Nos. 23-235, 23-236

IN THE

Supreme Court of the United States

U.S. FOOD & DRUG ADMINISTRATION, ET AL.,

Petitioners,

—v.—

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,

Respondents.

DANCO LABORATORIES, L.L.C.,

Petitioner,

—v.—

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,

Respondents.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF OF *AMICI CURIAE* AMERICAN CIVIL LIBERTIES UNION, CENTER FOR REPRODUCTIVE RIGHTS, AND LAWYERING PROJECT IN SUPPORT OF PETITIONERS

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STATEMENT OF INTEREST[1]

The American Civil Liberties Union is a nationwide, non-profit, non-partisan organization dedicated to the principles of liberty and equality embodied in the Constitution and the nation's civil rights laws, including the right of individuals to make their own reproductive decisions.

The Center for Reproductive Rights is a global non-profit human rights organization that works to ensure reproductive rights, including access to abortion, are protected in law as fundamental human rights.

The Lawyering Project, a fiscally sponsored project of Tides Center, is a nonprofit, legal advocacy organization that blends traditional impact litigation with movement lawyering to promote reproductive health, rights, and justice throughout the United States.

Amici have represented clients in numerous cases relating to abortion where the courts examined the scientific integrity of the witnesses and research on which Respondents rely here. Time and again, when courts have had the opportunity to review deposition transcripts or observe cross-examinations of these witnesses, they have found their testimony unworthy of credence. Here, by contrast, the district court "declined to avail itself" of an "adversarial hearing[]" to parse the "conflicting evidence" about medication abortion. *In re Abbott*, 956 F.3d 696, 719 (5th Cir. 2020), *vacated and dismissed as moot sub*

[1] No party or counsel for a party authored this brief in whole or in part, and no one other than amici, their members, and their counsel have paid for the preparation or submission of this brief.

nom., *Planned Parenthood Ctr. for Choice v. Abbott*, 141 S. Ct. 1261 (2021). Instead, both lower courts accepted at face value Respondents' assertions about the purported harms of medication abortion, and then credited those assertions over the scientific judgment of the U.S. Food and Drug Administration ("FDA") based on more than two decades of high-quality research. *Amici* submit this brief to supply this Court with evidence reflecting the lack of credibility of the witnesses and research cited in the decisions below.

SUMMARY OF ARGUMENT

In rejecting the scientific basis for FDA's actions with respect to mifepristone, the lower courts uncritically relied at every stage on patently unreliable witnesses and studies. The courts cited Respondents' witnesses' untested declarations and outlier studies to justify standing, establish irreparable harm, and second-guess FDA's scientific judgment. They did so without any adversarial testing or any even minimally discerning review of their studies. Yet when other courts have engaged directly with the credibility of these same witnesses and studies, they have routinely discredited Respondents' evidence for lack of scientific integrity.

For instance, the court of appeals cited **Dr. Ingrid Skop** seventeen times, including for critical points about mifepristone's safety. But in 2022, Dr. Skop's live testimony on abortion safety was rejected by a court as "inaccurate and overstated."[2] Indeed, Dr.

[2] *Planned Parenthood of Sw. & Cent. Fla. v. State* (*PPSCF*), No. 2022 CA 912, 2022 WL 2436704, at *13 (Fla. Cir. Ct. July 05, 2022), *rev'd on other grounds*, 344 So. 3d 637 (Fla. Dist. Ct. App. 2022), *pet. for review granted*, Nos. SC2022-1127, SC2022-1050 (Fla. Jan. 23, 2023).

Skop admitted in 2020 that she is "not a really good researcher,"[3] and that she routinely "lift[s]" language from other authors without attribution, claiming she "didn't realize that, you know, using wording from a paper that you agreed with qualified as plagiarism."[4] The two articles she highlighted in her declaration as "reflect[ing] [her] research" on medication abortion, J.A.161–62, were published by an advocacy group that advances blatantly false conspiracy theories, such as that former President Barack Obama hypnotized listeners with his speeches.

The court of appeals cited **Dr. Donna Harrison** nine times. Yet numerous courts have discredited her opinions as, *inter alia*, "inaccurate and incomplete,"[5] "generally at odds with solid medical evidence," "exaggerated or distorted," and "shaped primarily by the position she is advocating at the moment."[6] Respondent **Dr. George Delgado** is best known for advancing "an unproven" "theory" of so-called abortion pill reversal that leading medical authorities and courts have rejected because it is "devoid of scientific support."[7] Courts have found that

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[3] Dep. Ingrid Skop, M.D., at 120:25–121:7, *Planned Parenthood Ass'n of Utah v. Miner*, No. 2:19-cv-00238 (D. Utah Sept. 2, 2020) ("Skop Utah Dep."), https://www.aclu.org/documents/FDAvAHM-amicusbriefsources (at 1–9).

[4] *Id.* at 257:20–259:19.

[5] *Planned Parenthood Ark. & E. Okla. v. Jegley*, No. 4:15-cv-00784, 2018 WL 3029104, at *42 (E.D. Ark. June 18, 2018).

[6] *MKB Mgmt. Corp. v. Burdick*, 855 N.W.2d 31, 68 (N.D. 2014) (Kapsner, J., op.).

[7] *Am. Med. Ass'n v. Stenehjem*, 412 F. Supp. 3d 1134, 1150–51 (D.N.D. 2019), *inj. terminated sub nom. Am. Med. Ass'n v.*

his "research has numerous flaws,"[8] and that he opines on topics on which he "lacks significant experience" while also failing to "provide any supporting data for his conclusions."[9]

Many of Respondents' other witnesses are similarly unreliable. **Dr. Nancy Wozniak**'s opinions in support of abortion restrictions have been discounted as "clearly inconsistent with currently accepted medical standards of care," and "not anchored in any referenced medical research or literature or even her own personal experiences."[10] **Dr. Christina Francis**' testimony about abortion restrictions has been dismissed as "contrary to the great weight of current medical evidence."[11]

Dr. Jeffrey Barrows offers broad, citationless opinions about the clinical impact of FDA's 2016 and 2021 actions while obscuring that he has not been in clinical practice since well before 2016. And **Mario Dickerson** is not a doctor at all—his only advanced education is in Theological Studies.

Wrigley, No. 1:19-cv-125, 2023 WL 8866596 (D.N.D. Oct. 18, 2023).

[8] *Planned Parenthood of Tenn. & N. Miss. v. Slatery*, 523 F. Supp. 3d 985, 1003 (M.D. Tenn. 2021).

[9] *S. Bay United Pentecostal Church v. Newsom*, 494 F. Supp. 3d 785, 801–02 (S.D. Cal. 2020), *vacated on other grounds and remanded*, 981 F.3d 765 (9th Cir. 2020).

[10] *Whole Woman's Health All. v. Rokita*, 553 F. Supp. 3d 500, 540, 528 & n.25 (S.D. Ind. 2021), *vacated on other grounds*, No. 21-2480, 2022 WL 26632080 (7th Cir. July 11, 2022).

[11] *Bernard v. Indiv. Members of Ind. Med. Licensing Bd.*, 392 F. Supp. 3d 935, 944–45 (S.D. Ind. 2019), *vacated on other grounds*, No. 1:19-cv-01660, 2022 WL 3009741 (S.D. Ind. July 7, 2022).

Notwithstanding all these reasons for skepticism, the courts below relied on these witnesses' say-so for scientific conclusions central to the courts' legal analysis, crediting their opinions over FDA's expert assessment and the overwhelming medical consensus regarding mifepristone's safety.

The glaringly flawed studies relied on by the courts below—many co-authored by these same unreliable witnesses—provide no greater basis for their decisions. For its theory that serious complications from mifepristone are not captured by the reporting system FDA employs for *all* prescription drugs, the court of appeals relied on a study co-authored by Dr. Harrison, ignoring that the data gaps her study purports to show have nothing to do with serious complications. And the district court went even further—casting aside the rigorous medical evidence underlying FDA's actions in favor of studies that are overtly biased or suffer from "serious methodological flaws,"[12] mischaracterizing research in ways disclaimed by the study authors, and drawing broad generalizations about the impact of abortion from a qualitative analysis of 98 anonymous blogs on the website *abortionchangesyou.com*.

The evidence upon which the lower courts relied cannot survive even passing scrutiny. While the Administrative Procedure Act authorizes judicial review of agency action in limited circumstances, the courts below committed clear error when they displaced FDA's judgment based on junk science.

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[12] *Adams & Boyle, P.C. v. Slatery*, 494 F. Supp. 3d 488, 536–38 (M.D. Tenn. 2020), *rev'd on other grounds sub nom. Bristol Reg'l Women's Ctr., P.C. v. Slatery*, 7 F.4th 478 (6th Cir. 2021).

ARGUMENT

I. Respondents' Witnesses Are Not Credible.

From standing to the merits to irreparable harm, the decisions below turn largely on Respondents' witnesses' assertions, which the lower courts accepted without adversarial testing. But even a minimal examination of the witnesses' declarations, prior testimony, biographical material, and credibility determinations by other courts makes plain the inappropriateness of crediting them over FDA.

A. Dr. Ingrid Skop

No witness features more prominently in the court of appeals' decision than Dr. Ingrid Skop, an obstetrician-gynecologist and member of Respondent American Association of Pro-Life Obstetricians and Gynecologists ("AAPLOG"), who also works at an anti-abortion research organization. J.A.161. The court of appeals cited Dr. Skop seventeen times, highlighting her opinions about the risks of mifepristone and that FDA's actions increased those risks. Pet.App. 20a–25a, 28a, 31a–32a, 34a, 36a–40a; *see also* Pet.App. 122a–23a, 127a, 146a–47a (district court citing Dr. Skop directly and via citations to Respondents' brief). But there are many reasons why the courts should not have credited Dr. Skop.

As an initial matter, her admissions in other cases gravely undermine her credibility. Dr. Skop, who has never held an academic position and did not author a single publication or make a single public presentation between the late 1990s and 2018,[13]

[13] Tr. Bench Trial – Day 2 at 143:25–144:2, *SisterSong Women of Color Reprod. Just. Collective v. State*, 2022 WL 16960560 (Ga.

conceded in 2020 that she is "not a really good researcher."[14] She admitted that she cited the website abort73.com for statistics in an expert report because she could not find any other data source—and that she did so despite not knowing "who created the website" or "who supplies the numbers."[15] She explained that given her "not * * * really good" research skills, "it is possible that [a better source] was easy to find and I just didn't find it."[16]

At the same deposition, Dr. Skop admitted that portions of her recent publications were "lift[ed]" from another author's work.[17] Dr. Skop conceded that *all her publications* might suffer from similar plagiarism,[18] and professed not to know whether "identical republication of material from another author without attribution is consistent with standards of academic integrity."[19] She claimed she

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Sup. Ct. Oct. 25, 2022) (No. 2022-cv-367796), https://www.aclu.org/documents/FDAvAHM-amicusbriefsources (at 10–12); Skop Utah Dep. at 220:7–12.

[14] Skop Utah Dep. at 120:25–121:7.

[15] *Id*. at 120:9–123:9.

[16] *Id.* at 120:25–121:7.

[17] *Id*. at 257:20–258:8 ("I thought that if the ideas were unique that I didn't realize that it was a problem to lift a couple of sentences here and there."); *see also id.* at 245:19–256:17 (admitting portions of her "peer reviewed" articles are "identical" or "nearly identical" to report by witness in separate case).

[18] *Id.* at 258:20–259:4 ("Q: So is it possible that all of your publications include sentences or paragraphs that originated from someone else that are not attributed to them? A. It is possible that is the case.").

[19] *Id.* at 251:18–24.

"didn't realize that, you know, using wording from a paper that you agreed with qualified as plagiarism."[20]

The two "peer-reviewed" articles Dr. Skop highlighted in her declaration were published in an advocacy journal, not a reputable scientific publication. J.A.161. Dr. Skop's testimony on the need for in-person "supervision" was the principal basis for the court of appeals' finding that "supervision is necessary to ensure patients' safety," and thus that FDA's suspension of its in-person dispensing requirement for mifepristone contributed to Respondents' injuries. Pet.App. 38a. But the courts ignored that both of her articles on this topic were published in the journal of the American Association of Physicians and Surgeons—an advocacy group that, among other false stances,[21] has accused former President Barack Obama of "hypnotiz[ing]" listeners with his speeches,[22] and published an article in 2015 arguing that HIV does not cause AIDS.[23]

In 2022, a Florida trial court rejected Dr. Skop's testimony about abortion safety, finding that she:

> admitted that her testimony on the risks of certain abortion complications

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[20] *Id.*

[21] Olga Khazan, *The Opposite of Socialized Medicine*, Atlantic (Feb. 25, 2020), https://perma.cc/EFQ2-XML9 ("fringe views" include that "Medicare is 'evil.'").

[22] Am. Ass'n Physicians & Surgeons, *Oratory – or Hypnotic Induction?* (Oct. 5, 2008), https://perma.cc/9VYS-32D6 ("Obama's logo * * * resembles a crystal ball, a favorite of hypnotists").

[23] Donald W. Miller, J.D., M.D., *Fallacies in Modern Medicine: the HIV/AIDS Hypothesis*, 20 J. Am. Physicians & Surgeons 18 (2015), https://perma.cc/FFM7-ZH7Z.

> was inaccurate and overstated, or based on data from decades ago; admitted that her views on abortion safety are out of step with mainstream medical organizations; and provided no credible scientific basis for her disagreement with recognized high-level medical organizations in the United States.

PPSCF, 2022 WL 2436704, at *13. Just weeks after this ruling, Dr. Skop doubled down on those opinions, submitting very similar testimony in Georgia without correcting critical omissions brought to her attention in the Florida litigation.[24]

Testimony from a witness who has recently admitted under oath that she has shoddy research

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[24] *Compare* Resp. Mot. Interloc. Inj. & TRO, Ex. A, Aff. Ingrid Skop, M.D., ¶ 27, *SisterSong Women of Color Reprod. Just. Collective v. State*, No. 2022CV367796 (Ga. Sup. Ct. Aug. 3, 2022), https://www.aclu.org/documents/FDAvAHM-amicusbrief sources (at 13–16) (criticizing U.S. Centers for Disease Control and Prevention ("CDC') abortion data "because most of their data is obtained from maternal death certificates, and maternal death certificates are often incomplete"), *with* Dep. Ingrid Skop, M.D., at 175:12–178:25, *PPSCF*, 2022 WL 2436704 (Fla. Cir. Ct. June 27, 2022) (No. 2022 CA 00912), https://www.aclu.org/documents/FDAvAHM-amicusbriefsources (at 17–26) (acknowledging that CDC also identifies potential abortion-related deaths through "media reports" and "reports by public health agencies, state-based maternal mortality review committees, professional organizations, healthcare providers, and individuals"); *and id.* at 191:2–195:25 (acknowledging that "for all potential abortion-related deaths," an "in-depth investigation [is] conducted" in which "two clinically trained CDC epidemiologists separately review" "medical records and autopsy reports").

skills, that she provided "inaccurate and overstated" opinions about abortion harms, *PPSCF*, 2022 WL 2436704, at *13, and that she engages in pervasive plagiarism, does not provide a credible basis either to supplant FDA's scientific judgment and the medical consensus as to mifepristone's safety, or to support Respondents' tenuous theories of standing. Yet the courts below relied on Dr. Skop's untested declaration for precisely those ends. *See, e.g.*, Pet.App. 38a (quoting her testimony that "FDA's actions harm women, including my patients," because abortion providers "often underprepare women for the severity and risks" of mifepristone"), Pet.App. 23a (quoting her testimony about the "dangers of taking mifepristone" as an "example[] of medical cases that occur across the county [sic] * * * not just to the declarants, [Respondents] say, but to all of the Organizations' members who are doctors"), Pet.App. 34a (citing Dr. Skop for the proposition that "FDA's actions cause women to present at the emergency room with complications that involve a unique level of trauma and distress"); *see also* Pet.App. 123a (district court quoting Dr. Skop's testimony that abortion patients "often present to overwhelmed emergency rooms in their distress, where they are usually cared for by physicians other than the abortion prescriber").

B. Dr. Donna Harrison

The court of appeals cited Dr. Donna Harrison, President of Respondent Alliance for Hippocratic Medicine and the immediate past-CEO of Respondent AAPLOG, nine times. J.A.126, 152; Pet.App. 23a, 25a, 31a, 37a–38a, 60a. The court relied on Dr. Harrison for key facts about the risks of mifepristone, the impact of FDA's 2016 and 2021 actions, the adequacy of the FDA Adverse Event Reporting System

("FAERS"), and for Respondents' standing. Pet.App. 25a, 31a, 37a–38a, 60a; *see also* Pet.App. 119a, 127a, 146a–47a (district court citing Dr. Harrison directly and via citations to Respondents' brief).

Yet courts across the country have discredited Dr. Harrison's testimony on abortion, finding her expert opinions inaccurate, unsupported by research, and distorted to serve her ideological goals. *See Little Rock Fam. Plan. Servs. v. Rutledge*, 397 F. Supp. 3d 1213, 1268, 1273, 1282 (E.D. Ark. 2019) (finding that the articles Dr. Harrison cited in her declaration "d[id] not support" her assertions), *aff'd in part, vacated in part*, 984 F.3d 682 (8th Cir. 2021), *vacated and remanded*, 142 S. Ct. 2894 (2022); *Jegley*, 2018 WL 3029104, at *42 (rejecting Dr. Harrison's testimony on complications of medication abortion as "inaccurate and incomplete"); *Planned Parenthood Ark. & E. Okla. v. Jegley*, No. 4:15-cv-00784, 2016 WL 6211310, at *22 (E.D. Ark. Mar. 14, 2016) (finding that Dr. Harrison's "statements [we]re contradicted and disputed by record evidence" and the "studies [she] cite[d], for a variety of reasons, d[id] not support her position"), *vacated and remanded on other grounds*, 864 F.3d 953 (8th Cir. 2017); Order Granting in Part & Denying in Part Pls.' Mot. Strike Third. Aff. Donna Harrison, M.D., & Mot. Strike Fourth Aff. Donna Harrison, M.D. 2, *Okla. Coal. for Reprod. Just. v. Cline*, No. CV-2014-1886 (Dist. Ct. Okla. Cnty. Sept. 6, 2017) (striking 22 paragraphs from Dr. Harrison's declaration in support of medication abortion regulations);[25] *MKB Mgmt. Corp.*, 855 N.W.2d at 68 (Kapsner, J., op.) ("Dr. Harrison's opinions have shifted dramatically over time, and appear to be shaped primarily by the

[25] https://www.aclu.org/documents/FDAvAHM-amicusbrief sources (at 27–30).

position she is advocating at the moment."); *id.* (her opinions "lack scientific support, tend to be based on unsubstantiated concerns, and are generally at odds with solid medical evidence. To the extent she referenced published studies during her testimony, Dr. Harrison tended to present the results in an exaggerated or distorted manner"); *MKB Mgmt. Corp. v. Burdick*, No. 09-2011-cv-02205, 2012 WL 1360641 (N.D. Dist. Ct. Feb. 16, 2012) (prohibiting Dr. Harrison from testifying regarding "the regulatory role played by the FDA, the process that led to the approval of mifepristone or Mifeprex, or the legal effect of any of this").

Nor can Dr. Harrison defend her heavily criticized research skills with claims of relevant clinical expertise. While she is an obstetrician-gynecologist, Dr. Harrison has not practiced medicine in nearly a quarter century. *See Rutledge*, 397 F. Supp. 3d at 1256, 1306. Her final year of practice was 2000, the year mifepristone was first approved.[26] That did not stop her from opining in this case: "*In my experience*, many patients do not fully understand the nature of chemical abortion or the risks that these drugs present to them," which "results in an increase in the frequency of women seeking emergency medical care." J.A.132 (emphasis added).

Despite her lack of scientific rigor or relevant experience, Dr. Harrison's opinions played an integral role in the decisions below. The court of appeals relied upon Dr. Harrison to support its strained theories of

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[26] Donna Harrison, M.D., Curriculum Vitae, *All-Options, Inc. v. Att'y Gen. of Ind.*, No. 1:21-cv-1231 (S.D. Ind. June 14, 2021), ECF No. 57-5, https://www.aclu.org/documents/FDAvAHM-amicusbriefsources (at 31–33).

injury and traceability, including that FDA's 2016 actions put Respondents' members "at increased risk of being forced to violate their conscience rights," Pet.App. 37a, that FDA's 2021 action "harms women and obstetrics professionals," Pet.App. 38a–39a, and that complications from mifepristone "require significantly more time and attention from providers than the typical OB/Gyn patient requires," Pet.App. 25a; *accord* Pet.App. 31a. The court also relied upon Dr. Harrison's testimony that "[m]any doctors likely do not know about the need to report adverse events related to chemical abortion to the FDA" and "many doctors likely do not know how to report adverse events," Pet.App. 60a—treating this unsupported speculation from someone who has not practiced medicine since the turn of the century as crucial evidence that the reporting system FDA uses for all prescription drugs is deficient. *See* Br. Fed. Pet'rs 43.

C. Dr. George Delgado

Respondent Dr. George Delgado is a family medicine physician who has devoted his career to a scientifically unproven and widely discredited protocol to "reverse" a medication abortion. The courts below relied on his testimony as evidence that, *inter alia*, FDA's 2016 changes increased complications from medication abortion, Pet.App. 127a (citing Respondents' brief, citing Complaint, citing Dr. Delgado), 146a–47a (same), and that complications after medication abortion "involve a unique level of trauma and distress," supporting Respondents' standing, Pet.App. 34a.

Yet Dr. Delgado's research and opinions have been repudiated by the scientific community and discounted by multiple courts. Courts have found that

his theory of abortion "reversal" is "devoid of scientific support, misleading, and untrue," *Stenehjem*, 412 F. Supp. 3d at 1150, "an unproven medical and scientific theory" about which there is "no real, serious debate within the medical profession," *id.* at 1150–51, and based on research with "numerous flaws," *Slatery*, 523 F. Supp. 3d at 1003, and "substantial limitation[s]," *All-Options, Inc. v. Att'y Gen. of Ind.*, 546 F. Supp. 3d 754, 766 (S.D. Ind. 2021). The American College of Obstetricians and Gynecologists ("ACOG") has "rejected Delgado's studies as 'junk science.'" *Stenehjem*, 412 F. Supp. 3d at 1150.[27]

The problems plaguing Dr. Delgado's research are reflected in its publication saga. All but one of the journals to which he submitted his abortion-reversal case series "declined to publish it." *Slatery*, 523 F. Supp. 3d at 994. The paper was eventually published in *Issues in Law & Medicine*,[28] a journal that Dr. Delgado conceded "is not particularly well-known in the medical field," which "publishes legal briefs along with medical studies," *Slatery*, 523 F. Supp. 3d at 994, and which was previously co-sponsored by a

[27] *See also* ACOG Practice Bulletin No. 225 at 3, https://perma.cc/X6ZM-YJBL; Royal Coll. Obstetricians & Gynaecologists et al., Joint Statement on 'Abortion Reversal' (July 7, 2022), https://perma.cc/M7MX-6JJD.

[28] Although *Issues in Law & Medicine* claims to be peer reviewed and references "COPE (Committee on Publication Ethics) Ethical Guidelines for Peer Reviewers," *see Attention Authors: Submit Your Manuscripts Below*, Issues in Law & Medicine, https://perma.cc/VNJ5-XSKB, it is not in fact a member of COPE, the major organization overseeing peer review. *See Members*, COPE, https://perma.cc/9P8H-NLWN.

subsidiary of AAPLOG.[29] Even there, Dr. Delgado's study was temporarily withdrawn from the journal because of problems with its Institutional Review Board approval. *Slatery*, 523 F. Supp. 3d at 994.[30]

Dr. Delgado's lack of expertise and scientific integrity extends beyond abortion. He conceded in 2020 that he has never served as a peer reviewer for any medical publication.[31] And when he submitted expert testimony in a challenge to restrictions on in-person gatherings during the height of the COVID-19 pandemic, the court "assigned [his] declaration minimal weight." *S. Bay United Pentecostal Church*, 494 F. Supp. 3d at 801–02. Dr. Delgado had "purport[ed] to calculate—without data—that the risk of contracting COVID-19 at a house of worship is '12.5% the risk at the grocery store' or '1% the risk at public protests.'" *Id.* The court noted that he "lacks significant experience in epidemiology. Moreover, he does not explain the basis for his model used to assess the precise comparative risk of religious services and

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[29] Dep. Donna Harrison, M.D., at 59:6–60:1, *Planned Parenthood of Tenn. & N. Miss. v. Slatery*, 523 F. Supp. 3d 985 (M.D. Tenn. Nov. 13, 2020) (No. 3:20-cv-00740), https://www.aclu.org/documents/FDAvAHM-amicusbriefsources (at 34–36); *see also Issues In Law & Medicine*, AAPLOG, https://perma.cc/U3JQ-S3FP (links on AAPLOG's website to entirety of journal).

[30] *See also* Tr. Proceedings Vol. II at 226:17–227:7, *Planned Parenthood of Tenn. & N. Miss. v. Slatery*, 523 F. Supp. 3d 985 (M.D. Tenn. Jan. 4, 2021) (No. 3:20-cv-00740), ECF 65, https://www.aclu.org/documents/FDAvAHM-amicusbriefsources (at 37–40).

[31] Dep. George Delgado, M.D., at 15:3–10, *Planned Parenthood of Tenn. & N. Miss. v. Slatery*, 523 F. Supp. 3d 985 (M.D. Tenn. Nov. 17, 2020) (No. 3:20-cv-00740), https://www.aclu.org/documents/FDAvAHM-amicusbriefsources (at 41–43).

other activities—nor does he provide any supporting data for his conclusions." *Id.* at 801.

D. Mario R. Dickerson

Mario R. Dickerson is the Executive Director of Respondent Catholic Medical and Dental Association ("CMDA"). Mr. Dickerson is not a doctor. He does not provide any professional credentials in his declaration, and it appears his only advanced degree is a Master's in Theological Studies.[32] Undaunted, Mr. Dickerson made wholly unsupported medical assertions in his declaration, including that FDA actions have "led to an increasing risk that women and girls may suffer adverse events from chemical abortion." J.A.120.

The district court relied in part on Mr. Dickerson for multiple facts, including that FDA's 2016 actions have increased and will continue to increase the rate of complications from medication abortion. *See* Pet.App. 119a–20a, 127a, 188a (citing Respondents' brief, citing Complaint, citing Mr. Dickerson). And the court of appeals cited Mr. Dickerson's declaration for the proposition that "[s]everal doctors testified that supervision is necessary to ensure patients' safety," Pet.App. 38a—notwithstanding that Mr. Dickerson is not a doctor and provided no data or supporting evidence regarding the purported need for in-person dispensing, *see* J.A.118–23.

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[32] *Executive Director*, Catholic Med. Ass'n, https://perma.cc/GW6U-PRGX.

E. Other Witnesses Credited by the Courts Below Are Similarly Unreliable.

Other witnesses relied upon by Respondents and the courts below likewise have serious credibility flaws. For instance, the lower courts cited testimony by **Dr. Nancy Wozniak**, an AAPLOG board member, J.A.170, for conclusions central to standing, the merits, and irreparable harm: namely, that both FDA's 2016 and 2021 actions increased complications associated with abortions. Pet.App. 37a, 39a–40a; *see also* Pet.App. 119a, 127a (citing Respondents' brief, citing Complaint, citing Dr. Wozniak). But when an Indiana district court examined Dr. Wozniak's "concerns" about medication abortion, it found that her opinions "were not anchored in any referenced medical research or literature or even her own personal experiences." *Rokita*, 553 F. Supp. 3d at 528. The court observed that she has "never * * * conducted any research in this area of [abortion] care," *id.* at 528 n. 25, and Dr. Wozniak admitted that she did not even "consult any medical literature" before forming her expert opinion regarding the need for certain abortion restrictions.[33] The court declined to credit another one of her opinions on the basis that it was "clearly inconsistent with currently accepted medical standards of care." *Rokita*, 553 F. Supp. 3d at 540.

Courts have also discounted testimony by **Dr. Christina Francis**, the current CEO of Respondent AAPLOG. J.A.152. One federal court found her testimony relating to abortion "contrary to the great

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[33] Tr. at 159:11–13, *Whole Woman's Health All. v. Rokita*, 553 F. Supp. 3d 500 (S.D. Ind. June 24, 2021) (No. 1:18-cv-01904), https://www.aclu.org/documents/FDAvAHM-amicusbriefsources (at 44–45).

weight of current medical evidence." *Bernard*, 392 F. Supp. 3d at 944–45. In another case, the Seventh Circuit concluded that Dr. Francis' "one anecdote" was "far from compelling evidence" sufficient to justify an abortion restriction. *Planned Parenthood of Ind. & Ky., Inc. v. Comm'r of Ind. State Dep't of Health*, 896 F.3d 809, 828–29 (7th Cir. 2018) (quoting district court), *vacated and remanded*, 141 S. Ct. 184 (2020). By contrast, Dr. Francis' two anecdotes involving mifepristone complications—one in which the patient obtained a medication "from India" that "almost certainly did not involve FDA-approved Mifeprex," and one in which it was Dr. Francis' partner, not she, who provided the follow-up care, J.A.153–54; Pet.App. 20a n.3—were integral to the lower courts' standing analysis. Pet.App. 19a–20a, 24a–25a, 28a, 31a–32a; *see also* Pet.App. 123a, 127a.

Finally, like Dr. Harrison—who testified about her personal "experience" with medication abortion patients while omitting that she has not practiced medicine since 2000—**Dr. Jeffrey Barrows** obscures his lack of recent clinical experience. Dr. Barrows works on "bioethics and public policy" at Respondent CMDA. J.A.139. He touts his expertise as a "board-certified obstetrician-gynecologist" with 28 years' experience in practice, *id.*, but fails to mention that he has not been licensed to practice medicine since well before FDA took either of the actions at issue here.[34] Dr. Barrows did not provide a single piece of data supporting his opinions that FDA's 2016 and 2021

[34] *See Jeffrey Johnson Barrows*, eLicense Ohio Professional Licensure, https://perma.cc/CAJ7-EZ4R (medical license expired in 2011); *Find a Physician*, Iowa Bd. Med. Online Servs., https://perma.cc/QSA5-M2FH (already-inactive license relinquished in 2015).

actions have increased complications and emergency department visits. J.A.140–43. Nevertheless, the court of appeals cited Dr. Barrows for the proposition that "the 2016 Amendments will increase the number of women who suffer complications as a result of taking mifepristone," Pet.App. 36a, and directly quoted his citationless assertion that "the expanded use of telemedicine" resulting from FDA's 2021 changes "expose[s] women to a higher likelihood of undetected serious complications," Pet.App. 39a.

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The decisions below countermanded FDA's scientific judgment and the medical consensus that mifepristone is safe and effective under its current REMS and labeling. To justify this second-guessing, the lower courts relied almost exclusively on citationless "expert" opinions from declarants whose testimony has been repeatedly discredited by other courts based on the witnesses' flawed research, damning admissions, and lack of relevant expertise. Their testimony provides no credible factual basis for the decisions below, and the fact that the courts uncritically accepted it underscores the impropriety of their decisions. While judicial review of FDA decisions under the Administrative Procedure Act is, of course, authorized, the Act does not permit using widely discredited and ideologically tainted junk science to supplant FDA's considered judgment. *See Pharm. Mfg. Rsch. Servs., Inc. v. FDA*, 957 F.3d 254, 262 (D.C. Cir. 2020) ("In the context of a challenge to the FDA's decisionmaking, we give a high level of deference to the agency's scientific analysis of the evidence before it, and must avoid unduly second-guessing those scientific judgments." (alterations and citations omitted)).

II. Respondents' Research Is Unreliable and Inapposite.

Respondents attempted to bolster their witnesses' testimony with a small batch of low-quality studies purporting to show, contrary to the rigorous, vetted evidence underlying FDA's decisions,[35] that mifepristone is not safe. Here too, the courts credulously accepted Respondents' transparently flawed research without any critical examination, while also relying on studies for propositions they expressly do not support. Under any objective review, these studies provide no greater basis for upholding the court of appeals' decision than did the testimony of Respondents' witnesses. Indeed, much of this "research" was authored by the very same oft-discredited witnesses.

A. The Courts' Findings on Adverse Events Are Based on Patently Flawed Research and Studies that Do Not Support the Courts' Conclusions.

The lower courts' standing, merits, and irreparable harm analyses all turn on Respondents' assertions that there are a "large number of women who experience serious medical complications due to mifepristone," Pet.App. 23a–24a; *see also, e.g.*, Pet.App. 37a ("more women" will experience "serious complications resulting from mifepristone" because of FDA's actions), and that FDA did not have sufficient data on the scope of these serious complications to justify its scientific conclusions, Pet.App. 54a–57a, 59a–63a; *see also, e.g.*, Pet.App. 121a, 119a, 127a, 146a–147a & n.22, 159a, 177a–78a, 188a. The courts found that FDA lacked adequate data on

[35] *See, e.g.*, Br. ACOG et al. *Amici* Supp. Pet'rs (Oct. 12, 2023).

mifepristone's safety even though the agency's actions were informed by (1) numerous high-quality studies examining mifepristone's safety and efficacy; (2) 15 years of mandatory reporting of all serious adverse events associated with mifepristone; (3) ongoing mandatory reporting of all deaths associated with mifepristone; and (4) ongoing reporting of adverse events associated with mifepristone through FAERS, the system FDA uses to ensure the safety of the 20,000 prescription drugs it regulates. *See* Br. Fed. Pet'rs 43.[36] Yet in the face of FDA's expert assessment of this abundant evidence, the lower courts relied on flawed studies authored by the same witnesses on whose testimony they mistakenly relied.

For example, the court of appeals discussed a study co-authored by Dr. Harrison and two members of Respondents AAPLOG and CMDA that purports to show a significant gap between adverse-event data compiled by abortion providers and adverse-event data reflected in the FAERS database. C.A.ROA 1872–76. The court observed that the study identified 866 more adverse events in the abortion-provider data than in the FAERS database for 2010, Pet.App. 60a, and found that "[t]hese discrepancies render FAERS inadequate to evaluate the safety of mifepristone abortions," *id.* (quoting Dr. Harrison's testimony about her study). Even accepting the accuracy of Dr. Harrison and her collaborators' findings, this study provides feeble support for the conclusions for which the court of appeals used it, including to countermand FDA's elimination of its in-person dispensing requirement. The court ignored that the discrepancy

[36] *See also FDA At a Glance*, Food & Drug Admin. (Nov. 2020), https://perma.cc/Z2JK-DSSE.

the study identifies was composed entirely of additional cases of *ongoing pregnancy* after mifepristone use, *see* C.A.ROA 1874, not any serious medical complication that could justify overriding FDA's safety conclusions—much less reinstating a type of use restriction that Congress permits only where "required 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)(A) (emphasis added).

The safety data that the district court cited likewise provides no credible alternative basis for the court of appeals' decision. For instance, the court highlighted a study purporting to show "20 deaths, 529 life-threatening events, and 1,957 *severe* adverse events" relating to mifepristone between 2000 and 2019, accepting these data without question.[37] Yet this study was co-authored by Dr. Harrison (who "tend[s] to present [study] results in an exaggerated or distorted manner")[38] and other AAPLOG members, C.A.ROA 1846, 1876; adverse events were coded for severity by members of AAPLOG's "Mifeprex Adverse Events Coding Team," including Dr. Skop (whose opinions on abortion risks are "inaccurate and overstated"),[39] C.A.ROA 1869–70; and the study was published in *Issues in Law and Medicine*, *see supra* Part I(C), for which "one of the editors" is Dr. Harrison herself, *Slatery*, 523 F. Supp. 3d at 994.

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[37] Pet.App. 178a (emphasis in original) (citing Kathi Aultman et al., *Deaths and Severe Adverse Events After the Use of Mifepristone as an Abortifacient from September 2000 to February 2019*, 36 Issues L. & Med. 3 (2021)).

[38] *MKB Mgmt. Corp.*, 855 N.W.2d at 68 (Kapsner, J., op.); *see supra* Part I(B).

[39] *PPSCF*, 2022 WL 2436704, at *13; *see supra* Part I(A).

As another example, to justify standing, the district court relied on a study purporting to show high rates of emergency room visits after mifepristone and that FDA's data on adverse events are incomplete.[40] The court nowhere mentioned that the study authors again include Drs. Harrison and Skop, as well as discredited anti-abortion researcher David Reardon (*see infra* Part II(B)). C.A.ROA 1480. The editor and publisher of this article have since issued an "Expression of Concern," noting that they "were alerted to potential issues regarding the representation of data in the article and author conflicts of interest" and "an investigation is underway."[41]

The district court also used a study of abortions in Finland to compare adverse events for medication and surgical abortions.[42] In a recent interview, a co-author of the study "disputed the [court's] characterization of the research," saying that Respondents and the court were "purposely misunderstanding his work and overemphasizing 'adverse events' despite overwhelming scientific

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[40] Pet.App. 119a n.9, 147a n.22, 170a n.45 (citing James Studnicki et al., *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions*, *1999-2015*, 8 Health Servs. Rsch. & Managerial Epidemiology 1 (2021)).

[41] *EXPRESSION OF CONCERN: A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions*, 10 Health Servs. Rsch. & Managerial Epidemiology (July 2023), https://perma.cc/YEU3-5LZD.

[42] Pet.App. 167a n.38 (citing Maarit Niinimäki et al., *Immediate Complications After Medical Compared With Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology 795 (2009)).

evidence of the drug's safety and the study itself noting the rarity of serious complications."[43]

That study was conducted in Finland, where the medication abortion regimen used by study participants differed both in timing and method of administration from the FDA-approved regimen.[44] Moreover, "in Finnish health registries any return visit to the health facility, even for additional consultation, is categorized as a complication."[45] Thus, the authors cautioned, because their study drew its data from Finnish health registries, "many of the 'complications' are not really such, but rather concerns or adverse events that bring women back to the health care system" only for "consultations."[46] The authors clarified that the "[r]ate of serious, 'real' complications is rare."[47] But the district court ignored all of this. The court also misleadingly stated that FDA "agrees with this study," Pet.App. 167a–68a n.38 (citing J.A.409), omitting both FDA's discussion of the "inherent weaknesses" in studies of this type and its emphasis

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[43] Lauren Weber et al., *Unpacking the Flawed Science Cited in the Texas Abortion Pill Ruling*, Wash. Post (Apr. 13, 2023), https://perma.cc/3HPD-VWBH.

[44] Maarit Niinimäki et al., *In Reply: Immediate Complications After Medical Compared With Surgical Termination of Pregnancy*, 115 Obstetrics & Gynecology 660 (2010), https://www.aclu.org/documents/FDAvAHM-amicusbriefsources (at 46–47).

[45] Mary Fjerstad et. al, *To the Editor: Immediate Complications After Medical Compared With Surgical Termination of Pregnancy*, 115 Obstetrics & Gynecology 660 (2010), https://www.aclu.org/documents/FDAvAHM-amicusbriefsources (at 46).

[46] Niinimäki, *In Reply*, supra n.44.

[47] *Id.*

that the study authors "concluded that both methods [of abortion] are generally safe," J.A.409.

B. The Courts' Findings on the Purported Psychological Harms of Abortion Have No Credible Scientific Basis.

As part of its standing analysis, the court of appeals found that the "'enormous stress and pressure' that is involved with treating women suffering complications from taking mifepristone" "augment the Doctors' conscience injuries." Pet.App. 34a–35a (quoting Dr. Wozniak). The court explained that this "emotional stress" is tied to the fact that medication abortions "frequently cause 'regret' or 'trauma' for the patients and, by extension, the physicians." Pet.App. 24a (quoting Respondents). Similarly, the district court made findings about "trauma," "depression," "drug abuse" and the like purportedly caused by medication abortion. Pet.App. 123a–24a, 147a, 168a–69a, 175a, 188a.

All of these findings are directly contradicted by extensive validated evidence and find no credible support in the studies the district court cited. The court abdicated its duty to critically examine scientific evidence before relying on it—a gatekeeping function that is all the more critical where Respondents' evidence is contrary to both FDA's scientific judgment and the medical community consensus. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 158–59 (1999) (Scalia, J., concurring) (trial courts do not have "discretion to abandon [their] gatekeeping function" and must "exclude[e] expertise that is *fausse* and science that is junky").

For instance, the district court repeatedly recited statistics about women's experiences with

mifepristone drawn from a study of 98 blogs from 2007–2018 on the website *abortionchangesyou.com*—a site on which "bloggers post anonymously" and do not even "need to create an account in order to post."[48] Even on its own terms, this study does not support the court's quantitative assertions: its authors described their article as exclusively a "*qualitative* case stud[y]" and expressly cautioned that it had "a *lack of generalizability* due to the limited scope: we only analyzed women's medication abortion narratives anonymously posted to one website." C.A.ROA 517 (emphasis added).

Nevertheless, in its associational-standing analysis, the district court emphasized that, "[i]n one study, fourteen percent of women and girls reported having received insufficient information" about medication abortion." Pet.App. 120a. The court omitted that this 14 percent figure represents "[f]ourteen women" *total* across more than a decade, C.A.ROA 514, and is drawn from a pool of 98 anonymous bloggers—a denominator bearing no relation to the number of people who have obtained medication abortions. Compounding the error, the court again relied only on this qualitative study in observing: "Other studies show eighty-three percent of women report that chemical abortion 'changed' them—and seventy-seven percent of those women reported a *negative* change. Thirty-eight percent of

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[48] Pet.App. 120a (citing Katherine A. Rafferty & Tessa Longbons, #AbortionChangesYou*: A Case Study to Understand the Communicative Tensions in Women's Medication Abortion Narratives*, 36 Health Commc'n 1485 (2021)), 168a n.40 (same); *see also* Pet.App. 123a (citing amicus brief relying exclusively on #AbortionChangesYou study for this point); C.A.ROA 511–12 (study's description of website).

women reported issues with anxiety, depression, drug abuse, and suicidal thoughts because of the chemical abortion." Pet.App. 168a (emphasis in original). Yet these statistics are transparently unfounded, as they are drawn from a study of self-selecting bloggers who opted into a website named *abortionchangesyou.com*. Indeed, the court defied the authors' own caution that "the population of women who write an anonymous post about their abortion experience may be different from those who do not." C.A.ROA 517.

The trial court's finding that abortion patients "often" experience negative mental health sequelae likewise has no footing in legitimate scientific data. Pet.App. 123a–24a. The theory that abortion causes psychiatric harm has been rejected by leading national and global authorities—including the nonpartisan National Academies of Science, Engineering, and Medicine ("National Academies"), the American Psychological Association ("APA"), and the United Kingdom's Royal College of Psychiatrists ("Royal College")—following exhaustive scientific reviews.[49] In its comprehensive analysis of the Safety

[49] Brenda Major et al., Am. Psych. Ass'n, Report of the APA Task Force on Mental Health and Abortion (2008), https://perma.cc/YLZ9-4R3G; Brenda Major et al., *Abortion and Mental Health: Evaluating the Evidence*, 64 Am. Psych. 863 (2009) (update to APA Task Force Report 2008), https://perma.cc/Q4J4-8P8Y; Nat'l Acads. of Science, Eng'g & Med., The Safety and Quality of Abortion Care in the United States (2018), https://perma.cc/7PF8-LCSN; Nat'l Collaborating Ctr. for Mental Health (NCCMH), Acad. of Med. Royal Colls., Induced Abortion and Mental Health: A Systematic Review of the Mental Health Outcomes of Induced Abortion, Including Their Prevalence and Associated Factors (2011), https://perma.cc/UWB5-RD35; Position Statement on Abortion and Women's Reproductive

and Quality of Abortion Care (discussed by *Amici* Medical and Public Health Societies, C.A.ROA 4015), the National Academies evaluated the quality of research on abortion and mental health, emphasized the scrupulous selection criteria used in systemic reviews by the APA and the Royal College, and endorsed the studies that *Amici* Medical and Public Health Societies highlighted in their brief.[50] The National Academies criticized the methodology of two studies, by Priscilla Coleman and David Reardon, respectively, that purport to show an association between abortion and mental illness.[51]

Instead of this authority, the district court relied on baseless findings about the alleged mental health consequences of abortion to support Respondents' third-party standing. Pet.App. 123a–24a. The court cited only three sources in support of its finding that abortion causes "shame, regret, anxiety, depression, drug abuse, and suicidal thoughts." *Id*.

First, the court relied on an amicus brief submitted by "The Human Coalition," an advocacy group "committed to * * * making abortion unthinkable." Pet.App. 123a (citing C.A.ROA 3730); C.A.ROA 3713. For this point, the Human Coalition cited only the aforementioned study of 98 anonymous blogs. C.A.ROA 3730.

Health Care Rights, Am. Psychiatry Ass'n (2020), https://perma.cc/JA5Y-39KE.

[50] Nat'l Acads., *supra* n.49, at 149–52.

[51] *Id.* at 150.

Second, the court relied on a meta-analysis by Priscilla Coleman[52] that has "been almost uniformly rejected by other experts in the field." *Planned Parenthood of Ind. & Ky., Inc. v. Comm'r, Ind. State Dep't of Health*, 273 F. Supp. 3d 1013, 1036 (S.D. Ind. 2017), *aff'd*, 896 F.3d 809, 826, 830 (7th Cir. 2018) (affirming district court findings as to Dr. Coleman's "much maligned" meta-analysis), *vacated sub nom. Box v. Planned Parenthood of Ind. & Ky., Inc.*, 141 S. Ct. 184 (2020); *see also Adams & Boyle, P.C.*, 494 F. Supp. 3d at 536–38 (after discussing meta-analysis at length, finding that Dr. Coleman's testimony was "not credible and not worthy of serious consideration" and that "her work has serious methodological flaws").

Third, the court relied on a study by Drs. Reardon, Coleman, and others,[53] which claims to show "higher death rates associated with abortion [that] persist over time."[54] While the study abstract says "[h]igher death rates associated with abortion * * * may be explained by self-destructive tendencies, depression, and other unhealthy behavior aggravated by the abortion experience,"[55] Dr. Coleman admitted under oath that this was merely a hypothesis and "*wasn't a statement that was based on the actual*

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[52] Pet.App. 124a (citing Priscilla K. Coleman, *Abortion and Mental Health: Quantitative Synthesis and Analysis of Research Published 1995–2009*, 199 Brit. J. Psychiatry 180 (2011)).

[53] Pet.App. 123a (citing David C. Reardon et al., *Deaths Associated With Pregnancy Outcome: A Record Linkage Study of Low Income Women*, 95 S. Med. J. 834 (2002)).

[54] Reardon et al., *supra* n.53, www.aclu.org/documents/FDAv AHM-amicusbriefsources (at 48–55).

[55] *Id.*

findings."[56] Yet the district court cited this study for precisely that unfounded theory.

The quality of Dr. Reardon's work has been roundly discredited—even by Dr. Coleman, his long-time collaborator, who admitted under oath that Dr. Reardon is "not good at statistics" and "too political."[57] And the unreliability of the specific study cited by the district court is apparent on its face. The study counted deaths for *any reason, any time* in the eight years following an abortion.[58] As Dr. Coleman has conceded, if a woman was "randomly robbed in a parking lot five years after her abortion and shot and killed," that was counted as an abortion-associated death in the study.[59]

The district court's finding that "[m]any" medication abortion patients "also experience intense psychological trauma and post-traumatic stress," Pet.App. 147a, likewise elevates cherry-picked anecdotes and small-scale, qualitative data over comprehensive literature reviews by such authorities as the National Academies, the Royal College, and the APA—which used methodologically rigorous selection criteria in reviewing research encompassing

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[56] Dep. Priscilla Coleman, PhD, at 244:2–6, *Planned Parenthood Ass'n of Utah v. Miner*, No. 2:19-cv-00238 (D. Utah Sept. 16, 2020) ("Coleman Utah Dep."), https://www.aclu.org/documents/FDAvAHM-amicusbriefsources (at 56–58) (emphasis added).

[57] Tr. Proceedings Vol. 3-A at 88:1–17, *Adams & Boyle, P.C. v. Slatery*, 494 F. Supp. 3d 488 (M.D. Tenn. Sept. 25, 2019) (No. 3:15-cv-0705), ECF 221, https://www.aclu.org/documents/FDAvAHM-amicusbriefsources (at 59–62).

[58] Reardon et al., *supra* n.53, at 836.

[59] Coleman Utah Dep. at 246:12–23.

thousands of study participants.[60] The court cited only two sources in support of this finding, both fundamentally flawed. Pet.App. 147a.

First, the court cited a qualitative study published more than two decades ago involving approximately 100 medication abortion patients admitted to hospitals for their abortions.[61] The authors gave no explanation why these patients' abortions were performed inpatient at a hospital. In fact, contrary to the most basic scientific standards, the authors did not even include a Limitations section.[62]

Second, the court again turned to The Human Coalition's amicus brief, which based its description of the psychological harms from abortion on (1) the 22-year-old study described above, and an even older study of hospital-based abortions by the same authors,[63] (2) the study of 98 anonymous bloggers, (3) an article describing the study of 98 bloggers,[64] (4) a Newsweek article from 1995—five years *before*

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[60] Nat'l Academies, *supra* n.49, at 132–33, 149–52; NCCMH, *supra* n.49, at 21–35; Major et al., *supra* n.49, at 21–22.

[61] Pauline Slade et al., *Termination of Pregnancy: Patients' Perception of Care*, 27 J. Fam. Plan. & Reprod. Health Care 72 (2001), https://perma.cc/JH74-2ZAJ.

[62] *See generally id.*

[63] Pauline Slade et al., *A Comparison of Medical and Surgical Termination of Pregnancy: Choice, Emotional Impact and Satisfaction with Care*, 105 Brit. J. Obstetrics & Gynaecology 1288 (1998), https://perma.cc/VUA3-5QG6.

[64] Kim Hayes, *"The Pain and Emptiness Stays There Forever" - #Abortionchangesyou Study Looks at Personal Chemical Abortion Experiences*, Pregnancy Help News (July 22, 2020), https://perma.cc/QVF8-P44A.

mifepristone was approved for use in the United States,[65] (5) an article from the National Catholic Register discussing a study of abortions performed *on rats*;[66] and (6) three anonymous anecdotes submitted to the Human Coalition's "Abortion Memorial" website. C.A.ROA 3730–34.[67]

In short, rather than relying on solid scientific evidence, as did FDA, the district court instead built its findings about the supposed psychological consequences of medication abortion on faulty research by discredited authors.

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The courts' findings about alleged physical and psychological harm from medication abortion and the inadequacy of FDA's adverse-event data have no valid scientific basis, as would have been evident from any meaningful examination of the underlying evidence. These studies—like the witnesses who authored and trumpeted them—fall far short of justifying the lower courts' decisions to substitute their own judgments for FDA's scientific assessment. The Administrative Procedure Act authorizes judicial review of agency decision-making, but does not countenance courts rejecting agency action based on junk science or advocacy posing as objective evidence. Yet that is precisely what happened here.

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[65] Newsweek Staff, *Blood and Tears*, Newsweek (Sept. 17, 1995), https://perma.cc/A8G9-P3MJ.

[66] Celeste McGovern, *Study Confirms Women's Testimonies About Abortion Pill's Link to Depression, Anxiety*, Nat'l Catholic Reg. (July 30, 2019), https://perma.cc/9ZA9-YR2V.

[67] *Abortion Memorial*, Human Coal., https://perma.cc/6EEX-54EK.

CONCLUSION

For the reasons set forth above and in the Briefs for the Petitioners, the judgment below should be reversed.

January 30, 2024

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