No. 23-2194

IN THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

GENBIOPRO, INC.
Plaintiff-Appellant,

v.

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

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

BRIEF OF *AMICUS CURIAE* JUDICIAL WATCH, INC. IN SUPPORT OF DEFENDANTS-APPELLEES

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STATEMENT OF AMICUS CURIAE

Judicial Watch, Inc. ("Judicial Watch") is a non-partisan educational organization that seeks to promote transparency, accountability, and integrity in government and fidelity to the rule of law. Judicial Watch regularly files *amicus curiae* briefs to advance its public interest mission.

Judicial Watch seeks participation in this case for two reasons. First, this case concerns a subject matter in which Judicial Watch has been involved for over two decades: drugs approved by the federal government that intentionally end pregnancy. *See e.g.*, *Judicial Watch, Inc. v. FDA*, 449 F.3d 141 (D.C. Cir. 2006). Judicial Watch has used the Freedom of Information Act ("FOIA") law and subsequent lawsuits to obtain information vital to this case. *Id.*; *see also Judicial Watch, Inc. v. U.S. Dep't of Health and Human Services*, Civil Case No. 22-cv-3152 (D.D.C., Mehta, J.). Second, the broader implication of this case extends beyond the specific subject matter into the larger concern of extreme undue deference given to federal agencies, even in the face of improper political interference or professional negligence. Throughout its existence, Judicial Watch has championed the constitutional principles of separation and balance of powers and defending states' rights, and seeks to assist the Court in analyzing the implications of extreme undue deference given to a federal agency – particularly when there is evidence of questionable agency actions.

Judicial Watch files this *amicus curiae* brief pursuant to Fed. Rule App. P. 29(a)(2) and Local Rule 29 in support of Appellees, Kristina D. Raynes and Patrick Morrisey, in their official capacities, and urges this Court to affirm the judgment of the District Court.[1]

SUMMARY OF THE ARGUMENT

Appellant GenBioPro, Inc. ("GenBio") claims it is entitled to sell its generic mifepristone drug for the purpose of abortion in the State of West Virginia because the drug is approved by the Food & Drug Administration ("FDA"), and the FDA is the sole authority – the "gatekeeper" – of all legal control regarding the distribution and use of mifepristone. *See* Opening Brief of Plaintiff-Appellant GenBioPro, Inc. ("App. Br.") at 5. GenBio claims that, despite the U.S. Supreme Court very clearly returning the issue of abortion to the individual states, its mifepristone must be permitted to be sold in West Virginia for the termination of pregnancies in contravention of state law simply because the FDA permits its use. *See Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 292 (2022). This misconception of agency authority is shockingly telling for several reasons. First, the FDA, like every other federal agency, is subject to the U.S. Supreme Court's authority and

[1] Judicial Watch submits this brief with the consent of the parties and certifies that no counsel for a party authored this brief in whole or in part and no person or entity, other than amicus, its members, or its counsel, has made any monetary contribution to its preparation or submission.

drug manufactures cannot bypass the law of the land by running to a politically favored federal agency to let them in through the backdoor. Second, the FDA's approval of mifepristone and other dubious drugs shows how dangerous political favors can be for the public health and safety. And lastly, GenBio's "gatekeeper" theory would eviscerate states' rights to protect the health and safety of their own citizens – a right recognized by the highest courts.

ARGUMENT

I. No Legal Precedent Prevents West Virigina from Enacting the Unborn Child Protection Act.

In September 2022, in response to the Supreme Court's *Dobbs* decision, West Virginia passed the Unborn Child Protection Act ("UCPA") which, subject only to a few delineated exceptions, outlawed abortion. W. Va. Code § 16-2R-1, *et seq*. Included in this prohibition was the use of medicines or drugs taken for the purpose of abortion. W. Va. Code § 16-2R-2. GenBio claimed the UCPA is unconstitutional, and that the Supremacy Clause barred West Virginia from limiting the sale or use its drug for abortion.[2] GenBio is mistaken.

Succinctly put, the Supremacy Clause forbids state laws that "'interfere with, or are contrary to,' federal law." *Hillsborough County v. Automated Medical Laboratories, Inc*., 471 U.S. 707, 712-713 (1985) (internal citations omitted).

[2] GenBio made additional legal arguments, but Judicial Watch's focus in this *amicus* brief is the Supremacy Clause.

Federal preemption can be achieved through both federal statutes and regulations. *Id*. at 713. Preemption is not, however, presumed. In fact, this Court has recognized the presumption *against* federal preemption of state law in areas "traditionally left to the states." *See Pinney v. Nokia, Inc*., 402 F.3d 430, 457 (4th Cir. 2005); *see also City of Falls Church v. Fairfax County Water Authority*, 272 Fed. Appx. 252, 256 (4th Cir. 2008) ("the presumption against preemption has particular force in the areas of public health and safety that have traditionally been regulated by the states.")

The U.S. Supreme Court has articulated this principle against preemption of state law as a method of furthering the balance of state and federal powers. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Court held:

> First, because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' we 'start 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.'

Id. at 485 (internal citations omitted).

Federal agencies do not wield independent preempting power – the only preemption power the agencies have comes from Congress. In other words, federal preemption of state law must flow from a Congressional source. *Id*. at 485-486. Therefore, GenBio must demonstrate that Congress intended, either expressly

or impliedly through a specific statute, that mifepristone as an abortifacient should be federally preempted. Neither the Federal Food, Drug, and Cosmetic Act ("FDCA") nor the Food and Drug Administration Amendments Act ("FDAAA") – the statutes relied on by GenBio – contain an express grant of federal preemption. This leaves GenBio with the burden of proving Congress implied federal preemption. GenBio cannot meet that burden as even a generous reading of the statutes fails to produce any evidence that Congress intended that the FDA preempts state laws restricting the sale and use of mifepristone as an abortifacient.

This is particularly clear in light of the *Dobbs* case which returned the issue of abortion to the states. *Dobbs*, 597 U.S. at 292. GenBio complains that the lower court "overstated" the relevance of *Dobbs,* but the miscalculation of relevance is on the part of GenBio. App. Br. at 61-63. It is uncontested that the only use of GenBio's mifepristone that West Virginia is restricting in its UCPA is the abortifacient purpose. GenBio's creative attempt to carve out an exception in *Dobbs* falls far short of showing the UCPA is unconstitutional.

II. The FDA's Troubling History Should Give Pause to the Undue Deference Granted to Its Approval of Drugs.

GenBio's inventive legal theory that *Dobbs* doesn't apply to its abortifacient drug is not the most troublesome aspect of this appeal. This Court is more than qualified to weigh the legal arguments presented and apply the appropriate precedent. The truly unsettling aspect of this appeal is the undercurrent of extreme

undue deference GenBio avers the FDA's actions are warranted. As shown below, the approval of mifepristone in the U.S. is a prime example of a federal agency trading political favors to gain approval of a dangerous drug that should give this Court pause before lauding deference on the FDA.

A. The Approval of Mifepristone in the U.S.

In reviewing the FDA's process for initially granting approval for mifepristone in 2000, as well as the contemporaneous evidence related to the decision, it becomes apparent that the FDA's decision was not in accordance with law and was the result of political pressure. The FDA approved Mifeprex – the brand-name of the mifepristone drug – pursuant to the accelerated approval procedure provided in 21 C.F.R. § 314.500, which is reserved for certain drugs needed for serious or life-threatening illnesses. *See* 57 FR 58942. To be approved under this section, the FDA would have needed to demonstrate that, (1) pregnancy was a "serious or life-threatening illness" or a "disease," and (2) that the drug "provided a meaningful therapeutic benefit to patients over existing treatments." *Id.* Even the sponsor of the brand-name mifepristone, Population Council, objected to the using the Subpart H approval path, as it would require twisting pregnancy into a disease to fit.[3] But the FDA ignored the sponsor's objection and

[3] *See e.g.*, RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and

steamrolled forward, despite the disingenuousness of its actions.[4] The question, of course, is "why?" Why would the FDA so thoroughly pervert the meaning of "pregnancy" to accelerate the approval of a drug? While the FDA publicly asserted that the rationale for approving Mifeprex was for the health of American women, the evidence shows that the true motivation was political.[5] After the FDA first approved mifepristone as an abortifacient, it became known that President

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Human Res., Committee on Government Reform, 109th Cong. (May 17, 2006) at 71 and n.9, full transcript available at https://www.govinfo.gov/content/pkg/CHRG-109hhrg31397/html/CHRG-109hhrg31397.htm.

[4] Prior to the 2000 approval of Mifeprex, the FDA granted accelerated approval pursuant to Subpart H 37 times. Of these 37 accelerated approvals, 21 related to HIV drugs and 10 related to cancer drugs. The remaining accelerated approvals were related to chronic low blood pressure, tuberculosis, leprosy, and bacterial infections. Since the 2000 approval of Mifeprex, the FDA has granted accelerated approval pursuant to Subpart H 26 times. Of these 26 accelerated approvals, 9 related to HIV drugs, 10 related to cancer drugs, 3 related to hypertension, and 2 related to blood disorders. The remaining accelerated approvals were related to hypogonadotropic hypogonadism (pituitary problem) and narcolepsy. Unlike pregnancy, each one of these drugs treats a condition widely considered a "disease" by both the medical community as well as the FDA. In 64 instances of granting accelerated approval pursuant to Subpart H, there is exactly one drug that targets something non-disease related: Mifepristone. *See* FOOD & DRUG ADMINISTRATION, "Drug and Biologic Approval and IND Activity Reports: Accelerated and Restricted Approvals Under Subpart H," updated last on August 24, 2014, https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/accelerated-and-restricted-approvals-under-subpart-h-drugs-and-subpart-e-biologics.

[5] *See* Judicial Watch, "A Judicial Watch Special Report: The Clinton RU-486 Files" (April 26, 2006) for an in-depth review of the politics at play in the FDA's approval of mifepristone as an abortifacient.

Clinton, the FDA, the U.S. Department of Health and Human Services ("HHS"), and Population Council brokered a backroom deal to approve Mifeprex in the U.S.[6] The evidence uncovered was eye-opening; it shows the Clinton administration and the FDA applying political pressure on not only international corporations, but on international governments – including evidence of communications admitting that pressure was needed to convince these companies to bring the abortion drug to the U.S.[7]

Even after approval, the FDA continued to tinker with the safety restrictions of mifepristone. For over a decade, between 2000 and 2016, the FDA maintained that strict safety restrictions were necessary for the distribution and use of mifepristone, including a 2004 "black box" warning resulting from a string of sepsis deaths, and the institution of a new risk evaluation and mitigation strategy ("REMS") triggered by the FDAAA. *See Alliance for Hippocratic Medicine v. FDA*, 78 F.4th 210, 224-225 (5th Cir. 2023). However, despite being very clear

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6 *Id*. at 5-7.

7 The FDA helped pressure both Roussel, a French company, and Hoechst AG, the German pharmaceutical company and majority shareholder of Roussel, to bring the abortion pill to the U.S. *See* Judicial Watch, *supra* note 5. Hoechst was opposed to producing the drug for the U.S. and in fact, ordered Roussel to cease producing the abortion drug altogether. The government of France exerted its legal and economic powers and forced Hoechst to continue producing the abortion drug. *See* Melanie Israel, "Chemical Abortion: A Review," THE HERITAGE FOUNDATION, No. 3603, March 26, 2021 available at: https://www.heritage.org/life/report/chemical-abortion-review.

about the need for mifepristone safety restrictions in its approval criterion, the FDA radically revised the brand-name mifepristone labeling and REMS in 2016 and *reduced* the safety requirements. *Id*. at 225-226. These changes included significantly altered dosage, removal of the follow-up medical visit, removal of the requirement to take the drug in a doctor's office, and expansion of the use through 70 days gestation.[8] Also of significance and concern, the FDA modified the REMS to require reporting of only deaths attributable to the drug. No longer would hospitalizations, transfusions, or other serious adverse events need to be reported.[9]

In 2021, using the COVID-19 pandemic as a tool, abortion proponents, led by the American College of Obstetricians and Gynecologists ("ACOG"), sued the FDA to dispense with the REMS in-person medical visit as a prerequisite for obtaining mifepristone and permit the drug to be mailed.[10] The FDA accepted ACOG's request and temporarily suspended the in-person medical visit based

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8 *See* Israel, *supra* note 7.

9 *Ibid.*

10 *See* American College of Obstetricians and Gynecologists, "The FDA's Decision Lifting the Burdensome Restriction on Mifepristone during the Pandemic: What You Need to Know," ACOG ADVOCACY AND HEALTH POLICY (April 21, 2021), https://www.acog.org/news/news-articles/2020/07/courts-order-lifting-burdensome-fda-restriction-what-you-need-to-know.

solely on the COVID-19 pandemic.[11] COVID-19 was, however, just pretext for the FDA's decision. With the pandemic declared over by President Biden on September 18, 2022, the foundation of concern for in-person medical visits should have ended.[12] Instead, the FDA maintained its temporary suspension and continued permitting Mifeprex to be mailed. Then, on December 16, 2022, in a blatantly deceptive maneuver, the FDA permanently removed the REMS requirement for any in-person medical visits.[13]

Removing any in-person medical visit and permitting Mifeprex to be mailed does not allow the prescriber to ascertain the gestational age of the baby or determine whether there is an ectopic pregnancy – two essential pieces of information in the Mifeprex safety approval.[14] The FDA's rationalization for permanently removing in-person medical visits was:

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[11] *See* Irving Spitz, "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," NEW ENGLAND JOURNAL of MEDICINE, 1998, 338 (18) 1241-47.

[12] *See e.g.*, Zachary B. Wolf, "Biden declares pandemic over. People are acting like it too," CNN (Sept. 19, 2022), https://www.cnn.com/2022/09/19/politics/biden-covid-pandemic-over-what-matters/index.html.

[13] *See e.g.*, Anne Flaherty, "FDA lifts restriction on abortion pill, permanently allowing delivery by mail," ABC NEWS (Dec. 16. 2021), https://abcnews.go.com/Politics/fda-women-obtain-abortion-pill-mail/story?id=81798959.

[14] Ectopic pregnancies occur in approximately 1-2% of pregnancies, though that percentage can rise significantly due to certain factors like smoking, IVF treatments, or IUD usage. *See* Erin Hendricks, MD, Rachel Rosenberg, MD, and

> [T]he FDA analyzed postmarketing data to determine if there was a difference in adverse events between periods when in-person dispensing was and was not enforced. Based on this review, the agency concluded that there did not appear to be a difference in adverse events between periods when in-person dispensing was and was not enforced.[15]

The FDA made this public assertion despite the FDA Commissioner acknowledging that the study designs it relied on were "limited" and "do not appear to show increases in serious safety concerns."[16] And critically missing from this rationalization is the admission that the FDA's 2016

Linda Prine, MD, "Ectopic Pregnancy: Diagnosis and Management," AM FAM PHYSICIAN 2020: 101 (10), https://www.aafp.org/pubs/afp/issues/2020/0515/p599.html. Fatal ectopic pregnancies account for roughly 2.7% of maternal deaths. *Id*. ACOG's own website states that ectopic pregnancies can be life-threatening and recommends the involvement of a health care professional. *See* American College of Obstetricians and Gynecologists, "Ectopic Pregnancy," ACOG (Feb. 2018), https://www.acog.org/womens-health/faqs/ectopic-pregnancy; *see also* Virginia Allen, "FDA Has Made Abortion 'Wild West' With Rule Change on Drugs, OB-GYN Says," DAILY SIGNAL (Jan. 18, 2023), https://www.dailysignal.com/2023/01/18/fda-has-made-abortion-wild-west-rule-change-drugs-ob-gyn-says.

[15] U.S. FOOD & DRUG ADMINISTRATION, "Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation," last updated January 4, 2023, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[16] April 12, 2021 letter from FDA Commissioner Janet Woodock to American College of Obstetricians and Gynecologists ("ACOG"), available at https://www.aclu.org/sites/default/files/field_document/fda_acting_commissioner_letter_to_acog_april_12_2021.pdf.

REMS changes dispensed of the reporting requirement for any nonfatal adverse events.[17] The "serious safety concerns" the Commissioner was "reviewing" had not been routinely reported in nearly ***five years***.

From disingenuously forcing pregnancy into a "serious illness" category to ensure accelerated approval under 21 C.F.R. § 314.520, to using a pandemic to irresponsibly ship a dangerous drug to individuals under no doctor's professional supervision, the FDA's approval of mifepristone and subsequent removal of key safety features were accomplished through political force at the expense of science. This alone is reason enough for the Court to seriously question giving deference to the FDA. However, mifepristone is far from the first politically motivated dangerous drug approval. The FDA has a history of elevating political ideology over science that is becoming increasingly frightening. A brief look at the FDA's history in the past few decades shows a federal agency fraught with corruption, conflicts of interest, and an immense amount of professional negligence that has cost millions of human lives.[18]

B. Other FDA Regulatory Disasters.

Perhaps the FDA disaster with the heaviest human toll is the opioid debacle.

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17 *See* Israel, *supra* note 7.

18 *See e.g.*, *Alliance for Hippocratic Medicine,* 78 F.4th at 270-271 (Ho, J., dissenting).

OxyContin (oxycodone), first approved by the FDA in 1995, is seen now by many in the medical field as the spark that created the opioid crisis in the United States.[19] In records obtained by ProPublica, it is now known that the drug was originally meant to treat short term, severe or end-of-life pain, but the manufacturer, Purdue Pharma, recognized the market value of a more widely accessible pain killer. Therefore, despite lacking any scientific evidence supporting broad use, the FDA approved OxyContin much more broadly for moderate and chronic pain.[20] Purdue's only clinical trial began with 133 elderly osteoarthritis patients, 70 of whom did not complete the trial.[21] Of the 63 participants who completed the trial, 82% had an adverse reaction.[22] The FDA also approved Purdue's medication insert assertion that claimed OxyContin had a "delayed absorption" that reduced

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19 *See e.g.*, Andrew Kolodny, M.D., "How FDA Failures Contributed to the Opioid Crisis," AMA Journal of Ethics, Vol. 22, 8:E743-750 (August 2020), https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2020-08/joe-2008_0.pdf.

20 Gerald Posner, "FDA's Janet Woodcock failed to stop the opioid epidemic," USA TODAY (Feb. 3, 2021), https://www.usatoday.com/story/opinion/2021/02/03/janet-woodcocks-failure-fda-opioid-epidemic-column/4352787001/.

21 Shraddha Chakradhar and Casey Ross, "The history of OxyContin, told through unsealed Purdue document," STAT (Dec. 3, 2019), https://www.statnews.com/2019/12/03/oxycontin-history-told-through-purdue-pharma-documents/.

22 *Ibid*.

the drug's addictiveness.[23] The label stated unequivocally that addiction was "rare."[24] But this claim was not based on any clinical trials.[25] None. Science had nothing to do with the claim. Janet Woodcock, former FDA Commissioner, who oversaw approval of OxyContin as the Director of the Center for Drug Evaluation and Research ("CDER"), admitted in 2022 that there was a "miscalculation about projected harms" when she led the OxyContin approval.[26] A miscalculation would require a calculation and an error of said calculation. But the FDA approved OxyContin without *any* scientific calculation of projected harms and more than a million people are dead because of it.[27] In addition to the vast amounts of money Purdue made on OxyContin sales, two of the principal reviewers of Purdue's OxyContin application took high-paying jobs at Purdue after leaving the FDA.[28]

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23 *See* Posner, *supra* note 20.

24 *Ibid*.

25 *Ibid*.

26 Celine Castronuovo, "OxyContin Decision Involved FDA 'Miscalculation,' Woodcock Says," Bloomberg Health Law & Business (June 15, 2022), https://news.bloomberglaw.com/health-law-and-business/fdas-woodcock-admits-to-miscalculation-in-oxycontin-decision.

27 Centers for Disease Control, "The Drug Overdose Epidemic: Behind the Numbers," CDC OPIOIDS (Aug. 8, 2023), https://www.cdc.gov/opioids/data/index.html.

28 *See* Kolodny, *supra* note 19.

And in 2013, despite the clear evidence of an opioid crisis and the highest number of opioid prescriptions ever being written in 2012, the FDA approved *another* extended-release hydrocodone drug application, Zogenix.[29] This approval came after the FDA advisory panel voted 11-2 ***against*** approving the drug.[30] One of the biggest concerns was that, being an extended-release drug, Zogenix contained a higher dosage of hydrocodone than other options already on the market.[31] Perhaps most alarming was the fact that, in addition to snubbing the advisory committee's vote and concerns, Zogenix was approved without any abuse-resistant features.[32] The sheer recklessness of this approval is arresting.

Another example of regulatory failure is Nuplazid, a drug approved by the FDA for Parkinson's patients in 2016. Nuplazid failed to show any benefit in its first two clinical trials, and, in fact, more patients died or experienced serious side

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29 Lars Noah, "State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products," 2016 Mich. St. L. Rev. 1, 3; *see also* Matej Mikulic, "Number of annual opioid prescriptions in the U.S. from 2006 to 2022," STATISTA (Jan. 18, 2024), https://www.statista.com/statistics/753149/total-number-of-opioid-rx-prescriptions-in-us/.

30 *See* Noah, *supra* note 29 at 3, n. 9.

31 *Id*. at 5 and n. 16.

32 *Id*. at 5.

effects from the medication than having no treatment at all.[33] Acadia Pharmaceuticals, Nuplazid's manufacturer, requested that the study scale be revised, thereby making it statistically more probable that a benefit would result in the third clinical trial.[34] The FDA acquiesced, then agreed to grant Nuplazid's "breakthrough therapy" designation, consequently requiring only one positive trial.[35] Nuplazid's third trial produced a small benefit in participants who took the drug versus the placebo.[36] The FDA advisory committee would vote 12-2 in favor of accelerated approval after hearing from 15 members of the public.[37] It did not seem to trouble the FDA committee that three speakers were paid Acadia consultants, four worked with an advocacy organization funded by Acadia, three were family members of Parkinson's patients whose travel was paid for by Acadia, and one became a paid "ambassador" for Acadia following the hearing.[38] In the

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33 Caroline Chen, "FDA increasingly approves drugs without conclusive proof they work," PBS NEWSHOUR (June 26, 2018), https://www.pbs.org/newshour/health/fda-increasingly-approves-drugs-without-conclusive-proof-they-work.

34 *Ibid*.

35 *Ibid*.

36 *Ibid*.

37 *Ibid.*

38 *Ibid*.

two years following Nuplazid's FDA approval, 887 deaths were attributed to the drug.[39] Altering the study scale was not based on science or clinical evidence.

Yet another example is Aduhelm, a drug purporting to treat Alzheimer's disease. Biogen, the manufacturer, conducted two trials of over 3,200 patients.[40] One trial assessed no statistical difference in the groups and the second showed a difference, but not one that was "clinically significant."[41] Biogen submitted Aduhlem for approval based on the second trial. An FDA advisory committee met and expressed concern that the first trial, which was nearly identical to the second, did not show any benefit and 40% of the participants developed abnormalities.[42] Ten of the 11 committee members voted against approval, but the FDA granted approval anyway in 2021.[43] Several FDA committee members resigned following this rogue approval, criticizing Aduhelm as lacking evidence of a benefit while having significant adverse effects on patients.[44] After the FDA granted accelerated

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39 *Ibid*.

40 Stephanie Diu, "Slowing Down Accelerated Approval: Examining the Role of Industry Influence, Patient Advocacy Organizations, and Political Pressure of FDA Drug Approval," 90 Fordham L. Rev. 2303, 2323 (2022).

41 *Id*. at 2324-2325.

42 *Id.* at 2325-2326.

43 *Id.* at 2326.

44 *Id.* at 2327.

approval, it was revealed that the FDA and Biogen had a very close relationship which has caught the attention of the U.S. Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") and members of Congress.[45] Meanwhile, Aduhelm remains on the market without clinical evidence of benefit, giving false hope to Alzheimer's patients and potentially harming them.

These are just a few examples of the FDA's questionable decisions in approving drugs. These approval decisions, however, are not the only concerning issue at hand. The FDA's approval process is rife with disturbing trends of trading in speed and political favors for safety. For instance, the flow of money from the pharmaceutical industry and patient advocacy groups to the FDA is astounding. The pharmaceutical industry and patient advocacy groups contributed 75% or $905 million of the FDA's scientific review budget in 2017.[46] Additionally, there is the "revolving door" of employment between the pharmaceutical industry and the FDA. In 2018, a study revealed that in 28 product approvals, 11 of the 16 FDA medical reviewers who approved the products worked for the companies whose product they reviewed.[47]

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45 *Id.* at 2330.

46 *See* Chen, *supra* note 33.

47 *See* Kolodny, *supra* note 19 at 746.

Also concerning is the dramatic increase in the FDA's use of the accelerated approval path and "breakthrough therapy" label.[48] Increasing accelerated approval decreases the stringent pre-market testing required and sets up a "partial end run" around the once gold standard for safety testing.[49] In the mid-90's 80.6% of new drugs were backed by at least two trials.[50] Roughly 20 years later, only 52.8% were so supported.[51] And the FDA has seemingly turned a blind eye to overseeing the completion of post-marketing studies. In 2022, HHS' OIG reported that, of the 278 drugs approved under the accelerated approval label, 104 had not yet completed the required post-marketing trials and more than half of the trials are submitted late.[52] Yet, the FDA has never penalized a single manufacturer with a monetary penalty.[53] Will the FDA determine in the future that some of these drugs involved a "miscalculation of projected harms" like the OxyContin approval? How many patients will experience adverse effects or even death while the FDA

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48 *See* Chen, *supra* note 33.

49 Daniel A. Aaron, "The fall of FDA Review," 22 Yale J. Health Pol'y L. & Ethics 95, 129 (2023).

50 *Id.* at 132.

51 *Ibid*.

52 *Id*. at 129.

53 *Ibid*.

plays protector of the public health with its eyes closed? How many families will go bankrupt on treatments that offer no real medical benefit but line the pockets of the drug industry and politicians? The FDA has demonstrated that it is not immune from politicization and elevating ideology over science and clinical data. Its approval decisions should be carefully reviewed, and deference regarded at a minimum.

III. GenBio's GateKeeper Theory Eviscerates the Proper Sphere of the Individual States' Rights to Protect Its Citizens.

GenBio's theory that the FDA's "gatekeeper" role somehow prevents states from enacting additional restrictions on FDA-approved products is contrary to the principles of federalism, legal precedent, and reality. App. Br. at 5. As shown briefly above, the individual states' right to protect its own citizens is clearly recognized by both this Court and the U.S. Supreme Court. *See supra* § I. Additionally, states have in fact historically enacted additional restrictions on FDA-approved drugs. For example, states have moved FDA-approved drugs from one schedule of drugs to a higher, more restrictive schedule of drugs. Illinois moved the FDA-approved painkiller Talwin from Schedule IV where the FDA placed it, to Schedule II, a far more restrictive schedule.[54] This is not an insubstantial move. Schedule IV drugs are drugs that have a proven medical use

[54] *See* Noah *supra*, note 29 at 19.

and a "low probability" of misuse or abuse.[55] Examples of commonly known Schedule IV drugs are Xanax, Ativan, and Valium.[56] Illinois weighed the safety concerns of Talwin and moved it to Schedule II which covers drugs with limited medical uses that are considered highly addictive, with a high potentional for misuse and abuse.[57] Examples of commonly known Schedule II drugs are Methadone, OxyContin, and Fentanyl.[58]

Soma is another example of states moving an FDA-approved drug from its FDA-approved schedule to a controlled substance schedule.[59] Soma is a muscle relaxant approved by the FDA in 1959.[60] Seventeen states bucked the FDA's classification and independently classified Soma as a controlled substance.[61]

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55 *See* AMERICAN ADDICTION CENTERS, "Drug Scheduling and Classifications," updated March 8, 2024, https://americanaddictioncenters.org/prescription-drugs/classifications.

56 *Ibid*.

57 *Ibid*.

58 *Ibid*.

59 *See* Noah, *supra* note 29 at 19-20 and n. 73.

60 *See* FOOD & DRUG ADMINISTRATION, "Highlights of Prescribing Information: SOMA," (revised August 2018) https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/011792s048lbl.pdf.

61 *See* Noah, *supra* note 29 at n. 73.

Ironically, the FDA followed the examples of these states and changed its own classification of Soma in 2011.[62]

The case of pseudoephedrine is well-known. Recognizing the dangerous correlation the drug posed with the creation of methamphetamine, Congress stopped waiting for the FDA to act and passed the Combat Methamphetamine Epidemic Act of 2005, which required all pseudoephedrine products to be sold behind the counter. Pub. Law 109-177, 120 Stat. 192, 258-61 (2006).[63] Importantly, Congress did not preempt more restrictive state laws by including a savings clause. *Id*. at 263.[64] Mississippi and Oregon both require prescriptions for pseudoephedrine products and several other states have independently classified it as a controlled substance.[65]

These are all state actions – states taking *additional* safety measures for the health and safety of their own citizens. GenBio's gatekeeper theory would prohibit all of these. And state actions protecting their own citizens go beyond just drugs.

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62 *Id*. at 19-20.

63 *Id*. at n. 74.

64 *Ibid*.

65 DRUG TOPICS, "Pseudoephedrine Primer: Federal and State Regulations," (July 10, 2015), https://www.drugtopics.com/view/pseudoephedrine-primer-federal-and-state-regulations.

States have routinely imposed greater restrictions on products bearing the FDA-approval such as food additives, antibiotics used in farm animals, alcohol, and certain chemicals.[66] For example, in 2015 the State of California passed a law prohibiting the use of antibiotics in healthy livestock. *See* 2015 Cal ALS 758, Cal SB 27, 2015 Cal. Stats. ch. 758. The bill was born from a concern over the possible connection between the amount of antibiotics injected into healthy livestock and the growing number of people who were antibiotic-resistant.[67] Acting out of concern for its citizens, California took action, despite the FDA's inaction. GenBio would have the State of California ignore its concerns of its citizens dying from "superbugs" and antibiotic-resistant infections, unless or until the FDA acts. The FDA has been considering action on livestock antibiotics since the 1970's. How many of its citizens' lives has California saved because it refused to abdicate its constitutional duty to protect?

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[66] *See e.g.*, AMERICAN ADDICTION CENTERS, "Alcohol Laws and Regulations," (last updated Sept. 26, 2023), https://alcohol.org/laws/; *see also* Nicholas Bellos, "How State and Federal Food Regulations Can – And Should – Work Together," THE REGULATORY REVIEW (Nov. 2, 2018), https://www.theregreview.org /2018/11/02/bellos-how-state-federal-food-regulations-work-together/; Lauren Berryman, "States Move to Regulate Toxic Chemicals; Federal Government Still Behind," PUBLIC HEALTH WATCH (May 10, 2022), https://publichealthwatch.org /2022/05/10/states-move-to-regulate-toxic-chemicals-federal-government-still-far-behind/.

[67] *See e.g.*, Juliet Williams, "California enacts strictest law limiting antibiotics in livestock," ASSOCIATED PRESS (Oct. 12, 2015); https://www.cbsnews.com/news /california-enacts-strictest-law-limiting-antibiotics-in-livestock/.

GenBio's gatekeeper theory threatens to upend our carefully crafted principles of federalism and subject the States to an unelected fourth branch of government – the FDA. And the FDA has proven itself time and again an unreliable protector of the public health and safety.

CONCLUSION

This Court should affirm the lower court and dismiss GenBio's complaint.

April 15, 2024

Respectfully submitted,

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I hereby certify that:

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April 15, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 15, 2024, I caused the foregoing to be electronically filed with the Clerk of Court using the CM/ECF system, which sent notification of such filing to all registered attorneys of record.

Respectfully submitted,

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
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- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
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No. 23-2194 Caption: GenBioPro v. Raynes, et al.

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1. Is party/amicus a publicly held corporation or other publicly held entity? ☐ YES ☑ NO

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If yes, identify all parent corporations, including all generations of parent corporations:

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If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: Meredith Di Liberto Date: April 15, 2024

Counsel for: Judicial Watch, Inc. - Amicus Curiae

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