No. 26-30203

United States Court of Appeals for the Fifth Circuit

STATE OF LOUISIANA, ET AL.,
PLAINTIFFS-APPELLANTS/CROSS-APPELLEES,

v.

FOOD & DRUG ADMINISTRATION, ET AL.,
DEFENDANTS-APPELLEES,

v.

GENBIOPRO, INC.,
INTERVENOR-APPELLEE/CROSS-APPELLANT,

v.

DANCO LABORATORIES, L.L.C.,
INTERVENOR-APPELLEE/CROSS-APPELLANT.

APPEAL FROM THE U.S. DISTRICT COURT FOR THE WESTERN DISTRICT OF LOUISIANA, NO. 26-CV-1491, HON. DAVID C. JOSEPH, PRESIDING

BRIEF OF AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS AS *AMICUS CURIAE* SUPPORTING APPELLANTS

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SUPPLEMENTAL CERTIFICATE OF INTERESTED PARTIES

State of Louisiana v. FDA, No. 26-30203:

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1, in addition to those listed in the briefs of the parties, have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

***Amicus*:** American Association of Pro-Life Obstetricians and Gynecologists does not have a parent corporation and is not publicly held.

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/s Christopher Mills
Christopher Mills

Counsel for *Amicus Curiae*

June 22, 2026

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INTEREST OF *AMICUS CURIAE*

The American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG)[*] is a nonprofit professional medical organization with about 8,000 medical professional members, including many experts in reproductive healthcare. AAPLOG equips its members and other medical practitioners with an evidence-based rationale for protecting the lives of the pregnant mother and her preborn child. Its CEO, Dr. Christina Francis, has filed a declaration detailing the problems with the FDA's relaxation of the prescription regime for abortion drugs. Doc. 20-21.[1] And AAPLOG has previously explained in detail its evidence-based concerns about the harms of mifepristone, particularly when dispensed without an in-person evaluation.[2] Recently, Dr. Francis went undercover on abortion pill websites to expose how easily these drugs can be obtained with zero medical oversight. Dr. Francis successfully received a prescription despite entering a medical history flagging her as a 13-year-old with anemia, an IUD in place, a history of C-sections and a previous ectopic pregnancy, and use of blood thinners—all of which make these drugs potentially life-threatening. These sites often require no age verification,

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[*] All parties consented to this brief. No party's counsel authored this brief in whole or in part, and no person other than *amicus* or their members or counsel contributed money to fund preparing or submitting it.

[1] All "Doc." references are to the district court docket in this case.

[2] *See* Complaint, *Alliance for Hippocratic Med. v. FDA*, No. 22-cv-223, 2022 WL 17091784 (N.D. Tex. Nov. 18, 2022).

no physician consultation, and no identity checks—allowing minors, women with life-threatening contraindications, and even abusers to order the pills with nothing more than a self-reported form and a small payment.[3] Of note, when the abortion drugs arrived at her house in Indiana (where abortion is largely illegal), with no prescriber information other than an address in Los Angeles, the mifepristone was from GenBioPro.[4]

AAPLOG was formed in 1973 as a "special interest group" within ACOG after ACOG leadership departed from science and the Hippocratic Oath by committing ACOG to elective abortions on demand without consulting membership. AAPLOG has an interest in showing that ACOG's abortion advocacy stems from its ideology, not scientific evidence or practice. ACOG does not represent all OB-GYNs, and its views here should be interpreted by the Court for what they are: ideological advocacy favoring unregulated abortion throughout pregnancy.

INTRODUCTION

I. The American College of Obstetricians and Gynecologists (ACOG) applauds itself "as a leading provider of authoritative scientific data,"[5] including about the abortion drug regime. Especially about induced abortion, it is not. Rather,

[3] *See Doctor Goes Undercover to Buy Abortion Pills. The Reality is Worse Than You Think* (Mar. 11, 2026), https://www.youtube.com/watch?v=4qAG4V-zHD4.
[4] *See AAPLOG Post*, X (May 5, 2026), https://perma.cc/NP5G-AGHJ.
[5] Brief of *Amici Curiae* ACOG et al. 13, *Planned Parenthood of the Heartland, Inc. v. Reynolds*, No. 22-2036 (Iowa Mar. 20, 2023), https://perma.cc/9U3V-42HW.

ACOG has become an interest group committed to its leadership's pro-abortion ideology. ACOG's history, guidelines, and policy positions show that it has long prioritized ideological advocacy over sound medical care when it comes to abortion.

Presumably those ideological blinders are why ACOG's "authoritative" arguments about induced abortion to courts across the country are routinely contradicted by the scientific evidence. ACOG has misled courts about fetal development facts. It has rewritten its "evidence-based" guidelines to bolster pro-abortion litigation positions. And it so reflexively supports unregulated abortions—without consideration of the mother's safety or the preborn child's life—that its arguments deviate from its own bulletins. While ACOG's bulletin found "limited or inconsistent" evidence supporting the safety of medication abortion "by telemedicine,"[6] ACOG told the Supreme Court (and the district court) that telemedicine abortions are unqualifiedly "safe and effective."[7]

There is significant reason to distrust ACOG's ideological claims about abortion. ACOG functions as a pro-abortion activist group, and it does not accurately represent scientific evidence about induced abortion, the views of its membership,

[6] ACOG, *Medication Abortion Up to 70 Days of Gestation*, https://perma.cc/C25E-6K96.

[7] Brief of ACOG et al. as *Amici Curiae* 20, *FDA v. Alliance for Hippocratic Med.*, Nos. 23-235, 23-236, 2024 WL 399937 (U.S. Jan. 30, 2024) (hereinafter "ACOG Brief"); Doc. 224, at 2, 4.

or the expertise of the over 80% of obstetricians and gynecologists in the United States who do not perform abortions.

II. Though FDA's action relied on a few studies purportedly involving dispensing abortion drugs by mail without in-person evaluation, none supports that action. The studies largely required in-person, pre-abortion testing, so the studies do not reflect real-world use enabled by FDA. None offered a statistically significant comparison involving wholly remote abortion. And most found higher emergency visits after telemedicine abortion compared to the current label information.

Because the motions panel appropriately recognized FDA's concession that its 2023 REMS is inadequate, the Court should reverse for entry of a stay against the 2023 REMS, which would merely put back into place the pre-existing requirements and already-approved FDA labeling that were in place until the 2023 labeling change.

ARGUMENT

I. ACOG is driven by ideology, not science.

The major medical interest group here is ACOG, whose views are routinely treated as fact by defenders of the FDA's relaxed abortion drug regime—and relied on by the drug manufacturers here.[8] But ACOG's cheerleading of drug-induced abortions is not based on the best available evidence, mothers' safety, or any interest

[8] Doc. 54-4, at 24.

in the preborn child—a life whose existence ACOG ignores (and recently removed from its logo completely). Rather than being medically sound, ACOG's views here are rooted in its pro-abortion ideology.

A. ACOG has a long history of abortion advocacy.

Though ACOG now cheerleads any abortion "without restrictions, without limitations and without barriers,"[9] it was not always so. The ancient Hippocratic Oath prohibited doctors from performing abortions: "I will neither give a deadly drug to anybody if asked for it, nor will I make a suggestion to this effect. Similarly I will not give to a woman an abortive remedy."[10] Physicians who practice in accord with the Hippocratic Oath do not perform elective abortions or euthanasia. When the continued union of the mother and her baby poses a genuine, imminent threat to the mother's life, OB-GYNs are trained to separate the mother and the baby. If this emergency separation takes place when the baby could survive outside the womb, the separation is done in a way that maximizes the chances of survival for both mother and baby. Rarely is this separation necessary before the baby can survive outside the womb. Pre-viability maternal-fetal separations were historically termed therapeutic abortions. They posed no violation of Hippocratic ethics, because the

[9] Christopher Zahn et al., *In the Abortion Debate, Honesty Matters*, Wash. Post (Aug. 30, 2023), https://bit.ly/4a6qxVk.

[10] Gilbert Berdine, *The Hippocratic Oath and Principles of Medical Ethics*, 3(9) Southwest Respiratory & Critical Care Chronicles 28, 30 (2015), https://perma.cc/GJ4V-RQLA.

decision facing the doctor was the loss of one life (the baby) or two lives (both the baby and the mother). By contrast, an elective (or induced) abortion occurs absent a threat to the mother's life. An induced abortion's purpose is to produce a dead baby. *See, e.g.*, *Gonzales v. Carhart*, 550 U.S. 124, 139–40 (2007).

Early on, ACOG recognized the contradiction between the Hippocratic Oath and induced abortions, and its "policy on abortion derived from the view that professional standards should be based on scientific evidence."[11] ACOG was formed in the 1950s, and its 1959 *Manual of Standards in Obstetric-Gynecologic Practice* accepted abortion only "where the death of the mother might reasonably be expected to result from natural causes, growing out of or aggravated by the pregnancy, unless the child is destroyed."[12]

But ACOG could not withstand societal pressure for long, especially as hospitals eagerly expanded therapeutic abortions "for mental health reasons."[13] In the 1960s, pro-abortion ACOG leaders began making subtle changes to its abortion policy, altering the definition of "therapeutic" with a novel and vague component

[11] Nancy Aries, *The American College of Obstetricians and Gynecologists and the Evolution of Abortion Policy, 1951–1973: The Politics of Science*, 93 Am. J. Pub. Health 1810, 1812 (2003), https://perma.cc/3W8V-NMP4.
[12] ACOG, *Manual of Standards in Obstetric-Gynecologic Practice*, at 35 (1959).
[13] Aries, *supra* note 11, at 1813.

about the mother's "health," considering "the patient's total environment, actual or reasonably foreseeable."[14]

In the 1970s, ACOG filed *amicus* briefs in *Doe v. Bolton* and *Roe v. Wade* announcing that "[a] decision to perform an abortion should be regarded as strictly a medical decision and a medical responsibility."[15] ACOG overruled the objection of a board member, who explained that ACOG had not made any consideration of the relative "rights of a mother" and "the fetus" (and who would help found AAPLOG).[16] ACOG's leadership did not dispute the point, framing the briefs instead as a way for ACOG to attack policies that "could be seen as work restrictions on physicians."[17] "Science" merely provided "the ideological veneer for [ACOG's] political position[s]."[18]

Since *Doe* and *Roe*, ACOG has filed dozens of briefs in abortion-related cases, but *amicus* is unaware of any instance in which ACOG has filed or joined a brief in support of any regulation whatsoever on abortion.[19] Only one explanation exists for this remarkable streak: ideology. That ideology—centrally, ACOG's belief that the preborn child has no significance and that women do not deserve fully informed

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[14] *See id.* at 1814–15.
[15] Brief of ACOG et al. 3, *Roe v. Wade*, No. 70-18, 1971 WL 128053 (U.S. 1971).
[16] Aries, *supra* note 11, at 1817.
[17] *Id.*
[18] *Id.* at 1810.
[19] *See* Brief of *Amicus Curiae* AAPLOG 20–27, *June Medical Services LLC v. Gee*, Nos. 18-1323, 18-1460, 2019 WL 7397763 (U.S. Dec. 27, 2019).

consent about the harms of induced abortion—has nothing to do with scientific evidence, and in fact is contradicted by that evidence.

B. ACOG's ideology drives its abortion advocacy.

Though ACOG leadership's extreme abortion advocacy is out of step with the over 80% of OB-GYNs who do not perform abortions,[20] ACOG is ideologically committed to advancing abortion and does not believe that the child carries any significance until (at least) birth.[21] ACOG's position that the preborn child has no significance is a purely ideological belief unmoored from "evidence-based medicine," science, history, and logic.

The science is clear: at the moment of fertilization, a new, distinct, living human being comes into existence.[22] A preborn child "is alive and possesses its unique DNA."[23] At five weeks' gestation, the preborn child's heart starts beating,

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[20] *See* Brittni Frederiksen, *A National Survey of OBGYNs' Experiences After* Dobbs, KFF (Jun. 21, 2023), https://perma.cc/W432-CVJS.

[21] ACOG, *Statement on "Personhood" Measures* (Nov. 9, 2022), https://perma.cc/9376-B5A4 ("Assigning rights to [unborn children] compromises access to essential facets of medical care."); *cf.* ACOG, *ACOG President Condemns the Passage of 'Born-Alive' Legislation* (Jan. 11, 2023), https://perma.cc/J8J7-7N32 (ACOG opposing born-alive protections).

[22] *See Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 736 (8th Cir. 2008) (en banc).

[23] *Memphis Ctr. for Reprod. Health v. Slatery*, 14 F.4th 409, 450 (6th Cir. 2021) (Thapar, J., concurring in judgment in part and dissenting in part) (citing Enrica Bianchi et al., *Juno Is the Egg Izumo Receptor and Is Essential for Mammalian Fertilization*, 508 Nature 483, 483 (2014)); *see* Doc. 20-21 ¶ 9.

and the heart is fully formed by around nine weeks.[24] By six weeks, brain waves are detectable.[25] By ten weeks, multiple organs begin to function, and the child has the neural circuitry for spinal reflex, an early response to pain.[26] By twelve weeks, the child can open and close fingers and sense stimulation from the outside world.[27] Scientifically, the preborn child meets all the criteria for a living human being.

ACOG's position also has no historical or legal support. "[A]n unbroken tradition of prohibiting abortion" "persisted from the earliest days of the common law until 1973." *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 250 (2022). Even *Roe v. Wade* recognized that the State's "important and legitimate interest in protecting the potentiality of human life" becomes "compelling" later in pregnancy. 410 U.S. 113, 162 (1973).

ACOG's position has no logical or popular support. There is no sound reason to view the humanity of a 28-week-old child in utero differently from a child born at the same time. Location or dependency are not markers of humanity. And

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[24] See Keith L. Moore et al., *The Developing Human E-Book: Clinically Oriented Embryology* 8945, 2662 (Kindle ed. 2020).
[25] Thomas W. Sadler, *Langman's Medical Embryology* 72 (14th ed. 2019); *see generally id.* at 59–95.
[26] *See* Johns Hopkins Med., *The First Trimester*, https://perma.cc/8N6H-M6CN; Carlo V. Bellieni & Giuseppe Buonocore, *Is Fetal Pain a Real Evidence?*, 25 J. Maternal-Fetal & Neonatal Med. 1203, 1203–08 (2012); Richard Rokyta, *Fetal Pain*, 29 Neuroendocrinology Letters 807, 807–14 (2008).
[27] *See* Cleveland Clinic, *Overview* (Mar. 19, 2024), https://perma.cc/9YB5-ZFFG.

ACOG's position is far outside the mainstream: Gallup found that 70% of Americans think third-trimester abortions generally should be illegal.[28]

Last, ACOG's position is barbaric. Late-term abortions generally involve "dismember[ment]" "limb from limb" of a viable human child who can feel pain, until the child "bleeds to death." *Stenberg v. Carhart*, 530 U.S. 914, 958–59 (2000) (Kennedy, J., dissenting). Despite updated scientific evidence of the presence of fetal pain capability by 12 weeks,[29] ACOG continues to deny the existence of fetal pain until "after at least 24–25 weeks"[30]—again ignoring medical knowledge for the purpose of advancing its pro-abortion agenda. And, of course, ACOG supports abortions long after even *it* recognizes that preborn children feel pain.

In short, ACOG has a metaphysical, unscientific, and ideological belief that preborn life is less than human and deserves no protection at any point.

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[28] Gallup, *Where Do Americans Stand on Abortion?* (July 7, 2023), https://perma.cc/HV96-U5JN; *cf. Thornburgh v. Am. Coll. of Obstetricians & Gynecologists*, 476 U.S. 747, 778 (1986) (Stevens, J., concurring) ("I should think it obvious that the State's interest in the protection of an embryo . . . increases progressively and dramatically as the organism's capacity to feel pain, to experience pleasure, to survive, and to react to its surroundings increases day by day.").

[29] Stuart W. G. Derbyshire et al., *Reconsidering Fetal Pain*, 46 J. Med. Ethics 3 (2020).

[30] ACOG, *Facts Are Important: Gestational Development and Capacity for Pain*, https://perma.cc/G9P2-CLY6.

C. ACOG's guidelines and statements are suffused with ideology, not evidence.

ACOG's guidelines and policy statements confirm that ideology is its guiding star on abortion.

A comprehensive study found "that only a third of the recommendations put forth by [ACOG's] practice bulletins are based on high-quality, consistent scientific evidence."[31] Most were "based on limited or inconsistent evidence" or even less—"consensus and expert opinion."[32] And only 28% of ACOG's recommendations mirrored those of Britain's Royal College of Obstetricians and Gynaecologists.[33] As this study explained, "[m]any experts have pointed out the problems that arise when guidelines rely on expert opinion that is subject to bias."[34] ACOG's abortion drug bulletin was written by an ACOG committee "in collaboration with Mitchell D. Creinin, MD, and Daniel A. Grossman, MD"—two abortionists who believe that "[p]hysicians need to be activists" about abortion.[35] ACOG's relevant abortion "practice bulletins," including on medication and second-trimester abortions, do not

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[31] Jason D. Wright et al., *Scientific Evidence Underlying the American College of Obstetricians and Gynecologists' Practice Bulletins*, 118(3) Obstetrics & Gynecology 505, 509 (2011), https://perma.cc/7RUY-W44R.
[32] *Id.*
[33] *Id.* at 511.
[34] *Id.*
[35] ACOG, *Medication Abortion*, *supra* note 6; Physicians for Reproductive Health, *Mitchell Creinin* (Apr. 25, 2020), https://perma.cc/4EDR-6FP6.

claim to constitute systematic reviews.[36] As ACOG agrees, systematic reviews are atop "the hierarchy of evidence,"[37] for they "offer complete insights" on the available literature, "minimiz[ing] bias."[38] But its abortion practice bulletins, including the one about abortion drugs, are drafted *without* such a review.

ACOG cannot even be trusted to accurately convey basic facts about fetal development. For years, ACOG told courts that "a fetal heartbeat exists only after the chambers of the heart have developed and can be detected via ultrasound, which typically occurs around 17 to 20 weeks' gestation."[39] But ACOG was egregiously wrong. The heart's chambers are formed *and* can be viewed *long* before 17 to 20 weeks. "The 4 chambers form by the end of week 7,"[40] and the "fetal heart is already fully developed by 9 1/7 weeks gestation."[41] A recent study found that a four-chambered heart could be identified in 80% of women by week 10.[42]

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[36] *See* ACOG, *Medication Abortion*, *supra* note 6; ACOG, *Second-Trimester Abortion*, https://perma.cc/5LWK-QJTK.
[37] ACOG, *Clinical Practice Guideline Methodology* (Sept. 2021), https://perma.cc/ZB88-FBGM.
[38] Arvind Vatkar et al., *Understanding the Levels of Evidence in Medical Research*, 15(5) J. Orthopaedic Case Reports 6, 7 (2025), https://perma.cc/Z4KR-4DW6.
[39] *E.g.*, Brief, *supra* note 5, at 22–23.
[40] Cheryl Tan & Adam Lewandowski, *The Transitional Heart: From Early Embryonic and Fetal Development to Neonatal Life*, 47 Fetal Diagnosis & Therapy 373, 376 (2020).
[41] Katherine Bishop et al., *Ultrasound Examination of the Fetal Heart*, 72 Obstetrical & Gynecological Survey 54, 59 (2017).
[42] Darren Hutchinson, *First-Trimester Fetal Echocardiography*, 30 J. Am. Soc'y Echocardiography 763, 763, 766–67 (2017).

There is no scientific dispute on this point—nor was there ever. ACOG just repeated medically incorrect facts to further its ideological position on abortion. ACOG *knows* it was wrong—that's why it eventually deleted its grossly inaccurate claim from its Abortion Guide.[43] But it never admitted or took responsibility for misleading courts and policymakers.

In abortion drug litigation, ACOG files *amicus* briefs boasting of its purported "deep expertise in medical research," trumpeting that "[c]ourts frequently rely on *amici*'s medical and scientific expertise in cases involving pregnancy."[44] Incredibly, ACOG supports this claim by citing the exact page of a South Carolina Supreme Court opinion that relied on ACOG's false claim about fetal heart development.[45]

Nor is this some isolated incident. ACOG has long tailored its supposed scientific policy statements to its ideological agenda. In striking down Nebraska's partial-birth abortion regulation in 2000, the Supreme Court relied on language that "purported to come from a 'select panel'" of ACOG stating that partial-birth abortion "may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman."[46] *See Stenberg*, 530 U.S. at 932, 935–

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[43] *Compare ACOG Guide to Language and Abortion*, WebArchive (Sept. 21, 2023), https://bit.ly/46mueoN, *with ACOG Guide to Language and Abortion*, https://perma.cc/44VW-3JBL (as of Jan. 22, 2026).
[44] ACOG Brief 6; *see* Doc. 224, at 2.
[45] ACOG Brief 6 n.2; *see* Doc. 224, at 2 n.2.
[46] Shannen W. Coffin, *Kagan's Abortion Distortion*, Nat'l Rev. (June 29, 2010), https://perma.cc/5H6N-MASN.

36. Lower courts likewise parroted the statement, deferring to it because it was supposedly produced by "expert medical professionals."[47]

"The problem is that the critical language of the ACOG statement was not drafted by scientists and doctors."[48] "Rather, it was inserted into ACOG's policy statement at the suggestion of" a Clinton White House policy advisor concerned that the original statement—that ACOG's panel "could identify no circumstances under which this procedure . . . would be the only option to save the life or preserve the health of the woman"—"would be a disaster."[49] So the advisor "drafted the critical language" changing ACOG's position, and ACOG's executive board dutifully copied the language "into its final statement"—where it became Science not subject to dispute.[50]

In sum, ACOG's guidelines and policy statements on politically charged issues like abortion are tethered to ideology, not science.

D. ACOG's abortion ideology infects its views here.

All this brings us to the issue here: abortion drugs. ACOG's practice bulletin on these drugs is not based on a rigorous review of the evidence, but on the ideology of an ACOG committee and two abortionists—at least one of whom has financial

[47] *Id.*
[48] *Id.*
[49] *Id.*
[50] *Id.*

ties to the manufacturer of mifepristone that were not disclosed in the bulletin.[51] By its own account, most of ACOG's recommendations here are *not* "based on good and consistent scientific evidence."[52] Yet ACOG insists that abortion drugs are "safe and effective."[53] That is wrong.

First, when ACOG proclaims the "safety" of abortion drugs, it is subordinating any interest in fetal or maternal health to its extreme abortion beliefs. Physicians providing obstetric care to pregnant women are in fact caring for *two* patients. Abortion drugs are not only harmful for mothers, as the Plaintiffs show, but they are in no sense "safe" for the preborn child—a life recognized by the laws of Louisiana and many other States. *See* La. Stat. Ann. § 40:1061.1(A)(1); *cf.* 18 U.S.C. § 1841. Those drugs are intended to—and usually do—end that life. ACOG's prior brief on this issue to the Supreme Court managed to run thousands of words without a single apparent reference to the preborn child.[54]

Second, ACOG's sweeping claims about the safety of FDA's relaxed REMS for abortion drugs are unsupported by evidence—and often contradicted by ACOG's own out-of-court statements. For instance, ACOG told the Supreme Court (and the district court here) that "[f]or prescription of mifepristone for use in medication

[51] See ACOG, *Mitchell D. Creinin*, https://perma.cc/KE42-RD57.
[52] *Medication Abortion*, *supra* note 6.
[53] *Id.*
[54] *See* ACOG Brief.

abortion or early pregnancy loss, telehealth protocols offer the same protections as in-person dispensing and provide an equivalent level of care."[55] Putting aside the obvious falsity of this statement—anyone with passing familiarity with Zoom knows it is not "equivalent" to in-person interaction—it is contradicted by ACOG's own bulletin. Though that bulletin is itself an ideological document unmoored from a rigorous evidentiary review, even it concedes that the "scientific evidence" for the proposition that "[m]edication abortion can be provided safely and effectively by telemedicine" is "limited or inconsistent."[56] That evidentiary deficiency is no technical fault: it means that the true relationship between drug-induced abortion without an in-person evaluation and safety/efficacy may be the opposite of what ACOG claims.[57]

One example: a Zoom call would not enable the abortionist to diagnose an ectopic pregnancy (if such an interaction even occurs, which it often doesn't per Dr. Francis's recent experience), which would make prescription of the abortion drugs even more dangerous to the mother. ACOG's own bulletin acknowledges this danger but seems to dismiss it by suggesting that only patients with "a medical history of ectopic pregnancy" or "medical risk factors" "should have pretreatment clinical

[55] *Id.* at 23; *see* Doc. 224, at 11.
[56] *Medication Abortion*, *supra* note 6.
[57] *Cf.* Howard Balshem et al., *GRADE Guidelines*, 64 J. Clinical Epidemiol. 401, 404 (2011), https://perma.cc/2KDY-6BW5; *contra* Doc. 170-1, at 1 n.1 (ACOG dismissing this language as "industry" jargon).

evaluation, which may include ultrasonography."[58] Yet ACOG's bulletin on ectopic pregnancies explains that "[o]ne half of all women who receive a diagnosis of an ectopic pregnancy do not have any known risk factors."[59] And ectopic pregnancies comprise 2% of all pregnancies,[60] disproportionately affecting people of color.[61]

In the district court, ACOG argued that "no-test telehealth abortion . . . sometimes facilitates earlier detection and treatment of ectopic pregnancy."[62] That notion is facially implausible; the whole point of telehealth abortion is that there is no in-person interaction or test, which is necessary to detect ectopic pregnancy. ACOG's only support was an article recounting interviews with 15 women who all sought telehealth abortion.[63] Nearly a third of interviewees "experienced excruciating or 'dull' abdominal pain" after taking the abortion drug—requiring further interventions.[64] Yet ACOG uses this article to gloss over ectopic pregnancy. Even worse, ACOG supports dispensing abortion drugs online without even a "telehealth" visit or any interaction or review by a medical professional at

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[58] ACOG, *Medication Abortion*, *supra* note 6.
[59] ACOG, *Tubal Ectopic Pregnancy*, at 91, https://perma.cc/HW5J-WSQF; *see* Doc. 20-21 ¶ 23.
[60] *Tubal Ectopic Pregnancy*, *supra* note 59, at 91.
[61] *See, e.g.*, Tina Raine-Bennett et al., *Disparities in the Incidence of Ectopic Pregnancy in a Large Health Care System in California, 2010–2019*, 26(3) Permanente J. 61 (2022), https://perma.cc/45B6-QTP5.
[62] Doc. 224, at 13–14.
[63] MA Biggs et al., *Experiences of Ectopic Pregnancy Among People Seeking Telehealth Abortion Care*, 134 Contraception 110405 (2024).
[64] *Id.*

all.[65] The current lack of an in-person dispensing requirement has led to nearly all "telehealth" mifepristone abortions being self-managed, as meaningful evaluation by a medical professional is rarely occurring.

Likewise, ACOG sweeps away the problem that under a telehealth regime, women are highly likely to take the abortion pill regime later than the ten-week gestational age cutoff that the FDA has approved. ACOG suggests that "evidence has shown that a patient's certain last menstrual period [LMP] when within the prior 56 to 63 days is accurate."[66] But once again, ACOG's own statement on gestational age—reaffirmed in 2025—is to the contrary, explaining that only "approximately one half of women accurately recall their LMP."[67] And the FDA has limited the abortion regime to under ten weeks for good reasons: drug-induced abortions after that have much higher rates of surgical intervention and other complications.[68]

The point is that an honest broker of scientific evidence would admit (at minimum) that it could not determine on the available evidence whether drug-induced abortion via telehealth is safe. But ACOG is not such a broker. Presumably

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[65] ACOG, *Self-Managed Abortion*, https://perma.cc/L7KB-AJQ4.
[66] *Medication Abortion*, *supra* note 6.
[67] ACOG, *Methods for Estimating the Due Date*, at 2, https://perma.cc/EL97-LK3S.
[68] *See, e.g.*, Maarit J. Mentula et al., *Immediate Adverse Events after Second Trimester Medical Termination of Pregnancy*, 26(4) Human Reproduction 927 (2011).

that's why ACOG's brief below failed to muster any meaningful response to AAPLOG.[69]

II. FDA's cited studies do not support the safety of telemedicine abortions.

FDA relied primarily on five studies to "support dispensing mifepristone and misoprostol by mail after a telemedicine visit": Raymond 2019, Chong 2021, Anger 2021, Kerestes 2021, and Aiken 2021.[70] The drug manufacturers rely on them, too. But these studies offer scant support; if anything, they confirm that remote abortions are more dangerous.

Before getting to the studies' details, consider what the FDA ignored: the shared origin of most of these studies in Gynuity Health Projects, which describes itself as "at the forefront of efforts to increase women's access to medication abortion."[71] Three of the studies (Raymond, Chong, and Anger) were based on work sponsored by Gynuity.[72] Six co-authors of Raymond were Gynuity affiliates,[73] as

[69] *See* Doc. 224 at 1 n.1.
[70] Doc. 1-50, at 69–75 (ECF page numbers).
[71] Gynuity Health Projects, *Medication Abortion*, https://perma.cc/6R6S-6MM9.
[72] Doc. 1-50, at 69–70.
[73] Elizabeth Raymond et al., *TelAbortion: Evolution of a Direct to Patient Telemedicine Abortion Service in the United States*, 100 Contraception 173 (2019).

were six of Chong's co-authors[74] and five of Anger's co-authors.[75] The fourth study, Kerestes, was also partially based on Gynuity; 71 of 75 participants who received mailed drugs were from the Gynuity study.[76]

Gynuity's founder and president, Beverly Winikoff—also a co-author on all three of the Gynuity-based studies—was previously "employed for 25 years at the Population Council where she was Director for Reproductive Health."[77] The Population Council boasts how it "developed and secured [FDA] approval" for abortion drugs during Winikoff's time.[78] In 1994, a French pharmaceutical company donated rights for medical uses of mifepristone in the United States to the Population Council,[79] which sublicensed mifepristone to Danco, a new company incorporated in the Cayman Islands.[80] In 2000, Danco received approval from the FDA to

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[74] Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience during the COVID-19 Pandemic*, 104 Contraception 43 (2021).
[75] Holly A. Anger et al., *Clinical and Service Delivery Implications of Omitting Ultrasound before Medication Abortion Provided via Direct-to-Patient Telemedicine and Mail in the U.S.*, 104 Contraception 659 (2021).
[76] Doc. 1-50, at 70; *see* Courtney Kerestes et al., *Provision of Medication Abortion in Hawai'i during COVID-19: Practical Experience with Multiple Care Delivery Models*, 104 Contraception 49 (2021).
[77] Gynuity Health Projects, *Staff*, https://perma.cc/JQ4Y-C926.
[78] Julia Bunting, *Reaffirming Our Resolve to Uphold Global Reproductive Rights*, Population Council (May 17, 2022), https://perma.cc/92F4-RWLK.
[79] Katharine Q. Seelye, *Accord Opens Way for Abortion Pill in U.S. in 2 Years*, N.Y. Times (May 17, 1994), at A1.
[80] *Abortion Pill Maker Revealed*, CBS News (Oct. 13, 2000), https://perma.cc/5L3Q-EQLZ.

distribute it.[81] Danco has said that it is dependent on the mifepristone abortion pill for all its revenue.[82] While at the Population Council during the 1980s and 1990s, Winikoff was meeting with the FDA to push for mifepristone's approval with minimal restrictions.[83]

Fast forward to 2015, when Winikoff (now at Gynuity) convened the "Coalition to Improve Access to Mifepristone" with Planned Parenthood, NARAL, and others.[84] The Coalition urged Danco "to petition the FDA to modify the Mifeprex label" and loosen its prescription regime, but "Danco said they didn't have the funds to file a supplemental NDA to make the change."[85] So the Coalition "agreed to help Danco raise" funds for the application via foundations that continue to fund Gynuity and other "groups advocating for medication abortion."[86]

The links between Gynuity and Danco reveal especially problematic conflicts when it comes to studies cheerleading medication abortion: Danco has funded Ibis

[81] Gina Kolata, *U.S. Approves Abortion Pill*, N.Y. Times, Sept. 29, 2000, at A1.
[82] Intervenor Danco Laboratories, LLC's Memorandum in Opposition to Plaintiffs' Motion for a Preliminary Injunction at 1–2, 25, *Alliance for Hippocratic Med. v. FDA*, No. 22-cv-223, 2023 WL 2974521 (N.D. Tex. Feb. 10, 2023).
[83] Michelle La Mothe, *A 20-Year Journey: The History of the Abortion Pill*, Free Republic (Feb. 9, 2006), https://perma.cc/W7PC-4B5P.
[84] Carrie N. Baker, *Abortion Pills: US History and Politics* 79 (2024).
[85] *Id.*
[86] *Id.* at 79, 216.

Reproductive Health, which funds Gynuity—which churns out studies purportedly supporting Danco's drug.[87] But none of the studies discloses such a conflict.

Not only were the primary studies that the FDA relied on run by organizations and individuals invested in the abortion drug industry, but the studies do not support FDA's action. To begin, none of the five studies performed a controlled comparison between prescribing mifepristone via the existing regime and mifepristone fully via telemedicine and mail. Without this critical comparison, it is impossible for any of these studies to provide sound evidence about the relative safety or efficacy of fully remote abortions. Plus, two studies were purely descriptive and had no control group at all. "[D]escriptive studies, which do not have a comparison group, do not allow assessment of associations."[88] The other three had non-randomized control groups (generally involving different dosages and gestational ages) that still were never compared to a fully remote group. As Judge Posner put it, "a statistical study that fails to correct for salient explanatory variables, or even to make the most elementary comparisons, has no value as causal explanation." *People Who Care v. Rockford Bd. of Educ., Sch. Dist. No. 205*, 111 F.3d 528, 537 (7th Cir. 1997). Because these studies did not conduct a relevant comparison even to the limited extent they tried to control

[87] *See, e.g.*, Ibis Reproductive Health, *Funders*, https://bit.ly/3Oiv5Rc (Oct. 3, 2018); Gynuity Health Projects, *Funders*, https://bit.ly/3NVcxGH (Mar. 3, 2020).
[88] David A. Grimes, *An Overview of Clinical Research*, 359 Lancet 57, 58 (2002).

for any variables, they are among the weakest forms of evidence and cannot show relative safety or efficacy. FDA glossed over this core deficiency.

Turning to the specific studies, though Raymond purported to evaluate the safety "of a direct-to-patient telemedicine service that enabled people to obtain medical abortion without visiting an abortion provider in person," the study required initial tests at in-person facilities.[89] Each participant "had pre-treatment laboratory tests and ultrasound," with the package containing abortion drugs mailed only if the mother was determined to be eligible after the in-person tests.[90] Likewise, participants in Chong "obtained any needed preabortion tests locally" before being sent the study packages.[91] Describing the project that was the basis for Raymond, Chong, and Anger, Gynuity states that women "obtain screening tests at facilities close to them," then have "post-abortion tests at facilities close to [them]."[92] Thus, none of these studies examined the fully remote provision of abortion drugs—what the FDA authorized.

Further, even though Raymond and Chong had more in-person safeguards than the FDA now requires, the results of this partially-remote distribution of mifepristone were troubling. Raymond reported that outcomes were unknown for

[89] Raymond, *supra* note 73, at 173.
[90] *Id.* (emphasis added).
[91] Chong, *supra* note 74, at 43.
[92] Gynuity Health Projects, *Medication Abortion*, *supra* note 71.

23% of the participants.[93] And "[o]f the 217[] package recipients who provided meaningful follow-up data[], one was hospitalized for postoperative seizure and another for excessive bleeding, and 27 had other unscheduled clinical encounters, 12 of which resulted in no treatment."[94] Thus, even excluding the twelve whose unscheduled clinical encounters did not result in treatment, almost 8% of study participants (17/217) required in-person follow-up treatment. Even FDA conceded that required follow-up emergency care in this study was about *double* that in the existing labeling for mifepristone.[95]

Chong—which included the patients from Raymond—reported similar findings of increased emergency visits: "[t]here were seventy unplanned visits (6%) to emergency rooms or urgent care centers for reasons related to the abortion," and "[t]en serious adverse events (SAEs) occurred, including five transfusions (0.4%)."[96] Though the study asserted that the adverse events were not attributable to telemedicine, this does not account for the other emergency room visits, or the further 92 (7.8%) "[o]ther outpatient visit[s]" that are reported in the study's results tables.[97] And Chong likely underestimated adverse events because of high loss of

[93] Raymond, *supra* note 73, at 176.
[94] *Id.* at 173.
[95] Doc. 1-50, at 29.
[96] Chong, *supra* note 74, at 46.
[97] *Id.* at 45.

patients before follow-up (13%) and exclusion of certain adverse events.[98] Chong also underscores the lack of controls in the Gynuity studies, as their sample was "more educated, and more likely to identify as white" than the population of "people obtaining abortions"—and reported a 0% ectopic pregnancy rate, compared to the 2% population rate.[99]

Before moving on from Chong, the mismatch between that article's data and its conclusions is striking. Chong engaged in no statistical analysis. It engaged in no comparative analysis of telemedicine versus in-person medication abortions. And though (by its own account) "FDA required that our protocol retain the screening ultrasound requirement,"[100] the study skipped that requirement for a quarter of participants—without reporting comparative outcomes for this cohort. So the study is incapable of providing *any* statistical proof. Yet Chong made sweeping assertions about its findings, claiming to show that "[m]edical abortion using telemedicine" "can be safely provided without a pretreatment ultrasound."[101] Again, the study reported no comparisons between *either* telemedicine/in-person abortions *or* ultrasound/no-ultrasound telemedicine abortions, much less controlled for any rele-

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[98] *See id.* at 48; *compare id.* at 45, *with* FDA, *What is a Serious Adverse Event?*, https://perma.cc/2VCW-4BZU (showing that Chong used a more limited definition of "serious adverse event" than FDA does).
[99] Chong, *supra* note 74, at 46, 48.
[100] *Id.* at 46.
[101] *Id.* at 43.

vant variable. But the study's concluding sentence announced that "our data *disprove*[*s*] the notion that medication abortion pills must be dispensed in-person."[102] This absurd claim—from a study with no comparisons, no controls, no randomization, an unrepresentative sample, and an intentional disregard of the required study protocol—confirms the unreliability of the Gynuity studies.

The next study, Anger, tried to use Gynuity's departure from their own research protocol—skipping ultrasounds or pelvic exams for some patients—to compare outcomes for participants who had a pre-abortion ultrasound or pelvic exam and those who did not.[103] But as the study conceded, "patients were not randomized [into these two groups] and the two groups differed on factors that may affect outcomes."[104] If anything, the study again provides evidence *against* abandoning in-person testing. According to the study, the likelihood that "[a]bortion was not complete with pills alone" was "significantly higher" for patients in the no-test group.[105] Concerningly, "[t]he proportion of participants who had unplanned clinical encounters after treatment was" also "significantly higher" in the no-test group.[106] Despite these statistically significant negative results, the Gynuity authors announced that "[o]verall, our results support the continued use of no-test

[102] *Id.* at 48 (emphasis added).
[103] Anger, *supra* note 75, at 2.
[104] *Id.* at 6.
[105] *Id.* at 3.
[106] *Id.*

[medication abortion]."[107] Inexplicably, even though the prior Gynuity studies had reported and tried to justify rates of emergency follow-up, Anger chose not to even report the "number of ED/urgent care visits" after abortion.[108]

Next, Kerestes provided observations about different groups, but failed to conduct any statistical analysis or control for any variables. By its own account, its sample sizes were so small that the study was too "underpowered" to generate results of statistical significance.[109] Kerestes purported to divide patients into three groups: one had telemedicine with in-person pickup of the abortion drugs, another had telemedicine with abortion drugs mailed, and the third had traditional in-person visits. But 71 out of 75 in the group central to the FDA's actions—the second one, with purportedly no clinical interactions at all—actually *had* a pre-abortion ultrasound, because they were patients reused from the Gynuity studies who "were required to have an ultrasound or pelvic examination performed before being mailed medications."[110] So the study provided practically no information on the critical question before the FDA. And once again, if anything the results counsel against the FDA's actions, as they show that the rates of emergency room visits for abortion-

[107] *Id.* at 6.
[108] Doc. 1-50, at 72.
[109] Kerestes, *supra* note 76, at 53.
[110] *Id.* at 50–51.

related concerns were almost twice as high for the pickup group compared to the in-clinic group, and approaching three times as high for the mail group.[111]

Last, FDA itself declined to put much reliance on Aiken because its "design did not capture all serious safety outcomes, thus limiting the certainty of the findings."[112] (None of the studies did, in fact.) Not only did Aiken fail to report basic outcomes like hospitalizations related to abortion and emergency-room visits, but all the groups it compared included patients who had in-person dispensing—meaning that the study is incapable of offering comparisons relevant to FDA's action.[113] So while FDA dismissed Aiken on the ground that "the study's design did not capture all serious safety outcomes," it should have also dismissed its findings on efficacy because the study did not have any relevant comparison.[114] Further, Aiken was "unable actively to follow up patients after their abortion," depriving the study of relevant outcome data.[115]

The FDA concluded that "[t]aken together, the three Gynuity study reports and Kerestes support dispensing mifepristone and misoprostol by mail after a

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[111] *Id.*
[112] Doc. 1-50, at 73–75.
[113] *Id.* at 74 ("Outcomes stratified by type of mifepristone dispensing were not reported.").
[114] *Id.* at 75.
[115] Abigail R.A. Aiken, *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided via Telemedicine*, 128 BJOG 1464, 1471 (2021).

telemedicine visit" as "safe and effective."[116] This conclusion makes little sense: none of these studies even *tried* to examine wholly remote abortion pill prescription, much less examine that issue in a controlled, statistically rigorous way. To the extent these studies offered any observations of relevance, they consistently found that follow-up emergency medical care was far more likely in telemedicine abortions.

CONCLUSION

For these reasons, the Court should grant a stay against the 2023 REMS.

Respectfully submitted,

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[116] Doc. 1-50, at 73, 75.

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/s Christopher Mills
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