is not a major questions case, and the major questions doctrine does not bar Plaintiff's arguments as to preemption and the dormant Commerce Clause. Whether the UCPA or prior restrictions violate either the Supremacy or Commerce Clause is a different question and is considered below.

B. Preemption

The Supremacy Clause provides that federal law "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. It follows inexorably that "Congress has the power to preempt state law." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (citing *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000); *Gibbons v. Ogden*, 9 Wheat. 1, 210–211, 6 L.Ed. 23 (1824)). Accordingly, "the purpose of Congress is the ultimate touchstone in every preemption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (internal quotation omitted). "Congress may indicate pre-emptive intent through a statute's express language or through its structure and purpose." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008). However, there is a presumption against preemption, especially in a field traditionally occupied by the States. *Wyeth v. Levine*, 555 U.S. 555, 565 (2009).

Generally, there are three types of preemption: (1) express preemption, (2) conflict preemption, and (3) field preemption. *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1480 (2018); *Mayor & City Council of Balt. v. BP P.L.C.*, 31 F.4th 178, 198 n.2 (4th Cir. 2022). Both "conflict" and "field" are considered types of implied preemption. *Kurns v. Railroad Friction Prods. Corp.*, 565 U.S. 625, 630-31 (2012). On occasion, the Supreme Court has delineated further, treating "impossibility" and "obstacle" preemption as two separate entities within "conflict" preemption. *See Arizona*, 567 U.S. at 399-400. The Court has admitted that it "sometimes use[s] different labels" but that "these categories are not rigidly distinct." *Va. Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1901 (2019) (quoting *Crosby*, 530 U.S. at 372, n.6). This Opinion considers both whether the challenged state provisions "conflict" with or provide an "obstacle" to federal law, treating these as one form of "conflict" preemption, in accordance with *e.g.*, *Murphy*, 138 S. Ct. at 1480.

The FDCA does not include an express preemption provision. *See Wyeth*, 555 U.S. at 574 ("If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA's 70–year history.") The 1962 Amendments to the FDCA, however, include an express preemption saving clause. *See* Drug Amendments of 1962, § 202, 76 Stat. 793 ("Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law . . . unless there is a direct and positive conflict between such amendments and such provision of State law"). Of further import, regulation of health and safety is a field that States have traditionally occupied. *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 716 (1985). The Supreme Court has made it clear that regulating abortion is a matter of health and safety upon which States may appropriately exercise their police power. *See*

Dobbs, 142 S. Ct. at 2279. Regulation of medical professionals—which the UCPA directly accomplishes—is arguably a field in which the States have an even stronger interest and history of exercising authority. *See id*. at 2284 (emphasizing the States' interest in "the preservation of the integrity of the medical profession"); *Dent v. West Virginia*, 129 U.S. 114 (1889) (holding that West Virginia has the authority to regulate medical licensure).

Keeping these principles in mind, the Court will consider the arguments as to implied preemption.

a. Conflict Preemption

As an antecedent matter, the Court cannot find any evidence of Congressional intent in the FDCA or FDAAA amendments to preempt state laws of the type challenged here. Again, "the purpose of Congress is the ultimate touchstone in every preemption case." *Wyeth*, 555 U.S. at 565 (quoting *Medtronic*, 518 U.S. at 485). Congressional intent must be determined in context, as "our interpretation of [statutory] language does not occur in a contextual vacuum." *Medtronic*, 518 U.S. at 485.

In determining the purpose of the contested FDAAA "access" provisions, the Court "begin[s] by analyzing the statutory language" as "[w]e must enforce plain and unambiguous statutory language according to its terms." *Hardt v. Reliance Standard Life Ins. Co.*, 560 U.S. 242, 251 (2010). The relevant portion of the statute reads as follows:

> **(f) Providing safe access for patients to drugs with known serious risks that would otherwise be unavailable**
>
> **(1) Allowing safe access to drugs with known serious risks**
>
> The Secretary, in consultation with the offices described in subsection (c)(2), may require that the risk evaluation and mitigation strategy for a drug include such elements as are necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness, if the Secretary determines that—

> **(A)** the drug, which has been shown to be effective, but is associated with a serious adverse drug experience, can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug; and
>
> **(B)** for a drug initially approved without elements to assure safe use, other elements under subsections (c), (d), and (e) are not sufficient to mitigate such serious risk.

(2) ***Assuring access and minimizing burden***

Such elements to assure safe use under paragraph (1) shall—

> **(A)** be commensurate with the specific serious risk listed in the labeling of the drug;
>
> **(B)** within 30 days of the date on which any element under paragraph (1) is imposed, be posted publicly by the Secretary with an explanation of how such elements will mitigate the observed safety risk;
>
> **(C)** considering such risk, *not be unduly burdensome on patient access* to the drug, considering in particular—
>
> > **(i)** patients with serious or life-threatening diseases or conditions;
> >
> > **(ii)** patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and
> >
> > **(iii)** patients with functional limitations; and
>
> **(D)** to the extent practicable, *so as to minimize the burden on the health care delivery system—*
>
> > **(i)** conform with elements to assure safe use for other drugs with similar, serious risks; and
> >
> > **(ii)** be designed to be compatible with established distribution, procurement, and dispensing systems for drugs.

21 U.S.C. § 355-1(f) (italics added, bold in original).

Plaintiff argues that this language—repeatedly emphasizing ensuring access and minimizing undue burden—shows Congressional intent to designate access determinations for drugs subject to a REMS with elements to assure safe use to the FDA, thus preempting any conflicting state access determinations. Admittedly, Section 355-1(f)(2) requires the FDA to consider patient access and burden. However, this requirement is plainly a limitation on the FDA's *own restrictions* on a drug, rather than a command that the FDA assure access for all patients: "[s]uch elements to assure safe use *under paragraph (1)* shall" not be "unduly burdensome." Accordingly, Congress's purpose in directing the FDA to consider burden and access when promulgating REMS with elements to assure safe use was to ensure that the elements *themselves* would not be unduly burdensome upon patient access.

The context in which the FDAAA was passed confirms this interpretation. At the time Congress passed the FDAAA in 2007, mifepristone was approved for usage up to 49 days of pregnancy under the Subpart H regulatory scheme. Compl. ¶¶ 39, 58. In 2007, *Planned Parenthood v. Casey*'s "undue burden" or "substantial obstacle" standard was the touchstone for assessment of the constitutionality of abortion restrictions, and the Court recognized "the right of the woman to choose to have an abortion before viability." 505 U.S. at 846; *see Stenberg v. Carhart*, 530 U.S. 914, 921 (2000) (providing that "a law designed to further the State's interest in fetal life which imposes an undue burden on the woman's decision before fetal viability is unconstitutional" (internal quotation marks omitted)); *Cincinnati Women's Servs., Inc. v. Taft*, 468 F.3d 361, 367-69 (6th Cir. 2006) (discussing and applying *Casey*). While debate over the ethics of abortion roiled the nation, no Congressperson in 2007 could have credibly doubted that abortion was legal up to 49 days of pregnancy, long before the point of viability. In fact, in 2006, the Sixth Circuit upheld a district court's preliminary injunction on an Ohio ban of off-label

usage of mifepristone as unconstitutional under *Casey* and *Carhart*. *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 508-09, 518 (6th Cir. 2006). Consequently, while Congress deemed mifepristone to have in effect a REMS, and included language concerning access in the REMS scheme, it is not plausible to infer an intent from this language to preclude state abortion law by granting mifepristone access decisions to the FDA. In 2007, the issue of access to abortion up to 49 days of pregnancy was conclusively determined (so we thought) by the Supreme Court, and an appellate court had applied that standard to mifepristone. Absent express language to the contrary, the Court finds it difficult to conclude that Congress intended for the FDAAA access language to preempt state abortion restrictions which would have been unconstitutional at the time the FDAAA was passed.

Therefore, the Court finds that the UCPA and abortion restrictions do not pose an "unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Wyeth*, 555 U.S. at 563-64 (internal quotation omitted); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (seminal case finding obstacle preemption). As discussed above, "conflict" preemption has been variously deconstructed into "conflict," "impossibility," and "obstacle" preemption. Some Supreme Court decisions have elevated obstacle preemption to sit alongside field and conflict preemption, treating the later as synonymous with "impossibility" preemption, while others conflate "obstacle" and "conflict" preemption. *Compare, e.g., Virginia Uranium*, 139 S. Ct. at 1907 (treating "conflict" and "obstacle" preemption as synonymous), *with Arizona*, 567 U.S. at 399 (delineating two types of "conflict" preemption as "impossibility" and "obstacle" preemption). Regardless of taxonomies, both parties treat "conflict" or "impossibility" preemption and "obstacle" preemption as distinct pathways to an implied preemption holding,

and the Court will consider those claims as they have arisen before it. *See* Def. Morrisey's Mem. of Law in Supp. of Mot. to Dismiss at 11; Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 14.

The Court finds that while the FDAAA requires the FDA to consider accessibility in making REMS determinations, the plain language of the statute indicates that "access" considerations are made with regards to the FDA's own limitations it imposes upon obtaining medications subject to a REMS, rather than broadly legislating geographical access to the entire population. The context in which the FDAAA was passed confirms this interpretation of the objectives of Congress. Any additional or incidental burden West Virginia has placed upon patients wishing to obtain mifepristone does not provide an unconstitutional "obstacle" to the FDAAA's unambiguous directive to the FDA.

Congruently, the Court rejects Plaintiff's assertion of "direct" or "impossibility" type conflict preemption. Conflict preemption may occur when "compliance with both federal and state regulations is a physical impossibility." *Arizona*, 567 U.S. at 399 (quoting *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963)). The Supreme Court has "long recognized that state laws that conflict with federal law are 'without effect.'" *Altria Group*, 555 U.S. at 76 (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). Theoretically—regardless of the intent of the FDAAA—the mifepristone REMS could directly conflict with West Virginia's restrictions, thereby creating a system in which individuals regulated by both federal and state law could not comply with both mandates. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 486-87 (2013) (finding preemption due to direct conflict between state tort law and FDCA labelling requirements); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011) (same).

Yet, the Court finds that GenBioPro is not subject to a catch-22, whereby it may either comply with the UCPA or the REMS regulations. In fact, GenBioPro is not regulated by the

UCPA *at all*. The UCPA regulates "licensed medical professionals," defined as persons licensed under either West Virginia Code § 30-3-1 *et seq.* or § 30-14-1 *et seq*., which govern licensure of the practice of medicine, surgery, podiatry, and osteopathic medicine or surgery for physicians and physicians' assistants. W. Va. Code §§ 16-2R-2; 16-2R-3. As discussed above, the UCPA prohibits licensed medical professionals from performing, inducing, or attempting to perform or induce an abortion by any means, subject to a limited series of exceptions. W. Va. Code § 16-2R-3. The prohibited act is further defined as "an act or the omission of an act that, under the circumstances as the person so acting or omitting to act believes them to be, constitutes a substantial step in a course of conduct intended to culminate in an abortion." W. Va. Code § 16-2R-2. Whether this definition could include GenBioPro's sale of mifepristone to doctors and pharmacies is debatable, but the Court need not decide that question today, as GenBioPro is not a "licensed medical professional" under either West Virginia Code § 30-3-1 *et seq.* or § 30-14-1 *et seq*. Accordingly, GenBioPro is not caught between obeying state and federal law in a manner which would offend the Supremacy Clause.[10]

However, this Court has found that GenBioPro may assert the interests of its vendees, who are subject to the strictures of the UCPA. Mem. Op. & Order at 18-22, ECF No. 54. GenBioPro sells to doctors and pharmacies nationwide and would like to sell to those same vendees in West Virginia. Compl. ¶¶ 77-79. While the Court's previous opinion focused on the ability of GenBioPro to represent the interests of its vendees who fall outside the UCPA's definition of "licensed medical professional," there is no doubt that many of GenBioPro's vendees would be "licensed medical professionals" under the UCPA. *See* Mem. Op. & Order at 21-22;

[10] As an aside, the Court rejects Defendants' argument that GenBioPro may simply choose to stop selling mifepristone in West Virginia, and thus avoid any conflict between state and federal law. *See Bartlett*, 570 U.S. at 488 (rejecting a "stop-selling rationale").

Compl. ¶ 71. So, the question remains: does the UCPA conflict with the REMS such that licensed medical professionals cannot lawfully comply with both?

The REMS specify the methods by which mifepristone may be prescribed. For example, the REMS indicate which providers may prescribe the drug, whether it may be prescribed remotely or in person, and what diagnostic criteria is appropriate for prescribing mifepristone. 2023 REMS; *see also* 21 U.S.C. § 355-1(f)(3) (indicating which elements to assure safe use may be included in a REMS). The UCPA, on the other hand, instructs licensed medical professionals in the State of West Virginia to only perform abortions when certain extrinsic criteria are present—both medical and non-medical—such as an ectopic pregnancy, or reported rape or incest. W. Va. Code § 16-2R-3(a), (b). The additional state law restrictions include an active prohibition on telemedicine prescription of mifepristone and a dormant set of restrictions mostly involving informational disclosure requirements. *See* W. Va. Code §§ 16-2I-2; 16-2R-9; 30-3-13a(g)(5); 30-1-26(b)(9). A licensed medical professional in West Virginia, therefore, must surmount several hurdles to prescribe mifepristone: first ascertaining whether a patient may obtain an abortion under the UCPA, then whether mifepristone is appropriate for that patient under the REMS, and finally, the method by which mifepristone may be prescribed to the patient in consideration of both the REMS and the West Virginia restrictions. This scheme coheres with traditional conceptions of the practice of medicine and the scope of physicians' authority as state matters. *See, e.g.*, *Dent*, 129 U.S. at 122 (describing the "time immemorial" power of the State to regulate the practice of physicians).

Accordingly, the Court finds that the UCPA is a restriction on the incidence of abortion, rather than a state directive in direct conflict with the logistical REMS regulations. The Supreme Court has repeatedly indicated that similarly broad state regulations are not preempted by

intricate federal regulatory systems. For instance, in *Virginia Uranium*, mining companies and owners of uranium-rich land sued Virginia, alleging that a state law preventing uranium mining was preempted by the federal Atomic Energy Act's regulations on the practice of uranium mining. *Virginia Uranium*, 139 S. Ct. at 1901. As the decision to disallow uranium mining is separate from the regulations on the act of mining itself—and in an area of authority traditionally left to the States—the Court found that the Atomic Energy Act did not preempt state bans on uranium mining. *Id*. at 1903, 1907-08. Similarly, the Court has found that state bans on horsemeat are not preempted by the federal regulatory scheme dictating how horses are to be slaughtered. *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 467 (2012).[11] Here, West Virginia's UCPA has limited *when* an abortion may be performed, without touching *how* medication abortion is to be performed. The mifepristone REMS only concern themselves with the latter.[12] As the Court found States may ban uranium mining despite a federal scheme of uranium mining regulation, or horsemeat in the face of a federal scheme of horse slaughter regulation, so this Court is compelled to find that federal regulation of medication abortion prescription does not conflict with severe state limitations on abortion.

[11] While *National Meat Association v. Harris* decided that the Federal Meat Inspection Act (FMIA) preempted a California law regulating the slaughter of non-ambulatory pigs, the Court emphasized that its holding on the pigs did not imply that state laws banning horse meat would be similarly preempted by the FMIA, stating: "A ban on butchering horses for human consumption works at a remove from the sites and activities that the FMIA most directly governs. When such a ban is in effect, no horses will be delivered to, inspected at, or handled by a slaughterhouse, because no horses will be ordered for purchase in the first instance." 565 U.S. at 467. The Court has reiterated this dictum as to the legality of bans on horse slaughter in subsequent cases. *Virginia Uranium*, 139 S. Ct. at 1914 (Ginsburg, J., concurring); *see also Nat'l Pork Prod. Council v. Ross*, 143 S. Ct. 1142, 1163 (2023) (discussing state horsemeat bans).

[12] The Court is aware that the REMS do dictate "when" an abortion may be performed with mifepristone, in the sense of gestational limits and locations. But there are different kinds of "when." West Virginia creates pre-requisites to accessing abortion care, while the REMS delineate logistical safety standards once a patient has sought medication abortion.

b. Field Preemption

Likewise, the Court rejects Plaintiff's arguments as to field preemption.

Field preemption precludes States from "regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance." *Arizona*, 567 U.S. at 399 (citing *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 115 (1992) (Souter, J., dissenting)). To put it another way, field preemption "occurs when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation.'" *Murphy*, 138 S. Ct. at 1480 (quoting *R.J. Reynolds Tobacco Co. v. Durham Cty.*, 479 U.S. 130, 140 (1986)). Where Congress has made this determination, States may not regulate in the same "field," even where those regulations might be "parallel to federal standards." *Arizona*, 567 U.S. at 401.

Plaintiff has argued that Congress occupied the field specifically as to drugs subject to a REMS which include "elements to assure safe use." Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 9.[13] A subset of REMS must contain "elements to assure safe use," if the Secretary determines that the regulated drug requires such elements "as part of [a] strategy to mitigate a specific serious risk listed in the labeling of the drug." 21 U.S.C. § 355-1(f)(1). These drugs, Plaintiff asserts, are subject to a more "pervasive framework" than other drugs regulated under the FDCA, utilizing the imperative "shall" when instructing the FDA to consider patient "access" in making REMS determinations. Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 9. Essentially, once the FDA concludes a REMS including such elements is necessary for a drug, the FDA is required to take a series of steps in promulgating a REMS including elements to

[13] While Plaintiff's Opposition appears to argue that Congress occupied the field as to all drugs subject to a REMS, at oral argument GenBioPro clarified that its field preemption argument is only as to drugs subject both to a REMS and to additional elements to assure safe use. *See* Tr. of Proceedings at 34-35, ECF No. 62.

assure safe use. *See* 21 U.S.C. §§ 355-1(a), (c), (f), (h). Plaintiff believes this requirement is sufficient to demonstrate that Congress has "occupied the field" when it comes to such drugs.

In reply, Defendant Morrisey points to the FDCA's 1962 express saving clause, demonstrating Congressional intent for state law to play a complementary role in the field. Reply in Supp. of Mot. to Dismiss at 6, ECF No. 45. Defendant Morrisey notes that "the presence of a savings provision 'is fundamentally incompatible with complete field preemption.'" *Id*. (quoting *Farina v. Nokia Inc.*, 625 F.3d 97, 121 (3d Cir. 2010); *Aldridge v. Miss. Dept. of Corr.*, 990 F.3d 868, 874-75 (5th Cir. 2021); *In re NOS Commc'ns*, 495 F.3d 1052, 1058 (9th Cir. 2007)). Included in the 1962 Amendments to the FDCA, the saving clause has been interpretated to allow for state tort law's complementary role in shaping safety standards for products regulated under the FDCA. *See Wyeth*, 555 U.S. 555. Accordingly, the Court agrees that the 1962 saving clause has foreclosed any argument for complete field preemption. However, Plaintiff has been clear in its assertion that Congress has only occupied the field as to a subsection of drugs subject to a REMS with elements to assure safe use. *See* Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 9.

Nevertheless, Plaintiff's argument fails for want of Congressional intent in the FDAAA amendments, as discussed in depth above. Where Congress acts in a field traditionally occupied by the States, the presumption against preemption is strongest. *Wyeth*, 555 U.S. at 565. There is no disputing that health, medicine, and medical licensure are traditional areas of state authority. *See, e.g.*, *Hillsborough*, 471 U.S. at 716. Furthermore, the Supreme Court has repeatedly held that the FDCA does not preempt state action in the field of healthcare or medicine, absent a direct conflict. *Compare Wyeth,* 555 U.S. at 581 (not finding preemption because state tort law did not directly conflict with FDCA), *with Bartlett*, 570 U.S. at 486-87 (finding preemption due

to direct conflict between state tort law and FDCA labelling requirements). While the Supreme Court has yet to address the wrinkles of the REMS provision, Plaintiff has not advanced a convincing argument that the Court would treat that statutory subsection differently than any other portion of the FDCA.

To that end, Plaintiff cites *United States v. Locke*, 529 U.S. 89 (2000). In *Locke*, Washington State passed more stringent regulations on oil tankers than existed under the national regulatory scheme. *See id*. at 97. Washington's personnel qualifications for oil tanker employees were found to be preempted by federal requirements, given historical federal occupation of the field. *Id*. at 112-15. In reaching this conclusion, the *Locke* Court emphasized that the Coast Guard was given non-discretionary authority to ensure oil tanker personnel met the minimum federal requirements. *Id*. at 115-16. Here, Plaintiff argues that the FDA is subject to a similarly non-discretionary requirement that it ensure drugs which require both a REMS and elements to assure safe use consider access in promulgating those elements. *See* Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 9; 21 U.S.C. § 355-1(f)(1)-(3). Therefore, just as the *Locke* Coast Guard only must ensure oil tanker employees meet minimum qualification requirements, GenBioPro asserts that the FDA has been commanded to ensure mifepristone is available subject only to its REMS.

However, *Locke* is distinguishable for several reasons. First, the *Locke* Court repeatedly emphasized that regulating interstate navigation is historically an area of federal concern, dating back to the Constitutional Convention; here, the Court has found the opposite is true. *Id*. at 99-100; *see Hillsborough*, 471 U.S. at 716; *Dobbs*, 142 S. Ct. at 2248-55 (discussing the history of abortion laws). Second, much of *Locke* circled around a preemption savings clause in the Oil Pollution Act of 1990, which indicated Congress only intended to leave room for complementary state action in a specified area of discretionary federal authority. 529 U.S. at 105-06. In contrast,

the Supreme Court has found the 1962 FDCA saving clause to contain breadth, given the general language of the clause, the historical state police powers implicated, and the fact Congress included express preemption provisions in a different amendment to the FDCA. *Wyeth*, 555 U.S. at 567. Conversely, *Locke* found that a particular sub-field of an area of historical federal concern had been fully occupied by Congress, given the existence of a separate preemption saving clause indicating a differing sub-field would permit complementary state action. The limited language in the *Locke* opinion focusing on the Coast Guard command must be read in this broader context, which stands in stark contrast to the manner in which the Court has treated how traditional state authority over healthcare has been affected by the FDCA.

Accordingly, the Court finds that Congress has not expressed an intent to occupy the field of drugs subject to a REMS in a manner which would preempt West Virginia's abortion restrictions.

c. Telemedicine Restriction

There is one provision which is unambiguously preempted by the 2023 REMS: the prior restriction on prescribing mifepristone via telemedicine. *See* W. Va. Code §§ 30-3-13a(g)(5); 30-1-26(b)(9). Unlike the other prior restrictions, the telemedicine provision is still in effect. *See* W. Va. Code § 16-2R-9. Accordingly, the Court's finding that the UCPA is not preempted by the REMS is irrelevant to consideration of the telemedicine restriction. The 2023 REMS reflects a determination by the FDA that when mifepristone is prescribed, it may be prescribed via telemedicine.[14]

[14] Again, the Court notes that the Fifth Circuit's recent decision in *Alliance for Hippocratic Medicine* stayed the 2023 REMS and the 2021 FDA decision to allow prescription of mifepristone via telemedicine. *See* 2023 WL 5266026, at *1-2. Therefore, this Court's decision as to the West Virginia telemedicine restriction will not change the current Fifth Circuit injunction prohibiting telemedicine, subject to the Supreme Court's order. *See id*. at 4.

The telemedicine restriction is not "upstream" from the REMS, in the manner of the UCPA. Rather than indicating what procedures are allowed in West Virginia, the telemedicine restriction dictates the manner in which mifepristone may be prescribed. This is a determination which Congress has allocated to the FDA. 21 U.S.C. § 355-1(f)(3)(C) (stating that a REMS may include a restriction specifying that "the drug be dispensed to patients only in certain health care settings, such as hospitals."). The FDA has evaluated the criteria Congress designated and has come to the reasoned conclusion that mifepristone may be prescribed via telemedicine. 2023 REMS. This conflict between the REMS and the state statute creates the kind of impossibility preemption discussed above—a licensed medical professional prescribing mifepristone could not comply with both the access determination made by the FDA and the access determination made by West Virginia as to telehealth.

The other prior restrictions might be likewise preempted by direct conflict with the REMS, as they similarly dictate the way mifepristone may be prescribed. *See* W. Va. Code § 16-2I-2. Regardless, the Court has not found that the UCPA is unconstitutional. As none of these prior restrictions are currently in effect, this Court may not issue an advisory opinion as to the constitutionality of a law not presently operative.

Accordingly, Defendants' Motions to Dismiss Count I are **DENIED,** as to the telemedicine restriction, and **GRANTED**, as to the UCPA and other prior restrictions.

C. Dormant Commerce Clause

The Commerce Clause grants Congress the power to regulate interstate commerce. U.S. Const. Art. I, § 8, cl. 3. The Supreme Court has long recognized that the Commerce Clause contains a corollary command, "effectively forbidding the enforcement of certain state economic

regulations even when Congress has failed to legislate on the subject." *Nat'l Pork Prod. Council v. Ross*, 143 S. Ct. 1142, 1152 (2023) (quoting *Okla. Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 179 (1995)) (cleaned up). Known as the "dormant Commerce Clause," this doctrine has previously been characterized as forbidding States from enacting laws which either discriminate against interstate commerce or regulate extraterritorially. *See, e.g.*, *Ass'n for Accessible Medicines v. Frosh*, 887 F.3d 664, 667-69 (4th Cir. 2018) (relying on *Healy v. Beer Inst.*, 491 U.S. 324, 335–36 (1989); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 582–83 (1986); *Edgar v. MITE Corp.*, 457 U.S. 624, 642–43 (1982) (plurality opinion); *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935)). Even if a law did not discriminate or regulate extraterritorially, it could still fail the "balancing test" announced in *Pike v. Bruce Church*, 397 U.S. 137 (1970). Under this standard, if plaintiffs can demonstrate that the challenged law burdens interstate commerce, then the Court determines "whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits." *Id*. at 142; *see Nat'l Pork*, 143 S. Ct. at 1165-66 (Sotomayor, J., concurring) (discussing the threshold burden requirement for *Pike* balancing).

On May 11, 2023, the Supreme Court issued its decision in *National Pork Producers Council v. Ross*, 143 S. Ct. 1142 (2023). *National Pork* affirmed a lower court decision to dismiss a pork industry plaintiff's challenge to a California law limiting the sale of certain kinds of pork in the State. The pork plaintiffs argued that the law violated the dormant Commerce Clause by forcing them to broadly change their business practices. *Id*. at 1151. As a preliminary matter, the Court rejected plaintiff's interpretation of *Healy*, *Brown-Forman*, *Edgar*, and *Baldwin* as engendering an "almost per se rule" against extraterritoriality.[15] *Id*. at 1154-57. Accordingly, this Court finds

[15] The Court appeared to limit dormant Commerce Clause extraterritoriality claims to statutes

that to whatever extent the Fourth Circuit's dormant Commerce Clause jurisprudence employed a similar "principle against extraterritoriality" founded in those same cases, it has been abrogated by *National Pork*. *See Ass'n for Accessible Med.*, 887 F.3d at 667-69. While Justice Gorsuch's majority opinion could not come to a consensus on the application of the *Pike* balancing test to the pork industry group's claims, in three partial concurrences a minimum of six Justices[16] upheld some form of *Pike* balancing. *See id*. at 1165-72. At least a plurality held that "derivative harms" of legislation may be considered when employing the *Pike* balancing test. *Id*. at 1169 (Roberts, C.J., concurring in part); *see id*. at 1165-66 (Sotomayor, J., concurring in part) (potentially supporting usage of derivative harms as a factor in *Pike* analysis). Throughout, the opinions emphasize that an "antidiscrimination principle lies at the 'very core' of our dormant Commerce Clause jurisprudence," forbidding States from enacting statutes "driven by economic protectionism." *Id*. at 1153 (majority).

In its Opposition to Defendant Morrisey's Motion to Dismiss, Plaintiff argues that the challenged statutes "violate the Clause by imposing an undue burden on interstate commerce, by regulating extraterritorially, and by functionally banning an article of commerce." Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 23. However, following the decision in *National Pork*, this

that discriminate against interstate commerce by tying in-state prices to out-of-state prices. *Id*. at 1154-55 (relying on *Healy*, 491 U.S. 324).

[16] As this Court reads *National Pork*, Justices Sotomayor and Kagan upheld *Pike*'s balancing test with no further elaboration, stating only that plaintiff had failed to meet the threshold requirement for consideration under *Pike*. *Id*. at 1165-66. Chief Justice Roberts and Associate Justices Alito, Kavanaugh, and Jackson applied *Pike* to the facts of the case, further interpreting the balancing test. *Id*. at 1167-72.

Justices Gorsuch, Barrett, and Thomas's view might be interpreted as upholding *Pike* as applying only to cases in which commensurate values could be balanced. *Id*. at 1159-61; 1166-67 (Barrett, J., concurring). Whether one considers that view to be upholding traditional *Pike* balancing or as partially overturning *Pike* likely depends on whether one agrees with the arguments made by those Justices. Regardless, this opinion is clearly the minority and will not be applied here.

Court ordered the parties to file supplemental briefing addressing how *National Pork*'s holding applied to the instant allegations. ECF No. 55. GenBioPro's Supplemental Brief admits that *National Pork* forecloses the Complaint's argument that West Virginia has violated the dormant Commerce Clause by regulating extraterritorially. Pl.'s Supp. Br. at 14-15, ECF No. 58. This Brief further re-categorizes GenBioPro's argument that the Clause was violated by "functionally banning an article of commerce" as a factor of consideration under the *Pike* balancing test, rather than as an independent means by which West Virginia could have violated the Clause. *Compare* Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 27, *with* Pl. Supp. Br. at 11-12. Therefore, the Court will only consider whether the Complaint has plausibly alleged that the challenged laws fail the *Pike* balancing test, in light of any recent refinement of *Pike* by *National Pork*.

Post-*National Pork*, Plaintiff asserts that West Virginia's laws fail that test for three reasons: "(1) they intrude on an area in which Congress requires nationally uniform regulation; (2) they functionally ban a product for its indicated use; and (3) they inflict 'derivative harms' by imperiling the health and safety of pregnant West Virginians and the national market for medications." Pl.'s Supp. Br. at 7. The Court will consider each asserted ground in turn.[17] But first, the Court notes that *National Pork* made clear that *Pike* balancing is meant to "serve[] as an important reminder that a law's practical effects may also disclose the presence of a discriminatory purpose." 143 S. Ct. at 1157. While the Court recognized that "a small number of our cases have invalidated state laws that appear to have been genuinely nondiscriminatory,"

[17] The Court acknowledges Defendant Morrisey's analysis of the potentially conflicting concurrences in *National Pork*, and their implications to the present dispute. *See* Def.'s Supp. Br., ECF No. 59. In fact, Defendant's Supplemental Brief contains a more prudent jurisprudential approach to applying *National Pork* to Plaintiff's Complaint. However, at the Motion to Dismiss stage, the Court takes care to draw all reasonable inferences in favor of the non-moving party and therefore employs Plaintiff's proffered post-*Pork* approach in dismissing its claims. Accordingly, Defendant Morrisey's crisp application of conflicting doctrine is valued but not utilized here.

they referred to ferreting out discriminatory laws as the "heartland" of the *Pike* test. *Id*. GenBioPro's claim falls far outside of this heartland, declining to assert that West Virginia was motivated by economic protectionism or that it had a discriminatory intent in passing the UCPA. As with the pork plaintiffs, this "is not an auspicious start." *Id*.

a. Required Nationally Uniform Regulation

Plaintiff distinguishes the holding in *National Pork*, arguing that while the pork plaintiff was merely concerned with the "cost of compliance," GenBioPro is concerned about "an area where there is a compelling need for national uniformity." Pl.'s Supp. Br. at 8 (quoting *Yamaha*, 401 F.3d at 572).

Yet again, regulation of health, medicine, and the medical profession are areas in which the States have traditionally exercised authority. *E.g.*, *Hillsborough*, 471 U.S. at 716. Accordingly, the Supreme Court has repeatedly found that there is a complementary role for state law, even where Congress has acted to regulate health and medicine. *E.g.*, *Wyeth,* 555 U.S. at 581. If Congress had created a system mandating national uniformity, the Court would expect to see some evidence of intent to preempt historical complementary state action. As analyzed in depth above, here there is no such expressed intent to occupy the field. A "compelling need for national uniformity" could exist absent field preemption, of course, but GenBioPro has not plausibly alleged any such need.

Most importantly, it's unclear where *National Pork* or its predecessors indicate that a "compelling need for national uniformity" entails a dormant Commerce Clause violation pursuant to *Pike*. Plaintiff points to language in the Chief Justice's concurrence. *See Nat'l Pork*, 143 S. Ct. at 1170 ("The *Pike* balance may well come out differently when it comes to interstate transportation, an area presenting a strong interest in 'national uniformity.'"). However, the

majority opinion dispensed of this interpretation. *Id*. at 1158 n.2. ("[T]his Court has only rarely held that the Commerce Clause itself pre-empts an entire field from state regulation, and then only when a lack of national uniformity would impede *the flow* of interstate goods." (internal quotation marks omitted, emphasis in original)). There is no argument that the UCPA or other restrictions impede *the flow* of mifepristone nationally.

b. Banning an Article of Commerce

GenBioPro's argument that the UCPA fails the *Pike* test by functionally banning an article of commerce is misplaced. In making this argument, Plaintiff leans heavily upon an 1898 case in which the Court found that the dormant Commerce Clause forbids States from banning "oleomargarine" as an "article of commerce." Pl.'s Supp. Br. at 11 (citing *Schollenberger v. Pennsylvania*, 171 U.S. 1 (1898)). In *Schollenberger*, the Court stated that

> The general rule to be deduced from the decisions of this court is that a lawful article of commerce cannot be wholly excluded from importation into a state from another state where it was manufactured or grown. A state has power to regulate the introduction of any article, including a food product, so as to insure [sic] purity of the article imported, but such police power does not include the total exclusion even of an article of food.

171 U.S. at 12. Be that as it may, the Court finds that *National Pork* put to rest any debate over whether States may enact product bans under their police power. Without acknowledging the existence of the oleomargine case, the various fractured opinions in *National Pork* made it clear that state bans of products as diverse as horsemeat, fireworks, and plastic bags do not offend the United States Constitution. 143 S. Ct. at 1163 (plurality); 1171 (Roberts, C.J., concurring) (responding to the plurality by arguing the broader market is affected by California's economy, rather than arguing a per se rule against banning products); 1150 (majority) ("While the Constitution addresses many weighty issues, the type of pork chops California merchants may sell is not on that list."). Circuit Courts have upheld both partial and full bans of foie gras,

horsemeat, and shark fins in the face of dormant Commerce Clause challenges. *See Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937 (9th Cir. 2013) (foie gras); *Cavel Int'l, Inc. v. Madigan*, 500 F.3d 551 (7th Cir. 2007) (horsemeat); *Chinatown Neighborhood Ass'n v. Harris*, 794 F.3d 1136 (9th Cir. 2015) (shark fins). Relevant to the instant case is the fact that many of the bans upheld by the Appellate Courts and name-checked by the Supreme Court plurality were enacted under state police power to regulate the health and morality of the community—the same authority under which the UCPA and other provisions were enacted. *See, e.g.*, *Cavel Int'l,* 500 F.3d at 555, 557 (finding a ban on horsemeat to be within the state's power to regulate animal welfare); *Nat'l Pork*, 143 S. Ct. at 1163 (plurality; citing *Cavel Int'l*).

Plaintiff attempts to distinguish product bans which *National Pork* found acceptable from the "ban" of mifepristone,[18] arguing that "(1) the products involved are not necessities," "(2) they often cause severe harms or offer little public benefit, and (3) Congress did not subject these items to an integrated, and inherently national, system . . . much less limit 'burdens' on that system." Pl.'s Supp. Br. at 11. First, the Court finds that the determination that any given product is a "necessity" invites the Court to engage in second-guessing of state legislatures, with no limiting principle. Second, and similarly, the conclusion that any given product causes "severe harms or offer[s] little public benefit" is surely one for the legislative body enacting any given statutory ban—not for this Court. Furthermore, at oral argument in *National Pork*, the plaintiff pressed the Court to distinguish bans enacted for health and safety from bans enacted solely pursuant to a State's moral authority; the Court declined. *See Nat'l Pork*, 143 S. Ct. at 1160.

[18] Plaintiff characterizes the UCPA and other restrictions as a "functional ban" of mifepristone. Pl.'s Supp. Br. at 11-12. Given the exceptions enumerated within the UCPA (and the fact mifepristone is not regulated directly by any of the challenged provisions), the Court is skeptical of this claim. *See* W. Va. Code § 16-2R-3(a) & (b).

Finally, while Plaintiff claims "[h]orsemeat and shark fins fit those three criteria," this is incorrect; both animal products are subject to an "inherently national system," demonstrating that such products may be subject to state bans. *See, e.g.*, FMIA, 21 U.S.C. § 601 *et seq.* (regulating horsemeat); Shark Conservation Act of 2010, Pub. L. 111–348; 124 Stat. 3668 (regulating shark fins).[19] More fundamentally, the Court cannot find any support in *National Pork* for the proposition that any of these criteria should be considered when considering state law limitations on the sale of consumer goods.

Accordingly, the Court finds that impeding the sale of an "article of commerce" is not an intrinsic violation of the dormant Commerce Clause, and that *Schollenberger* has been abrogated.[20] If West Virginia has "functionally banned" mifepristone, it was well within its rights to do so.

c. Derivative Harms

Next, Plaintiff argues that, under *Pike*, non-economic "derivative harms" caused by the UCPA and challenged restrictions should be weighed against the putative benefits or interests of the State in enacting the legislation. Pl.'s Supp. Br. at 12-14.

[19] The Shark Conservation Act of 2010 ("SCA") amended the High Seas Driftnet Fishing Moratorium Protection Act and the Magnuson-Stevens Fishery Conservation and Management Act ("MSA") to require all sharks caught in the United States be brought to shore with their fins naturally attached. Pub. L. 111–348; 124 Stat. 3668. The SCA is the most recent in a series of actions taken by the federal government to regulate shark finning. *See, e.g.*, The Shark Finning Prohibition Act of 2000, Pub. L. 106-557; 114 Stat. 2772. The caselaw referenced by Plaintiff found that a ban on possession of shark fins—even when those fins were obtained legally pursuant to the federal finning scheme—was neither preempted by the MSA nor in violation of the dormant Commerce Clause. *See Chinatown Neighborhood Association*, 794 F.3d 1136. As might be inferred, the parallels between *Chinatown* and the instant case are not particularly favorable to GenBioPro.

[20] This is not the first Court to conclude that a literal interpretation of *Schollenberger* would be anomalous and out-of-step with modern dormant Commerce Clause jurisprudence. *See Association des Eleveurs*, 729 F.3d at 949-50 (implicitly interpreting *Schollenberger* to apply only where a "nationally uniform business" and national system of regulation are implicated).

GenBioPro asserts derivative harms "to pregnant West Virginians by depriving them of essential medicine." Pl.'s Supp. Br. at 13. First, while this Court has granted Plaintiff third-party standing to pursue the interests of its vendees, it has not granted GenBioPro third-party standing as to "pregnant West Virginians." Nor has Plaintiff petitioned the Court to consider these interests prior to this Supplemental Brief. The Court does not doubt, however, that there are substantial derivative harms to pregnant West Virginians caused by a decrease in access to mifepristone.

Unfortunately, the Court cannot consider any such holistic derivative harms to pregnant West Virginians under *Pike* balancing. As fractured as *National Pork* is, the scant emphasis on "derivative harms" within the concurring opinion clarifies that—in the context of the dormant Commerce Clause—such harms are primarily economic in nature. *See* 143 S. Ct. at 1169 ("Our precedents have long distinguished the costs of complying with a given state regulation from *other economic harms to the interstate market*." (emphasis added)). The concurrence focused on harms to interstate commerce and interstate trade generally—such as difficulties in interstate shipping and employment—rather than harms to individuals within the challenged State. *Id*. (discussing *Bibb v. Navajo Freight Lines, Inc.*, 359 U.S. 520 (1959)). Again, in discussing application of *Pike*, the Chief Justice's concurrence emphasizes that these are derivative "harms to the interstate market" which are "in no sense noneconomic." *Id*. (internal quotation marks omitted). Accordingly, this Court concludes that derivative harms to pregnant West Virginians are not the type of harm it may consider when employing the *Pike* balancing test.

Plaintiff also argues that the UCPA and restrictions "upend the national market for drugs." Pl.'s Supp. Br. at 13. A state law which spawned chaos in the national prescription drug market would likely cause the type of derivative economic and interstate harm which could be

considered under the *Pike* balancing test. But the Court is not convinced that Plaintiff has plausibly pled facts to support any "upending" of the national market for mifepristone caused by West Virginia's legislation. Further, as alluded to above, many States restrict abortion in a manner which likely limits the sale of mifepristone. *See, e.g.*, Miss. Code Ann. § 97-3-3(1) (banning abortion with very limited exceptions). Plaintiff has not alleged that the national prescription drug market has been upended by the incidental restriction of mifepristone in many States.

d. *Pike* Threshold Showing

The Court appreciates the gravity of Plaintiff's claims and has taken pains to address them at length above—but even if Plaintiff were correct that national uniformity, functionally banning an article of commerce, and the various alleged derivative harms were sufficient to swing the *Pike* balance in GenBioPro's favor, the Court remains skeptical that Plaintiff could meet the threshold burden necessary to invoke *Pike*. Admittedly, it's unclear what exactly a party would need to do to meet the threshold to be considered under the *Pike* balancing test, as muddled by *National Pork*. Justice Sotomayor's concurrence in *National Pork* averred that the pork producers had failed to meet this threshold burden, without elaboration into the facts of the case. 143 S. Ct. at 1165. This confusion is another reason the Court has considered the *Pike* claims at length above.

Regardless of whether it met the threshold burden, the pork producer plaintiff in *National Pork* plausibly alleged significant disruption to the national pork industry. *See id*. at 1151-52. Due to the size of the California market, the national producers of pork alleged they would be compelled to alter their national production standards in order to continue to sell within California. *Id*. And yet, it appears a majority of the Justices found this insufficient to meet the threshold "burden on interstate commerce" required under *Pike*. Here, Plaintiff has undoubtedly

alleged less of a burden on interstate commerce than was alleged by the pork producers. None of West Virginia's laws require Plaintiff to alter its national production methods in order to access the State's market. Nor will compliance with the UCPA and other restrictions entail broad re-working of the entire pharmaceutical industry. At most, Plaintiff has plausibly alleged that one prescription medication will be prescribed less for one indicated purpose within one State.

Another comparison: in *Association for Accessible Medicine v. Frosh*, the Fourth Circuit found that a Maryland statute regulating pharmaceutical price-gouging burdened interstate commerce in prescription drugs in violation of the dormant Commerce Clause. 887 F.3d at 673. There, the Court of Appeals found that the challenged statute "set[] prescription drug prices in a way that 'interfere[s] with the natural function of the interstate market' by superseding market forces that dictate the price of a good." *Id*. (quoting *McBurney v. Young*, 569 U.S. 221, 235 (2013)). Accordingly, if many States adopted laws analogous to the Maryland act, there was the potential to create "the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude." *Id*. at 674 (quoting *Healy*, 491 U.S. at 337). There is no such potential here. The UCPA can hardly be characterized as an economic regulation, and even if every State adopted a differing regulation on when abortion is permissible—and, to be frank, *this has already happened*—it would not entail competition on mifepristone pricing between the States.

States enact laws pursuant to their police power to regulate public health and morality. Morality-based laws often curtail the sale of goods. The vendors of curtailed goods may lose sales opportunities. Outraged, vendors can feel the laws must somehow be unconstitutional. And yet, the Supreme Court and Courts of Appeals have repeatedly affirmed that morality-based

product bans do not intrinsically offend the dormant Commerce Clause. Accordingly, Defendants' Motions to Dismiss Count II are **GRANTED**.

IV. CONCLUSION

Defendant Mark A. Sorsaia and Defendant Patrick Morrisey's Motions to Dismiss (ECF Nos. 17 & 19) are **GRANTED,** in part, and **DENIED** in part.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented parties.

ENTER: August 24, 2023

ROBERT C. CHAMBERS
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA HUNTINGTON DIVISION

GENBIOPRO, INC., Plaintiff, v. KRIS RAYNES, in her official capacity as Prosecuting Attorney of Putnam County, and PATRICK MORRISEY, in his official capacity as Attorney General of West Virginia, Defendants.	Civil Action No. 3:23-cv-00058 Hon. Robert C. Chambers

PLAINTIFF GENBIOPRO, INC.'S NOTICE OF SUBSTITUTION

GenBioPro, Inc. gives notice that Mark A. Sorsaia resigned as Prosecuting Attorney of Putnam County effective August 1, 2023 and, that by appointment of the Putnam County Commission, effective August 31, 2023, Kris Raynes is now serving as Prosecuting Attorney of Putnam County. Pursuant to Rule 25(d) of the Federal Rules of Civil Procedure, Ms. Raynes is automatically substituted as a party defendant and all further proceedings should be in her name.

Dated: September 11, 2023

Respectfully submitted,

GENBIOPRO, INC.
By Counsel

s/ Anthony J. Majestro
Anthony J. Majestro (WVSB 5165)
Christina L. Smith (WVSB 7509)
POWELL & MAJESTRO PLLC
405 Capitol Street, Suite P1200
Charleston, WV 25301
Ph: 304-346-2889
amajestro@powellmajestro.com
csmith@powellmajestro.com

David C. Frederick (pro hac vice)
Ariela M. Migdal (pro hac vice)
Eliana Margo Pfeffer (pro hac vice)
Mary Charlotte Y. Carroll (pro hac vice)
KELLOGG, HANSEN, TODD, FIGEL & FREDERICK, P.L.L.C.
1615 M Street, NW, Suite 400
Washington, D.C. 20036
Ph: 202-326-7900
dfrederick@kellogghansen.com
amigdal@kellogghansen.com
epfeffer@kellogghansen.com
mcarroll@kellogghansen.com

John P. Elwood (pro hac vice)
Daphne O'Connor (pro hac vice)
Robert J. Katerberg (pro hac vice)
ARNOLD & PORTER KAY SCHOLER LLP
601 Massachusetts Avenue, NW
Washington, D.C. 20001
john.elwood@arnoldporter.com
daphne.oconnor@arnoldporter.com
robert.katerberg@arnoldporter.com

Skye L. Perryman (pro hac vice)
Kristen Miller (pro hac vice)
DEMOCRACY FORWARD FOUNDATION
PO Box 34553
Washington, D.C. 20043
Ph: 202-448-9090
sperryman@democracyforward.org
kmiller@democracyforward.org

CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of September, 2023, I electronically filed the foregoing **"PLAINTIFF GENBIOPRO, INC.'S NOTICE OF SUBSTITUTION"** with the Clerk of the Court and served all parties using the CM/ECF system.

s/ Anthony J. Majestro
Anthony J. Majestro (WVSB 5165)

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

***Plaintiff*,**

v.

KRISTINA RAYNES, *in her official capacity as Prosecuting Attorney of Putnam County*, AND PATRICK MORRISEY, *in his official capacity as Attorney General of West Virginia*,

Defendants.

Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)

MOTION TO AMEND COMPLAINT
AND JOINT STIPULATION

Plaintiff GenBioPro, Inc., moves for leave to amend its complaint, Dkt. No. 1, under Federal Rule of Civil Procedure 15(a)(2) by filing Plaintiff's First Amended Complaint, attached as Exhibit A. Plaintiff's purpose in amending its complaint is to bring proceedings in this Court to a close and to facilitate an appeal of the remaining issues in this litigation.

Plaintiff GenBioPro, Inc., and Defendants Kristina Raynes, in her official capacity as Prosecuting Attorney for Putnam County, and Patrick Morrisey, in his official capacity as Attorney General of the State of West Virginia, stipulate and consent to the filing of Plaintiff's First Amended Complaint under Federal Rule of Civil Procedure 15(a)(2). The Amended Complaint, attached as Exhibit A, no longer brings a federal preemption challenge to West Virginia's laws prohibiting providers from prescribing mifepristone via telemedicine, W. Va. Code §§ 30-1-26(b)(9), 30-3-13a(g)(5). Other than this change, the Amended Complaint is substantively identical to the Original Complaint Plaintiff filed on January 25, 2023, Dkt. No. 1. A redline comparison showing differences between the Original Complaint and Amended Complaint is

attached for the Court's convenience as Exhibit B.

Plaintiff has met and conferred with Defendants, and all parties consent to this motion. Defendants agree to waive notice and service of the Amended Complaint.

The parties jointly stipulate and agree that Plaintiff will no longer challenge West Virginia Code sections 30-1-26(b)(9) and 30-3-13a(g)(5) — the statutes governing prescribing mifepristone by telemedicine — as federally preempted. Plaintiff dismisses its preemption challenge to sections 30-1-26(b)(9) and 30-3-13a(g)(5) with prejudice.

As to the remaining claims, the parties stipulate that the Amended Complaint presents no new bases for relief. The parties stipulate that the Court's memorandum opinions and orders on the motions to dismiss, Dkt. Nos. 54, 66, apply to the claims in the Amended Complaint. The parties preserve all objections and their rights to appeal.

WHEREFORE, the parties jointly stipulate that:

1. Plaintiff's First Amended Complaint shall be the operative complaint in this case;
2. Plaintiff dismisses with prejudice its federal preemption challenge to West Virginia Code sections 30-1-26(b)(9) and 30-3-13a(g)(5); and
3. Because the Amended Complaint presents no new bases for relief, the Court's memorandum opinions and orders on the motions to dismiss, Dkt. Nos. 54, 66, apply to the Amended Complaint.

Dated: October 18, 2023

Respectfully submitted,

PATRICK MORRISEY
West Virginia Attorney General

/s/ Curtis R. A. Capehart (by permission)
Douglas P. Buffington, II (WV Bar # 8157)
Chief Deputy Attorney General
Curtis R. A. Capehart (WV Bar # 9876)
Deputy Attorney General
OFFICE OF THE ATTORNEY GENERAL
State Capitol Complex
1900 Kanawha Boulevard E.
Building 1, Room E-26
Charleston, WV 25305-0220
Tel.: (304) 558-2021
Fax: (304) 558-0140
curtis.r.a.capehart@wvago.gov

Counsel for Defendant Patrick Morrisey, in his official capacity as Attorney General of the State of West Virginia

KRISTINA RAYNES
Putnam County Prosecuting Attorney

/s/ Jennifer Scragg Karr (by permission)
Jennifer Scragg Karr (WV Bar # 8051)
Assistant Prosecuting Attorney
OFFICE OF THE PROSECUTING ATTORNEY
Putnam County Judicial Building
12093 Winfield Rd.
Winfield, WV 25213
Tel.: (304) 586-0205
Fax: (304) 586-0269
jkarr@putnamwv.org

Counsel for Defendant, Kristina Raynes, in her official capacity as Prosecuting Attorney for Putnam County

GENBIOPRO, INC.

/s/ Anthony J. Majestro
Anthony J. Majestro (WV Bar # 5165)
Christina L. Smith (WV Bar # 7509)

POWELL & MAJESTRO P.L.L.C.
405 Capitol Street, Suite 807
Charleston, WV 25301
Tel.: (304) 346-2889
amajestro@powellmajestro.com
csmith@powellmajestro.com

Counsel for Plaintiff, GenBioPro, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

***Plaintiff*,**

v.

KRISTINA RAYNES, *in her official capacity as Prosecuting Attorney of Putnam County*, AND PATRICK MORRISEY, *in his official capacity as Attorney General of West Virginia*,

Defendants.

Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)

CERTIFICATE OF SERVICE

I hereby certify that, on this 18th day of October, 2023, I electronically filed the foregoing stipulation with the Clerk of Court and all parties using the CM/ECF System.

/s/ Anthony J. Majestro
Anthony J. Majestro

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

Plaintiff,

v.

KRISTINA RAYNES, ***in her official capacity as Prosecuting Attorney of Putnam County,*** **AND PATRICK MORRISEY,** ***in his official capacity as Attorney General of West Virginia,***

Defendants.

Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)

ORDER REGARDING MOTION TO AMEND COMPLAINT AND JOINT STIPULATION

The Court hereby **GRANTS** the Motion to Amend Complaint and Joint Stipulation filed by the parties on October 18, 2023, Dkt. No. 73, and deems Plaintiff's First Amended Complaint to be the operative complaint in this case.

The Clerk is directed to send copies of this Order to those counsel of record who have registered to receive an electronic NEF.

IT IS SO ORDERED this 19th day of October, 2023.

Robert C. Chambers
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

***Plaintiff*,**

v.

KRISTINA RAYNES, *in her official capacity as Prosecuting Attorney of Putnam County*, AND PATRICK MORRISEY, *in his official capacity as Attorney General of West Virginia*,

Defendants.

Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)

FIRST AMENDED COMPLAINT

INTRODUCTION

1. This case is about a federally approved medication that Congress subjected to a substantial and detailed federal regulatory program with which West Virginia law interferes. That state law must give way to the comprehensive federal regime Congress enacted and the Food and Drug Administration ("FDA") implemented.

2. Plaintiff GenBioPro, Inc. ("GenBioPro") is a private company that spent almost a decade developing a generic version of the drug mifepristone to give patients a safe, effective, non-invasive medication option for terminating a pregnancy. Mifepristone is the first drug in a two-drug regimen FDA approved that facilitates a medication abortion: (1) mifepristone interrupts early pregnancy by blocking the effect of progesterone, a hormone necessary to maintain a pregnancy, and (2) misoprostol causes uterine contractions, leading to the contents of the uterus being expelled.

3. Since 2019, when it received approval from FDA to sell generic mifepristone, GenBioPro has marketed and sold approximately 850,000 units of generic mifepristone

throughout the United States. Between 2017 and 2020 (a year after GenBioPro began marketing its product), the number of medication abortions in the United States increased by 45 percent, even as the number of abortions overall has declined significantly since the 1990s.[1] Medication abortion now accounts for the majority of pregnancy terminations in the United States, despite the fact that people can use medication only to terminate early pregnancies.[2]

4. Medical termination of pregnancy offers patients significant advantages. Patients can take the medication at home, at a time of their choosing, and in complete privacy. Medication abortions do not require administration of anesthesia; many patients use over-the-counter analgesics like Advil to relieve the period-like cramps patients typically experience.[3] Medical termination often costs less than a surgical termination, too.[4]

5. FDA approved branded mifepristone ("Mifeprex") for sale in 2000 and, in doing so, imposed specific restrictions it determined were necessary to assure the drug's safe use. For example, in that early period FDA required that mifepristone be prescribed by a qualified physician, and be dispensed to patients by their physician, rather than at a pharmacy. Mifepristone joined the ranks of just fifteen other drugs that FDA had determined to warrant special restrictions.

---

[1] Rachel K. Jones, Marielle Kirstein & Jesse Philbin, *Abortion Incidence and Service Availability in the United States, 2020*, 54 Persps. on Sexual & Reprod. Health 128, 136 (Dec. 2022).

[2] *Id.*

[3] Univ. of Cal. S.F. Health ("UCSF"), *Aspiration Versus Medication Abortion*, https://www.ucsfhealth.org/education/aspiration-versus-medication-abortion (last visited Jan. 22, 2023); Am. College of Obstetricians & Gynecologists, *Medication Abortion Up to 70 Days of Gestation*, 136 Obstetrics & Gynecology e31, e37 (Oct. 2020, reaffirmed 2023), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation.

[4] Allison McCann, *What It Costs to Get an Abortion Now*, N.Y. Times (Sept. 28, 2022), https://www.nytimes.com/interactive/2022/09/28/us/abortion-costs-funds.html.

6. In 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. No. 110-85, 121 Stat. 823, codifying many of FDA's risk management regulations into law, and authorizing FDA to design and implement risk evaluation and mitigation strategies for drugs moving forward.

7. As part of the FDAAA, Congress specified that the 16 drugs FDA had already approved with "elements to assure safe use" — including mifepristone — would immediately be "deemed to have in effect an approved risk evaluation and mitigation strategy."[5] *Id.* § 909(b)(1), 121 Stat. 950-51, *reprinted at* 21 U.S.C. § 331 note. In other words, Congress approved of how FDA regulated medications that previously had been approved with "elements to assure safe use."

8. The FDAAA requires FDA to ensure that any elements to assure safe use of drugs subject to a risk evaluation and mitigation strategy "[p]rovid[e] safe access for patients" while "assur[ing the drug's] safe use." *Id.* § 505-1(f), 121 Stat. 926, 930 (codified at 21 U.S.C. § 355-1(f)). Restrictions may "not be unduly burdensome on patient access to the drug" and must "minimize the burden on the health care delivery system." *Id.* § 505-1(f)(2)(C)-(D), 121 Stat. 930 (codified at 21 U.S.C. § 355-1(f)(2)(C)-(D)).

9. Since Congress "deemed" mifepristone to have a risk evaluation and mitigation strategy in effect in 2007, FDA has regulated mifepristone under the FDAAA's special congressional mandate. As required by statute, FDA regularly reevaluates whether mifepristone should remain subject to this strategy and updates the restrictions on the drug in light of its

[5] FDA identified those 16 drugs by name in a list published in the Federal Register. Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007, 73 Fed. Reg. 16313 (Mar. 27, 2008).

assessment of evolving scientific evidence. Most recently, on January 3, 2023, FDA updated the REMS elements on mifepristone to enable patients to receive it through certified pharmacies.

10. Despite that federal statutory and regulatory regime, which carefully balances patient access and safety, West Virginia officials banned mifepristone.

11. In September 2022, in the wake of the Supreme Court's holding in *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), West Virginia's Legislature enacted the Unborn Child Protection Act (the "Criminal Abortion Ban" or the "Ban"). This law prohibits abortion in almost all cases, at any stage of pregnancy. W. Va. Code § 16-2R-1 *et seq*.; *id.* § 61-2-8. The Criminal Abortion Ban severely constricted the market for mifepristone statewide.

12. Even before the Ban took effect, West Virginia law restricted the provision of mifepristone. *See id.* §§ 16-2I-2 (requiring a waiting period and counseling before an abortion procedure); 30-3-13a(g)(5) (prohibiting providers from prescribing mifepristone via telemedicine); *see also id.* § 30-1-26(b)(9) (providing for a rule banning prescribing mifepristone via telemedicine) (collectively "Restrictions").

13. The Ban declares that some of these Restrictions (such as the waiting period and counseling requirement) have "no effect" while the Ban is in force. But if a court rules the Ban statute is unconstitutional, the limitations on abortion the Ban paused will again "become immediately effective." *Id.* § 16-2R-9 (articles 2F, 2I, 2M, 2O, 2P, and 2Q of chapter 16 and article 42 of chapter 33).[6] Once back in effect, these Restrictions will obstruct West Virginia

[6] Article 2F contains provisions requiring parental notification before a minor undergoes an abortion procedure. W. Va. Code § 16-2F-1 *et seq.* Article 2I contains counseling and waiting period requirements patients must fulfill before obtaining an abortion. *Id.* § 16-2I-1 *et seq.* Article 2M prohibited providers from performing abortions after 20 weeks of gestation. *Id.*

residents' access to mifepristone and stifle GenBioPro's ability to conduct business in West Virginia.

14. Other restrictions, such as West Virginia's prohibitions on providers using telemedicine to prescribe mifepristone, are in force. *Id.* § 30-3-13a(g)(5); *see id.* § 30-1-26(b)(9).

15. Federal law preempts West Virginia's Ban and waiting period and counseling requirements. These laws impermissibly restrict patients' access to mifepristone and GenBioPro's opportunity and ability to market, promote, and sell the medication in the State. In "deem[ing]" mifepristone to be one of the few drugs subject to heightened FDA regulation, Congress authorized FDA, and only FDA, to impose restrictions on access to mifepristone. Before FDA may impose any restrictions, Congress requires the agency to determine that they are necessary for patient safety and will not unduly burden patient access. The Ban and waiting period and counseling requirements frustrate and conflict with that congressional mandate. West Virginia cannot override FDA's determinations about the appropriate restrictions on a medication that FDA approved for use and Congress subjected to this enhanced regulatory regime.

16. West Virginia's Ban and Restrictions also burden the healthcare delivery system in violation of the Supremacy Clause of the U.S. Constitution. U.S. Const. art. VI, cl. 2. The Ban and Restrictions make it impossible for providers to prescribe and dispense — and in turn,

---

§ 16-2M-1 *et seq.* Article 2O prohibited abortions using the dilation and evacuation method. *Id.* § 16-2O-1. Article 2P contains steps providers had to follow if an attempted abortion procedure resulted in a live birth. *Id.* § 16-2P-1. Article 2Q banned abortions sought because of fetal disability. *Id.* § 16-2Q-1. Article 42 of chapter 33 prohibited "partial-birth" abortions, defined as "abortion[s] in which the person performing the abortion partially vaginally delivers a living fetus before killing the fetus and completing the delivery." *Id.* § 33-42-3(3); *see id.* § 33-42-1 *et seq.*

make it nearly impossible for GenBioPro to market, promote, and sell — mifepristone for its indicated use.

17. West Virginia's Ban and Restrictions also violate the Commerce Clause of the U.S. Constitution. U.S. Const. art. I, § 8, cl. 3. Congress determined that mifepristone, a drug subject to a REMS, should be subject to FDA's determinations that balance risks against access. Individual state regulation of mifepristone destroys the national common market and conflicts with the strong national interest in ensuring access to a federally approved medication to end a pregnancy, resulting in the kind of economic fracturing the Framers intended the Clause to preclude. A State's police power does not extend to functionally banning an article of interstate commerce — the Constitution leaves that to Congress.

18. This Court should declare West Virginia's Ban and Restrictions invalid and enjoin their enforcement because they adversely affect the sale and use of mifepristone within the State.

JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1343(a)(3) because GenBioPro's claims present federal questions that arise under the laws of the United States, including the Supremacy and Commerce Clauses of the U.S. Constitution, Article VI, Clause 2 and Article I, Section 8, Clause 3, 21 U.S.C. § 355-1, and 42 U.S.C. § 1983.

20. This Court has authority to grant declaratory and injunctive relief under 42 U.S.C. § 1983 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

21. This Court has jurisdiction and equitable power to enjoin actions by state officials that are preempted by federal law. *See Ex parte Young*, 209 U.S. 123, 150-51 (1908).

22. Venue is proper in this district under 28 U.S.C. § 1391(b) because all Defendants maintain an office and conduct official duties in this judicial district and because a substantial part of the events giving rise to the claims at issue occurred in this district.

PARTIES

23. Plaintiff GenBioPro, Inc. is a Nevada corporation headquartered at 651 Lindell Road, Suite D1041 (P.O. Box 32011), Las Vegas, Nevada 89103. GenBioPro holds an approved abbreviated new drug application for generic mifepristone, No. 091178, and sells the drug nationwide. GenBioPro sells only generic mifepristone and misoprostol. Both drugs are used in medication abortions, and their sales are the company's sole source of revenue.

24. Defendant Kristina Raynes is the Prosecuting Attorney for Putnam County, West Virginia, and maintains an office at 12093 Winfield Road, Winfield, West Virginia 25213. Defendant Raynes has authority to prosecute violations of the Criminal Abortion Ban and other criminal restrictions on abortion in Putnam County. *See* W. Va. Code § 7-4-1(a). In 2022, the Prosecuting Attorney for Putnam County was quoted as stating publicly that "[a]s prosecutors we have a clear obligation to enforce the laws of our state. I believe if abortion is illegal then no responsible medical provider will be doing them."[7] This Complaint is brought against Defendant Raynes in her official capacity.

25. Defendant Patrick Morrisey is the Attorney General and chief legal officer of West Virginia and maintains an office at 1900 Kanawha Boulevard E., Charleston, West Virginia 25305. As Attorney General and chief legal officer, Defendant Morrisey has responsibility for enforcing the laws of West Virginia. Attorney General Morrisey recently signed a public letter

[7] Rachel Pellegrino, *West Virginia Lawmakers to Provide Clarity on* Roe v. Wade, WOWK (July 1, 2022), https://www.wowktv.com/news/local/west-virginia-lawmakers-to-provide-clarity-on-roe-v-wade.

calling FDA's determinations with respect to mifepristone "illegal and dangerous" and evincing his intent to stand by state law imposing restrictions on mifepristone notwithstanding FDA's determinations pursuant to its congressional mandate.[8] The Attorney General has the authority to enforce restrictions on abortion at the request of the Governor. *See* W. Va. Code § 5-3-1. This Complaint is brought against Defendant Morrisey in his official capacity.

26. This Court has equitable authority to enjoin these Defendants from enforcing unconstitutional state laws. *See Ex parte Young*, 209 U.S. at 150-51.

FACTUAL ALLEGATIONS

A. Congress Authorized FDA To Approve Drugs Like Mifepristone For Distribution And Sale In The United States

27. Congress first authorized FDA to regulate food and drugs more than a century ago in the Pure Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938).

28. In 1938, Congress created the modern framework for FDA's regulation of prescription drugs in the Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. § 301 *et seq.*). The FDCA authorized the agency to develop a comprehensive regulatory scheme governing medications sold in the United States and to promote the public health by reviewing clinical research promptly and taking appropriate action on applications for marketing those drugs. 21 U.S.C. § 393(b)(1). The FDCA prohibited a drug manufacturer from distributing a drug until it submitted a new drug application to FDA for review, and authorized FDA to reject an application if it determined the drug was unsafe. FDCA § 505(a), (d)-(e), 52 Stat. 1040, 1052 (codified at 21 U.S.C. § 355).

[8] *See* Letter from Att'ys Gen., to Robert Califf, Comm'r, U.S. Food & Drug Admin. (Jan. 13, 2023) ("Letter from Att'ys Gen."), https://www.alabamaag.gov/Documents/news/Letter_from_Ala_Atty_Gen_Steve_Marshall_et_al_to_FDA.pdf.

29. In 1951, Congress amended the FDCA to define a new category of drugs — drugs that must be prescribed by a healthcare provider (as opposed to drugs that patients could obtain over the counter). Act of Oct. 26, 1951, Pub. L. No. 82-215, 65 Stat. 648. These "prescription" drugs included medications that required medical supervision to ensure their safe use. *Id.*

30. In 1962, Congress amended the FDCA to further strengthen FDA's mandate "[t]o protect the public health" and "assure the safety, effectiveness, and reliability of drugs." Drug Amendments of 1962, Pub. L. No. 87-781, pmbl., 76 Stat. 780, 780. Before 1962, Congress required FDA to demonstrate that a drug was harmful to deny an application and keep the drug from entering interstate commerce; after the amendment, Congress required *manufacturers* to prove to FDA that their products were safe and effective. Once FDA approved a manufacturer's application, it authorized that manufacturer to sell and distribute its product nationwide.

31. The 1962 amendments included a provision stating: "Nothing in the amendments made by this Act . . . shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." *Id.* § 202, 76 Stat. 780, 793. When there is such a conflict, state law must yield.

32. In the half century since then, Congress has enacted additional statutes and amendments enhancing FDA's mandate to ensure safe and effective drugs are available to patients in the United States. *E.g.*, Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, §§ 101(j)(1), 202(e)(1), 98 Stat. 1585, 1603 (Sept. 24, 1984) (codified at 21 U.S.C. §§ 271(e)(1), 355(j)(1)) (establishing an expedited approval process for generic drugs along with incentives for generic manufacturers to make generic drugs available on the

market quickly)[9]; 21 U.S.C. § 393(b)(1), (2) (enacted in 1997) (requiring FDA to "promptly and efficiently review[ ] clinical research and tak[e] appropriate action on the marketing of regulated products in a timely manner"); *id.* § 360bbb(b), (c) (enacted in 1997) (authorizing FDA to "[e]xpand[ ] access to unapproved therapies and diagnostics," by allowing access to "investigational drug[s]" under certain circumstances); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-15, § 101(1), 111 Stat. 2296, 2298 (Nov. 21, 1997), *reprinted at* 21 U.S.C. § 379g note (stating that "prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease"); 21 U.S.C. § 356c(g) (enacted in 2012) (requiring FDA to mitigate and prevent shortages of certain drugs), *id.* § 356c-1 (enacted in 2012) (requiring FDA to report annually to Congress its actions to prevent or mitigate drug shortages).

33. The FDCA also requires manufacturers to label drugs with adequate instructions for their safe use, prescribing information, and the treatment for which that drug is approved (the "indication"). 21 U.S.C. §§ 352(f), 355(a); *see also* 21 C.F.R. § 201.57(c).

1. For The Past Forty Years, FDA Has Developed And Implemented Strategies For Ensuring The Safety Of Certain Drugs

34. While Congress charges FDA with assessing drug safety, FDA's determination that a drug is safe for use for an indication does not mean that the drug is completely risk free. All drugs, even over-the-counter drugs, carry some risk. Rather, FDA approves a drug if its benefits to patients outweigh those risks. Furthermore, FDA can impose special regulatory

[9] *See also Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (explaining that the purpose of the 1984 amendments was to "get generic drugs into the hands of patients at reasonable prices — fast" (citation omitted)).

programs to mitigate a drug's risks that facilitate regulatory approval of the drug and its availability to patients.

35. FDA began developing risk management programs to mitigate drug risks in the 1980s. One early example is FDA's risk management program for isotretinoin (then sold as "Accutane"), a drug that treats severe acne. After approving Accutane in 1982, FDA determined that, if taken by a pregnant person, Accutane could affect fetal development. To minimize the risk that a pregnant person might take Accutane, FDA created special package inserts and developed educational programs to warn providers and patients.

36. By the 1990s, FDA had promulgated regulations enabling it to approve drugs that treat "serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments" subject to certain "restrictions to assure safe use." *See* 21 C.F.R. §§ 314.500, 314.520. These regulations (known as "Subpart H") limited any restriction FDA could impose to those "commensurate with the specific safety concerns presented by the drug product." *Id.* § 314.520.

37. Under Subpart H, FDA implemented risk management programs with "elements to assure safe use" for only 16 drugs and biologics.[10] One of those drugs was mifepristone.

2. After Determining That It Was Safe And Effective, FDA Approved Branded Mifepristone Under Subpart H

38. French pharmaceutical company Roussel Uclaf developed mifepristone in 1980. Since its development, more than eighty countries have approved mifepristone's use in

[10] The 16 drugs and biologics included: abarelix, alosetron, ambrisentan, bosentan, clozapine, dofetilide, eculizumab, fentanyl PCA, fentanyl citrate, isotretinoin, lenalidomide, mifepristone, natalizumab, the smallpox vaccine, sodium oxybate, and thalidomide.

medication abortions.[11] The United States joined those ranks in 2000, when FDA approved a new drug application for Mifeprex — the brand name for mifepristone as distributed and marketed by Danco Laboratories, LLC ("Danco") — for the medical termination of intrauterine pregnancy through 49 days' gestation.

39. In approving Mifeprex for sale, FDA determined that it treats a serious or life-threatening condition (*i.e.*, unwanted or unintended pregnancies), and provides a "meaningful therapeutic benefit to some patients over surgical abortion."[12] According to FDA, "unwanted pregnancy, like a number of illnesses or conditions, can be serious for certain populations or under certain circumstances."[13] FDA recognized that, despite being associated with some risks, mifepristone conferred important therapeutic benefits and therefore approved Mifeprex subject to certain restrictions under Subpart H.

3. In The FDAAA, Congress Authorized FDA To Create Risk Evaluation And Mitigation Strategies And Imposed A Strategy On Mifepristone

40. In 2007, Congress enacted the FDAAA to require FDA to ensure patient access to medications for which there is a potential risk of a serious adverse drug experience. 21 U.S.C. § 355-1. The FDAAA functionally codified FDA's risk management regulations and instructed FDA to continue regulating access to particular drugs to ensure that they remain available, and that any restrictions do not unduly burden patient access or the healthcare delivery system.

---

[11] U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 4, 2023), https://perma.cc/AB7X-64A5.

[12] *Id.*

[13] *See* Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Amin., to Donna Harrison, Executive Dir., Am. Ass'n of Pro Life Obstetricians & Gynecologists, Gene Rudd, Sr. Vice Pres., Christian Med. & Dental Ass'ns, & Penny Young Nance, CEO & Pres., Concerned Women for Am. (Mar. 29, 2016) ("Woodcock Letter").

41. To do so, Congress authorized FDA to implement a program called a Risk Evaluation and Mitigation Strategy ("REMS"). A REMS represents a determination by FDA that when a drug is prescribed or administered in a particular manner, that drug's benefits outweigh the risk of a serious adverse drug experience. *See id.* § 355-1(a).

42. After amending the FDCA with the FDAAA, Congress directed that drugs FDA had previously approved with restrictions under Subpart H — including Mifeprex — would be "deemed to have in effect" an approved REMS. FDAAA § 909(b)(1), 121 Stat. 950-51. Congress thereby codified the restrictions FDA had imposed under Subpart H on this group of drugs, including Mifeprex. *See id.*

43. As part of the FDAAA, Congress required those 16 drugs' sponsors to submit new REMS to FDA for the agency's consideration. *Id.* The FDAAA authorized FDA to modify, or even remove, the REMS for those drugs. *E.g.*, 21 U.S.C. § 355-1(g)(4)(B), (h).

44. The FDAAA specifies how FDA must assess whether a REMS is appropriate. It requires FDA first to determine whether a REMS is necessary and evaluate "[t]he seriousness of any known or potential adverse events that may be related to the drug." *Id.* § 355-1(a). If FDA concludes the drug poses a risk of an "adverse drug experience" and determines a REMS is necessary to ensure that the drug's benefits outweigh its risks, FDA must design and implement a REMS. *Id.* An adverse drug experience includes "any adverse event associated with the use of a drug . . . whether or not" the adverse event is "considered drug related." *Id.* § 355-1(b)(1).

45. In imposing a REMS, FDA can require drug companies to include medication guides or inserts for patients, implement communications plans (which may include sending letters to healthcare providers), or dispense the drug in special packaging to ensure patients use the drug safely. *Id.* § 355-1(e).

46. The statute authorizes FDA to impose additional REMS elements "necessary to assure safe use of the drug" (also referred as "ETASU"). These elements may be imposed only if FDA determines the drug is "associated with a serious adverse drug experience" and requires a REMS to mitigate that "specific serious risk." *Id.* § 355-1(f)(1). A "serious risk" or "serious adverse drug experience" includes adverse drug experiences that could result in "inpatient hospitalization" or a "substantial disruption of the ability to conduct normal life functions." *Id.* § 355-1(b)(4), (5).

47. The elements FDA imposes must be "commensurate with the specific serious risk listed" on the drug's label. *Id.* § 355-1(f)(2)(A). For example, FDA may restrict dispensing of the drug to certain settings, like hospitals. *Id.* § 355-1(f)(1), (3).

48. If FDA determines that it can approve a drug only with a REMS that incorporates such additional elements to assure safe use, Congress directs FDA to ensure that these elements "[p]rovid[e] safe access for patients to [these] drugs." *Id.* § 355-1(f).

49. In a provision entitled, "Assuring access and minimizing burden," Congress mandates that these elements to assure safe use, considering the drug's risk, "not be unduly burdensome on patient access to the drug," taking into account three considerations: patients with serious or life-threatening conditions, patients with difficulty accessing healthcare (such as patients in "rural or medically underserved areas"), and patients with functional limitations. *Id.* § 355-1(f)(2)(A), (C)(i)-(iii). Congress requires any additional elements or restrictions to be compatible with the requirements for similar drugs and compatible with established drug distribution systems, "so as to minimize the burden on the health care delivery system." *Id.* § 355-1(f)(2)(D).

50. In creating a REMS, FDA must seek input from patients and healthcare providers in evaluating the restrictions to ensure they are not "unduly burdensome on patient access to the drug," *id.* § 355-1(f)(5), and minimize the "burden on the health care delivery system," *id.* § 355-1(f)(2)(D). In other words, Congress mandated that FDA balance two competing values: the safety of the drug and patient access to the drug.

51. Any person can petition FDA to amend a drug's REMS by submitting a citizen petition pursuant to 21 C.F.R. § 10.30.

52. Section 355-1 requires FDA to reassess a drug's REMS periodically. 21 U.S.C. § 355-1(d). After each reassessment, FDA may eliminate a REMS — or a component of a REMS — if it determines that the REMS elements are no longer necessary to ensure a medication's benefits outweigh its risks.

53. Congress provided that, although either a drug's manufacturer or FDA can propose a modification to a REMS, any such modification requires prior FDA approval. Without that approval, the existing REMS remains in effect. *Id.* § 355-1(g)(1), (h)(1), (h)(2)(A)-(B).

54. Of the more than 20,000 prescription drugs FDA has approved for marketing in the United States, the agency has subjected only 301 to a REMS.[14] FDA has subjected 97 of those drugs to additional elements to assure safe use.[15]

[14] U.S. Food & Drug Admin., *FDA Risk Evaluation and Mitigation Strategy (REMS) Public Dashboard* (Jan. 17, 2023), https://fis.fda.gov/sense/app/ca606d81-3f9b-4480-9e47-8a8649da6470/sheet/994e7e67-d815-4204-8758-095c2abe2eda/state/analysis.

[15] *Id.*

B. FDA Determined That Mifepristone Requires A REMS With Additional Elements To Assure Safe Use

1. The Early Mifeprex REMS

55. After Congress mandated that Mifeprex be "deemed to have in effect" an approved REMS in the FCAAA, in September 2008, Danco submitted a supplemental new drug application proposing a REMS for Mifeprex. FDA approved the proposed REMS in June 2011.

56. As approved, the 2011 REMS required that only certified physicians prescribe Mifeprex; specified that Mifeprex be dispensed only in certain healthcare settings such as clinics (known as the "in-person dispensing requirement") and taken in a provider's clinic; and required Danco to ensure that every doctor prescribing Mifeprex was specially certified.

57. In approving these REMS, FDA "determined that a REMS [wa]s necessary" for Mifeprex "to ensure the benefits of the drug outweigh[ed] the risks of serious complications by requiring prescribers to certify that they [were] qualified to prescribe" the drug, and could "assure patient access to appropriate medical facilities to manage any complications."[16]

58. In 2015, Danco submitted a supplemental new drug application to FDA to revise Mifeprex's label and REMS. FDA approved almost all of Danco's proposed modifications to the label and REMS, including: increasing the gestational age through which Mifeprex is indicated from 49 days to 70 days; reducing the number of patient visits to a clinic; and expanding those who could be certified to prescribe Mifeprex to include "healthcare providers," rather than just "physicians."

[16] Letter from Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., to Danco Labs., LLC 1 (June 8, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/020687s014ltr.pdf.

59. FDA determined that the remaining REMS requirements, such as the in-person dispensing requirement, "remain[ed] necessary to ensure that the drug's benefits outweigh its risks"[17] and to assure Mifeprex's safe use.[18]

2. FDA Approved GenBioPro's Generic Mifepristone

60. GenBioPro spent almost a decade bringing a generic version of mifepristone to market. On April 11, 2019, FDA approved GenBioPro's application to manufacture and market generic mifepristone within the United States. As required by section 355, GenBioPro's generic mifepristone and Danco's Mifeprex have substantively identical labels. *See* 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G).

61. FDA subjected GenBioPro's generic mifepristone to a REMS pursuant to 21 U.S.C. § 355-1(i). FDA determined that the branded and generic mifepristone should share a single REMS, to be called the "Mifepristone REMS Program."

3. FDA Halted Enforcement Of, And Reevaluated Part Of, The Mifepristone REMS

62. In April 2021, FDA announced it would stop enforcing the in-person dispensing requirement of the Mifepristone REMS Program. The agency determined that requiring a patient to visit a clinic during the COVID-19 public health emergency could pose serious risks to patients and healthcare personnel and that new clinical data demonstrated that the in-person dispensing requirement was not necessary to ensure mifepristone remained safe for patients.

---

[17] Letter from Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., to Danco Labs., LLC 2 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/020687Orig1s020ltr.pdf.

[18] *See* U.S. Gov't Accountability Off., GAO-18-292, Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts 12 (2018).

63. FDA continued its review of the Mifepristone REMS Program during the COVID-19 pandemic. In addition to analyzing newly published scientific literature, FDA evaluated safety information submitted to the agency during the COVID-19 public health emergency, reports of adverse events related to the drug, the first REMS assessment report for the Mifepristone REMS Program, and other information provided by the public. In December 2021, FDA announced its determination that certain elements of the Mifepristone REMS Program remained necessary to assure the drug's safe use, while other elements would need to be modified "to reduce burden on patient access and the health care delivery system and to ensure the benefits of [mifepristone] outweigh [its] risks."[19]

64. After completing that review, FDA instructed Danco and GenBioPro to modify the Mifepristone REMS Program by removing the requirement that mifepristone be dispensed only in certain healthcare settings and adding a requirement that pharmacies dispensing mifepristone be specially certified.

65. In December 2021, FDA responded to a Citizen's Petition from American Association of Pro Life Obstetricians and Gynecologists, the Christian Medical Association, and Concerned Women for America, rejecting their requests to impose additional burdens on access to mifepristone, including (1) limiting mifepristone's indication to 49 days' gestation; (2) requiring physicians, and not other providers, to prescribe mifepristone; (3) requiring patients to make three different office visits to their physicians as part of the REMS; and (4) requiring that mifepristone be dispensed only in certain healthcare settings.[20]

---

[19] U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Dec. 16, 2021), https://perma.cc/V7RX-ZUAX.

[20] *See* Woodcock Letter, *supra* note 13, at 5, 9, 13-15, 18-19, 25.

4. FDA Updated The Mifepristone REMS Program, Expanding Methods By Which Patients May Access Mifepristone

66. On January 3, 2023, FDA published a new, shared system REMS for mifepristone (the "2023 REMS") covering both Mifeprex and generic mifepristone.[21] Consistent with FDA's December 2021 statements, the 2023 REMS no longer limits mifepristone dispensing to certain healthcare settings; patients may receive mifepristone by mail or from a specially certified pharmacy.

67. The 2023 REMS requires patients to sign a Patient Agreement Form before receiving a prescription for mifepristone.[22] This form includes a section in which patients acknowledge having "decided to take "mifepristone and misoprostol to end [their] pregnancy" and agreeing to "follow [their] healthcare provider's advice about when to take each drug and what to do in an emergency."[23] The form requires patients to assert that they "understand" that they "will take mifepristone" and then "the misoprostol tablets 24 to 48 hours after" taking mifepristone.[24] FDA determined that these new REMS "continue to ensure the benefits of mifepristone for medical abortion outweigh the risks while minimizing the burden imposed by the REMS on healthcare providers and patients."[25]

---

[21] U.S. Food & Drug Admin., *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200mg* (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf.

[22] U.S. Food & Drug Admin., *Patient Agreement Form* (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf.

[23] *Id.*

[24] *Id.*

[25] *Id.*

C. West Virginia Law Restricts Patients' Access To Mifepristone And Regulates How The Healthcare Delivery System Provides Mifepristone

68. On September 13, 2022, the West Virginia governor signed the "Unborn Child Protection Act," banning abortion at all stages of pregnancy except in limited circumstances. *See* W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8. The law also declared that several provisions of the West Virginia Code related to abortion, including the counseling and waiting period requirements, would have "no force or effect unless any provision of the . . . Act is judicially determined to be unconstitutional." 2022 W. Va. H.B. 302. The legislature amended the Act's severability provision in March 2023, revising it to state that if a court invalidates the Act in its entirety, those restrictions are reactivated. W. Va. Code § 16-2I-9.

69. The Ban states that "[a]n abortion may not be performed or induced or be attempted to be performed or induced unless in the reasonable medical judgment of a licensed medical professional: (1) The embryo or fetus is nonviable; (2) The pregnancy is ectopic; or (3) A medical emergency exists." *Id.* § 16-2R-3(a).[26] As a result, West Virginians no longer have a meaningful choice about whether to carry a pregnancy to term or to terminate using medication abortion. *Id.* §§ 16-2R-3, 16-2R-7.

70. The Ban amends mifepristone's indication by changing the time for which mifepristone is indicated from a period spanning 70 days' gestation, to no time at all for most patients.

71. While the Ban does not punish patients who terminate their pregnancies, it subjects certain healthcare providers who perform abortions to loss of their professional license,

[26] The Ban also includes limited exceptions for a pregnancy that is within eight weeks' gestation (or, if a minor or incompetent or incapacitated adult, 14 weeks) and is the result of sexual assault or incest that the patient has reported to law enforcement. W. Va. Code § 16-2R-3(b), (c).

id. § 16-2R-7, and makes it a felony punishable by imprisonment for any other "person" to induce an abortion, *id.* § 61-2-8(a). The Ban imposes criminal penalties on some healthcare providers eligible to prescribe mifepristone under the 2023 REMS if they prescribe mifepristone to induce an abortion. *Id.* (defining "licensed medical professional" to exclude certain REMS-authorized providers); *see id.* § 16-2R-2.

72. In imposing the Ban, West Virginia officials eliminated access to mifepristone in the State in almost all circumstances. Even before the Ban, however, West Virginia regulated access to mifepristone in a manner restricting GenBioPro's ability to distribute its FDA-approved product to West Virginians who qualified for access to it in compliance with FDA requirements.

73. As part of these Restrictions, West Virginia:

(a) required providers to obtain "informed consent" from patients at least 24 hours before having a medication abortion, delaying care when, medically, it should be provided as soon as possible to ensure safety and effectiveness and avoid forcing patients out of the 70-day window in which mifepristone is indicated for use. *Id.* § 16-2I-2(a). The law enacting the Ban provides that this waiting-period requirement "is of no force or effect unless" a court rules any provision of the Ban (§ 16-2R-1 *et seq.*) unconstitutional. *Id.* § 16-2I-9.

(b) required providers to communicate specific information to patients that is not part of the Mifepristone REMS Program, including that: "[s]ome suggest that it may be possible to counteract the intended effects of a mifepristone chemical abortion by taking progesterone if the female changes her mind, before taking the second drug," *id.* § 16-2I-2(a)(4)(A); and "the

father, if his identity can be determined, is liable to assist in the support of her child," *id.* § 16-2I-2(b)(2). The law enacting the Ban provides that this counseling requirement "is of no force or effect unless" a court rules any provision of the Ban (§ 16-2R-1 *et seq.*) is unconstitutional. *Id.* § 16-2I-9.

(c) bans providers from using telemedicine to prescribe mifepristone, which means patients must visit a provider in person to obtain a prescription. *Id.* § 30-3-13a(g)(5) (stating that a "physician or health care provider may not prescribe any drug with the intent of causing an abortion" via telemedicine); *see id.* § 30-1-26(b)(9).

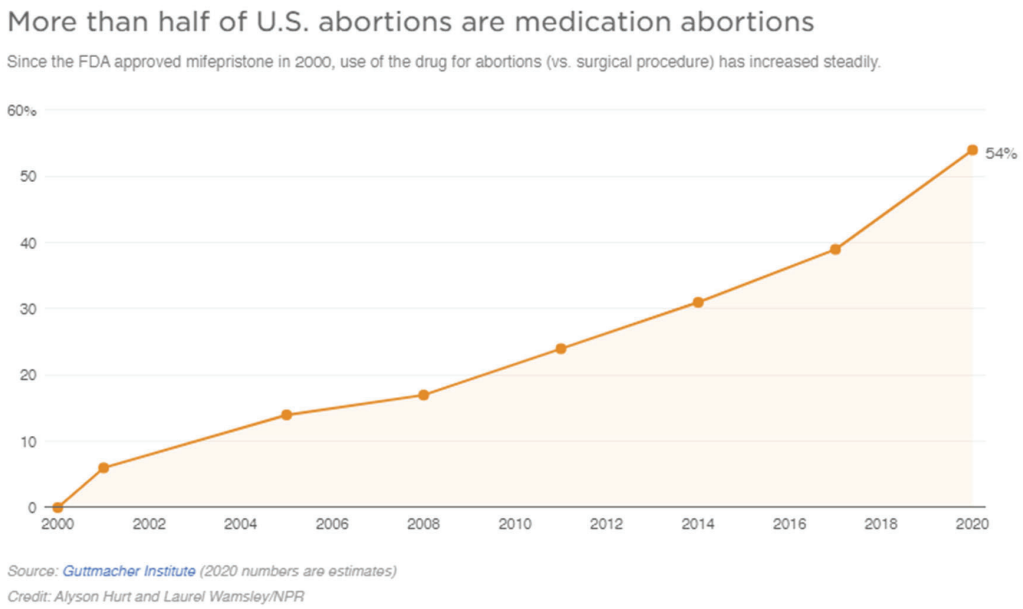
74. These Restrictions, which are in force or would become operative again if the Ban is judicially determined to be unconstitutional, constrict GenBioPro's ability to market its FDA-approved product to West Virginians who need it. The Ban makes such commercial opportunities virtually impossible.

75. On January 13, 2023, shortly after FDA issued the 2023 REMS, Defendant Morrisey, the Attorney General of West Virginia, joined a letter in which a number of state attorneys general proclaimed to FDA that they "will not yield" to FDA's federally based authority to approve drugs and to strike the optimal regulatory balance between risk mitigation and ensuring patient access because, in their view, the 2023 REMS fail "to protect women's health and safety." Defendant Morrisey and his co-signers wrote that "[t]o be crystal clear," FDA "ha[s] not negated any of our laws that forbid the remote prescription, administration, and use of abortion-inducing drugs" and "[n]othing in the FDA's recent changes affects" how they will enforce those laws.[27]

[27] Letter from Att'ys Gen., *supra* note 8, at 3.

D. West Virginia's Abortion Ban And Restrictions Harm GenBioPro And Prevent Patients From Accessing A Federally Approved Medication

76. More than eighty countries have approved mifepristone's use in medication abortions, and many patients in the United States use mifepristone.[28] In 2020, approximately 492,210 medication abortions occurred in the United States, up from approximately 339,650 just three years earlier.[29] The market for mifepristone is strong and sales have grown over time, even as the number of total U.S. abortions (including surgical) has declined.[30] Medication abortions account for more than half of U.S. abortions, despite the fact that FDA approves of mifepristone's use only up to 70 days' gestation.[31]



[28] U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 4, 2023), https://perma.cc/AB7X-64A5.

[29] Rachel K. Jones et al., *supra* note 1, at 135.

[30] *Id.*

[31] *Id.*; Laurel Wamsley, *How Medication Abortion Works and What the End of* Roe v. Wade *Could Mean for It*, NPR (May 13, 2022), https://www.npr.org/2022/05/13/1098000879/abortion-pills-medication-abortion-roe-v-wade.

77. Although Congress and FDA granted GenBioPro authority to sell mifepristone nationwide, West Virginia's severe abortion Restrictions and Criminal Abortion Ban make it impossible for GenBioPro to promote and market its product in West Virginia as it does in other states. The State has long had only a single clinic providing abortions.

78. Major national pharmacy chains, including Walgreens and CVS, which operate stores in Hurricane and Winfield, have indicated publicly that they intend to sell mifepristone now that the REMS permits them to do so.[32] Providing mifepristone through such pharmacies would enable GenBioPro to serve more patients with its product. West Virginia's Ban and Restrictions, however, block GenBioPro from providing mifepristone through these integral healthcare distribution mechanisms in West Virginia. HoneyBee Health, which ships prescription drugs nationwide, is also prevented by West Virginia's Ban and Restrictions from providing mifepristone to patients in West Virginia.[33]

79. West Virginia's Criminal Abortion Ban and Restrictions have caused significant, ongoing economic injury to GenBioPro in the form of lost sales, customers, and revenue. Defendants' enforcement of the Ban and Restrictions severely constricts GenBioPro's pool of potential customers — including healthcare providers that purchase from GenBioPro and certified pharmacies — and impermissibly constrains GenBioPro's ability to market its product in West Virginia.

---

[32] Spencer Kimball & Bertha Coombs, *CVS and Walgreens Plan to Sell Abortion Pill Mifepristone at Pharmacies After FDA Rule Change*, CNBC (Jan. 5, 2023), https://www.cnbc.com/2023/01/05/abortion-cvs-and-walgreens-will-sell-mifepristone-in-pharmacies.html.

[33] Celine Castronuovo, *Abortion Pill Access to Ease with First FDA-Certified Pharmacy*, Bloomberg News (Jan. 3, 2023), https://news.bloomberglaw.com/health-law-and-business/abortion-pill-access-to-ease-with-first-fda-certified-pharmacy.

80. GenBioPro further alleges that, based on the foregoing, healthcare providers in West Virginia would prescribe mifepristone to their patients and purchase that mifepristone from GenBioPro, and that pharmacies in West Virginia would dispense GenBioPro's mifepristone to their customers, but do not because of the Ban and the Restrictions.

E. West Virginia's Abortion Ban And Other Restrictions Conflict With Federal Law And Regulate Access To Mifepristone, A Function Congress Delegated Exclusively To FDA

81. West Virginia's Ban and abortion Restrictions frustrate and conflict with Congress's determination that FDA must exercise regulatory authority through REMS and elements to assure safe use under 21 U.S.C. § 355-1(f) that States are not free to second-guess or override. Developing such a REMS requires FDA to first determine that restrictions are necessary to ensure that the drug's benefits outweigh its risks, and then to impose restrictions that address the drug's risks while minimizing the burden on patients' access to the drug and on the healthcare delivery system. *See* 21 U.S.C. § 355-1(f)(2).

82. Section 355-1(f)(2) requires FDA to balance competing obligations, to maximize safety while minimizing burden, and to regulate patients' access to, and the healthcare delivery system's distribution of, mifepristone. The statute delegates to FDA exclusive authority to conduct that balancing, deploying its unique expertise in determining whether scientific evidence demonstrates that a serious adverse experience is associated with a drug, and how best to mitigate that risk while ensuring that its efforts do not unduly burden patient access to the drug. FDA's REMS therefore necessarily establishes both a "floor" and "ceiling" on permissible regulation of mifepristone. The elements FDA determined are necessary to ensure mifepristone's safety are the *only* restrictions that may be imposed on a patient's access to, and the healthcare delivery system's distribution of, mifepristone. Just as a state may not pass a law purporting to remove one of the REMS requirements (such as waiving the requirement of a

Patient Agreement Form), it also may not impose any other elements restricting access. Doing so would disturb the balancing that Congress required FDA to conduct in regulating access to mifepristone via the Mifepristone REMS Program.

83. West Virginia's Ban prevents almost all patients from accessing mifepristone, including those who otherwise would be eligible to receive the drug under the 2023 REMS. In so doing, it functionally displaces FDA's judgment in approving mifepristone and imposing a REMS. West Virginia's Ban also prevents the healthcare delivery system from distributing mifepristone to patients for whom providers would otherwise prescribe the drug. It burdens both the patient's access to mifepristone and the healthcare delivery system by imposing criminal and professional penalties on the prescription and distribution of mifepristone. *See* W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8.

84. The State's laws interfere with and seek to contradict Congress's directive to FDA to determine what elements will assure safe use of a REMS drug without being "unduly burdensome on patient access" and "minimiz[ing] the burden on the health care delivery system." 21 U.S.C. § 355-1(f)(2)(C), (D).

85. The Ban and Restrictions conflict with FDA's determinations pursuant to section 355-1(f)(2). The Ban and Restrictions make it impossible for GenBioPro to market and distribute mifepristone in West Virginia in accordance with FDA's requirements and determinations as to the balance Congress mandated between safety-based restrictions and patient access to the drug.

86. Even if the Ban is invalidated or repealed, the telemedicine ban will be in force and the counseling and waiting period requirements would again come into force. Each of these Restrictions conflicts with the 2023 REMS and regulates in an arena that Congress left to FDA.

87. West Virginia's waiting period and counseling requirements, W. Va. Code § 16-2I-2, require providers to obtain "informed consent" from patients at least 24 hours before prescribing mifepristone and require providers to communicate specific information to patients that is not part of the counseling required by the Mifepristone REMS Program. The prescriber agreement in the REMS requires only that a physician review the Patient Agreement Form, "fully explain[]" the "risks of the mifepristone treatment regimen," answer any "questions the patient may have," and ensure the patient receives and signs the Patient Agreement Form.[34]

88. West Virginia's telemedicine restrictions, *id.* § 30-3-13a(g)(5); *see id.* § 30-1-26(b)(9), purport to bar healthcare providers from prescribing any abortion drug via telemedicine. The Mifepristone REMS Program does not prohibit providers from using telemedicine to prescribe mifepristone. In 2019, several advocacy groups asked FDA to add a requirement to the REMS that a provider prescribe mifepristone in person, rather than by telemedicine or over the Internet. FDA specifically considered and rejected the proposed requirement as unnecessary to ensure mifepristone's safety. West Virginia's Restriction conflicts with this FDA determination.

89. West Virginia's Ban and Restrictions conflict with mifepristone's label and indication. FDA determined that mifepristone is indicated for use up to 70 days' gestation, but West Virginia law conflicts with that determination by banning use of mifepristone by nearly all patients at any stage of pregnancy and limiting mifepristone to emergency use.

90. By enacting the FDCA and its amendments, Congress authorized FDA to approve drugs in the United States and determine whether a manufacturer can sell its product in interstate

[34] U.S. Food & Drug Admin., *Patient Agreement Form* (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf.

commerce. *See*, *e.g.*, Act of Oct. 10, 1962, Pub. L. No. 87-781, § 104, 76 Stat. 780, 784; 21 U.S.C. § 393(b)(1). A state ban like West Virginia's constitutes a determination on the part of state legislators that a manufacturer *cannot* sell its product in the State, creating a direct conflict with federal law. *See* Act of Oct. 10, 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781.

91. A favorable decision from this Court declaring the Ban and waiting period and counseling restrictions invalid as applied to the sale and distribution of mifepristone and enjoining their enforcement by state officials due to their constitutional infirmities will remedy these conflicts and redress GenBioPro's economic injury by enabling West Virginians to access its product.

92. Settled preemption and Commerce Clause principles govern states' efforts to restrict access to an FDA-approved medication. The Supreme Court's decision in *Dobbs* did not displace Congress's and FDA's roles in protecting the public health by deciding whether drugs are safe and effective, determining which precautions — if any — are necessary to ensure a drug's safe use, and ensuring safe and effective drugs are available to the public. *Dobbs* addressed only the underlying personal constitutional privacy right as it pertains to abortion; it did not speak to federal law regulating a drug maker's sale and distribution of, or a patient's access to, medication that is FDA-approved for distribution nationwide.

CLAIMS FOR RELIEF

COUNT I

Declaratory and Injunctive Relief — 42 U.S.C. § 1983 — Federal Law Preempts West Virginia's Ban and Waiting Period and Counseling Requirements

93. GenBioPro re-alleges and incorporates by reference each of the preceding paragraphs.

94. The U.S. Constitution's Supremacy Clause makes federal laws enacted under the authority of the United States the "supreme Law of the Land." U.S. Const. art. VI, cl. 2. Under the Clause, federal law preempts any state regulation to the contrary. *See Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992).

95. West Virginia's Ban, W. Va. Code §§ 16-2R-1 *et seq.*, 61-2-8, and waiting period and counseling requirements, *id.* §§ 16-2I-2, 16-2I-9, are preempted by the FDCA as amended, 21 U.S.C. § 355-1. States may not restrict access to FDA-approved drugs in ways that countermand the agency's specific safety considerations or restrictions.

96. West Virginia's Ban and waiting period and counseling requirements conflict with that mandate, including by imposing the burden of criminal penalties on REMS-eligible providers' prescription of mifepristone. The Ban and waiting period and counseling requirements frustrate FDA's determinations about how mifepristone should be regulated and invade an area Congress determined only FDA may occupy. *See*, *e.g.*, *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 479-80 (2013); *Arizona v. United States*, 567 U.S. 387, 403 (2012); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000). The Ban and waiting period and counseling requirements further stand as an obstacle to FDA's determination that GenBioPro's mifepristone is safe and effective, and GenBioPro may distribute it to patients pursuant to the REMS.

97. Federal law therefore preempts Article 2R, Chapter 16 of the West Virginia Code and Section 61-2-8, insofar as these statutes ban patients from using mifepristone in almost all instances.

98. Federal law preempts West Virginia Code §§ 16-2I-2, 16-2I-9 insofar as it requires patients seeking mifepristone to fulfill waiting period and counseling requirements.

99. Section 1983 of Title 42 of the United States Code provides that "Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State . . . , subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress . . . ."

100. West Virginia's Ban and waiting period and counseling requirements conflict with the rights, privileges, or immunities secured by FDA approval of mifepristone under Title 21 of the United States Code and the REMS to market and distribute its FDA-approved product in West Virginia subject only to those regulations and restrictions FDA imposed pursuant to its mandate under the FDCA as amended, 21 U.S.C. § 355-1.

COUNT II

Declaratory and Injunctive Relief — 42 U.S.C. § 1983 —
West Virginia's Ban and Restrictions Violate the Commerce Clause

101. GenBioPro re-alleges and incorporates by reference each of the preceding paragraphs.

102. The Commerce Clause grants Congress alone the power to "regulate Commerce . . . among the several States." U.S. Const. art. I, § 8, cl. 3. It prevents a state from taking any action that may impede the free flow of trade in the national common market or create an undue burden on access to an article of commerce that requires uniform national regulation.

103. The Commerce Clause renders invalid state laws that impose "undue burdens" on interstate commerce, including by regulating articles of commerce Congress determined require a uniform system of regulation at the national level. *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2091 (2018). The Clause likewise invalidates state laws, such as West Virginia's Ban and

Restrictions, that preclude the use of a drug manufactured out of state for use in the State to terminate a pregnancy, *see Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989) (laws that, if imposed by several states, would have the "practical effect" of regulating commerce outside the state violate the Commerce Clause), or of banning an article of commerce, *see Schollenberger v. Pennsylvania*, 171 U.S. 1, 13 (1898).

104. Section 1983 of Title 42 of the United States Code provides a remedy for any person who suffers deprivation of rights, privileges, and immunities secured by the U.S. Constitution, including the Commerce Clause.

105. West Virginia's Ban, W. Va. Code § 16-2R-1 *et seq*.; *id.* § 61-2-8, and Restrictions, *id.* §§ 16-2I-2, 16-2I-9, 30-1-26(b)(9), 30-3-13a(g)(5), interfere with the uniform regulation of mifepristone, a drug subject to extensive federal regulation at the national level, thereby destroying the common market for mifepristone.

106. Article 2R, Chapter 16 of the West Virginia Code and § 61-2-8 violate the Commerce Clause by, in effect, banning an article of commerce and preventing GenBioPro from developing a market for its product, mifepristone, in West Virginia.

107. West Virginia Code § 16-2I-2 violates the Commerce Clause by forcing patients to fulfill waiting period and counseling requirements before accessing mifepristone. This State law disrupts FDA's federal regulatory scheme and undermines the need for national uniformity in the regulation of REMS drugs such as mifepristone.

108. West Virginia Code § 30-3-13a(g)(5) violates the Commerce Clause by preventing providers from prescribing mifepristone via telemedicine, meaning that patients are required to visit a healthcare professional in person to obtain a prescription. *See id.* § 30-1-

26(b)(9). This State law disrupts FDA's federal regulatory scheme and undermines the need for national uniformity in the regulation of mifepristone, as subject to the FDA's REMS.

109. Each of these Restrictions and West Virginia's Ban constrict the market for GenBioPro's product, excessively burden interstate commerce, and vitiate the national common market the Framers envisioned.

110. West Virginia's Ban and Restrictions conflict with the rights, privileges, or immunities secured by FDA approval of mifepristone under Title 21 of the United States Code and the REMS to market and distribute the drug under applicable federal rules. As such, 42 U.S.C. § 1983 provides a cause of action and remedy for such violations.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter an order and judgment as follows:

A. A declaratory judgment, pursuant to 28 U.S.C. § 2201, that West Virginia Code §§ 16-2R-1 *et seq*., 16-2I-2, 16-2I-9, and 61-2-8 are invalid and unenforceable because they violate both the Supremacy Clause and the Commerce Clause of the U.S. Constitution;

B. A declaratory judgment, pursuant to 28 U.S.C. § 2201, that West Virginia Code §§ 30-1-26(b)(9) and 30-3-13a(g)(5) are invalid and unenforceable because they violate the Commerce Clause of the U.S. Constitution;

C. Such further relief as permitted under 28 U.S.C. § 2202, including a permanent injunction enjoining Defendants from enforcing the challenged provisions;

D. Injunctive relief under this Court's equitable power to enjoin enforcement of unconstitutional state laws;

E. An order awarding GenBioPro its costs and attorneys' fees pursuant to 42 U.S.C. § 1988; and

F. Such other and further relief as the Court deems just and proper.

Dated: October 18, 2023

Respectfully submitted,

/s/ Anthony J. Majestro

Anthony J. Majestro
W. Va. Bar No. 5165
Christina L. Smith
W. Va. Bar No. 7509
POWELL & MAJESTRO P.L.L.C.
405 Capitol Street
Suite P-1200
Charleston, WV 25301
Tel: (304) 346-2889
amajestro@powellmajestro.com
csmith@powellmajestro.com

David C. Frederick*
Ariela M. Migdal*
Eliana Margo Pfeffer*
Mary Charlotte Y. Carroll*
KELLOGG, HANSEN, TODD, FIGEL & FREDERICK, P.L.L.C.
1615 M Street, N.W., Suite 400
Washington, D.C. 20036
Tel: (202) 326-7900
dfrederick@kellogghansen.com
amigdal@kellogghansen.com
epfeffer@kellogghansen.com
mcarroll@kellogghansen.com

Skye L. Perryman*
Kristen Miller*
DEMOCRACY FORWARD FOUNDATION
P.O. Box 34553
Washington, D.C. 20043
Tel: (202) 448-9090
sperryman@democracyforward.org
kmiller@democracyforward.org

John P. Elwood*
Daphne O'Connor*
Robert J. Katerberg*
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, N.W.
Washington, D.C. 20001
john.elwood@arnoldporter.com
daphne.oconnor@arnoldporter.com
robert.katerberg@arnoldporter.com

** Admitted pro hac vice*

Counsel for Plaintiff GenBioPro, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

***Plaintiff*,**

v.

KRISTINA RAYNES, *in her official capacity as Prosecuting Attorney of Putnam County*, AND PATRICK MORRISEY, *in his official capacity as Attorney General of West Virginia*,

Defendants.

Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)

JOINT STIPULATION AND JOINT MOTION TO ENTER FINAL JUGDMENT

Plaintiff GenBioPro, Inc., and Defendants Kristina Raynes, in her official capacity as Prosecuting Attorney for Putnam County, and Patrick Morrisey, in his official capacity as Attorney General of the State of West Virginia, stipulate that all claims in Plaintiff's First Amended Complaint were decided in the Court's memorandum opinions and orders on the motions to dismiss, Dkt. Nos. 54, 66, and further stipulate that the Court should enter a separate order of judgment on Plaintiff's First Amended Complaint, Dkt. No. 75, as required by Federal Rule of Civil Procedure 58, for the reasons stated in Dkt. Nos. 54, 66.

The parties therefore move the Court to enter a separate order of judgment on its First Amended Complaint, Dkt. No. 75, as required by Federal Rule of Civil Procedure 58, for the reasons stated in Dkt. Nos. 54, 66. The parties preserve all objections and rights to appeal.

Dated: November 3, 2023

Respectfully submitted,

PATRICK MORRISEY
West Virginia Attorney General

/s/ Douglas P. Buffington, II
Douglas P. Buffington, II (WV Bar # 8157)
Chief Deputy Attorney General
Curtis R. A. Capehart (WV Bar # 9876)
Deputy Attorney General
OFFICE OF THE ATTORNEY GENERAL
State Capitol Complex
1900 Kanawha Boulevard E.
Building 1, Room E-26
Charleston, WV 25305-0220
Tel.: (304) 558-2021
Fax: (304) 558-0140
curtis.r.a.capehart@wvago.gov

Counsel for Defendant Patrick Morrisey, in his official capacity as Attorney General of the State of West Virginia

KRISTINA RAYNES
Putnam County Prosecuting Attorney

/s/ Jennifer Scragg Karr
Jennifer Scragg Karr (WV Bar # 8051)
Assistant Prosecuting Attorney
OFFICE OF THE PROSECUTING ATTORNEY
Putnam County Judicial Building
12093 Winfield Rd.
Winfield, WV 25213
Tel.: (304) 586-0205
Fax: (304) 586-0269
jkarr@putnamwv.org

Counsel for Defendant, Kristina Raynes, in her official capacity as Prosecuting Attorney for Putnam County

GENBIOPRO, INC.

/s/ Anthony J. Majestro
Anthony J. Majestro (WV Bar # 5165)
Christina L. Smith (WV Bar # 7509)

POWELL & MAJESTRO P.L.L.C.
405 Capitol Street, Suite 807
Charleston, WV 25301
Tel.: (304) 346-2889
amajestro@powellmajestro.com
csmith@powellmajestro.com

Counsel for Plaintiff, GenBioPro, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

***Plaintiff*,**

v.

KRISTINA RAYNES, *in her official capacity as Prosecuting Attorney of Putnam County*, AND PATRICK MORRISEY, *in his official capacity as Attorney General of West Virginia*,

Defendants.

Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)

CERTIFICATE OF SERVICE

I hereby certify that, on this 3rd day of November, 2023, I electronically filed the foregoing stipulation with the Clerk of Court and all parties using the CM/ECF System.

/s/ Anthony J. Majestro
Anthony J. Majestro

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

***Plaintiff*,**

v.

KRISTINA RAYNES, ***in her official capacity as Prosecuting Attorney of Putnam County,*** **AND PATRICK MORRISEY,** ***in his official capacity as Attorney General of West Virginia*,**

Defendants.

Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)

ORDER REGARDING JOINT STIPULATION AND JOINT MOTION

For the reasons stated in the Court's memorandum opinions and orders, Dkt. Nos. 54, 66, the First Amended Complaint is hereby dismissed, judgment is entered in favor of Defendants, and this case is closed.

The Clerk is directed to send copies of this Order to those counsel of record who have registered to receive an electronic NEF.

IT IS SO ORDERED this _____ day of November, 2023.

Robert C. Chambers
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

Plaintiff,

v.

KRISTINA RAYNES, ***in her official capacity as Prosecuting Attorney of Putnam County,*** **AND PATRICK MORRISEY,** ***in his official capacity as Attorney General of West Virginia,***

Defendants.

Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)

ORDER REGARDING JOINT STIPULATION AND JOINT MOTION

For the reasons stated in the Court's memorandum opinions and orders, Dkt. Nos. 54, 66, the First Amended Complaint is hereby dismissed, judgment is entered in favor of Defendants, and this case is closed.

The Clerk is directed to send copies of this Order to those counsel of record who have registered to receive an electronic NEF.

IT IS SO ORDERED this 6th day of November, 2023.

Robert C. Chambers
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

Plaintiff,

v.

KRISTINA RAYNES, ***in her official capacity as Prosecuting Attorney of Putnam County,*** **AND PATRICK MORRISEY,** ***in his official capacity as Attorney General of West Virginia,***

Defendants.

Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)

NOTICE OF APPEAL

Please take notice that Plaintiff GenBioPro, Inc., hereby appeals to the United States Court of Appeals for the Fourth Circuit from the Judgment entered in this action on November 6, 2023, Dkt. No. 77, and from the orders incorporated in that Judgment, *see* Dkt. Nos. 54, 66.

Dated: November 9, 2023

Respectfully submitted,

/s/ Anthony J. Majestro

Anthony J. Majestro
W. Va. Bar No. 5165
Christina L. Smith
W. Va. Bar No. 7509
POWELL & MAJESTRO P.L.L.C.
405 Capitol Street
Suite P-1200
Charleston, WV 25301
Tel: (304) 346-2889
amajestro@powellmajestro.com
csmith@powellmajestro.com

David C. Frederick*
Ariela M. Migdal*
Eliana Margo Pfeffer*
Mary Charlotte Y. Carroll*
KELLOGG, HANSEN, TODD, FIGEL & FREDERICK,
P.L.L.C. 1615 M Street, N.W.,
Suite 400 Washington, D.C. 20036
Tel: (202) 326-7900
dfrederick@kellogghansen.com
amigdal@kellogghansen.com
epfeffer@kellogghansen.com
mcarroll@kellogghansen.com

Skye L. Perryman*
Kristen Miller*
DEMOCRACY FORWARD FOUNDATION
P.O. Box 34553
Washington, D.C. 20043
Tel: (202) 448-9090
sperryman@democracyforward.org
kmiller@democracyforward.org

John P. Elwood*
Daphne O'Connor*
Robert J. Katerberg*
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, N.W.
Washington, D.C. 20001
john.elwood@arnoldporter.com
daphne.oconnor@arnoldporter.com
robert.katerberg@arnoldporter.com

* *Admitted pro hac vice*

Counsel for Plaintiff GenBioPro, Inc.

CERTIFICATE OF SERVICE

I hereby certify that, on February 7, 2024, I electronically filed the foregoing Joint Appendix with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit using the appellate CM/ECF system.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

/s/ David C. Frederick
David C. Frederick