IN THE COURT OF COMMON PLEAS
FOR HAMILTON COUNTY, OHIO

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, *et al.*,	:	Case No. A 2101148
Plaintiffs,	:	Judge Alison Hatheway
v.	:	
OHIO DEPARTMENT OF HEALTH, *et al.*,	:	
Defendants.	:	

THE STATE'S OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

This case presents a fundamental question about the meaning of Article I, Section 22 of the Ohio Constitution and the enduring role of the State in safeguarding the health, safety, and autonomy of the people it serves. Plaintiffs seek to transform the Reproductive Freedom Amendment—adopted in 2023 to ensure that reproductive decisions remain voluntary, informed, and grounded in evidence-based medical care—into a mandate that strips Ohio of its longstanding authority to regulate dangerous medications, require professional oversight, and enforce basic standards of clinical practice. Nothing in the text, structure, or purpose of Section 22 supports such an extraordinary proposition. The Amendment protects choice, not deregulation. It secures autonomy, not abandonment. It preserves the State's power to ensure that reproductive decisions are made safely, voluntarily, and with the benefit of sound medical judgment.

The statutes at issue here fall squarely within that protective framework. Each one reflects well-established medical standards that ensure abortion-inducing drugs are prescribed and administered in a manner consistent with the best available scientific evidence. The physician-only requirement for dispensing mifepristone aligns Ohio law with federal safety protocols and prevents the risks associated with unsupervised or incompetent prescribing. The seventy-day evidence-based-use provision mirrors the FDA's own limits and safeguards patients from elevated risks of incomplete abortion and emergency intervention at later gestational stages. And the telemedicine presence requirement ensures that the initial dose of a powerful, potentially dangerous medication is taken under conditions that protect patients against coercion, misdiagnosis, and adverse events that remote screening cannot reliably detect.

Plaintiffs ask this Court to declare these protections unconstitutional as a matter of law, but their own evidence exposes deep factual uncertainty about the very questions they claim are settled:

the comparative competence of APCs and physicians in high-risk medication management, the safety of extending medication abortion beyond seventy days, the reliability of remote screening for ectopic pregnancy or coercion, and the real-world dangers associated with unsupervised distribution of mifepristone. These disputes go to the heart of whether the laws advance patient health and preserve the voluntariness that Section 22 enshrines. They cannot be resolved on summary judgment—and certainly not on the one-sided record Plaintiffs present.

Section 22 does not compel this Court to invalidate decades of medical regulation or to constitutionalize a deregulated landscape in which abortion-inducing medications may be distributed without supervision, accurate diagnosis, or safeguards against coercion or abuse. The Amendment expressly preserves the State's ability to regulate in the interest of health, and it requires Plaintiffs—not the State—to prove that these regulations impose a burden on voluntary reproductive decision-making. They have not done so. And even if they had, the State has demonstrated that the challenged laws advance health in the least restrictive manner consistent with widely accepted standards of care.

Because Plaintiffs cannot satisfy the threshold showing required by Section 22(A), because undisputed evidence reveals substantial factual conflicts that must be resolved at trial, and because the laws at issue are valid health-protective measures under Section 22(B), their motion for summary judgment should be denied.

STATEMENT OF FACTS

I. Background of the Challenged Statutory Framework

This case concerns three categories of Ohio law regulating medication abortion: (1) physician-qualification requirements governing who may prescribe abortion-inducing drugs (primarily R.C. 2919.123 and 2919.124); (2) evidence-based-use requirements governing how those

drugs may be prescribed; and (3) telemedicine restrictions governing the circumstances under which abortion-inducing drugs may be distributed remotely (R.C. 2919.124). All three categories of regulation substantially predate the adoption of Article I, Section 22 and formed part of Ohio's legal framework when Ohio voters approved the Reproductive Freedom Amendment in November 2023.

Medication abortion typically involves a two-drug regimen consisting of mifepristone followed by misoprostol. *Alliance for Hippocratic Med. v. FDA,* 5th Cir. No. 23-10362, 2023 U.S. App. LEXIS 8898, at *8 (Apr. 12, 2023). Since its approval in 2000, mifepristone has been subject to enhanced federal safeguards designed to mitigate serious risks associated with its use. *Id.* The FDA approved mifepristone under restrictions requiring qualified physician supervision, gestational-age limitations, in-person evaluation, and adverse-event reporting. *Id.* The FDA later maintained those restrictions through the Risk Evaluation and Mitigation Strategy ("REMS") program. *Id.*; *see also* The State's Opposition to Plaintiffs' Second Motion for Preliminary Injunction ("2d Opp PI"), Ex. A.

The FDA's prescribing information identifies serious risks associated with medication abortion, including hemorrhage, infection, incomplete abortion, continuing pregnancy, and the need for surgical intervention. 2d Opp PI, Ex. B at 4-6, 17. The agency further recognizes that use beyond approved gestational limits increases the risk of incomplete abortion and serious bleeding. *Id.* at 4-5. The FDA's clinical review of mifepristone identified thousands of adverse events between 2000 and 2014, including hospitalizations, blood transfusions, serious infections, and other significant complications. 2d Opp PI, Ex. C at at 83.

The 2023 REMS modifications do not support Plaintiffs' theory that states are constitutionally prohibited from imposing safeguards related to medication abortion. On the contrary, the FDA's actions reflect a regulatory judgment that some restrictions could be relaxed while others remained necessary. Specifically, the FDA removed the in-person dispensing requirement and permitted dispensing by certified pharmacies but retained the requirement that mifepristone be prescribed only by certified prescribers and continued to approve the drug only "through 70 days gestation." FDA Approval Letter (Jan. 3, 2023); FDA, *Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, attached as Exhibit B. The agency therefore reaffirmed that medication abortion remains a subject of ongoing safety regulation even after the 2023 changes.

Ohio's statutory framework incorporates and reinforces these federal safeguards. Through R.C. 2919.123, R.C. 2919.124, and related provisions, Ohio requires physician involvement in the prescription and distribution of abortion-inducing drugs, requires compliance with applicable federal regulatory standards, and limits the use of medication abortion to evidence-based protocols reflected in applicable law. These provisions remained part of Ohio law for years before Article I, Section 22 was adopted and continued to govern medication-abortion practice until portions of them were preliminarily enjoined during this litigation.

II. Procedural History

Plaintiffs initiated this action on April 1, 2021, challenging Ohio's telemedicine restrictions governing medication abortion. Plaintiffs obtained temporary and preliminary injunctive relief, and proceedings were later stayed pending related abortion litigation before the Ohio Supreme Court.

After Ohio voters adopted Article I, Section 22 in November 2023 and the amendment became effective on December 7, 2023, Plaintiffs substantially expanded their challenge.

Plaintiffs amended their complaint to challenge not only Ohio's telemedicine restrictions but also Ohio's physician-only requirements governing medication abortion and Ohio's evidence-based-use provisions regulating the use of mifepristone. *See* Plaintiffs' Amended Complaint. Plaintiffs subsequently obtained preliminary relief directed at portions of those laws and have now moved for summary judgment on their constitutional claims.

III. Expert Testimony Submitted by the Parties.

Although Plaintiffs repeatedly contend that the challenged laws serve no meaningful health purpose, their own evidence recognizes the existence of the very medical concerns those laws address.

A. Plaintiffs' experts acknowledge that gestational-age determination is medically significant.

Plaintiffs' principal medical expert, Daniel Grossman, acknowledges that medication-abortion outcomes change as gestational age advances and that risks increase incrementally as pregnancy progresses. Pls' Ex. 6 ¶¶ 36-39, 55-57. During his deposition, Dr. Grossman further acknowledged that ultrasound produces more accurate gestational-age determinations than patient self-assessment, testifying that "the error is less with ultrasound compared to self-assessment overall." Daniel Grossman Deposition, attached as Exhibit C, at 166:2-6. Likewise, Bhavik Kumar explains that patients seeking telemedicine medication abortion are screened for gestational-age eligibility and that uncertainty concerning gestational age may result in referral for in-person care. Pls' Ex. 7 ¶¶ 16-20.

B. Plaintiffs' experts acknowledge the risks associated with ectopic pregnancy.

Plaintiffs' evidence also recognizes the importance of ectopic-pregnancy screening. Dr. Grossman admitted that medication abortion does not treat ectopic pregnancy. Ex. C at 107:25-108:13. He further acknowledged that some ectopic pregnancies occur in patients who have neither symptoms nor identifiable risk factors. Ex. C at 125:24-126:25. Similarly, Dr. Kumar explains that telemedicine patients are screened for ectopic-pregnancy concerns and that some patients are redirected to in-person care because of elevated ectopic-pregnancy risks, uncertainty, or concerning symptoms. Pls' Ex. 7 ¶¶ 17-24.

C. Plaintiffs' evidence reflects continuing physician involvement in abortion care.

Although Plaintiffs challenge Ohio's physician-only requirements, their own evidence repeatedly describes medication-abortion care as occurring within physician-supported systems. Joanne Spetz acknowledges that physician assistants continue to practice within physician-collaboration structures and explains that Ohio maintains physician-collaboration requirements for APC practice. Pls' Ex. 11 ¶¶ 31-32, 94-102. Likewise, Dr. Kumar explains that APCs providing medication-abortion care at Planned Parenthood of Greater Ohio function within physician-supervised systems, rely upon physician consultation, and depend upon physician-provided procedural backup when necessary. Pls' Ex. 7 ¶¶ 57-60.

D. Plaintiffs' evidence recognizes limitations in telemedicine screening.

Dr. Kumar describes extensive telemedicine-screening protocols designed to assess gestational age, identify ectopic-pregnancy risks, evaluate contraindications, and determine whether patients require direct clinical evaluation before proceeding with medication abortion. Pls' Ex. 7 ¶¶ 15-24. Similarly, Dr. Grossman acknowledged that some patients must be screened out of

telemedicine pathways and referred for in-person evaluation. Ex. C at 186:14-17. Thus, Plaintiffs' own evidence recognizes that telemedicine and direct clinical evaluation are not interchangeable in all circumstances.

E. Plaintiffs' experts acknowledge that medication-abortion outcomes change as pregnancy advances.

Plaintiffs advocate medication-abortion protocols extending beyond the seventy-day limit reflected in Ohio law. Yet in scaling back several of its REMS requirements, the FDA maintains its 70-day limit to this day. *See* Ex. B at 1. And Plaintiffs' experts acknowledge that gestational age affects outcomes. Dr. Grossman recognizes that advancing gestational age increases risks associated with medication abortion and affects rates of incomplete abortion and continuing pregnancy. Pls' Ex. 6 ¶¶ 36-39, 55-57; Ex. C at 38:17-25, 39:1-24. Dr. Kumar likewise explains that later-gestation medication-abortion protocols require different medication regimens and additional doses of misoprostol. Pls' Ex. 7 ¶¶ 53-54.

IV. The Expert Record Reflects Extensive Medical Disagreement Regarding the Challenged Laws.

The parties present sharply conflicting expert testimony regarding the constitutionality and medical justification of the challenged statutes.

Plaintiffs rely principally on the opinions of Daniel Grossman, Joanne Spetz, and Bhavik Kumar. Those experts generally opine that APCs can safely provide medication abortion, that telemedicine medication abortion can be safely delivered under appropriate circumstances, and that medication-abortion protocols may safely extend beyond seventy days LMP. Pls' Ex. 6 ¶¶ 54-63; Pls' Ex. 11 ¶¶ 79-106; Pls' Ex. 7 ¶¶ 40-60.

Defendants' ("the State") expert, Ingrid Skop, reaches materially different conclusions. Dr. Skop opines that physician qualifications advance patient health, that telemedicine has

important diagnostic limitations, that ultrasound provides clinically meaningful information, that ectopic-pregnancy screening presents significant challenges, and that increasing gestational age materially affects medication-abortion risks. Skop Report, attached as Exhibit A ("Ex. A"), ¶¶ 69-90, 103-132.

The experts further disagree regarding the significance of physician involvement, the adequacy of history-based and telemedicine screening, the value of ultrasound-based assessment, the safety of medication-abortion protocols beyond seventy days LMP, the importance of direct clinical evaluation, and whether the challenged laws advance patient health. Compare Pls' Ex. 6 ¶¶ 36-63; Pls' Ex. 11 ¶¶ 79-106; Pls' Ex. 7 ¶¶ 15-60, with Ex. A ¶¶ 69-132.

These competing medical opinions form the factual backdrop for the constitutional issues presented by Plaintiffs' motion and demonstrate that the challenged laws regulate subjects on which qualified experts continue to disagree.

STANDARD OF REVIEW

Summary judgment is proper only when there remains no genuine issue as to any material fact, the moving party is entitled to judgment as a matter of law, and it appears from the evidence that reasonable minds can come to but one conclusion, which is adverse to the nonmoving party. *Temple v. Wean United, Inc.*, 50 Ohio St.2d 317, 327 (1977); *Hudson v. Petrosurance, Inc.*, 2010-Ohio-4505, ¶ 29; *Sinnott v. Aqua-Chem, Inc.*, 2007-Ohio-5584, ¶ 29. The moving party bears the initial burden of informing the court of the basis for its motion and identifying those portions of the record that demonstrate the absence of a genuine issue of material fact. *Dresher v. Burt*, 75 Ohio St.3d 280, 293 (1996); *Mitseff v. Wheeler*, 38 Ohio St.3d 112, 115 (1988).

Because summary judgment terminates litigation, courts must apply the standard cautiously, resolving all doubts in favor of the nonmoving party. *Murphy v. Reynoldsburg*, 65 Ohio

St.3d 356, 358–359 (1992). A court may not weigh competing evidence, evaluate witness credibility, or select among differing reasonable inferences when ruling on the motion. *Turner v. Turner*, 67 Ohio St.3d 337, 341 (1993).

ARGUMENT

I. Section 22 Enshrines Voluntary and Safe Reproductive Decision-making, Not the Regulatory Void Plaintiffs Ask This Court to Create.

This case presents a question far broader than medication abortion. At its core lies the question whether Article I, Section 22 was understood by Ohio voters to eliminate the State's longstanding authority to regulate medical practice whenever abortion is involved. Plaintiffs urge precisely that interpretation. Under their theory, Ohio may not require physician involvement in prescribing abortion-inducing drugs, may not require compliance with FDA-reviewed medication protocols, and may not regulate the manner in which abortion-inducing drugs are distributed through telemedicine. But nothing in the text, structure, history, or public understanding of the Amendment supports such a sweeping result.

Ohio constitutional interpretation begins with the language adopted by the voters. When interpreting a voter-enacted constitutional provision, courts consider not only the words themselves but also how those words would have been understood by the electorate that approved them. *City of Centerville v. Knab*, 2020-Ohio-5219, ¶ 22. As the Ohio Supreme Court recently explained, courts construing constitutional text adopted through the initiative process consider "how the language would have been understood by the voters who adopted the amendment" and "how the words and phrases would be understood by the voters in their normal and ordinary usage." *Id.* The Court further recognized that voter intent may be informed by the circumstances surrounding adoption, the purpose of the amendment, and the public understanding presented to

voters during the ratification process. *Id.* at ¶¶ 22, 30; *State ex rel. Sylvania Home Tel. Co. v. Richards*, 94 Ohio St. 287, 294 (1916).

The Ohio Supreme Court has also repeatedly emphasized that constitutional amendments must be interpreted against the backdrop of existing law. Voters are presumed to have acted with knowledge of the statutory and constitutional framework already in place. As the Court explained in *State v. Carswell*, "the body enacting the amendment will be presumed to have had in mind existing constitutional or statutory provisions and their judicial construction, touching the subject dealt with." 114 Ohio St.3d 210, 2007-Ohio-3723, ¶ 6. The Court further stressed that repeals by implication are disfavored and that courts should not infer the invalidation of existing statutes unless the constitutional provision and statute are "clearly incompatible and irreconcilable." *Id.* at ¶ 8.

Those principles are decisive here. When Ohio voters approved Article I, Section 22 in November 2023, Ohio already maintained physician-only requirements governing abortion-inducing drugs, restrictions concerning telemedicine prescribing, informed-consent requirements, scope-of-practice limitations, and evidence-based medication regulations tied to federal standards. Those provisions were not hidden from the public. They constituted the legal landscape against which Article I, Section 22 was adopted. Under *Carswell*, this Court should not presume that voters silently abolished those longstanding protections absent language clearly requiring that result.

The Amendment's text confirms that no such repeal occurred. Section 22(A) protects an individual's right to make and carry out reproductive decisions. Section 22(B), however, expressly preserves the State's authority to regulate in furtherance of health. Thus, the Amendment itself contemplates the continued existence of health-based regulation. Plaintiffs' interpretation

effectively reads that reservation of authority out of the Constitution. If every regulation affecting abortion is constitutionally forbidden because it may impose some burden, then the provision expressly permitting health-based regulation becomes largely meaningless.

Ohio law requires courts to give effect to every part of a constitutional provision and to avoid interpretations that render any clause "meaningless or inoperative." *Cleveland v. State*, 157 Ohio St.3d 330, 2019-Ohio-3820, ¶ 20. Plaintiffs' construction violates that principle. Under their approach, Section 22(B)'s express recognition of health-based regulation would have almost no operative function because any meaningful regulation affecting abortion could be characterized as a burden. Article I, Section 22 cannot reasonably be read to contain an express reservation of regulatory authority while simultaneously eliminating that authority. The more faithful interpretation gives effect to both provisions: Section 22 protects reproductive decision-making, and Section 22(B) preserves Ohio's authority to regulate in furtherance of patient health through evidence-based standards of care.

The public understanding surrounding adoption of Issue 1 further supports that conclusion. As the State explained in its opposition to Plaintiffs' Second Motion for Preliminary Injunction[1] (2d Opp. PI), Ohio voters were repeatedly told that the Amendment would restore the legal framework that existed before *Dobbs v. Jackson Women's Health Organization*, not eliminate all abortion-related regulation. 597 U.S. 215 (2022). Public explanations from advocacy groups, commentators, and legal analysts repeatedly characterized the Amendment as restoring the legal status quo that existed under *Roe v. Wade,* 410 U.S. 113 (1973) and *Planned Parenthood v. Casey,* 505 U.S. 833 (1992). Nothing in the public campaign suggested that Ohio voters were being asked to

[1] The State incorporates the arguments made in that opposition brief here to avoid repetition.

abolish physician-qualification requirements, invalidate longstanding abortion-drug regulations, constitutionalize telemedicine abortion, or prohibit the State from regulating medication-abortion protocols. *See* 2d Opp, PI at III.A.2. To the contrary, assertions that the Amendment would eliminate all abortion regulation were frequently dismissed during the campaign as exaggerated or inaccurate. *See, e.g.,* Associated Press, *Ohio votes on abortion rights this fall. Misinformation about the proposal is spreading*, Spectrum News (Oct. 11, 2023), https://perma.cc/ZN7D-5789.

That understanding matters because the challenged laws would not have been regarded as constitutionally suspect under the pre-*Dobbs* framework voters were told the Amendment would restore. Indeed, courts repeatedly recognized the authority of states to regulate provider qualifications, establish prescribing requirements, and impose health-related safeguards while still protecting access to abortion. *See Casey*, 505 U.S. at 885 ("The Constitution gives the States broad latitude to decide that particular functions may be performed only by licensed professionals, even if an objective assessment might suggest that those same tasks could be performed by others."); *Mazurek v. Armstrong*, 520 U.S. 968, 973-75 (1997) (reaffirming that "the performance of abortions may be restricted to physicians"); *Roe v. Wade*, 410 U.S. 113, 165 (1973) ("[T]he State may define the term 'physician' . . . and may proscribe any abortion by a person who is not a physician as so defined."). The notion that Article I, Section 22 silently abolished all such authority finds support neither in the Amendment's text nor in the understanding presented to Ohio voters.

The Amendment itself also undermines Plaintiffs' suggestion that physician involvement became constitutionally irrelevant upon ratification. Article I, Section 22(B) expressly refers to the professional judgment of the patient's "treating physician" when addressing post-viability abortions necessary to protect the patient's life or health. Ohio Const., Art. I, § 22(B). The State

does not contend that this language alone resolves every issue in this case. But the provision does demonstrate that the Amendment contemplates a continuing role for physicians within Ohio's constitutional framework governing abortion. At minimum, it is difficult to reconcile Plaintiffs' theory of physician irrelevance with constitutional text that expressly recognizes physician judgment.

The challenged laws likewise regulate matters that have traditionally fallen within the State's police powers. *See Dobbs*, 597 U.S. at 292; *Washington v. Glucksberg*, 521 U.S. 702, 731-35 (1997). The statutes govern who may prescribe abortion-inducing drugs, how those drugs may be distributed, and under what conditions they may be used. Such regulations are fundamentally directed toward medical practice and patient safety. They do not prohibit abortion. They do not eliminate access to abortion. Rather, they regulate the methods, providers, and protocols through which abortion-inducing drugs may be administered.

Plaintiffs' interpretation would dramatically expand Article I, Section 22 beyond its text by transforming a constitutional protection for reproductive decision-making into a constitutional prohibition against ordinary medical regulation. Under their theory, disputes concerning physician qualifications, medication protocols, telemedicine safeguards, and professional standards would cease to be matters of legislative judgment and instead become constitutional mandates. Nothing in the Amendment requires such a result.

The more natural interpretation is the one consistent with Ohio precedent, constitutional structure, and voter understanding. Article I, Section 22 protects reproductive decision-making while preserving Ohio's authority to regulate medical practice and protect patient health. Because

Plaintiffs' contrary interpretation depends on an unprecedented expansion of the Amendment beyond both its text and its public understanding, it should be rejected.

II. Article I, Section 22 Does Not Create a Constitutional Right to a Particular Provider, Particular Drug Protocol, or Particular Method of Care Delivery.

While Article I, Section 22 protects a patient's right to obtain a pre-viability abortion, Plaintiffs are not entitled to judgment as a matter of law because the Amendment does not create a constitutional entitlement to a particular provider, a particular medication regimen, a particular prescribing protocol, or a particular method of healthcare delivery. The right secured by Section 22 is the right to make and carry out reproductive decisions. It is not a guarantee that abortion must be available through every category of healthcare provider, every proposed medication-abortion protocol, or every technological delivery mechanism preferred by abortion providers.

That distinction is not merely conceptual. It has already been recognized in litigation involving one of the very statutes challenged here. Ohio's evidence-based-use requirements governing mifepristone have previously been subjected to extensive constitutional review. In *Planned Parenthood Southwest Ohio Region v. DeWine*, the Sixth Circuit rejected the contention that constitutional protection of abortion necessarily extends to a preferred method of obtaining an abortion. 696 F.3d 490, 515-16 (6th Cir. 2012) (concurring opinion, incorporated by the court). Instead, the court held that constitutional protection concerns the decision whether to terminate a pregnancy, not a woman's preferred means of doing so. *Id* at 515.

That principle directly undermines a substantial portion of Plaintiffs' case. Plaintiffs' challenge to Ohio's evidence-based-use provisions depends upon the premise that Article I, Section 22 constitutionalizes medication-abortion protocols extending beyond the FDA-reviewed framework incorporated into Ohio law. But nothing in the Amendment confers a right to a

preferred medication-abortion protocol any more than the federal right addressed in *DeWine* conferred a right to a preferred abortion method. Plaintiffs' insistence that medication abortion may safely be offered through eighty-four days LMP demonstrates, at most, a disagreement regarding medical policy. It does not establish that the Amendment strips Ohio of authority to regulate the conditions under which abortion-inducing drugs are prescribed any more than it can serve to invalidate regulations that were deemed constitutional under the prior federal regime.

The same analysis applies to Plaintiffs' challenge to Ohio's physician-only requirements. States have long retained authority to determine which healthcare providers may perform particular medical functions. The United States Supreme Court has repeatedly recognized that abortion may be restricted to physicians. In *Mazurek v. Armstrong*, the Court reaffirmed that "the performance of abortions may be restricted to physicians" and summarily reversed a lower court decision that enjoined a physician-only abortion law. 520 U.S. 968, 973-75 (1997). The Court further observed that similar physician-only requirements existed throughout much of the country. *Id.* at 972 n.1.

Likewise, in *Planned Parenthood v. Casey*, the Supreme Court recognized that states possess "broad latitude" to determine that particular medical functions may be performed only by licensed professionals, "even if an objective assessment might suggest that those same tasks could be performed by others." 505 U.S. 833, 885 (1992). Indeed, even *Roe v. Wade* acknowledged that a state "may define the term 'physician'" and may prohibit abortions performed by persons who do not satisfy that definition. 410 U.S. 113, 165 (1973).

These authorities do not control interpretation of Article I, Section 22 directly. They remain important, however, because they demonstrate that physician-qualification requirements

have historically been understood as a classic form of medical regulation rather than as an inherent burden on abortion rights. Thus, when Ohio voters approved the Amendment, they did so against a legal backdrop in which physician-only abortion regulations had long been recognized as constitutionally permissible.

The Amendment's own text further undermines Plaintiffs' claim that physician involvement became constitutionally suspect after ratification. As discussed above, Section 22(B) expressly refers to the professional judgment of the patient's "treating physician." That language does not resolve every issue before the Court, but it does confirm that physician participation remains part of the constitutional framework adopted by Ohio voters. It is difficult to reconcile Plaintiffs' theory that physician involvement serves no constitutionally cognizable purpose with constitutional language that specifically recognizes physician judgment in evaluating life and health considerations.

The challenged telemedicine restrictions likewise do not implicate a constitutional right identified anywhere in Article I, Section 22. The Amendment says nothing about telemedicine. It says nothing about remote prescribing. It says nothing about mail-order distribution of abortion-inducing drugs. Plaintiffs instead ask the Court to infer a constitutional entitlement to a particular delivery platform because that platform is more convenient for providers and some patients. But telemedicine is simply a method of healthcare delivery. States routinely regulate healthcare-delivery mechanisms, prescribing practices, licensure requirements, informed-consent procedures, and professional oversight. Nothing in Article I, Section 22 suggests that abortion-related telemedicine enjoys immunity from such regulation.

Nor does the record support Plaintiffs' attempt to transform questions of provider preference into constitutional mandates. Their evidence repeatedly emphasizes that APCs permit clinics to offer more appointments, that telemedicine allows providers to reach more patients, and that extending medication-abortion protocols beyond seventy days LMP increases provider flexibility. Pls' Ex. 7 ¶¶ 40-44, 57-65. But Article I, Section 22 protects reproductive decision-making, not clinic expansion plans, staffing structures, telemedicine business models, or preferred prescribing practices.

Indeed, Plaintiffs' own experts repeatedly acknowledge the continuing importance of physician involvement. Joanne Spetz recognizes that physician assistants continue to practice within physician-collaboration systems and that Ohio maintains physician-collaboration requirements for APCs. Pls' Ex. 11 ¶¶ 31-32, 94-102. Dr. Kumar similarly explains that APCs providing abortion care at Planned Parenthood of Greater Ohio operate within physician-supervised systems, rely upon physician consultation, and depend on physicians when procedural intervention becomes necessary. Pls' Ex. 7 ¶¶ 57-60.

These admissions are revealing. Even Plaintiffs do not contend that physician involvement lacks value altogether. Their argument is instead that Ohio should require less physician involvement than it currently does. Whether that proposition is correct presents a policy dispute and, at minimum, a factual dispute. It does not establish a constitutional command.

The implications of Plaintiffs' theory illustrate its flaw. If accepted, the Amendment would not simply protect abortion access. It would constitutionalize APC prescribing, telemedicine abortion, medication-abortion protocols extending beyond FDA-reviewed limits, clinic staffing

decisions, and future developments in abortion practice. Such a sweeping transfer of authority from legislatures and medical regulators to courts cannot be inferred from silence.

The more natural and textually faithful interpretation is the narrower one. Article I, Section 22 protects reproductive decisions while preserving Ohio's traditional authority to regulate provider qualifications, prescribing standards, professional conduct, and methods of healthcare delivery. Under that reading, Plaintiffs must do more than demonstrate that they prefer APC prescribing, telemedicine abortion, or alternative medication-abortion protocols. They must show that the Constitution strips Ohio of authority to regulate those subjects. Nothing in the Amendment's text, history, or public understanding supports that conclusion. Accordingly, Plaintiffs' attempt to transform Article I, Section 22 into a constitutional guarantee of a particular provider, a particular protocol, and a particular delivery system should be rejected.

III. Plaintiffs Cannot Establish a Constitutionally Cognizable Burden as a Matter of Law Because Their Evidence Primarily Concerns Provider Preferences, Operational Constraints, and Access Considerations Rather Than the Voluntary Exercise of Reproductive Decision-Making.

Even accepting Plaintiffs' interpretation of Article I, Section 22 for purposes of summary judgment, Plaintiffs still cannot establish, as a matter of law, that the challenged statutes burden the constitutional interest protected by the Amendment. The Amendment primarily protects an individual's reproductive decision-making. Plaintiffs' proof, by contrast, focuses predominantly on clinic operations, provider staffing models, scheduling preferences, telemedicine delivery systems, and the manner in which abortion providers prefer to structure their practices. Those concerns may inform policy debates, but they do not automatically establish a constitutional burden on the exercise of a protected right.

The distinction matters because Ohio law requires constitutional plaintiffs to demonstrate a direct and concrete injury traceable to the challenged law itself. *Cuyahoga Cty. Bd. of Commrs. v. State*, 2006-Ohio-6499, ¶ 22. The Ohio Supreme Court has emphasized that standing is not "dispensed in gross" and that a plaintiff must establish injury with respect to each challenged provision. *Preterm-Cleveland, Inc. v. Kasich*, 153 Ohio St.3d 157, 2018-Ohio-441, syllabus ¶¶ 1-3; *id.* ¶ 30. Likewise, a plaintiff must show a direct and concrete injury caused by the challenged enactment rather than by independent circumstances. *Id.* at ¶¶ 21-22.

Much of Plaintiffs' evidence fails that test. Plaintiffs repeatedly point to physician shortages, clinic-capacity limitations, scheduling difficulties, travel burdens, childcare obligations, workforce challenges, and operational constraints experienced by abortion providers. Dr. Kumar explains that permitting APCs to provide medication abortion allows Planned Parenthood of Greater Ohio to expand appointment capacity, increase service availability, and offer care at additional locations. Pls' Ex. 7 ¶¶ 57-65. Likewise, Plaintiffs' telemedicine evidence focuses extensively on provider workflow, scheduling flexibility, and the operational advantages associated with remote care. *Id.* ¶¶ 15-24, 31-32, 48-50. These allegations primarily concern how providers wish to organize and deliver services rather than whether patients retain the ability to make reproductive decisions.

Indeed, Plaintiffs' own evidence repeatedly attributes many of the alleged delays and burdens to factors wholly independent of the challenged statutes. Dr. Kumar discusses the effects of transportation limitations, employment obligations, childcare responsibilities, financial hardship, poverty, domestic circumstances, provider shortages, and clinic-capacity constraints. *Id.* ¶¶ 46-51. Plaintiffs′ own evidence repeatedly identifies physician shortages, clinic-capacity

limitations, staffing constraints, transportation barriers, and scheduling difficulties as sources of delay, separate and apart from the challenged statutory provisions. Pls' Ex. 7 ¶¶ 46-51, 57-65; Quinn Decl. ¶¶ 13-24; Lewis Decl. ¶¶ 8-16. Thus, even on Plaintiffs' own evidence, the source of many alleged burdens remains disputed.

More importantly, Plaintiffs' experts repeatedly acknowledge the existence of the very medical concerns that Ohio's regulations are designed to address. Dr. Grossman admits that accurate gestational dating is medically significant and that medication-abortion risks increase as gestational age advances. Ex. C at 38:17-25, 39:1-24; Pls' Ex. 6 ¶¶ 36-39, 55-57. He further acknowledges that ultrasound dating is more accurate than self-assessment, testifying that "the error is less with ultrasound compared to self assessment overall." Ex. C at 166:2-6.

Similarly, Dr. Grossman acknowledges that medication abortion does not treat ectopic pregnancy and that some ectopic pregnancies present without symptoms or identifiable risk factors. Ex. C at 107:25-108:13; 125:24-126:25. Plaintiffs' own evidence therefore recognizes the existence of potentially serious medical conditions that require screening before abortion-inducing drugs are administered.

The testimony of Dr. Kumar reinforces the same conclusion. He explains that patients seeking medication abortion through telemedicine are screened for gestational-age uncertainty, ectopic-pregnancy concerns, contraindications, and other clinical factors before receiving care. Pls' Ex. 7 ¶¶ 15-24. Patients who cannot adequately answer gestational-dating questions or who present elevated ectopic-pregnancy concerns are directed into in-person care. *Id.* ¶¶ 17-24. Thus, Plaintiffs' own providers recognize that medication abortion requires screening, evaluation, and diagnostic judgment before treatment proceeds.

These admissions expose the central problem with Plaintiffs' burden theory. Plaintiffs do not actually dispute the importance of gestational-age assessment, ectopic-pregnancy screening, informed consent, follow-up care, physician consultation, or emergency intervention. Rather, Plaintiffs disagree with Ohio regarding the degree of regulation required to address those concerns. That disagreement represents a policy dispute—it does not establish that Ohio's regulations impose a constitutional burden as a matter of law.

Nor do Plaintiffs establish that Section 22 requires the State to prioritize provider convenience over medical safeguards. Their evidence repeatedly emphasizes the efficiencies associated with APC prescribing, telemedicine delivery, and expanded medication-abortion protocols. But Article I, Section 22 does not protect a clinic's preferred staffing arrangement, telemedicine model, prescribing protocol, or operational structure. Those are provider interests. The constitutional right belongs to the patient.

The distinction between provider burdens and patient burdens is particularly significant because Plaintiffs continue to rely heavily on injuries allegedly suffered by providers themselves. Dr. Kumar repeatedly emphasizes the manner in which the challenged laws affect provider recruitment, clinic expansion, staffing flexibility, physician utilization, and service delivery. Pls' Ex. 7 ¶¶ 57-65. Yet restrictions on how providers wish to practice medicine do not automatically translate into burdens on patients' constitutional rights. At a minimum, Plaintiffs must establish a causal link between those provider restrictions and a constitutionally significant burden on reproductive decision-making. Their own evidence reveals substantial factual disputes regarding that causal connection.

The Amendment's emphasis on voluntariness further confirms the insufficiency of Plaintiffs' showing. A decision cannot be meaningfully voluntary unless it is informed. Plaintiffs' own experts acknowledge the importance of diagnosis, eligibility assessment, screening, counseling, follow-up, and evaluation. Ex. C at 107:25-108:13, 125:24-126:25, 166:2-6; Pls' Ex. 7 ¶¶ 15-24, 33-39. Ohio's regulations address those very subjects. Whether the challenged statutes hinder or instead facilitate informed and voluntary decision-making is therefore itself a disputed factual question.

In the end, Plaintiffs seek summary judgment on the assumption that every operational inconvenience experienced by abortion providers constitutes a constitutional burden suffered by patients. The record does not support that assumption. Because Plaintiffs' evidence concerns provider preferences, provider operations, and independent socioeconomic obstacles at least as much as patient decision-making itself, and because substantial factual disputes exist regarding causation, voluntariness, and the medical significance of the challenged regulations, Plaintiffs cannot establish entitlement to judgment as a matter of law.

IV. Even If Plaintiffs Could Demonstrate a Burden Under Section 22(A), the Challenged Statutes Fall Squarely Within the Health-Preserving Authority Expressly Recognized by Section 22(B).

As explained in Section I, Article I, Section 22 was adopted against a backdrop of longstanding medical regulation and cannot reasonably be read to prohibit every law affecting abortion. The relevant question under Section 22(B) is therefore not whether Ohio may regulate at all, rather, the question is whether the challenged statutes constitute the kind of health-related regulation that the Amendment expressly preserves.

They do.

The challenged provisions regulate who may prescribe abortion-inducing drugs, under what circumstances those drugs may be used, and what safeguards accompany their administration. Those subjects lie at the core of medical regulation. Ohio's physician-only requirements, evidence-based-use provisions, and telemedicine restrictions all reflect legislative judgments about patient safety, diagnostic accuracy, complication management, and the appropriate use of potentially dangerous medications. Whether those judgments are optimal is open to debate. Whether they concern health is not.

Indeed, Plaintiffs' own evidence repeatedly confirms the existence of the health-related concerns underlying the challenged laws. Dr. Grossman acknowledges that medication-abortion risks increase as pregnancy advances, that incomplete abortion and continuing pregnancy become more likely at later gestational ages, that medication abortion does not treat ectopic pregnancy, that some ectopic pregnancies occur without symptoms or identifiable risk factors, and that ultrasound dating is more accurate than self-assessment. Ex. C at 38:17-25, 39:1-24, 107:25-108:13, 125:24-126:25, 166:2-6; Pls' Ex. 6 ¶¶ 36-39, 55-57. Dr. Kumar likewise describes extensive screening procedures for gestational age, ectopic pregnancy, contraindications, and post-treatment complications before medication abortion is prescribed. Pls' Ex. 7 ¶¶ 15-24, 33-39. Dr. Spetz acknowledges the continued role of physician-collaboration structures in APC practice. Pls' Ex. 11 ¶¶ 31-32, 94-102.

Those admissions are highly significant. Plaintiffs do not actually dispute that gestational age matters, that ectopic pregnancy presents serious risks, that screening is necessary, that physician consultation has value, or that medication abortion may require follow-up care and

procedural intervention. Instead, they dispute Ohio's judgment regarding how best to address those concerns. That is a fundamentally different proposition.

The record also demonstrates that the challenged laws concern areas of active medical disagreement. Plaintiffs' experts maintain that APCs can safely provide medication abortion, that telemedicine safeguards are sufficient, and that medication abortion remains appropriate through eighty-four days LMP. The State's expert reaches different conclusions regarding physician qualifications, telemedicine limitations, diagnostic reliability, ectopic-pregnancy screening, and later-gestation medication-abortion risks. Ex. A ¶¶ 69-90, 103-132. Thus, this case does not present a circumstance in which all qualified experts agree that Ohio's regulations confer no health benefit. It presents the opposite: a circumstance in which qualified experts disagree about the degree of risk posed by particular medical practices and the extent to which regulation advances patient health.

That disagreement matters because Article I, Section 22(B) does not authorize courts to invalidate longstanding statutes whenever experts disagree with the General Assembly's policy choices. The Ohio Supreme Court has repeatedly emphasized that courts do not substitute their own evaluation of legislative facts for that of the legislature. *Arbino v. Johnson & Johnson*, 116 Ohio St.3d 468, 2007-Ohio-6948, ¶ 58. The Court further explained that "this court is not the forum in which to second-guess such legislative choices." *Id.* at ¶ 71. Where competing expert opinions exist concerning medical risk, courts are not transformed into super-legislatures charged with selecting among competing schools of thought.

Nor should it be forgotten that these statutes enjoy a strong presumption of constitutionality. *State v. Romage*, 138 Ohio St.3d 390, 2014-Ohio-783, ¶ 7. Plaintiffs bear the burden of demonstrating constitutional invalidity beyond a reasonable doubt. *Wilson v. Kasich*, 134

Ohio St.3d 221, 2012-Ohio-5367, syllabus ¶ 2. That burden is especially demanding here, where the challenged laws predate Article I, Section 22 and address recognized medical concerns acknowledged by Plaintiffs' own experts.

Ultimately, Plaintiffs ask this Court to conclude that no reasonable policymaker could determine that physician qualifications, gestational-age limitations, telemedicine safeguards, diagnostic screening, or related protections advance patient health. The record simply does not permit such a conclusion. At minimum, Ohio's regulations address legitimate medical subjects, reflect traditional exercises of regulatory authority, and involve judgments about health and safety on which qualified experts disagree. That is precisely the kind of regulation Article I, Section 22(B) contemplates, and certainly not the kind of record upon which summary judgment should be granted.

V. Genuine and Material Factual Disputes Independently Preclude Summary Judgment.

Even if the Court were to accept Plaintiffs' legal interpretation of Article I, Section 22, summary judgment would remain improper because the record contains extensive disputes of material fact concerning nearly every medical, scientific, and practical premise underlying Plaintiffs' claims. Plaintiffs seek a ruling that Ohio's physician-only requirements, evidence-based-use provisions, and telemedicine restrictions provide no meaningful health benefit and cannot satisfy Article I, Section 22(B). Yet the parties' experts disagree sharply regarding physician qualifications, gestational-age limitations, diagnostic reliability, telemedicine screening, ectopic-pregnancy detection, medication-abortion complications, follow-up care, and the role of physician supervision. Resolution of those disputes would require the Court to weigh competing expert testimony and choose among conflicting medical judgments, a task that is incompatible with

summary-judgment review. *Temple v. Wean United, Inc.*, 50 Ohio St.2d 317, 327 (1977); *Dresher v. Burt*, 75 Ohio St.3d 280, 293 (1996); *Turner v. Turner*, 67 Ohio St.3d 337, 341 (1993).

A. The record contains fundamental disputes regarding gestational dating and medical eligibility.

One of Plaintiffs' central contentions is that direct clinical evaluation and ultrasound provide little or no meaningful benefit in determining eligibility for medication abortion. The record demonstrates otherwise. Plaintiffs' own expert, Daniel Grossman, acknowledged during deposition that ultrasound dating is more accurate than self-assessment, testifying that "the error is less with ultrasound compared to self-assessment overall." Ex. C at 166:2-6. He further testified that medication-abortion risks increase as gestational age advances. Ex. C at 38:17-25, 39:1-24; Pls' Ex. 6 ¶¶ 36-39, 55-57. Likewise, Dr. Kumar explains that providers screen patients for gestational-age eligibility before medication abortion is provided and that patients who cannot adequately answer gestational-dating questions are redirected into in-person care. Pls' Ex. 7 ¶¶ 16-20. He further explains that uncertainty concerning gestational age may itself require direct clinical evaluation. *Id.*

By contrast, Dr. Ingrid Skop concludes that ultrasound remains the gold standard for determining gestational age and that increased diagnostic accuracy advances patient safety, particularly as pregnancy progresses. Ex. A ¶¶ 83-90, 103-106.

Thus, the parties sharply disagree regarding whether Ohio may rely on more accurate methods of gestational-age determination in regulating abortion-inducing drugs. That disagreement concerns a material fact because gestational age affects both treatment eligibility and complication risk.

B. The record contains fundamental disputes regarding ectopic-pregnancy detection.

The experts likewise disagree regarding the adequacy of telemedicine screening for ectopic pregnancy and the importance of direct clinical evaluation. Dr. Grossman admitted that medication abortion does not treat ectopic pregnancy. Ex. C at 107:25-108:13. He further acknowledged that some ectopic pregnancies occur without symptoms and without identifiable risk factors. Ex. C at 125:24-126:25. Dr. Kumar similarly describes extensive efforts by Planned Parenthood of Greater Ohio to identify patients who may present elevated ectopic-pregnancy risks. He explains that telemedicine patients are screened for ectopic pregnancy concerns and that some patients are diverted into in-person care because of elevated risk factors, uncertainty, or concerning symptoms. Pls' Ex. 7 ¶¶ 17-24.

The State's expert reaches a different conclusion regarding the significance of those limitations and opines that ultrasound and direct clinical evaluation remain important safeguards because some ectopic pregnancies evade history-based screening entirely. Ex. A ¶¶ 85-89.

These competing opinions concern a potentially life-threatening condition and present a classic factual dispute. Whether direct evaluation provides meaningful health benefits beyond history-based telemedicine screening cannot be resolved as a matter of law on the current record.

C. The record contains fundamental disputes regarding physician qualifications and APC practice.

The parties also fundamentally disagree regarding whether physician-only prescribing requirements advance patient health. Plaintiffs contend that advanced-practice clinicians can safely provide medication-abortion care. Yet Plaintiffs' own evidence repeatedly acknowledges continuing physician involvement as an important component of abortion provision. Dr. Joanne Spetz recognizes that physician assistants commonly practice pursuant to physician-collaboration

arrangements and acknowledges Ohio's physician-collaboration requirements for APCs. Pls' Ex. 11 ¶¶ 31-32, 94-102. Likewise, Dr. Kumar explains that APCs providing abortion care at Planned Parenthood of Greater Ohio function within physician-supervised systems, rely on physician consultation, and depend upon physicians when procedural intervention becomes necessary. Pls' Ex. 7 ¶¶ 57-60. He further describes physician supervision, chart review, privileging decisions, and procedural backup as parts of the system through which APCs provide medication-abortion services. *Id.*

The State's expert concludes that physician training, diagnostic expertise, and procedural capability provide meaningful safety benefits and support physician-only prescribing requirements. Ex. A ¶¶ 122-132. Thus, even Plaintiffs' own evidence reflects continuing physician participation in medication-abortion care. Whether Ohio may require more direct physician involvement remains a disputed factual and medical question.

D. The record contains fundamental disputes regarding telemedicine safety and clinical limitations.

Plaintiffs repeatedly contend that telemedicine abortion is medically equivalent to in-person care. Their own evidence demonstrates substantial disagreement on that point. Dr. Kumar describes a telemedicine system that relies on detailed screening procedures to identify patients presenting contraindications, gestational-age uncertainty, ectopic-pregnancy concerns, or other clinical factors requiring direct evaluation. Pls' Ex. 7 ¶¶ 15-24. Patients who trigger those concerns are redirected into in-person care. *Id.* Similarly, Dr. Grossman acknowledged that some patients must be screened out of telemedicine pathways and referred for direct clinical assessment. Ex. C at 186:14-17, 135:20-25; 136:11-15.

At the same time, the State's expert opines that telemedicine cannot fully replicate direct observation, ultrasound evaluation, and physician examination. Ex. A ¶¶ 81-90. The significance of those acknowledged limitations remains vigorously disputed. Plaintiffs may ultimately persuade the factfinder that telemedicine adequately addresses those concerns. The State's disagree. Such a conflict cannot be resolved through summary judgment.

E. The record contains fundamental disputes regarding medication-abortion protocols beyond seventy day LMP.

The evidence-based-use provisions generate another substantial factual dispute. Plaintiffs' experts support medication-abortion provision through at least eighty-four days LMP. Pls' Ex. 6 ¶¶ 54-63; Pls' Ex. 7 ¶¶ 40-44. Yet those same experts acknowledge that risks and outcomes change as gestational age increases. Pls' Ex. 6 ¶¶ 36-39, 55-57; Ex. C at 38:17-25, 39:1-24. Dr. Kumar further acknowledges that later-gestation medication-abortion protocols require different treatment regimens and additional misoprostol dosing as pregnancy advances. Pls' Ex. 7 ¶¶ 53-54.

The State's expert reaches materially different conclusions regarding the significance of those increasing risks and concludes that increasing rates of medication-abortion failure, incomplete abortion, and continuing pregnancy justify adherence to FDA-reviewed gestational limits. Ex. A ¶¶ 69-76, 84, 103-106. Accordingly, the parties disagree not about whether gestational age affects medication-abortion outcomes, but about the medical significance of that effect and the appropriateness of Ohio's regulatory response. That disagreement is plainly material.

F. The Record Contains Fundamental Disputes Regarding Coercion Detection, Follow-Up Care, and Emergency Intervention.

The record also contains disputes concerning questions of coercion, follow-up care, and the continuing role of physicians after medication abortion occurs. Dr. Grossman acknowledged that the telemedicine studies on which he relies were not designed to evaluate coercion-detection

protocols. Ex. C at 137:5-138:24. Rather, those studies largely rested on the absence of reported coercion. *Id.* Likewise, Dr. Kumar describes extensive follow-up procedures, including centralized follow-up systems, physician consultation arrangements, escalation procedures, clinic follow-up evaluations, and emergency-room referrals when necessary. Pls' Ex. 7 ¶¶ 33-39.

Those procedures themselves reflect continuing concern regarding adverse outcomes, patient safety, and the need for additional clinical evaluation. Whether Ohio may take such realities into account when regulating abortion-inducing drugs remains a disputed issue. That disagreement is quintessentially factual.

G. Plaintiffs' own evidence demonstrates that health advancement remains hotly contested.

Perhaps most importantly, Plaintiffs' own experts repeatedly acknowledge facts that support the existence of the very health-related concerns addressed by the challenged laws. Plaintiffs' evidence confirms that ultrasound is more accurate than self-reporting. Ex. C at 166:2-6. It confirms that medication-abortion risks change as gestational age advances. Pls' Ex. 6 ¶¶ 36-39, 55-57. It confirms that ectopic pregnancies may present without symptoms or identifiable risk factors. Ex. C at 125:24-126:25. It confirms that medication abortion does not treat ectopic pregnancy. Ex. C at 107:25-108:13. It confirms that telemedicine systems rely on extensive screening protocols. Pls' Ex. 7 ¶¶ 15-24. It confirms that APCs function within physician-supported systems. Pls' Ex. 7 ¶¶ 57-60; Pls' Ex. 11 ¶¶ 94-102. And it confirms that follow-up systems involve ongoing physician consultation and escalation procedures. Pls' Ex. 7 ¶¶ 33-39.

These admissions are not incidental. They go directly to whether Ohio's physician-only requirements, telemedicine safeguards, diagnostic requirements, and evidence-based-use provisions can plausibly advance patient health. The State's expert concludes that they do.

Plaintiffs' experts disagree. Because qualified experts sharply disagree regarding the significance of these acknowledged medical concerns, the record is replete with genuine disputes of material fact. Those disputes independently require denial of Plaintiffs' Motion for Summary Judgment.

VI. Plaintiffs' Own Experts Supply Evidence Supporting Ohio's Position and Independently Demonstrate the Existence of Genuine Issues for Trial.

Perhaps the most significant obstacle to Plaintiffs' request for summary judgment is that their own experts repeatedly acknowledge facts that support the legitimacy of the State's health and safety concerns. This is not a case in which all qualified experts agree that the challenged laws serve no health-related purpose. Nor is it a case in which Plaintiffs have demonstrated that the relevant medical questions are settled. To the contrary, Plaintiffs' own witnesses admit the existence of the very risks, uncertainties, and clinical considerations that Ohio seeks to address through the challenged statutory framework. Those admissions do not automatically establish the constitutionality of the laws, but they do establish beyond any serious dispute that material factual questions remain for resolution at trial.

A. Plaintiffs' Experts Acknowledge the Clinical Importance of Accurate Gestational Dating.

One of Plaintiffs' principal themes is that the challenged restrictions provide little or no medical benefit. Yet Plaintiffs' own evidence confirms that accurate gestational dating remains clinically important. During his deposition, Dr. Grossman acknowledged that ultrasound provides greater accuracy than patient self-assessment in determining gestational age, testifying that "the error is less with ultrasound compared to self-assessment overall." Ex. C at 166:2-6. He further acknowledged that medication-abortion outcomes change as pregnancy advances and that risks increase incrementally with gestational duration. Ex. C at 38:17-25, 39:1-24; Pls' Ex. 6 ¶¶ 36-39, 55-57. Likewise, Dr. Kumar explains that Plaintiffs' own telemedicine protocols include extensive

gestational-dating assessments and that patients who cannot adequately answer gestational-age questions may be redirected to in-person care. Pls' Ex. 7 ¶¶ 16-20. Those practices demonstrate that Plaintiffs themselves regard accurate gestational dating as sufficiently important to warrant screening and eligibility determinations before medication abortion is prescribed.

Thus, while Plaintiffs disagree with Ohio regarding how gestational age should be determined and regulated, their own evidence confirms that gestational age materially affects treatment decisions and patient outcomes.

B. Plaintiffs' experts acknowledge the serious risks associated with ectopic pregnancy.

The same pattern appears with respect to ectopic pregnancy. Dr. Grossman admitted that medication abortion does not treat ectopic pregnancy. Ex. C at 107:25-108:13. He further acknowledged that some ectopic pregnancies occur in patients who present no symptoms and no identifiable risk factors. Ex. C at 125:24-126:25. Dr. Kumar similarly describes extensive screening procedures designed to identify patients who may present elevated ectopic-pregnancy risks. Pls' Ex. 7 ¶¶ 17-24. He explains that patients presenting heightened risk factors, uncertainty, or concerning symptoms may be diverted from telemedicine into direct clinical care. *Id.*

These admissions are difficult to reconcile with Plaintiffs' assertion that additional safeguards provide no meaningful health benefit. Plaintiffs' own evidence establishes that ectopic pregnancy presents a serious medical concern, that it cannot be treated with medication abortion, and that providers expend significant effort attempting to identify patients who may be affected. Whether Ohio's chosen safeguards appropriately address that concern is disputed. The existence of the concern itself is not.

C. Plaintiffs' experts acknowledge the continuing importance of physician involvement.

Plaintiffs likewise challenge Ohio's physician-only requirements while simultaneously relying upon physician-centered systems of care. Dr. Spetz acknowledges that physician assistants throughout the country commonly practice pursuant to physician-collaboration requirements and that Ohio maintains physician-collaboration structures for APC practice. Pls' Ex. 11 ¶¶ 31-32, 94-102. Dr. Kumar similarly explains that APCs providing abortion care at Planned Parenthood of Greater Ohio function within physician-supervised systems, rely upon physician consultation, and depend upon physicians when procedural intervention becomes necessary. Pls' Ex. 7 ¶¶ 57-60. He further describes physician supervision, chart review, privileging decisions, and procedural backup as integral components of the abortion-care system employed by Planned Parenthood of Greater Ohio. *Id.*

These admissions do not establish that Ohio's physician-only requirements are constitutionally required. They do, however, directly undermine Plaintiffs' contention that physician involvement lacks any appreciable value. Plaintiffs' own evidence repeatedly demonstrates that physicians continue to play an important role in diagnosis, consultation, supervision, escalation, and procedural intervention.

D. Plaintiffs' experts acknowledge that telemedicine requires extensive screening and limitations.

Plaintiffs consistently portray telemedicine abortion as interchangeable with in-person care. Yet their own evidence recognizes numerous circumstances in which telemedicine alone is insufficient. Dr. Kumar describes detailed screening requirements designed to identify patients who should not proceed through telemedicine because of gestational age uncertainty, ectopic-pregnancy concerns, contraindications, or other clinical factors. Pls' Ex. 7 ¶¶ 15-24. Patients who

present those concerns are redirected into in-person care. *Id.* Similarly, Dr. Grossman acknowledged that some patients must be screened out of telemedicine pathways and referred for direct evaluation. Ex. C at 186:14-17, 135:20-25; 136:11-15.

These admissions establish that telemedicine and in-person care are not identical. Even Plaintiffs' own providers recognize situations in which direct evaluation remains necessary. At minimum, the significance of those limitations is a disputed factual issue.

E. Plaintiffs' experts acknowledge that medication-abortion outcomes change as pregnancy advances.

Plaintiffs seek a declaration that Ohio's seventy-day limitation lacks any meaningful health justification. Yet their own experts acknowledge that medication-abortion outcomes change as gestational age increases. Dr. Grossman expressly recognizes that risks increase with advancing gestation and that incomplete abortion and continuing pregnancy become more likely later in pregnancy. Pls' Ex. 6 ¶¶ 36-39, 55-57; Ex. C at 38:17-25, 39:1-24. Dr. Kumar similarly acknowledges that later-gestation protocols require different medication regimens and additional misoprostol dosing as pregnancy advances. Pls' Ex. 7 ¶¶ 53-54.

Thus, Plaintiffs' experts do not dispute that gestational age affects outcomes. Rather, they dispute the significance of those effects and whether they justify Ohio's chosen regulatory response. That disagreement is quintessentially factual.

F. Plaintiffs' experts acknowledge the need for continuing physician consultation, follow-up care, and escalation procedures.

Plaintiffs' own evidence also reflects the continuing need for follow-up systems and physician availability after medication abortion is initiated. Dr. Kumar describes centralized follow-up teams, physician-consultation systems, escalation procedures, in-person follow-up appointments, and emergency referrals when needed. Pls' Ex. 7 ¶¶ 33-39. Likewise, Dr. Grossman

acknowledged that most ongoing pregnancies following medication abortion ultimately proceed to procedural intervention and testified that "80 percent or more" of such patients choose procedural abortion. Ex. C at 103:7-13. Those admissions demonstrate that medication abortion may require continuing clinical involvement and that physicians and other providers continue to play important roles after the initial prescription occurs.

G. Plaintiffs' own evidence confirms that the health-advancement inquiry remains deeply contested.

Taken together, Plaintiffs' evidence establishes that:

- ultrasound provides greater accuracy than self-reporting for gestational dating;
- ectopic pregnancies may occur without symptoms or identifiable risk factors;
- medication abortion does not treat ectopic pregnancy;
- telemedicine systems depend upon extensive screening and exclusion criteria;
- Physician consultation and procedural backup remain important features of abortion care;
- medication-abortion outcomes change as gestational age advances; and
- follow-up systems and escalation procedures remain necessary components of care.

See Ex. C at at 38:17-25, 39:1-24, 103:7-13, 107:25-108:13, 125:24-126:25, 135:20-25, 138:21-139:8, 166:2-6; Pls' Ex. 6 ¶¶ 36-39, 55-57; Pls' Ex. 7 ¶¶ 15-24, 33-39, 53-60; Pls' Ex. 11 ¶¶ 31-32, 94-102.

Those facts go directly to whether Ohio's physician-only requirements, telemedicine restrictions, and evidence-based-use provisions can plausibly advance patient health. The State's expert concludes that they do. Plaintiffs' experts disagree. Because qualified experts disagree about the significance of these acknowledged medical concerns, the health-advancement inquiry

required by Article I, Section 22(B) remains intensely contested. That alone is sufficient to defeat Plaintiffs' motion for summary judgment.

CONCLUSION

The Reproductive Freedom Amendment protects the right of Ohioans to make and carry out reproductive decisions. It does not, however, eliminate Ohio's longstanding authority to regulate the practice of medicine, establish provider qualifications, require diagnostic safeguards, regulate the distribution of powerful drugs, or adopt evidence-based measures designed to protect patient health. As demonstrated above, nothing in the Amendment's text, structure, history, or public understanding supports Plaintiffs' sweeping claim that Ohio voters silently repealed physician-qualification requirements, invalidated medication-abortion regulations, or constitutionalized telemedicine abortion. To the contrary, the Amendment expressly preserves the State's authority to regulate in furtherance of health through evidence-based standards of care.

Plaintiffs' motion also fails because it rests on the mistaken premise that Article I, Section 22 guarantees access to a particular provider, a particular medication-abortion protocol, and a particular method of care delivery. The Constitution protects reproductive decision-making—it does not constitutionalize every preferred staffing model, prescribing practice, telemedicine platform, or medication protocol advocated by abortion providers. As courts have long recognized, states retain authority to regulate who may perform medical functions, how dangerous drugs may be prescribed, and what safeguards accompany their use.

Even more fundamentally, Plaintiffs cannot satisfy the demanding standard required for summary judgment. Their own evidence confirms that gestational age matters, that medication-abortion risks increase as pregnancy advances, that ectopic pregnancies may occur without symptoms or identifiable risk factors, that medication abortion does not treat ectopic pregnancy,

that telemedicine requires extensive screening and exclusion criteria, and that APCs regularly function within physician-supervised systems. Ex. C at 38:17-25, 39:1-24, 107:25-108:13, 186:14-17, 135:20-25; 136:11-15, 125:24-126:25, 166:2-6; Pls' Ex. 6 ¶¶ 36-39, 55-57; Pls' Ex. 7 ¶¶ 15-24, 33-39, 53-60; Pls' Ex. 11 ¶¶ 31-32, 94-102. Those admissions directly support the proposition that Ohio's regulations address real medical concerns rather than hypothetical ones.

Indeed, the record is permeated by disputes concerning physician qualifications, telemedicine screening, ultrasound accuracy, ectopic-pregnancy detection, medication-abortion protocols, gestational-age limitations, follow-up care, and physician involvement. Plaintiffs' experts and the State's expert reach materially different conclusions on each of these issues. Resolving those conflicts would require the Court to weigh competing expert testimony and select between competing medical judgments—precisely the type of fact finding that cannot occur on summary judgment.

Finally, the challenged laws enjoy a strong presumption of constitutionality, and Plaintiffs bear the burden of demonstrating constitutional invalidity beyond a reasonable doubt. They have not carried that burden. At minimum, the record demonstrates that reasonable policymakers, reasonable medical professionals, and reasonable factfinders could disagree regarding whether the challenged laws advance patient health and satisfy Article I, Section 22(B). That disagreement alone precludes summary judgment.

For all these reasons, and because the record reveals pervasive and outcome-determinative disputes of material fact concerning every category of challenged regulation, Plaintiffs' Motion for Summary Judgment should be denied in its entirety.

Respectfully submitted,

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**Motion for pro hac vice forthcoming*

/s/ Amanda L. Narog
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Assistant Attorney General

Exhibit A:

Expert Report of Ingrid Skop, M.D.

IN THE COURT OF COMMON PLEAS
FOR HAMILTON COUNTY, OHIO

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, *et al*.,	:	Case No. A 2101148
Plaintiffs,	:	Judge Alison Hatheway
v.	:	
OHIO DEPARTMENT OF HEALTH, *et al.*,	:	
Defendants.	:	

EXPERT REPORT OF INGRID SKOP, M.D.

DAVE YOST
Ohio Attorney General

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Counsel for Defendant State of Ohio

IN THE COURT OF COMMON PLEAS
FOR HAMILTON COUNTY, OHIO

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, *et al.*,	:	Case No. A 2101148
Plaintiffs,	:	Judge Alison Hatheway
v.	:	
OHIO DEPARTMENT OF HEALTH, *et al.*,	:	
Defendants.	:	

AFFIDAVIT OF INGRID SKOP, M.D.

Now Comes affiant Ingrid Skop, having been first duly cautioned and sworn, deposes and states as follows:

1. I am over the age of 18 and fully competent to make this declaration. I have personal knowledge of the statement and facts contained herein.
2. For the purposes of this litigation, I have been asked by counsel for Defendants to analyze relevant data and provide my expert opinions.
3. To that end, I have personally prepared the report attached to this affidavit as Exhibit A and swear to its authenticity and to the faithfulness of the opinions expressed, and, to the best of my knowledge, the accuracy of the factual statements made therein.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 5/1/2026

Sworn and subscribed

eSigned by Black Knight EXP-DocVerify: 2026-05-01 14:33:52 EDT
Ingrid Skop
7474896:47207068:45931269

Ingrid Skop, M.D.

JOSHUA RICHARDSON
NOTARY PUBLIC
STATE OF OHIO
My Commission Expires May 23, 2026

eSigned by Black Knight EXP-DocVerify: 2026-05-01 14:34:38 EDT
7474896:47207068:529926

Notarial Act Performed by Audio visual communication

Exhibit A

IN THE COURT OF COMMON PLEAS
FOR HAMILTON COUNTY, OHIO

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, *et al.*,	:	
Plaintiffs,	:	**Case No. A 2101148**
v.	:	**Judge Alison Hatheway**
OHIO DEPARTMENT OF HEALTH, *et al.*,	:	
Defendants.	:	

EXPERT REPORT OF INGRID SKOP, M.D.

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1. I, Ingrid Skop, M.D., have been retained by counsel for the State Defendants as an expert witness in connection with this case. I have actual knowledge of the matters set forth in this report. My professional background, experience, and publications are detailed in my curriculum vitae. A true and accurate copy of my CV is attached as Exhibit B to this report.

BACKGROUND AND QUALIFICATIONS

2. I have been a board-certified obstetrician and gynecologist since 1998. I received a Bachelor of Science in physiology from Oklahoma State University, and a Doctorate of Medicine from Washington University School of Medicine. I completed a residency in Obstetrics and Gynecology at the University of Texas Health Science Center at San Antonio.

3. I practiced Obstetrics and Gynecology in a group practice in San Antonio from 1996 to 2022. I currently work part-time as an Obstetric Hospitalist and full-time as Vice President and Director of Medical Affairs at the Charlotte Lozier Institute. In my clinical work as an obstetrician/gynecologist, I have delivered over five thousand babies. I have also

evaluated and treated thousands of women after the experience of abortion and have cared for many women who have carried unplanned pregnancies to term. This clinical experience, as well as familiarity with the relevant research literature, informs my opinions herein regarding the physical effects of abortion, particularly abortions initiated with medications.

4. For a complete listing of my professional background, experience, research, responsibilities, and publications, please see my Curriculum Vitae, which is attached to this expert report as Exhibit B.

STATEMENT OF COMPENSATION

5. Because this work falls within my job responsibilities at the Charlotte Lozier Institute (CLI), CLI will be reimbursed $300/hour for written testimony preparation and $350/hour for deposition and trial testimony. My compensation is not tied to the outcome of this litigation or to any opinions or testimony I provide. If I am called to testify, I will do so truthfully and based on my independent expert judgment.

FACTS AND DATA CONSIDERED IN FORMING OPINIONS

6. In preparing this report, I considered the resources referenced herein, Plaintiffs' Complaint, Plaintiffs' expert witness reports, and the statutes at issue in this case.

BASES FOR OPINIONS

7. I have been asked by the State Defendants in this matter to offer my professional opinion regarding the medical implications of the challenged Ohio statutes. The opinions I express herein are based upon my medical education, training, research, and thirty years of clinical experience as an obstetrician and gynecologist, as well as my familiarity with the relevant medical literature. Each opinion offered in this report is made to a reasonable degree

of medical and scientific certainty. These opinions are my own and do not represent those of the institutions with which I am affiliated.

EXPERT OPINIONS

8. In my professional opinion, the challenged Ohio abortion requirements are medically appropriate and justified, including, among other elements, the requirement that an abortion provider must: (1) be a physician (Section 2919.123, 4723.44); (2) provide mifepristone in-person to the person seeking abortion (Section 2919.124); and (3) meet with the pregnant woman in person at least twenty-four hours prior to any abortion to inform her of the nature, purpose, and medical risks of the abortion procedure, the probable gestational age and development of the embryo or fetus, and the medical risks of carrying the pregnancy to term (Section 2317.56). These regulations enhance rather than detract from patient safety, improving the informed consent process, without unduly impeding access to available procedures or introducing unnecessary risks.

9. The Plaintiffs and their expert witnesses are incorrect in their assessment of these laws as they relate to medical abortion. The voters of Ohio approved a State Constitutional Amendment in 2023, *The Right to Reproductive Freedom with Protections for Health and Safety* ("Amendment"), which affirms that "every individual has a right to make and carry out one's own reproductive decisions, including but not limited to decisions on: contraception; fertility treatment; continuing one's own pregnancy; miscarriage care; and abortion." Although the Amendment notes that "[t]he State shall not, directly or indirectly, burden, penalize, prohibit, interfere with, or discriminate against…an individual's voluntary exercise of this right", it qualifies this by stating that limitations are permitted if 'the State demonstrates that it is using the least restrictive means to *advance the individual's health in accordance with widely*

accepted and evidence-based standards of care." Ohio, therefore, may enact legislation that regulates the procedure of abortion if doing so protects the safety or improves the health of women, and, in my expert opinion, these laws do perform that function.

10. The Plaintiffs challenge several laws that had been upheld by the courts prior to the *Dobbs* decision in 2022 and the Ohio Constitutional Amendment in 2023; the so-called "telemedicine ban", "advanced practice clinician ban" and "evidence-based use ban". They assert that, "Telemedicine medication abortion has been studied extensively and determined to be safe and effective" (Second Amended Complaint ¶ 5), the "Advanced practice clinician ban 'restrict(s) qualified and skilled APCs from providing medication abortion" (¶ 6), and the "Evidence-based use ban 'forc(es) abortion providers to prescribe mifepristone only in accordance with the FDA label for the drug" (¶ 6).

11. Although the Plaintiffs complain that the challenged laws are unnecessary, violating the Ohio Constitution's guarantee of substantive due process, equal protection and free choice in health care, they make these claims because they *overestimate the safety of abortion*, particularly when abortion drugs are not dispensed in-person, due to known limitations in data collection, and they *underestimate the potential for complications to women*. By doing so, Plaintiffs risk the health of women and violate the rights of humans not yet born. The challenged regulations are essential protections for a woman considering abortion.

12. Additionally, the Plaintiffs *disregard the critical need for informed consent counseling* when a woman is considering abortion. The *Right to Reproductive Freedom with Protections for Health and Safety* amendment affirms not just the right to make a reproductive decision for abortion, but to *continue one's own pregnancy*. Thorough informed consent is critical so that a woman understands all the implications of the reproductive decision that she

is making. If a woman chooses abortion when she would have preferred to give birth due to lack of information regarding abortion alternatives, or is she chooses an abortion procedure and suffers complications due to inadequate information regarding complication rates, the informed consent process has failed to protect that woman and her unborn child. Ohio must strive to prevent such a tragedy.

I. Abortion Data Deficiencies

13. It is important to be aware of the many data limitations affecting the accuracy of abortion statistics in the U.S.[1] No federal mandates require reporting of any data about abortion: neither its incidence, complications or deaths that follow abortion.[2]

14. The data is grossly misleading: the numbers of abortions that the U.S. Centers for Disease Control (CDC) reports is voluntarily shared by state health departments and is known to be incomplete. Due to privacy concerns and out-of-pocket payment for most abortions, there is no accurate central governmental database that tracks abortion numbers and complications. For example, in 2020, the Guttmacher Institute, aligned with the abortion industry, reported numbers as much as 50% higher than the CDC, which receives its data from the states, with some states such as California and Maryland refusing to provide any information to the CDC.[3]

15. Serious deficiencies exist in abortion complication data collection and reporting. The federal government does not have a mandatory centralized system to detect abortion complications. Although some states have passed laws requiring abortion providers to report

[1] Charlotte Lozier Institute: Fact Sheet: Deficiencies Affecting U.S. Abortion Data Collection and Application. July 2025. https://lozierinstitute.org/fact-sheet-deficiencies-affecting-u-s-abortion-data-collection-and-application/.
[2] Guttmacher Institute: Abortion in the United States. https://www.guttmacher.org/united-states/abortion.
[3] Charlotte Lozier Institute: Five Things We Don't Know about Abortion in the U.S. (but Could with Better Reporting) March 30, 2023. https://lozierinstitute.org/five-things-we-dont-know-about-abortion-in-the-u-s-but-could-with-better-reporting/.

their complications, there is rarely an enforced penalty for noncompliance. Even fewer states require other physicians, coroners, or emergency rooms to report abortion-related complications or deaths for investigation.[4]

16. These statistics have become even more incomplete due to remote prescribing and distribution of abortion drugs. There is no mechanism for tracking the drugs being mailed, often illegally from international distributors, nor confirmation that when received, the pills are being taken to cause an abortion. Recommendations for women to obtain the drugs via "advance provision"-obtaining them before pregnancy occurs in case they are needed, will further obscure the data.[5]

17. Although the Plaintiff's expert Dr. Grossman asserts that "[t]he FDA carefully monitors reports of complications from medication abortion, and the agency's data are as complete for mifepristone as they are for any other FDA-approved drug" (Grossman ¶ 41), he is ignoring the well-documented reality that the FDA Adverse Event Reporting System (FAERS), recently renamed the Adverse Event Monitoring System (AEMS), detects only a small fraction of drug-related complications. FAERS/AEMS is a voluntary, passive collection system, inadequate for obtaining accurate data, as it requires motivation of physicians or the public who suspect a drug injury to navigate the complex system to create a report.

18. The FDA reported they received only eight complication reports from FAERS related to remote prescribing of abortion drugs during the time period in which they were not enforcing the in-person dispensing requirement,[6] and uncritically accepted this extremely low

[4] Guttmacher Institute: State Bans on Abortion Throughout Pregnancy. https://www.guttmacher.org/state-policy/explore/state-policies-abortion-bans.
[5] Charlotte Lozier Institute: *How Many Abortions Are Occurring in America Post-Dobbs?* May 22, 2025 https://lozierinstitute.org/how-many-abortions-are-occurring-in-america-post-dobbs/.
[6] 2023 Mifepristone CDERS https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

number at face value, but it defies logic to believe these were the only complications resulting from remotely administered abortions. It has been documented that over a three-year period, nearly sixty times as many complications were documented by ***the only six states*** that required medication abortion complication reporting than the FAERS reported (despite presumably collecting data from all 50 states).[7]

19. The following example demonstrates the deception that often occurs related to complication reporting. The FDA mandated the reporting of complications by prescribers to the manufacturer Danco following mifepristone use from 2000-2016, through their post-marketing restrictions, in order to monitor safety, but they never made these reports public. To fill this data gap, independent researchers obtained this data via Freedom of Information Act (FOIA) requests and published two peer-reviewed analyses. The submitted data was poor. 16.8% of the reports contained insufficient information to determine clinical severity, but nonetheless 23 deaths, and hundreds of life-threatening and thousands of serious adverse events were reported.[8]

20. Even so, these numbers appeared undercounted, so the researchers compared the complications reported in 2009-2010 to two additional data sources. The first was data collected by the passive FDA Adverse Event Reporting System (FAERS), which allowed the public to voluntarily report complications online.[9] The second was a Planned Parenthood published peer-reviewed study documenting the serious adverse events (including only

[7] Charlotte Lozier Institute*: Fact Sheet: Three Problems with the FDA's Abortion Drugs Complications Data*. March 22, 2024. https://lozierinstitute.org/fact-sheet-three-problems-with-the-fdas-abortion-drugs-complications-data/.
[8] Aultman K, Cirucci CA, Harrison DJ, et al. *Deaths and severe adverse events after the use of mifepristone as an abortifacient from September 2000 to February 2019*. Issues Law Med 2021;36(1):3-26; Gary MM, Harrison DJ. *Analysis of severe adverse events related to the use of mifepristone as an abortifacient*. Ann Pharmacother 2006;40(2):191-197.
[9] FDA Adverse Event Reporting System (FAERS) Public Dashboard. https://www.fda.gov/drugs/fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard.

hospital admissions, transfusions, ER visits, infections requiring IV antibiotics or hospitalization, deaths, ongoing pregnancies, and ectopic pregnancies, but not including failed abortions requiring surgery) they were aware of occurring in 2009-2010. Planned Parenthood reported 1530 adverse events following 233,805 mifepristone prescriptions (0.65%), at a time when they performed 37% of U.S. abortions.[10] During this same time period, the FAERS online dashboard included a total of only 664 reports, and the FDA released only 330 AERs through FOIA.

21. This comparison demonstrated conclusively that Planned Parenthood either did not report all of their complications as required to Danco or the FDA did not release all their reports as required. Clearly the FAERS system and FDA's data released upon the FOIA request both dramatically undercounted complications. The FDA estimates that 3.7 million medication abortions occurred between 2000 and 2018. If the rate of adverse events is conservatively estimated at 2%, then approximately 74,000 complication reports would have been anticipated. This analysis suggests the FDA received reports on fewer than 5% of the estimated adverse events over that period of time.[11]

22. The FDA removed the requirement for prescriber reporting of non-fatal complications in 2016, so for the past ten years, mifepristone prescribers have only been required to report deaths following use of these drugs. Logically, it appears unlikely abortion providers will voluntarily report data that will challenge the safety narrative they have worked so hard to establish for their product, and the data appears to support this conclusion.

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[10] Cleland K, et al., *Significant adverse events and outcomes after medical abortion*, Obstet Gynecol 2013:121:166-169.

[11] Cirucci CA, Aultman KA, Harrison DJ. *Mifepristone adverse events identified by Planned Parenthood in 2009 and 2010 compared to those in the FDA Adverse Event Reporting System and those obtained through the Freedom of Information Act.* Health Serv Res Manag Epidemiol 2021;8:1-8.

23. For various reasons, women often fail to acknowledge a preceding abortion when they seek emergency care for complications, so often the medical provider caring for the emergency is unaware she has experienced an abortion if she does not return to the abortion prescriber. This has led to frequent miscoding of complications and the inability to accurately detect the true incidence of abortion-related complications requiring emergency room care by reviewing hospital records.

24. Records-linkage studies may avoid the errors introduced by voluntary reporting and loss to follow-up, because they link known insurance payments for abortions to subsequent medical events. Although a records-linkage study can document correlation of two events, it cannot always prove causation of events that may be caused by abortion but could also occur due to other factors (for example, a nonspecific diagnosis of pelvic infection may occur due to retained pregnancy tissue from an incomplete abortion but could also be due to concomitant but abortion unrelated sexually transmitted infection). Nonetheless, record-linkage studies can produce significant safety signals regarding events following abortion, particularly if compared to other pregnancy outcomes like childbirth, or by comparing different methods of abortion.

25. Another example will demonstrate how abortion data may be misrepresented. The Plaintiffs' experts referenced a 2015 records-linkage study by abortion advocate Ushma Upadhyay reporting that only 0.87% of 54,911 women receiving California Medi-Cal financed abortions presented to an emergency room with an abortion complication within six weeks. The researchers documented a major complication rate of 0.23% (defined as requiring hospital admission, surgery, or transfusion), but noted that when abortion clinic charts were included, 5.2% of women had complications after medication abortion, 1.3% after first-trimester

aspiration abortion, and 1.5% after second-trimester or later procedures. This four-fold increased risk of complications after early medical compared to surgical abortions has been replicated in several studies.[12] A follow-up study by these same researchers, documented that only 0.01% of ER visits in all reproductive aged women (not just the group known to be post-abortive) were related to abortion complications.[13]

26. However, a larger records-linkage study by independent researcher Jim Studnicki, analyzing 423,000 Medicaid financed abortions in seventeen states over 15 years, documented 2.2% of women presented to an ER with a surgical abortion related complication, and 5.2% presented with a medication abortion related complication within thirty days by 2015, the final year of the study.[14] [15]

27. What accounts for the disparity between these results? The study performed by the abortion advocates recorded complications with a diagnostic code specifically related to

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[12] Upadhyay U, Desai S, Zlidar V, et al. *Incidence of emergency department visits and complications after abortion*. Obstet Gynecol 2015;125:175-83.

[13] Upadhyay U, Johns NE, Barron R, et al. *Abortion-related emergency department visits in the United States: An analysis of a national emergency department sample*. BMC Medicine 2018;16:88.

[14] Studnicki J, Harrison DJ, Longbons T, et al. *A longitudinal cohort study of emergency room utilization following mifepristone chemical and surgical abortions, 1999-2015*. Health Serv Res Manag Epidemiol 2021;8:1-8. (Retracted under dispute)

[15] It will surprise no one to acknowledge that we live in an age of censorship culture regarding highly politicized issues, and those who advocate for readily accessible abortion are often willing to misrepresent and silence any data that does not promote their ideology. The compelling data from Studnicki's research group was cited in a lawsuit that eventually was heard by the U.S. Supreme Court, *Food and Drug Administration et al v Alliance for Hippocratic Medicine et al*. Despite failing to demonstrate that the articles contained, "clear evidence of major errors, data fabrication, or falsification that compromise the reliability of the research findings", as required by the Committee on Publication Ethics (COPE) criteria, the journal Health Services Research and Managerial Epidemiology retracted the previously mentioned paper. Apparently recognizing that they needed an excuse for the retractions, the journal then alleged that the authors failed to acknowledge conflicts of interest (because they were affiliated with a pro-life organization, a standard that the journal has not applied to articles published by pro-abortion organizations), even though the title page of each article documented for the reader the pro-life institutional affiliations of the authors. To add another quasi-excuse for the retractions, the journal also alleged that the double-blinded peer-review process had been compromised because they assigned a reviewer who was affiliated with Charlotte Lozier Institute as an Associate Scholar, even though the reviewer did not know whose article they were reviewing and that person remains unknown to us (due to the double-blinded process). For good measure they retracted two more articles that had been reviewed by the same individual, even though they documented no potential problems with those articles. We are disputing these undeserved and clearly politically motivated retractions in litigation. Further details can be found here: https://assaultonscience.org/?__hstc=85124486.d7099df5dd5241e5fde1ded27c2d5a57.1694546662626.1746187315889.1746284413645.297&__hssc=85124486.1.1746284413645&__hsfp=2831666935#papers.

abortion (ICD-9 635.0-635.82).[16] The independent researchers looked at all pregnancy related codes documenting complications (ICD-9 630-639), because the records documented that all the women had preceding abortions, thus all pregnancy complications were caused by abortion, even if miscoded as resulting from another pregnancy outcome, because it would be physiologically impossible for a repeat pregnancy to occur in that short time period of one month.

28. The independent researchers documented that 60% of known abortion related complications in 2015 were *miscoded as due to miscarriages*, shining further light on deficiencies in abortion complication detection.[17] Subsequent analysis by these researchers documented this problem worsening following the FDA's 2016 REMS changes which loosened restrictions. From 2015 to 2021, 84% of abortion-related ER visits were miscoded as resulting from miscarriages.[18]

29. Although abortion advocacy researchers sometimes imply that most of the ER visits following abortion are uncomplicated visits strictly for patient reassurance, another records-linkage study by the same independent investigators documented the majority of post-abortion complications necessitating an emergency room visit were serious. Over 12 years, 60.5% of post-surgical abortion ER visits (n=57,303) and 69.9% of post-medication abortion ER visits (n=14,454) visits were given a severe or critical acuity Current Procedure Terminology (CPT) code, indicating that these complications were substantial. The likelihood of receiving these

[16] Upadhyay U, Johns NE, Barron R, et al. *Abortion-related emergency department visits in the United States: An analysis of a national emergency department sample*. BMC Medicine 2018;16:88.
[17] Studnicki J, Harrison DJ, Longbons T, et al. *A longitudinal cohort study of emergency room utilization following mifepristone chemical and surgical abortions, 1999-2015*. Health Serv Res Manag Epidemiol 2021;8:1-8. (Retracted under dispute).
[18] Studnicki J, Fisher JW, Cox TL, et al. *Determining the Period Prevalence and Acuity of Emergency Department Visits Following Induced Abortion Mistakenly Identified as Spontaneous Abortion: An Analytic Observational Prospective Cohort Study*. Family Medicine and Primary Care: Open Access. 2025;9:282.

high acuity codes was double (for medication abortion) and 50% higher (for surgical abortion) compared to receiving such codes following childbirth.[19]

30. An even larger database is available for U.S. records-linkage analysis. The Ethics in Public Policy Center (EPPC) published preliminary data on 865,727 mifepristone and misoprostol abortions based on insurance records obtained from a "commercially available all-payer health insurance claims database including de-identified data for all U.S. patients during the years 2017 to 2023. It includes information on hospital and office visits, diagnoses, procedures, and prescriptions processed through private health insurance, Medicaid, Medicare, TRICARE, and the Department of Veterans Affairs (VA)." While not peer-reviewed, the paper demonstrates a far higher serious adverse event rate associated with medication abortions than the FDA's prior data or that abortion industry studies have documented. Among the compelling statistics in this paper were 1257 transfusions (0.15%), 5699 hospitalizations (0.66%), 40,960 ER visits (4.73%), 3062 ectopic pregnancies undiagnosed prior to the abortion (0.35%) and 1956 other life-threatening events (0.22%). Surgical aspiration was documented in 24,563 women (2.84%).[20]

31. Further increasing the risk of complications, many abortion providers are unsupervised by governing organizations, such as Planned Parenthood or National Abortion Federation (which make recommendations for standards of abortion practice), permitting isolated abortionists to practice poor-quality medicine.[21] Even big abortion providers like

[19] Studnicki J, Fisher J, Cox T, et al. *Comparative Acuity of Emergency Department Visits Following Pregnancy Outcomes Among Medicaid Eligible Women*, 2004-2015. International Journal of Epidemiology and Public Health Research. 2024;5(2).
[20] Hall JB and Anderson RT. The Ethics and Public Policy Center. *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*. April 28, 2025. https://eppc.org/publication/stop-harming-women/.
[21] Business Insider. *Horrifying Illegal Abortion Clinic Wasn't Inspected For 17 Years Due To Pro-Choice Policy*. Erin Fuchs. April 10, 2013. https://www.businessinsider.com/kermit-gosnell-clinic-not-inspected-2013-4.

Planned Parenthood have been the subject of critical scrutiny for provision of poor-quality care,[22] and even deaths, which they reportedly sometimes attempt to conceal.[23] The political nature of abortion makes it unlikely that local health departments regularly and consistently provide oversight unless reports of egregious violations of standard practice occur.

32. Finally, it is probable that most abortion-related maternal deaths remain undetected. The CDC relies primarily upon death certificate documentation to identify deaths associated with pregnancy for further analysis to determine pregnancy-relatedness. Yet U.S. death certificates do a poor job of documenting a prior abortion, causing many deaths following abortion to remain unknown and unexamined. Abortion-related deaths are undercounted, because the CDC relies upon death certificate documentation or deaths that happen to come to its attention, but for many reasons these deaths may not be documented. For example, the initiating pregnancy event may be unknown to the death certifier, may be known but not reported, or may be intentionally concealed due to ideologic commitments. There may be technologic or coding limitations in the data collection system, unavailable autopsy results, or incomplete medical records. Due to stigma surrounding abortion, the patient or her family may hide the fact of a preceding abortion. Linkage of death certificate records from women of reproductive age with birth certificates, another method of maternal mortality detection, cannot be performed when a pregnancy loss (either induced or spontaneous) occurs in the first half of pregnancy, because certificates are not assigned for early losses.[24]

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[22] New York Times. *Botched Care and Tired Staff: Planned Parenthood in Crisis*. Feb 15, 2025. https://www.nytimes.com/2025/02/15/us/planned-parenthood-clinics.html.

[23] Pregnancy Help News. *Questions remain following teen mother's post-abortion death*. March 27, 2025. https://pregnancyhelpnews.com/questions-remain-following-teen-mothers-post-abortion-death.

[24] Charlotte Lozier Institute: *Handbook of Maternal Mortality: Addressing the U.S. Maternal Mortality Crisis, Looking Beyond Ideology*. January 26, 2023. https://lozierinstitute.org/handbook-of-maternal-mortality-addressing-the-u-s-maternal-mortality-crisis-looking-beyond-ideology/; Studnicki, et al. *Improving the Metrics and Data Reporting for Maternal Mortality: A Challenge to Public Health Surveillance and Effective Prevention*. Online Journal of Public

33. Better quality European studies demonstrate that reliance upon death certificates alone may miss detection of more than 94% of abortion-related deaths, demonstrating that the abortion-related deaths documented by the CDC likely represent only the tip of the iceberg.[25] Mental health related "deaths of despair", such as suicide, substance abuse and overdose and homicide due to intimate partner violence, are increasingly recognized as causes of maternal deaths following childbirth, but European studies document a woman is up to six times as likely to die from mental health causes in the year following abortion than if she had given birth. Thus, it is likely that many deaths from mental health causes follow abortion but are unable to be detected by the limited U.S. systems.[26] Other comprehensive studies demonstrate that deaths from all causes are also higher in the year following abortion than following childbirth.[27]

II. Abortion Safety

34. With these facts in mind, the Plaintiffs' assertion that abortion is safer than childbirth cannot be substantiated. In the Second Amended Complaint, they allege that "[t]he national risk of maternal mortality associated with live childbirth is approximately 14 times higher than the risk of death associated with induced abortion."[28] And Dr. Grossman doubled down on that poor-quality data by further asserting that "one recent study concludes that

Health Informatics. 2019;11(2):e17; Marmion P, Skop I. *Induced abortion and the increased risk of maternal mortality.* The Linacre Quarterly. 2020;87(3):302-310.

[25] Gissler M, Berg C, Bouvier-Colle MH, Buekens P. *Methods for identifying pregnancy-associated deaths: population-based data from Finland 1987–2000*. 2004;

[26] Karalis E, Ulander VM, Tapper AM, Gissler M. *Decreasing mortality during pregnancy and for a year after while mortality after termination of pregnancy remains high: a population-based register study of pregnancy-associated deaths in Finland 2001–2012*. BJOG 2016;

[27] Reardon DC, Thorp JM. *Pregnancy associated death in record linkage studies relative to delivery, termination of pregnancy, and natural losses: A systematic review with a narrative synthesis and meta-analysis*. Sage Open Med 2017 Nov 13;5: 2050312117740490.

[28] ¶ 59.

pregnancy-related deaths are more than forty-four times as likely as abortion-related deaths."[29] In both cases, the comparison is made by comparing maternal deaths related to childbirth (well-detected due to records-linkage) per 100,000 live births (accurate due to mandated birth certificates) to abortion-related deaths reported by the CDC (poorly detected as documented above) to 100,000 abortions (also unknown, as documented above). Since CDC data fails to detect most abortion-related deaths, this comparison cannot be accurately made, and these statements must be recognized as hopefully ideologic and fatally flawed, rather than evidence-based.[30]

35. The Plaintiffs accurately noted, "The maternal mortality rate is significantly higher for Black women in Ohio, where they are 1.5 to 2.5 times more likely than white women to die of causes related to pregnancy." Yet, unfortunately, Black women are overrepresented among women obtaining abortions, with approximately three times as many abortions as white women. Abortion does not appear to be protecting them from maternal mortality, and due to many other risk factors associated with abortion, it may worsen their risk of mortality.[31]

36. With these data deficiencies in mind, we will examine some studies referenced by the Plaintiffs as demonstrations of "safety". Biased studies published by researchers affiliated with the U.S. abortion industry report low complication rates of abortion.[32] Often, abortion industry studies and FDA data record only the reported numbers of *"serious adverse events",*

[29] Grossman Expert Report, ¶ 25.
[30] Charlotte Lozier Institute: *Fact Check: "Abortion is 14 Times Safer than Childbirth*" April 25, 2024. https://lozierinstitute.org/fact-check-abortion-is-14-times-safer-than-childbirth/.
[31] Charlotte Lozier Institute: *Twelve Reasons Women's Health and Maternal Mortality Will Not Worsen, and May Improve, in States with Abortion Limits*. September 22, 2023. https://lozierinstitute.org/twelve-reasons-womens-health-and-maternal-mortality-will-not-worsen-and-may-improve-in-states-with-abortion-limitations/.
[32] Grossman D, Grindlay K. *Safety of Medical Abortion Provided Through Telemedicine Compared With In Person.* Obstet Gynecol 2017 Oct;130(4):778-782; Academies of Science, Engineering and Medicine: *The Safety and Quality of Abortion Care in the United States*, The National Academies Press. 2018.

(generally comprised of severe complications requiring hospitalization, and death), implying that only life-threatening events should be considered as complications.[33]

37. Abortion industry studies often analyze medical records of high-volume abortion providers but may not reflect the quality of all providers. They often utilize terms that contradict the public's common-sense understanding. The mantra that "abortion is safe and effective" is frequently promoted, without adequate definition of the terms. For example, a study by Planned Parenthood reported medical abortion efficacy of 99.6% while acknowledging that 2.1% of the women required surgery for incomplete abortion. What they meant was only 4 out of 1000 embryos survived the abortion, even though many more women experienced retained products of conception (RPOC) when the medications killed the embryo or fetus but failed to expel all the pregnancy tissue. It is likely many women would consider abortion drugs failing to expel all the pregnancy tissue, necessitating surgery, to be "ineffective."[34]

38. It should be noted that surgery in this situation is different than if a woman had chosen a surgical abortion in the first place. In efforts to express the tissue, the uterus will continue to contract, causing continued pain. Bleeding may continue because the uterus is unable to fully contract due to obstruction from retained tissue, which is required to shut off the blood flow from open vessels. Sometimes this can be resolved with additional doses of misoprostol, but often retention of necrotic pregnancy tissue may require surgical aspiration for resolution.

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[33] Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2022. https://www.fda.gov/media/164331/download.

[34] Ireland L, Gatter M, Chen A. *Medical Compared with Surgical Abortion for Effective Pregnancy Termination in the First Trimester.* Obstet Gynecol. 2015;126:22-28.

39. A woman may suffer these symptoms for long periods of time before seeking care, increasing her emotional burden. I have cared for several women who bled daily for up to two months before finally seeking care. The retained dead pregnancy tissue could hasten an infection or lead to uterine damage that could impact a future pregnancy through the development of scar tissue, affecting placental attachment or even leading to pregnancy loss. The abortion industry chooses not to label this untoward event a complication, even though a standard definition of "complication" is "unanticipated problem that arises following, and as a result of, a procedure."[35] And, as will be discussed below, this complication is documented far more frequently in higher quality studies than the 2.1% reported by this study.

40. In approximately 1-3% of cases,[36] the medication abortion drugs fail to kill the embryo or fetus, allowing a continuing viable pregnancy. If this pregnancy continues until birth, teratogenic effects caused by misoprostol may lead to birth defects such as clubfoot, cranial nerve anomalies and limb abnormalities.[37] Fortunately, survival after mifepristone alone does not appear to increase the risk of congenital anomalies above baseline.[38] But if a woman does not recognize the continuing pregnancy early on, she may require a dilation and evacuation abortion—an much more dangerous second trimester surgical abortion procedure.

41. Additional serious complications can occur following a medication abortion. These include significant hemorrhage, which may necessitate blood transfusions; infection, which in severe cases can progress to life-threatening sepsis, especially from dangerous bacteria such

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[35] Medical Dictionary: *Definition of complication*. https://www.rxlist.com/complication/definition.htm.

[36] Raymond E, Weaver S, Winikoff B. *First trimester medical abortion with mifepristone 200 mg and misoprostol: A systematic review.* Contraception. 2013;87(1):36-37; Chen, Creinin M. *Mifepristone with buccal misoprostol for medical abortion: A systematic review.* Obstet Gynecol. 2015;126(1):12-21; Mentula. *Immediate Adverse events after 2nd trimester termination of pregnancy.* Human Reproduction. 2011;26(4):927-32.

[37] Vauzelle. *Birth defects after exposure to misoprostol in the first trimester of pregnancy: prospective follow-up study.* Reprod Toxicol. 2012;36:98-103.

[38] Delgado G. *A case series detailing the successful reversal of the effects of mifepristone using progesterone*. Issues in Law and Medicine. 2018;33(1): 21.

as Clostridium sordellii or C. perfringens;[39] and heightened risk of mental health issues, including new or worsening depression and anxiety, potentially linked to treatment-related inflammatory processes.[40]

42. From a pharmacological standpoint, mifepristone blocks progesterone and disrupts normal uterine vessel contraction. This mechanism can lead to excessive bleeding by preventing effective hemorrhage control. Moreover, mifepristone and the accompanying misoprostol each exert immunomodulatory effects: mifepristone interferes with uterine immune response, and misoprostol suppresses key innate immunity like macrophage activation, impairing defenses against infection such as Clostridium sordellii. These combined actions may significantly elevate the risk of serious or fatal infections when retained pregnancy tissue remains post-procedure. [41]

43. Mifepristone blocks glucocorticoid receptors which may impair a woman's immune system.[42] The second medication, misoprostol, also suppresses immunity,[43] and if dead tissue is retained, the combined effect of these three mechanisms may dramatically increase the risk of infection. The FDA maintains a "black box" warning on mifepristone alerting prescribers to the risk of a potentially fatal infection from clostridium sordellii.[44] In

[39] Aronoff DM, Hao Y, Chung J, et al. *Misoprostol impairs female reproductive tract innate immunity against Clostridium sordellii.* J Immunol. 2008;180(12):8222–8230. https://pmc.ncbi.nlm.nih.gov/articles/PMC2667109/
[40] Felger JC, Lotrich FE. *Inflammatory cytokines in depression: neurobiological mechanisms and therapeutic implications.* Neuroscience. 2013;246:199-229. doi:10.1016/j.neuroscience.2013.04.060
[41] Helmestam M, Lindgren KE, Stavreus-Evers A, Olovsson. *Mifepristone-exposured human endometrial endothelial cells in vitro.* Reproductive Sciences. 2014;21(3):408-414; Miech, et al. *Pathopharmacology of Excessive Hemorrhage in Mifepristone Abortions*. Annals of Pharmacotherapy, 2007;41(12):2002-2007.
[42] Miech RP. *Pathophysiology of Mifepristone induced septic shock due to Clostridium sordellii*. Ann Pharmacother 2005;39; Fischer. *Fatal Toxic Shock Syndrome Associated with Clostridium sordellii after Medical Abortion*. N Engl J Med 2005;353:2352-2360.
[43] Aronoff DM, Hao Y, Chung J, et al. *Misoprostol Impairs Female Reproductive Tract Innate Immunity against Clostridium Sordellii.* Journal of Immunology 2008:180:8222–8230.
[44] Mifepristone tablets label. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

addition, mifepristone releases inflammatory cytokines which have been implicated in causing depression.

44. In a rat model experiment, the mifepristone termination group had significantly decreased body weight, food intake, locomotor-related activity, and sucrose consumption, which are all animal proxies for depression and anxiety.[45]

45. Importantly, although abortion industry studies may reliably document the number of abortions they have sold, they often ignore the large number of women lost to follow-up, in whom the incidence of complications is unknown.[46] Incredibly, one study was published in a peer-reviewed journal even though over half of the abortion outcomes (57%) were unknown![47] Even when outcome data is obtained, it may be incomplete and of poor quality, often not obtained by in-person examination but by remote messaging. One study documented follow-up after telehealth abortion obtained by text messages, phone calls and emailed surveys, but nonetheless even in that study 26% of the patients were unresponsive to the meager outreach and their outcomes were unknown. [48]

46. Abortion industry studies also often assume that CPT-10 coding for abortion complications are always correct, even though there are many potential complications for

[45] Camilleri C, Beiter R, Puentes L, Scherk P, Sammut S. *Biologic, behavioral and physiologic consequences of Drug-induced pregnancy termination at first-trimester human equivalent in an animal model*. Frontiers in Neuroscience. 2019;13:544.

[46] Chong, et al. *A Prospective, Non-randomized Study of Home Use of Mifepristone for Medical Abortion in the U.S.* Contraception. 2015;92(3):215-219; Grossman, et al. *Safety of Medical Abortion Provided through Telemedicine Compared with in Person*. Obstet Gynecol. 2017;130(4); Raymond, E., et al. *TelAbortion: Evaluation of a Direct to Patient Telemedicine Abortion Service in the United States.* Contraception, 2019;100 (3), 173-177; Chong, E. et al. *Expansion of a Direct-to-patient Telemedicine Abortion Service in the United States and Experience during the COVID-19 Pandemic.* Contraception, 2021;104 (1), 43-48; Upadhyay U. *Safety and Efficacy of Telehealth Medication Abortions in the US during the COVID-19 Pandemic*. JAMA Netw Open., 2021;4; Grossman, D. *Medication Abortion with Pharmacist Dispensing of Mifepristone*. Obstet Gynecol, 2021;137:613-622.

[47] Simons HR, Dieert S, Passman R, Dean G. *An assessment of clinical outcomes of medication abortion without pretreatment ultrasonography in Planned Parenthood, United States, 2020-2021.* Contraception 2024 Aug:136:110469.

[48] Upadhyay U, Koenig LR, Meckstroth, et al. *Effectiveness and safety of telehealth medication abortion in the USA.* Nature Medicine. 2024;30:1191–1198.

which ICD-10 codes do not even exist, and despite the previously documented data deficiencies and miscoding.[49]

47. It is therefore unsurprising that Plaintiffs' expert, Dr. Daniel Grossman, asserts that abortion is "one of the safest treatments in contemporary medical practice."[50] The organization he directs—Advancing New Standards in Reproductive Health (ANSIRH)—has repeatedly promoted the overly simplistic claim that abortion medications are safer than common drugs such as acetaminophen ("Tylenol"), sildenafil ("Viagra"), ibuprofen, and even penicillin.[51] Yet no clinical study has ever directly compared these medications, which would be necessary to substantiate such broad safety claims in a scientifically rigorous manner.[52]

48. Sometimes abortion advocates will compare the number of reported deaths from abortion (likely undercounted as I have discussed) to the numbers of Americans who have died after exposure to the other compared medications. This comparison focuses only on deaths while neglecting to consider other complications, ignores the relative health of the populations consuming these drugs, fails to differentiate whether the drugs were misused or taken according to FDA recommendations, and also fails to consider the size and duration of the population exposed to each of the compared medications.

49. For example, it has been estimated that 60 million Americans consume acetaminophen-containing products each week[53] and most Tylenol-related deaths are

[49] Charlotte Lozier Institute: *Fact Sheet: Abortion Complications and Related ICD-10 Codes*. December 15, 2025. https://lozierinstitute.org/fact-sheet-abortion-complications-and-related-icd-10-codes/.
[50] Grossman Expert Report, ¶ 35.
[51] Advancing New Standards In Reproductive Health: *Safety and effectiveness of first-trimester medication abortion in the United States*. https://www.ansirh.org/sites/default/files/publications/files/medication-abortion-safety.pdf.
[52] Louttit C. *The Origins and Proliferation of Unfounded Comparisons Regarding the Safety of Mifepristone*. BioTech 2025, 14(2), 39; https://doi.org/10.3390/biotech14020039.
[53] Agrawal, S.; Khazaeni, B. *Acetaminophen Toxicity*. In StatPearls; StatPearls Publishing: Treasure Island (FL), 2024.

associated with overdoses of acetaminophen, not routine use.[54] With similar deception, the comparison to deaths following penicillin use can be traced back to a description of four fatal anaphylactic penicillin reactions in a Swiss town reported in a 1968 World Health Organization bulletin, extrapolated for comparison to far larger populations nearly decades later.[55]

50. Likewise, in an article describing 564 deaths following silendafil use, the author writes that "drugs like Viagra are largely taken by individuals with preexisting complex diseases, making it difficult to disentangle the roles of the drug and the underlying condition(s) in the observed mortality."[56] By comparison, most women consuming abortion drugs are healthy and would not be expected to experience complications if the drugs were safe.

51. Nonsteroidal anti-inflammatory medications like ibuprofen and aspirin may cause gastrointestinal bleeding in elderly patients,[57] yet this nuance is also ignored when making these comparisons.

52. On the other hand, the FDA's own data approving mifepristone documents that 2.9-4.7% of women present for emergency room evaluation after using abortion drugs,[58] and similar numbers are confirmed in many other studies. When approximately one in twenty-five patients taking a drug requires an emergency room visit, it seems counterintuitive to call that drug "safe".

III. FDA's Mifepristone Abortion Protocol

[54] Ostapowicz G, Fontana RJ, Schiødt FV; et al. *Results of a Prospective Study of Acute Liver Failure at 17 Tertiary Care Centers in the United States.* Ann. Intern. Med. 2002;137:947–954.
[55] Idsoe O, Guthe T, Willcox RR, et al. *Nature and Extent of Penicillin Side-Reactions, with Particular Reference to Fatalities from Anaphylactic Shock*. Bull World Health Organ. 1968;38:159–188.
[56] Sobel RE, Reynolds RF. *Integrating Evidence from Multiple Sources to Evaluate Post-Approval Safety: An Example of Sildenafil Citrate and Cardiovascular Events*. Curr Med Res Opin. 2008;24:1861–1868.
[57] Lanas A, Perez-Aisa MA, Feu F, et al. *A Nationwide Study of Mortality Associated with Hospital Admission Due to Severe Gastrointestinal Events and Those Associated with Nonsteroidal Antiinflammatory Drug Use.* Off J Am Coll Gastroenterol. 2005;100:1685.
[58] Mifeprex Prescribing Information Label.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

53. The abortion drug regimen approved by the U.S. FDA for use through the 10th week of gestation (based on Last Menstrual Period or LMP) is comprised of two drugs. The first, mifepristone (brand name: Mifeprex), blocks progesterone receptors to cut off hormonal support for the developing embryo or fetus, resulting in disruption of the implantation site—am action that results in the death of the fetus. The second, misoprostol (brand name: Cytotec), is consumed 24-48 hours later to induce contractions to expel the dead embryo/fetus and placental tissue.[59]

54. When the FDA initially approved this regimen in 2000, it imposed strict safeguards. Prescribing physicians were required to undergo specific training and become certified to dispense the drug. Distribution was limited to designated medical settings, and patients were to be fully informed of the risk of serious adverse events. Abortion providers were required to *accurately determine gestational age, confirm an intrauterine location, and intervene surgically if needed* (or have an arrangement with a provider who could perform that intervention). Critically, this core requirement is still mandated by the REMs despite other recent changes.

55. These requirements were consolidated by the FDA into a Risk Evaluation and Mitigation Strategy (REMS) in 2011, with the stated purpose of maintaining safe use of the drugs.[60] Although the agency later removed the requirement that the prescriber to be a physician,[61] this change has created significant challenges, as non-physician prescribers generally lack the surgical skills needed to manage complications. As a result, many women

[59] Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information.
[60] REMS approved in 2011. https://www.fda.gov/media/164648/download?attachment.
[61] REMS approved in 2016. https://www.fda.gov/media/164649/download?attachment.

experiencing adverse events are ultimately forced to seek care in already overburdened emergency departments.

56. Ohio has a legitimate safety interest in retaining a physician-only prescribing requirement to ensure that those who provide the drugs are also capable of managing the frequent complications—particularly those requiring surgical intervention. This requirement promotes continuity of care and enhances patient safety for women who experience complications following medication abortion.

57. Despite the ongoing REMS obligation that prescribers either provide or arrange necessary surgical care, the practical reality is that many women have no one to turn to but the emergency room when complications arise—especially when the drugs are dispensed through mail-order services by remote providers. If a woman does not disclose that she has taken abortion medications, the treating clinicians may not understand the clinical context, which impairs their ability to provide timely and appropriate care. Studies show that when complications are miscoded or clinicians are unaware of the preceding medication abortion, women are more likely to require hospitalization and often endure multiple emergency-room visits before receiving definitive treatment—typically surgical removal of retained pregnancy tissue.[62]

58. Plaintiffs' effort to extend the use of these drugs beyond the FDA-approved gestational limit reflects a willingness to disregard the very REMS safeguards established to ensure their safe use. Rather than prioritizing patient safety, this approach elevates the goal of

[62] Studnicki J, Longbons T, Harrison DJ, et al. *A Post Hoc Exploratory Analysis: Induced Abortion Complications Mistaken for Miscarriage in the Emergency Room are a Risk Factor for Hospitalization*. Health Services Research and Managerial Epidemiology. 2022;9. (Retracted, see additional discussion here: https://assaultonscience.org/?__hstc=85124486.d7099df5dd5241e5fde1ded27c2d5a57.1694546662626.1746187315889.1746284413645.297&__hssc=85124486.1.1746284413645&__hsfp=2831666935#papers.

expanding medication abortion access over adherence to evidence-based standards. The scientific literature overwhelmingly evaluates outcomes only through 9 weeks' gestation, creating an artificially reassuring safety profile because complication rates rise substantially as gestational age increases.[63] By seeking to push the regimen into periods where high-quality data are limited and known risks escalate, Plaintiffs effectively attempt to sideline the REMS program's core purpose—protecting women from preventable harm.

59. The Guttmacher Institute reported that 63% percent of abortions in the U.S. in 2023 were induced by these drugs.[64] Women in Ohio are being steered toward medication abortions for reasons that benefit the abortion provider rather than the woman. A surgical abortion requires the abortion facility to hire a skilled surgeon, provide and sterilize surgical instruments, dispense anesthesia, and incur other expenses. Medication abortion merely assumes the cost of pills that a woman will use to self-manage her own abortion.[65] Plaintiffs have acknowledged they have difficulty employing physicians to perform abortions, so there are several benefits for an abortion facility when a woman chooses a medical abortion over surgery, as it solves their staffing problems. There are even more benefits to the abortion prescriber when medication abortion can be transacted by telemedicine, decreasing costs further by obviating the need for brick and mortar facilities.

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[63] Winikoff B. *Extending outpatient medical abortion services through 70 days of gestational age*. Obstet Gynecol 2012:120:1070-1076; Dzuba IG, et al. *A noninferiority study of outpatient mifepristone-misoprostol medical abortion at 64-70 days and 71-77 days of gestation*. Contraception 2020;101:302-308.

[64] Guttmacher Institute: *Medication Abortion Accounted for 63% of All US Abortions in 2023*—An Increase from 53% in 2020. https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020#:~:text=New%20Guttmacher%20Institute%20research%20from,the%20formal%20health%20care%20system.

[65] Tschann M, Ly E, Hlliard, Hannah L. *Changes to Medication Abortion Clinical Practices in Response to the COVID-19 Pandemic.* Contraception. 2021;104:77-81.https://www.plannedparenthood.org/learn/ask-experts/how-much-does-an-abortion-cost; Jones R, Jerman J. *Abortion Incidence and Service Availability in the U.S.,* 2014. Perspectives on Sexual and Reproductive Health. 2017;49(1):17-27.

60. Plaintiffs express concern that requiring in-person dispensing may reduce abortion utilization by increasing travel distances for some women. While abortion providers may face financial consequences if remote prescribing is limited, there is no medical evidence that a modest increase in travel time imperils women's health. Women who are firmly committed to obtaining an abortion can still readily access one, whereas women who remain uncertain when confronted with minor logistical barriers may pause to reconsider their decision. From a public-health perspective, it is far more appropriate to prioritize patient safety and thoughtful decision-making than to elevate the financial interests of abortion providers or maximize the number of abortions performed.

61. Women often choose the medication abortion method under the false assumption that it is safer and more natural than a surgical abortion.[66] The medication abortion experience is a poor one for most women. The FDA's mifepristone labeling reveals that the average woman bleeds for 9-16 days after taking the drugs and eight percent will bleed longer than a month. The side effects of cramping, vaginal bleeding, hemorrhage, nausea, weakness, fever, chills, vomiting, headache, diarrhea, and dizziness occur in almost all women who undergo a medication abortion.[67] Approximately 40% of women describe the pain from medication abortion as "severe" or "labor-like."[68] Another study reported 30% found their pain to be "a lot more than expected."[69] These disturbing experiences are all considered normal side effects of the medication abortion regimen and are not considered complications.

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[66] Abortion finder. *Pill vs. procedure: How to decide*. https://www.abortionfinder.org/abortion-types/pill-vs-procedure-how-to-decide.

[67] Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information.

[68] Arena. *How much will it hurt? Factors associated with pain experience in women undergoing medication abortion during the first trimester*. Contraception. 2022;11(3).

[69] McCulloch H, Perro D, Taghinejadi N, et al. *Expectations and experiences of pain during medical abortion at home: a secondary, mixed-methods analysis of a patient survey in England and Wales*. BMJ Sex Reprod Health 2024;online.

62. Many abortion clinics fail to offer surgical abortions. The preferential promotion of medication abortion over surgical abortion is documented by the fact that 319 of 777 brick and mortar abortion clinics nationally only offer medication abortions.[70] Despite dramatically four-fold higher rates of complications following medication compared to surgical abortions in all women,[71] there are certain women who are at an even higher risk of medication abortion failure due to preexisting risk factors. It is unlikely they are notified of this when they are screened and counseled by an organization that has only medication abortion to offer. For example, one study documented that women with 5 or more deliveries undergoing medication abortion at < 9 weeks' gestation had 11.5% failures vs 3.5% in the overall study population of 2160 women.[72] Another study documented increased maternal age, prior C-section delivery, and prior manual placental removal all increased risk of medication abortion failure.[73]

63. In his report, Dr. Grossman referenced a 2018 book from the National Academies of Sciences, Engineering, and Medicine (NAS): *The Safety and Quality of Abortion Care in the U.S.,* which made the assertion that medication abortion is extremely safe.[74] The study was commissioned and funded by six abortion advocacy organizations: David and Lucile Packard Foundation, Grove Foundation, JPB Foundation, Tara Health Foundation, William and Flora Hewlett Foundation, and Susan Thompson Buffett Foundation (STB).[75]

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[70] Charlotte Lozier Institute: *How Many Abortions Are Occurring in America Post-Dobbs?* May 22, 2025. https://lozierinstitute.org/how-many-abortions-are-occurring-in-america-post-dobbs/.

[71] Niinimaki M, Pouta A, Bloigu A, et al. *Immediate complications after medical compared with surgical termination of pregnancy*. Obstet Gynecol 2009;114:795-804.

[72] Reeves MF, et al. *Predictors of uterine evacuation following early medical abortion with mifepristone and misoprostol.* Contraception. 2016;93:119-125.

[73] Meaidi A, et al. *Risk factors for surgical intervention of early medical abortion*. Am J Obstet Gynecol. 2019;220:478.

[74] Academies of Science, Engineering and Medicine: *The Safety and Quality of Abortion Care in the United States,* The National Academies Press. Washington DC. 2018. https://www.ncbi.nlm.nih.gov/books/NBK507236/.

[75] *Study Claiming Abortion is Safe Was Funded by Those Who Profit From it and the Media Fails to Investigate*. Live Action. Carole Novielli. https://www.nationalrighttolifenews.org/2019/08/study-claiming-abortion-is-safe-was-funded-by-those-who-profit-from-it-and-the-media-fails-to-investigate/.

64. These researchers performed an extensive literature review but excluded an extraordinary number of studies for perceived defects. Not surprisingly, by primarily using studies performed by fellow abortion advocates, their conclusions were perfectly aligned with the ideological priorities of their funding organizations: that serious complications or long-term physical or mental health effects are virtually nonexistent. In fact, they reported that abortion is so safe that the only deterrent to its safety is legislative restrictions enacted by the states that may prevent a woman from accessing an abortion immediately, "creating barriers to safe and effective care."[76] The bias implicit in this review is obvious.

65. Regarding short-term complications of mifepristone and misoprostol medication abortions, they referenced Chen's 2015 systematic review (documenting 3.3% of women requiring surgery for failed abortions) but did not remark on the higher 4.8% rates requiring surgery documented in Raymond's 2013 systematic review. They referenced other abortion industry studies (without discussing the data deficiencies mentioned earlier) and continued to propagate the illusion that serious adverse events are the only complications worth mentioning. They promoted telemedicine by referencing small hybrid studies that did not replicate the current conditions of use allowed by the FDA and reiterated the mythology that mifepristone complications are similar to those from commonly available over the counter drugs as addressed above.[77]

66. Instead, they reported that abortion has no long-term adverse effects and stated it specifically does not increase the risk of preterm delivery, mental health disorders, or breast cancer. However, when one examines the research studies they used for their conclusions, the

[76] Academies of Science, Engineering and Medicine: *The Safety and Quality of Abortion Care in the United States,* The National Academies Press. Washington DC. 2018. https://www.ncbi.nlm.nih.gov/books/NBK507236/.
[77] Ibid.

poor quality of the literature regarding long-term complications becomes apparent. For many questions, there were very few or no studies that they considered suitable for answering their questions. Yet rather than calling for more studies to supplement the limited data, they somehow produced strong assertions regarding their definitive conclusions.[78]

67. For example, they considered only five studies examining a link between abortion and preterm birth (even though seventy peer-reviewed studies documenting an increased risk exist in the literature since 2000, the arbitrary date they set for inclusion, and 163 studies exist in total);[79] three studies examining a link between abortion and breast cancer (even though seventy-six peer-reviewed studies exist in the literature, sixty showing a positive correlation, and thirty-six showing statistically significant increased risk)[80]; and considered only seven studies examining a link between abortion and mental health disorders (four were drawn from the same study group, the Turnaway cohort, whose limitations have been extensively criticized[81]). Yet, seventy-five peer-reviewed studies exist in the mental health literature from the past twenty-five years, and forty-nine of these (65%) show statistically significant increased risk of mental health disorders after abortion.[82]

68. Thus, in all cases, there were less than five study groups on which the NASEM committee based their definitive conclusion of "no long-term impact" while there were hundreds of studies they ignored. A non-biased committee in search of truth should have

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[78] Ibid.

[79] American Association of Pro-Life Obstetricians and Gynecologists. Practice Bulletin 5: *Abortion and Preterm Birth*. https://aaplog.org/resources/practice-guidelines/; American Association of Pro-Life Obstetricians and Gynecologists. Practice Bulletin 11: *A Detailed Examination of the Data on Surgical Abortion and Preterm Birth*. https://aaplog.org/resources/practice-guidelines/.

[80] American Association of Pro-Life Obstetricians and Gynecologists. Committee Opinion 8: *Abortion and Breast Cancer*. https://aaplog.org/resources/practice-guidelines/.

[81] Reardon D. *The Embrace of the Proabortion Turnaway Study: Wishful Thinking? or Willful Deceptions?* Linacre Quarterly 2018;85(3):204-212.

[82] American Association of Pro-Life Obstetricians and Gynecologists. Practice Bulletin 7: *Abortion and Mental Health*. https://aaplog.org/resources/practice-guidelines/.

recommended more studies if they found only a handful of studies they concluded were reliable.

69. Higher quality international data, however, confirms the underestimation of U.S. abortion industry data. A 2013 systematic review of 45,528 mifepristone and misoprostol abortions < 9 weeks documented that 4.8% failed requiring surgery, and 1.1% failed to kill the embryo. Higher failure rates were documented in cohorts that included more subjects in the higher gestational age groups.[83]

70. Another 2015 systematic review of 33,846 mifepristone with buccal misoprostol abortions documented failures requiring surgery of 3.3% < 9 weeks, noting that only 332 abortions had been studied in the literature between 9-10 weeks with a doubling of the failure rate to 6.9%. Ongoing pregnancy rate was 0.8%. By gestational age, failures were 1.9% < 7 weeks, 3.3% between 7-8 weeks, 4.8% between 8-9 weeks and 6.9% between 9-10 weeks.[84]

71. Within Canada's universal health care system, records-linkage analysis was performed linking abortions performed between 2017-2020 to subsequent adverse events within 42 days. 39,856 mifepristone and misoprostol abortions (gestational age was not specified, but they are usually performed at < 9 weeks in Canada although they may be used off label < 14 weeks), were compared to 65,176 procedural abortions < 14 weeks and 8861 procedural abortion < 9 weeks. Two definitions of complications were provided: serious adverse events (SAE) included severe maternal morbidity, end-organ damage, intensive care unit admission, and death. A broader analysis of any adverse events (AAE) included the previously defined SAE as well as hemorrhage, retained products of conception, infection, or

[83] Raymond E., et al. *First trimester medical abortion with mifepristone 200 mg and misoprostol.* Contraception. 2013;87(1):26-37.
[84] Chen M. & Creinin M. *Mifepristone with buccal misoprostol for medical abortion: a systematic review*. Obstetrics & Gynecology. 2015;126:12-21.

transfusion. The medication abortion group experienced 0.33% SAE, 2.89% AAE, 10.26% ER visits, and 4.89% required procedural completion; the procedural abortion group < 14 weeks experienced 0.18% SAE, 1.24% AAE, 7.26% ER visits and 1.14% required another procedural intervention. The procedural abortion group < 9 weeks had 0.33% SAE, 2.49% AAE, 9.29% ER visits and 1.36% required another procedural intervention.[85]

72. A 2011 Finnish records-linkage review of 18,248 medical abortions demonstrated 7.9% failed requiring surgery in the first trimester and 38.5% failed requiring surgery in the second trimester. Hemorrhage occurred in 17.2% of first trimester and 14.4% second trimester abortions, and infection occurred in 1.9% first trimester and 4% in second trimester abortions.[86]

73. Another 2011 Finnish study compared the outcomes of 3024 adolescent and 24,006 adult women undergoing medication abortion in the first 20 weeks of pregnancy. Adolescents were more likely to have chlamydia 5.7% vs 3.7%, but the rates of other adverse events were similar or lower in adolescents: hemorrhage 12.8 vs 15.4%, infection 2 vs 2%, incomplete abortion 7 vs 10.2%, and surgical evacuation 11 vs 13%.[87]

74. An additional 2009 Finnish records-linkage review of 42,619 abortions < 9 weeks gestation, divided almost equally into mifepristone & misoprostol abortions (using a slightly different regimen than currently used in the U.S.) and surgical abortions, documented 20% of women obtaining medical abortions had at least one complication (hemorrhage, infections, incomplete abortion, injuries requiring surgery, thromboembolic disease, psychiatric morbidity, and death), 15.6% hemorrhage, 6.7% incomplete abortion and 5.9% required

[85] Liu N and Ray JG. *Short-Term Adverse Outcomes After Mifepristone–Misoprostol Versus Procedural Induced Abortion: A Population-Based Propensity-Weighted Study*. Ann Intern Med. 2023;176:145-153.
[86] Mentula MJ, Niinimaki M, Suhonen S, et al. *Immediate adverse events after 2nd trimester termination of pregnancy: Results of a nationwide registry study.* Human Reproduction. 2011;26(4):937-942.
[87] Mentula MJ, Niinimaki M, Suhonen S, et al. Ninimikki. *Comparison of rates of adverse events in adolescent and adult women undergoing medical abortion: population register based study*. BMJ 2011;342:d2111.

surgical completion (compared to 5.6%, 2.1%, 1.6% and 1.8% of these events following surgical abortion.)[88]

75. It should be noted that even Planned Parenthood's own website documents statistics more in line with the higher-quality data than abortion industry studies. It lists the following failure rates: 8 weeks or less- 94% to 98% effective/2 to 6% failure rate; 8 to 9 weeks – 94 to 96% effective/4 to 6% failure rate; 9 to 10 weeks – 91-93% effective/7 to 9% failure rate; 10-11 weeks pregnant, 87% effective/13% failure rate.[89]

76. These high failure rates (ranging from 3.3-4.8% < 9 weeks to 13% < 11 weeks to 38.5% in the second trimester) are not negligible. Many women with failed medication abortions will not return to the abortion provider, but will present to an emergency room, bleeding heavily, where they will often require immediate surgery and sometimes hospitalization for blood transfusion or intravenous antibiotics. The FDA's Risk Evaluation and Mitigation Strategies (REMS) supervising medical abortion provision requires the abortion provider to provide surgical intervention when medical abortion fails or have an arrangement with another provider who can provide that emergency care, but far too often the prescriber does not perform the necessary care or appear to have made any attempt to have another provider available to provide such care in their stead.

77. The further a woman lives from the abortion provider, the greater her risk if she should suffer complications from a medication abortion. Without a physician-patient relationship or proximity to emergency care, a rural Ohio woman experiencing these common complications finds herself abandoned and at high risk for adverse events. The rural location

[88] Niinimaki. *Immediate complications of medical compared with surgical termination of pregnancy*. Obstet Gynecol. 2009;114(4):795-804.
[89] Planned Parenthood: *The Abortion Pill*. https://www.plannedparenthood.org/learn/abortion/the-abortion-pill.

of many Ohio women emphasizes the importance of accurate counseling to help a woman choose the appropriate abortion procedure. Women with limited access to emergency care would be far better served by a surgical abortion that is completed at the clinic and has a far lower incidence of complications. Remote location is an argument against medical abortion, not a reason to encourage it with telemedicine.

IV. Changes to Medication Safety Requirements

78. The FDA has inappropriately loosened safeguards on mifepristone provision. At the time of mifepristone's approval in 2000, the FDA maintained strict supervision over its use. In 2011, this was formalized as a Risk Evaluation and Mitigation Strategy (REMS). In addition to mandatory complication reporting and requirement to provide or arrange for surgical completion if a complication occurred, the REMS had several other provisions to ensure the procedure was as safe as possible for the woman. This included registration and training of the abortion provider, providing the woman with documentation of the risks, and most importantly, in-person provision of mifepristone.

79. The FDA approved a supplemental application in 2016 which loosened the restrictions and extended use until 70 days gestational age. Mandatory in-person visits were decreased from three to only one. Dose, timing, and route of administration were modified. Abortion providers were no longer required to report a complication unless it resulted in a woman's death.[90]

80. Finally, in December 2021, the FDA *permanently removed the in-person dispensing requirement* (which had been temporarily removed due to the Covid-19 pandemic). This action was justified to allow telemedicine but does not prevent on-line ordering from

[90] REMS approved in 2016. https://www.fda.gov/media/164649/download?attachment.

remote websites and delivery in the mail, without any provider interaction. This has allowed the provision of mifepristone *without ultrasound, labs, physical exam or even looking a woman in the eye to confirm that she desires an abortion*.[91] Investigative journalists[92] and even an ob/gyn[93] have documented the ease with which abortion drugs can be obtained through on-line ordering and mail order delivery without any pre-abortion testing, even in the presence of substantial risk factors.

V. Risks of Telemedicine Abortion

81. What harms may result from the removal of the in-person dispensing requirement? Failure to document accurate gestational age[94] or the presence of an intrauterine pregnancy with ultrasound or to document blood Rh status and provide RhoGAM if indicated,[95] may lead to immediate or future complications. Additionally, failure to document that the recipient of the drugs is a woman desiring abortion may encourage coercion of hesitant women by unwilling partners, incestuous abusers, and sex traffickers into unwanted abortions, an increasingly recognized concern, [96] and, unfortunately, a recently realized outcome.[97]

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[91] REMS approved in 2021. https://www.fda.gov/media/164651/download?attachment.

[92] Daily Caller. *We Found Out How Easy It Is To Order An Abortion Pill. The Results Are Shocking*. June 19, 2025. https://dailycaller.com/2025/06/19/chemical-abortion-pill-order-online/.

[93] Pulling Back the Curtain on AAPLOG's Undercover Abortion Pill Video. https://www.youtube.com/watch?v=mmkqMVsOWWE.

[94] Ellertson C, Elul B, Ambardekar S, et al. *Accuracy of assessment of pregnancy duration by women seeking early abortions.* Lancet 2000;355:877-881; Taipale P, Hiilesmaa V. *Predicting delivery date by ultrasound and last menstrual period in early gestation.* Obstet Gynecol 2001;97(2):189-194; Savitz DA, Terry JW, Dole N, et al. *Comparison of pregnancy dating by last menstrual period, ultrasound scanning, and their combination*. AJOG 2002;187(6):1660-1666.

[95] American College of Obstetricians and Gynecologists. Practice Bulletin 181: *Prevention of Rh D Alloimmunization*. Obstet Gynecol 2017;130(2):481-483; Fiala C, Fux M. *Rh-prophylaxis in early abortion*. Acta Obstet Gynecol Scand 2003;82(10): 892-903.

[96] Bourassa D, Bérubé J. *The prevalence of intimate partner violence among women and teenagers seeking abortion compared with those continuing pregnancy*. J Obstet Gynecol Canada 2007;29(5): 415-423; Hall M, Chappell L, Parnell B, Seed P, Bewley S. *Associations between intimate partner violence and termination of pregnancy: a systematic review and meta-analysis*. PLOS Medicine 2014;11(1):e1001581; Lederer L, Wetzel C. *The health consequences of sex trafficking and their implications for identifying victims in healthcare facilities.* Ann Health Law 2014;23(1):61-91.

[97] Casiano, L. *Ohio surgeon accused of forcing abortion pills on sleeping girlfriend*. December 10, 2025. https://www.ktvu.com/news/ohio-surgeon-accused-forcing-abortion-pills-sleeping-girlfriend

82. This change will undoubtedly increase the risk of failures and adverse events after medication abortions, especially when women knowingly or unknowingly take the drugs past the 10-week gestational cutoff. As documented earlier, complications rise substantially as gestational age increases. This expected increase in complications will be difficult to study and document, however, because abortion advocates sometimes encourage women not to report that they have taken abortion drugs if they experience a complication requiring medical treatment, and they also advocate for removal of any existing state complication reporting requirements.[98] These actions will cause the already poor-quality data to become worse.

83. An ultrasound is necessary to ensure safe use of abortion drugs for several reasons: Ultrasound is the gold standard for *correct estimation of gestational age*.[99] Providing abortion drugs without an ultrasound assumes that a woman will be able to accurately determine her gestational age based on her last menstrual period. Many women have irregular menses, conceive on contraception, or simply do not accurately recall the date of their last menstrual period.[100] A study in Georgia found that 15% of women were in error in estimating their gestational age by at least two weeks.[101] Even skilled obstetricians may not be able to detect these errors by physical exam alone, especially if a woman is obese. Increasing obesity in our country has led to a high incidence of polycystic ovarian syndrome causing irregular ovulation

[98] Guttmacher Institute: *With Risks to Patients and Providers Growing, States Should Revisit Abortion Reporting Requirements.* March 2025. https://www.guttmacher.org/2025/03/risks-patients-and-providers-growing-states-should-revisit-abortion-reporting-requirements#:~:text=Repeal%20or%20Reform%20of%20State,collection%20now%20outweigh%20its%20benefits

[99] American College of Obstetricians and Gynecologists. Practice Bulletin Number 175. *Ultrasound in Pregnancy*. Obstet Gynecol 2016;128(6):1459–1460.

[100] Taipale P, Hiilesmaa V. *Predicting delivery date by ultrasound and last menstrual period in early gestation*. Obstet Gynecol 2001;97(2):189-194; Savitz DA, Terry JW, Dole N, et al. *Comparison of pregnancy dating by last menstrual period, ultrasound scanning, and their combination.* Amer J Obstet Gynecol 2002;187(6):1660-1666; *The accuracy of using last menstrual period to determine gestational age for first trimester medication abortion: a systematic review*. Contraception. 2014;90(5):480-487.

[101] Ellertson C, Elul B, Ambardekar S, et al. *Accuracy of assessment of pregnancy duration by women seeking early abortions.* Lancet 2000;355:877-881.

and menstruation. Implantation bleeding may lead a woman to assume she had a period when in fact she is already pregnant.

84. Complications and failures of medication abortion increase as gestational age increases, so errors in calculation may, and likely will, harm women. Studies document that medical abortion performed at less than nine weeks gestation has a failure rate of 3.3-4.8%[102] but increases to 6.9-7.8% between 9-10 weeks gestation (at the FDA's cutoff), 13.3% between 10-11 weeks gestation,[103] and skyrockets to 38.5% if abortion drugs are accidentally or intentionally consumed in the second trimester.[104]

85. The danger of providing mifepristone and misoprostol without ruling out an *ectopic pregnancy* by ultrasound first cannot be overemphasized. These drugs cannot treat an ectopic pregnancy because they exert their actions primarily upon the uterus. When abortion drugs are given without confirmation of an intrauterine pregnancy, it may be days or longer before a woman becomes aware of a problem, seeks medical assistance, and is correctly diagnosed with an ectopic pregnancy. Whereas, an early diagnosis can often be treated medically with a methotrexate injection, a later diagnosis will often require surgery or other emergent interventions.[105]

86. During the time that it remains undiagnosed, an ectopic pregnancy may continue to grow, possibly to the point of tubal rupture, which can lead to catastrophic bleeding and death.

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[102] Chen M & Creinin M. *Mifepristone with buccal misoprostol for medical abortion: a systematic review*. Obstetrics & Gynecology. 2015;126:12-21; Raymond E., et al. *First trimester medical abortion with mifepristone 200 mg and misoprostol.* Contraception. 2013;87(1):26-37.

[103] Winikoff B., Dzuba I.G., Chong E. *Extending outpatient medical abortion services through 70 days of gestational age.* Obstetrics & Gynecology. 2012;120(5):1070-1076; Dzuba IG, et al. *A noninferiority study of outpatient mifepristone-misoprostol medical abortion at 64-70 days and 71-77 days of gestation.* Contraception 2020;101:302-308.

[104] Mentula, et al. *Immediate adverse events after 2nd trimester termination of pregnancy: Results of a nationwide registry study*. Human Reproduction. 2011;26(4):937-942.

[105] ACOG Practice Bulletin 193: *Tubal Ectopic Pregnancy*. Obstet Gynecol 2018;131(3):e91-e103.

It has been documented that a woman is 30% more likely to die from a ruptured ectopic pregnancy while seeking abortion if it remains undiagnosed, because she may interpret the warning signs of pain and bleeding as signs the medication abortion pills are working rather than a warning sign that her life is in danger.[106] While ectopic implantations occur in only 2% of pregnancies, ruptured ectopic pregnancies account for up to 10% of maternal deaths.[107] Half of women with ectopic pregnancies have no risk factors for this serious condition, and the gold standard for diagnosis is ultrasound.[108]

87. A 2022 Planned Parenthood retrospective study of a cohort < 6 weeks with no sonographic visualization of pregnancy examined the outcomes of 55 women who started abortion drugs that day against those of 394 for whom the medication was delayed until the location of the pregnancy could be definitively diagnosed. None of the patients who started the drugs immediately was subsequently diagnosed with an ectopic pregnancy, although 12.7% were lost to follow-up and may have had ectopic pregnancies treated elsewhere. However, 7.9% (31/452)) of those whose treatment was delayed were subsequently treated for ectopic pregnancies, many with serious adverse events: four ruptured tubes, four hospitalized, two hemorrhage, eight unplanned major surgery. This group also had a high loss to follow-up of 16.8% and may have included other ectopic pregnancies that remained unknown to the researchers. Notably, 14.6% of those whose abortion was started on the day of nondiagnostic ultrasound experienced a failed abortion (vs 3.3% whose abortion was delayed), and 10.4% had on-going pregnancy (vs 2.5% in the delayed group), demonstrating that provision of

[106] Atrash HK, MacKay HT, Hogue CJ, et al. *Ectopic pregnancy concurrent with induced abortion: Incidence and mortality.* Am J Obstet Gynecol 1990;162(3):726-730.
[107] Marion LL, Meeks GR. *Ectopic pregnancy: history, incidence, epidemiology, and risk factors*. Clin Obstet Gynecol 2012;55(2):376-386.
[108] ACOG *Ectopic Pregnancy FAQs*. https://www.acog.org/womens-health/faqs/ectopic-pregnancy.

mifepristone at too early a gestational age may also be associated with more complications, a fact that is rarely mentioned. Although 80% of those with ectopic pregnancy had symptoms of bleeding or pain, 49.6% of those without an ectopic also had these same symptoms, so clearly symptoms or lack thereof cannot be used as a reliable screen for ectopic pregnancy. Even though the women in this study were followed until their pregnancy location was known and all ectopic pregnancies were eventually diagnosed, this study is referenced to promote abortion drug distribution without requiring follow-up.[109]

88. By downplaying these reasonable but serious concerns, abortion advocates are placing women at substantial risk and minimizing the suffering they may endure. Delayed diagnosis of an ectopic pregnancy can significantly worsen outcomes. What could have been managed medically with methotrexate may instead require surgical intervention, and a rupture may necessitate removal of the entire fallopian tube (salpingectomy) rather than removal of only the ectopic tissue while preserving the tube (salpingostomy). Both scenarios place a woman's future fertility at increased risk. A delayed diagnosis can also result in substantial blood loss requiring transfusion, and in rare cases may even be fatal. These serious complications are largely preventable when the ectopic pregnancy is identified and treated promptly.

89. Ultrasound will prevent illegal and dangerous abortions. Abortions are illegal in Ohio beyond a certain gestational age and infants may be born alive after failed later abortion procedures, so an ultrasound demonstrating advanced gestational age will inform a woman that she has passed the legal limit to obtain an abortion. Additionally, anatomic abnormalities, such as uterine fibroids, septum or unusual orientation, and abnormal placentation may not be

[109] Goldberg AB, et al. *Mifepristone and misoprostol for undesired pregnancy of unknown location*. Obstet Gynecol. 2022;139(5):771-780.

detected without ultrasound and could complicate the abortion procedure and place the woman's life in danger.

90. By prohibiting remote dispensing of abortion drugs, Ohio will improve the safety for women seeking abortion in other ways. In-person evaluation will allow other critical laboratory testing to be more easily performed. Failure to perform laboratory testing to screen for Rh-D negativity and provide RhoGAM prophylaxis, if indicated, may lead to alloimmunization, a maternal immune response directed against future unborn children, which can lead to life-threatening complications of severe fetal and neonatal anemia, brain damage and stillbirth or neonatal death.[110] Although abortion advocates have recently stated that RhoGAM is not necessary in the first trimester,[111] alloimmunization has been documented in the first trimester,[112] and the failure to accurately determine the gestational age by ultrasound will lead to underestimation of gestational age in some cases, causing some women to fail to receive indicated RhoGAM in the second or third trimester.

91. The process by which the Rh recommendations were amended is instructive of the mindset of abortion advocates. In 2017, the American College of Obstetricians and Gynecologists (ACOG) stated that "Rh D immune globulin should be given to Rh D-negative women who have a pregnancy termination, either medical or surgical." They further documented that "Rh testing is standard of care in the U.S. and Rh immunoglobulin should be administered if indicated."[113] In their 2020 updated medical abortion recommendations,

[110] American College of Obstetricians and Gynecologists. Practice Bulletin 181: *Prevention of Rh D Alloimmunization*, Obstetrics & Gynecology 2017;130(2):481-483; Fiala C, Fux M. Rh-prophylaxis in early abortion. Acta Obstet Gynecol Scand 2003;82(10): 892-903.

[111] Horvath, S et al. *Society of Family Planning committee consensus on Rh testing in early pregnancy*, Contraception, 2022;114:1-5.

[112] de Haas, M et al. *Anti-D prophylaxis: past, present and future,* Transfusion Medicine, 2014;24(1): 1-7; Bowman, J. *Thirty-five years of Rh prophylaxis*, Transfusion, 2003;43(12):1661-1666.

[113] American College of Obstetricians and Gynecologists (2017). Practice Bulletin 181: *Prevention of Rh D Alloimmunization*. Obstetrics & Gynecology, 130(2): 481-483.

ACOG continued to recommend Rh testing and Rh immunoglobulin when indicated, but then hedged by saying, "in situations where (these) are not immediately available or would significantly delay medication abortion, shared decision making is recommended."[114] Thus, without any new clinical information, this pro-abortion medical organization opened the door to lowering the standard of care, to the detriment of the health of women and their future children. If these recommendations are ignored and isoimmunization occurs, fourteen percent of untreated infants will be stillborn, and half will suffer neonatal death or brain injury.[115] The failure of the Plaintiffs to err on the side of caution and patient health, as they seek to remove the opportunity for pre-abortion testing of ultrasound and labs, demonstrates a prioritization of immediate abortion over the safety of women and the health of future unborn children.

92. Additionally, failure to perform labs for sexually transmitted infections will miss the diagnosis and treatment of chlamydia and other sexually transmitted infections that may place a woman's future fertility at risk. Failure to exclude women with severe anemia from medication abortion provision may cause some women to need transfusions if they experience significant blood loss.

VI. FDA's Reliance on Faulty Data

93. What studies did the FDA rely upon to make these changes? Beginning over a dozen years ago, the abortion industry began publishing studies which attempted to reassure that in-person provision or follow-up of medication abortion was unnecessary. A 2011 systematic review of eight articles utilizing a standardized post-abortion assessment of women's symptoms combined with low-sensitivity urine pregnancy testing and telephone

[114] ACOG Practice Bulletin 225: *Medication Abortion Up to 70 Days of Gestation*. American College of Obstetricians and Gynecologists. Obstet Gynecol 2020;136:e31–47.
[115] de Haas, M et al. *Anti-D prophylaxis: past, present and future,* Transfusion Medicine, 2014;24(1): 1-7.

consultation demonstrated a sensitivity of 90%, which means one in ten women with a failed abortion might not recognize the failure through remote follow-up.[116] Another case control study < 9 weeks gestation found that pregnancy symptoms and degree of bleeding accurately identified only 2/3 (68%) of medication abortion failures.[117]

94. Plaintiffs' expert, Dr. Grossman, led the charge promoting remote, "no test" medication abortion in his 2017 study analyzing outcomes of Iowa's telemedicine experiment. Between 2008 and 2015, Planned Parenthood facilitated 8,765 medication abortions by telemedicine and 10,405 in person. Notably, *standard pre-abortion screening (ultrasound and labs) was utilized for all women*, and a woman was ineligible for a medication abortion if she had severe anemia, if the ultrasound did not diagnose an intrauterine pregnancy or if she had other contraindications. Thus, this study *did not replicate the conditions of use now allowed by the FDA*, in which many women do not receive pre-abortion testing, especially ultrasounds. In an attempt to detect serious adverse events (hospital admission, major surgery, transfusion, emergency room treatment and death), complication reports submitted to mifepristone's manufacturer were examined (deficiencies of this method were explained above) and a survey was mailed to 119 emergency rooms in Iowa. Only 1/3 (n=42, 35%) of the ERs returned the survey and they denied knowledge of any serious complications, but it was not reported who completed the surveys or whether they would have reliably known about complications.[118]

95. Another 2017 article studied 1636 medication abortions < 9 weeks gestation provided to women in Scotland through Women on Web, a Toronto-based online telemedicine

[116] Grossman D and Grindlay K. *Alternatives to ultrasound for follow-up after medication abortion: a systematic review.* Contraception. 2011; 83(6):504-510.
[117] Jackson AV, et al. *Can women accurately assess the outcome of medical abortion based on symptoms alone?* Contraception. 2012;85:192-197.
[118] Grossman D and Grindlay K. *Safety of Medical Abortion Provided Through Telemedicine Compared With In Person.* Obstet Gynecol 2017;130:778–782.

service. 29% of the women were lost to follow-up with unknown outcomes. 5.3% had incomplete abortions and 4.5% required surgical intervention. 9.3% experienced symptoms for which they were advised to seek medical help, which clearly the Canadian abortion prescriber located over 3000 miles away was unable to provide.[119]

96. A 2019 "TelAbortion" study offered videoconference counseling to women in five states, with *standard pre-abortion ultrasound and labs*. The researchers offered 433 screenings and mailed 248 packages. 23% were lost to follow-up, and of the known outcomes, 7% required surgery.[120]

97. A 2021 follow-up study compared 287 women from the previous TelAbortion study who had no pre-abortion testing with 125 who did have testing due to concerns documented on screening. The documented failures were higher without pre-abortion testing (5.6 vs 1.9%), as well as unplanned encounters (12.5 v 8%.) It should be noted that the women who did not receive pre-abortion testing were those who had been *screened and determined not to need testing*. This is a different cohort than would be expected from an on-line website which does not have the ability to offer any pre-abortion tests in response to a positive screen, a critical distinction.[121]

98. Systematic reviews may give better quality data because a combination of numerous smaller studies will give a larger number of study subjects for analysis, but systematic reviews are still subject to the limitations of the included studies (for example, high numbers of women lost to follow-up with unknown outcomes). A 2019 systematic review

[119] Aiken AA, et al. *Self-reported outcomes and adverse events after medical abortion through online telemedicine: population-based study in the Republic of Ireland and Northern Ireland*. BMJ 2017;357:j2011.
[120] Raymond E, Chong E, Winikoff B, et al., *TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States*. Contraception, 2019;100 (3):173-177.
[121] Anger, et al. *Clinical and service delivery implications of omitting ultrasound before medication abortion provided via direct-to-patient telemedicine and mail in the US.* Contraception. 2021;104(6):659-665.

analyzed 13 studies of telemedicine abortion at < 10 weeks gestation. Up to 1.9% had continuing pregnancy, 3.6-6.2% required treatment for failed abortion, 0.9 to 19.3% required surgical evacuation, and critically, loss to follow-up ranged from 5-57%. While some subjects did not receive pre-abortion testing, *other women did receive pre-abortion ultrasounds*. The researchers themselves reported that the quality of evidence was low, all studies were observational and depended on self-reported outcomes, and most lacked a comparison group.[122]

99. Another 2023 systematic review analyzed 21 studies where no pelvic examination or ultrasound was provided to 10,693 patients. (In some studies, there was an arm that included pre-abortion testing, but the disaggregated data for the "no test" patients was obtained by the study authors.) Failures of these "no-test" medication abortions was 3.6% < 9 weeks gestation and 4.8% < 10 weeks gestation. The overall rate of surgical evacuation was 4.4%, need for additional misoprostol 2.2%, transfusion 0.5%, and undiagnosed ectopic 0.06%. Loss to follow-up rates in the individual studies were not included.[123]

100. A 2024 systematic review analyzed 21 studies of first trimester telehealth abortions (although only 445 of the tens of thousands of telehealth medication abortions included were in the gestational age group 10-12 weeks). Most were observational studies with no control group, and loss to follow-up was not documented. Overall, there were 8.9% failures, with no difference if provided by in-person vs telemedicine. An average of 7.8% of telemedicine

[122] Endler, M., et al., 2019. *Telemedicine for medical abortion: a systematic review*. British Journal of Obstetrics and Gynaecology, 126 (9), 1094-1102.
[123] Shapiro MP, et al. *No-Test Medication Abortion: A Systematic Review*. Obstet Gynecol 2023;141:23–34; Shapiro MP, et al. *Narrative Review: Remote Provision of Medication Abortion and Contraception Through Telemedicine.* Obstet Gynecol 2023;141:1056–61.

patients were evaluated in an emergency room, 4.1% required antibiotics, 1.3% were hospitalized, and 0.5% had a blood transfusion.[124]

101. At the time the FDA removed the in-person dispensing requirements in 2021, they referenced only four studies which they said proved that this action was safe. The smaller three studies followed a *hybrid model in which some women received pre-abortion ultrasounds (again, not replicating the real-world conditions of use in which high risk women often do not have the ability to obtain an ultrasound*). These studies had loss to follow-up rates ranging from 12-17%, surgery for failed abortion rates of 2-5% and ER visits in 6%.[125]

102. The largest study, based upon data obtained from the United Kingdom by Texas abortion advocacy researcher Abigail Aiken, contained over 95% of the abortions the FDA relied upon (52,142 abortions), but even in this cohort many of the women received *pre-abortion ultrasounds*. At first glance, the data reporting few complications appears hard to refute, because single-payer coverage in a socialized medical system would fund most abortions and cover most of the subsequent complications, theoretically creating high-quality records-linkage abortion data. However, a deeper look demonstrates significant *problems linking abortions performed with subsequent complications experienced*. There are two disparate systems in the U.K. that record abortion complications. The Abortion Notification System (ANS) is data collected at the time the abortion is performed (or in the case of medication abortion-the drugs are distributed but before they are consumed). Another system,

[124] Cely-Andrade, et al. *Telemedicine for the provision of medication abortion to pregnant people at up to twelve weeks of pregnancy: a systematic literature review and meta-analysis*. Reproductive Health. 2024;21:136.
[125] Chong E, et al. *Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic*, Contraception, 2021;104(1):43-48; Kerestes C, et al. *Provision of medication abortion in Hawai'i during COVID-19: practical experience with multiple care delivery models*. Contraception, 2021:104(1):49-53; Reynolds-Wright JJ, et al. *Telemedicine medical abortion at home under 12 weeks' gestation: a prospective observational cohort study during the COVID-19 pandemic*, BMJ Sexual & Reproductive Health, 2021;47(4): 246-251.

the Hospital Episode Statistics (HES), provides details of all admissions, Accident and Emergency (A&E) attendances and outpatient appointments to treat abortion complications at NHS hospitals in England. No patient identifier links these two systems, however, hampering the ability to link abortions provided in the ANS to complications cared for by HES. This study examined only ANS data reporting abortion complications, paperwork which is often completed before a woman has taken abortion drugs. When HES data is also examined, it estimates ten times the complication rate reported by these researchers and relied upon by the FDA.[126]

103. In summary, the best quality data shows frequent complications and failures following medication abortion, especially in the absence of in-person pre-abortion testing. Although abortion industry studies profess low complication rates, better quality studies demonstrate continuing viable pregnancy rates of 0.8-1.5%, retained pregnancy tissue rates of 1.1-6.7%, surgical completion rates of 3.3-5.9%, emergency room visit rates of 2.9-10.2%, and serious adverse events of 0.03-0.65% following medication abortion performed at < 10 weeks gestation as allowed by the FDA's current regimen.

104. Because complications increase as gestational age increases, and the FDA's removal of requirements for accurate determination of gestational age will likely result in increased use at higher gestational ages, only compounding complications further.

105. A 2019 systematic review of medication abortion between 9-12 weeks demonstrated 9.6% failures after mifepristone and misoprostol abortions, and 18.4% failures after misoprostol use alone.[127] Other studies have confirmed these dramatic increases in

[126] Aiken A, et al. *Effectiveness, safety and acceptability of no-test medical abortion provided via telemedicine: a national cohort study*. British Journal of Obstetrics and Gynaecology, 2021:128(9):1464-1474.
[127] Kapp, et al. *Medical abortion in the late first trimester: a systematic review*. Contraception 2019;99:77-86.

mifepristone and misoprostol abortion failures with increasing gestational age, with 7.8% failures requiring surgery between 9-10 weeks skyrocketing to 13.3% failures between 10-11 weeks.[128] Failure to confirm the gestational age estimated by a woman based on her recollection of her last menstrual period (LMP) with ultrasound, even if a small discrepancy, will lead to more failures.

106. In one study of medication abortions performed between 9-16 weeks' gestational age, 10.6% of 264 abortions required surgical completion. Nearly a quarter of the participants (23.5%) sought health care during or after the medication abortion, most commonly to confirm completion (15.9%), demonstrating that women are frequently unprepared for the abortion experience, causing them to seek medical help. And 9.1% needed further medical intervention (procedural evacuation, antibiotics, additional misoprostol, intravenous fluids, blood transfusion, or overnight stay in the facility).[129] A prior analysis by this same author (Moseson) of medical abortions throughout the entire second trimester demonstrated that 24% had failed abortions with 5% experiencing an ongoing viable pregnancy.[130]

107. The 2024 California Home Abortion by Telehealth (CHAT) study led by Ushma Upadhyay analyzed 6034 abortions provided by telehealth, documenting 97.7% had complete abortions with only 0.25% serious adverse events, 0.16% ectopic pregnancy, and 1.3% ER visits. Patients were screened with a no-test protocol, and those with risk factors for ectopic or underestimated gestational age were *referred for an ultrasound*.[131] This study followed an

[128] Dzuba IG, et al. *A noninferiority study of outpatient mifepristone-misoprostol medical abortion at 64-70 days and 71-77 days of gestation*. Contraception 2020;101:302-308.
[129] Moseson, et al. *Effectiveness of Self-Managed Medication Abortion Between 9 and 16 Weeks of Gestation*. Obstet Gynecol 2023;00:1–9.
[130] Moseson, et al. *Effectiveness of self-managed medication abortion between 13- and 24-weeks gestation: A retrospective review of case records from accompaniment groups in Argentina, Chile, and Ecuador*. Contraception. 2020;102(2):91-98.
[131] Upadhyay, UD, Koenig LR, Meckstroth K, et al. *Effectiveness and Safety of Telehealth Medication Abortion in the USA.* Nat Med 2024;30:1191-1198.

earlier smaller study by the same author during the Covid-19 pandemic where 141 patients were provided with telehealth abortion drugs. In that study, 14% were lost to follow-up with unknown outcomes and 5% had failures requiring surgery.[132] Notably, in both studies, *some women had ultrasounds when it was determined they had risk factors*. In the real world, when women are ordering drugs via internet from out of the state or even out of the country, the *abortion providing website often does not have the ability to order an ultrasound even if it was deemed necessary*. Thus, these study conditions cannot be replicated in reality.

VII. Informed Consent

108. Despite usually treating no disease, because abortion is a medical procedure, it must be subject to the doctrine of informed consent, which requires a physician to disclose enough about the risks and benefits of proposed treatments that the patient becomes sufficiently informed to participate in shared decision making.[133] The American Medical Association's guidelines on informed consent state that a patient should be given information about the diagnosis, the nature and purpose of recommended interventions, and the burdens, risks, and expected benefits of all options, including forgoing treatment.[134]

109. This was further outlined by the DC Circuit Court of Appeals in the *Canterbury v Spence* case regarding informed consent, which documented a physician must disclose: (1) the condition being treated; (2) the nature and character of the proposed treatment or surgical procedure; (3) the anticipated results; (4) the recognized possible alternative forms of treatment; and (5) the recognized serious possible risks, complications, and anticipated benefits

[132] Upadhyay U. *Safety and Efficacy of Telehealth Medication Abortions in the US during the COVID-19 Pandemic.* JAMA Network Open, 2021;4:xx.
[133] Murray B. *Informed consent: What must a physician disclose to a patient?* JAMA Journal of Ethics. 2012;14(7):563-566.
[134] American Medical Association: *Informed Consent.* https://code-medical-ethics.ama-assn.org/ethics-opinions/informed-consent.

involved in the treatment or surgical procedure, as well as the recognized possible alternative forms of treatment, including non-treatment.[135]

110. Unfortunately, it does not appear that fully informed consent is always given in abortion clinics. A 2005 governmental task force in South Dakota held a series of investigative hearings and concluded that Planned Parenthood did not (1) disclose the essential nature of the procedure-that it terminates the life of the woman's existing child, (2) when they did discuss the procedure, they provided misleading information in misleading terms, (3) gave misleading information about the psychological and physical risks to the mother, (4) assume the women have made their decisions before they reach the facility, (5) placed the burden upon the mothers to discover material facts on their own, (6) the abortion doctor's only contact with the mother consisted of a prerecorded audio tape, and the first face-to-face meeting of the doctor and patient was after she had signed the consent forms, paid for the surgery and was on the procedure table, (7) the pregnant mothers are often pressured into having an abortion by outside forces, (8) the contact and procedures by the facility personnel prior to the abortion are inherently coercive and force a quick decision, and (9) the fatal and irrevocable nature of the decision is not made known to the mother and adequate time for reflection is not provided.

111. While this represents earlier actions of Planned Parenthood in a different state, the allegations are concerning, and Ohio has addressed those significant concerns by ensuring that such blatant deviations from the standard of medical informed consent do not occur in this State. Indeed, South Dakota enacted a law after this investigation was completed that is substantially similar to the Ohio informed-consent laws at issue here. The South Dakota laws

[135] *Canterbury v. Spence*, 150 U.S.App.D.C. 263, 464 F.2d 772 (1972).

were upheld as constitutional under *Roe v. Wade* partly because they merely required the disclosure of truthful information.[136]

112. The requirement that patients receive information regarding the development of the embryo or fetus is important for informed consent. Biologists confirm that human life begins at fertilization[137] and even pro-abortion medical organizations define pregnancy as beginning at implantation (approximately 5-7 days after fertilization),[138] so by either definition, once a pregnancy can be detected, a new human life is in existence. The early embryo's cells divide, grow, differentiate and perform metabolic functions, all signs of life, and of course, his genetics are human because he is the offspring of two human parents. The question of when this unborn life has value and should be protected is not scientific but philosophical.

113. These statutes require that patients make two, in-person visits to the health center at least twenty-four hours apart and meet with the same physician who is providing the abortion, with the opportunity to ask questions. It requires medically accurate information that a reasonable patient would consider material to the decision of whether or not to undergo an abortion, a description of the abortion method, the immediate and long-term physical and psychological risks of the abortion method, anesthetic agents and other medications in light of gestational age and the woman's individual medical history and conditions, and alternatives to the abortion. The laws require a woman be offered an optional ultrasound before performing the abortion, which allows her to hear the fetal heartbeat if possible. Additionally, the law

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[136] *Report of the South Dakota Task Force to Study Abortion*. https://rewirenewsgroup.com/wp-content/uploads/2014/10/South-Dakota-Abortion-Task-Force-Report.pdf.

[137] Guyton. *Textbook of Medical Physiology*. 10th edition. Philadelphia: WB Saunders, 2000; Moore, *The Developing Human,* Clinically Oriented Embryology. 10th ed. Philadelphia: Elsevier, 2016; Sadler. *Medical Embryology*. 14th ed. 2019; Cunningham. *Williams Obstetrics*. 26th ed. New York. McGraw-Hill. 2022.

[138] Jacobs SA, *The Scientific Consensus on When a Human's Life Begins*. Issues in Law and Medicine. 2021;36(2):221-233.

requires physicians to refrain from performing an abortion if they have reason to believe that someone is coercing a patient to have an abortion.

114. Counseling a woman on ultrasound findings is a vital part of the informed consent process. In the case of elective abortion, this necessarily includes information about the development of the fetus, including the presence of movement and heartbeat, which can be detected as early as 6 weeks gestation by transvaginal ultrasound and 7 weeks by transabdominal ultrasound. Abortion ends the life of a complex, developing human being. It is a decision that cannot be undone once made.

115. Failure to inform a woman of this reality does not mean she will remain ignorant of these facts forever. When she later sees the development of another pregnancy on ultrasound, she may realize that her aborted pregnancy was not just a "blob of tissue" as she may have assumed (or worse, was told), but instead was a recognizable, living human being. The guilt and mental anguish of the belated recognition of this reality cannot be quantified. I have cared for hundreds of women during my career who express guilt about a prior abortion, often expressed when they are confronted with sonographic evidence of the humanity of a child they are currently carrying. Often, they say they had no idea the child was so developed at such a young gestational age.

116. These statutes ensure that every pregnant woman's decision to undergo an abortion is made voluntarily—precisely the right the Amendment was enacted to safeguard and uphold. In-person counseling 24 hours in advance of an abortion ensures that a woman has time to change her mind once she has received all the necessary information, and prevents the very arguments Plaintiffs rely on in this and other litigation—the time sensitive nature of abortion, the general but practical considerations for attending a second appointment, and lack of

available future appointment slots—from influencing her choice. When mifepristone is dispensed directly to the woman seeking abortion rather than delivered in the mail, it confirms that she is genuinely exercising her right reproductive choice and has not rushed into the decision.

117. Intentionally ending unborn human life is a momentous decision—one that should not be rushed or made without adequate understanding of the actual consequences of that choice. Post-abortion regret is common, as evidenced by the proliferation of counseling programs in churches and pregnancy resource centers for suffering women. Additionally, in-person counseling prevents illicit use by others who may benefit from the loss of the baby, such as sex traffickers, incestuous abusers, and coercive boyfriends or husbands. It has been documented that many women experiencing sex trafficking have been forced into multiple abortions. Interaction with the health care system is an opportunity for these women to be identified and helped, but ready availability of abortion pills to abusers will remove this opportunity for intervention.

118. Determination of fetal life and health should be documented. Approximately 15% of recognized pregnancies result in miscarriage. An ultrasound may document the lack of a fetal heartbeat and thus spare a woman an abortion. Selling an abortion when in fact, the pregnancy will miscarry, will cause many women to undergo an unnecessary procedure, as well as carry the guilt of ending a life. Failure to make this critical diagnosis may be the reason that only 1% of Planned Parenthood's pregnancy services are miscarriage management, while 97% are elective abortions.[139] In addition, some women seek abortion because they are

[139] *Pregnancy Trends in the U.S.* https://www.guttmacher.org/fact-sheet/pregnancy-trends-united-states; Planned Parenthood 2024 Annual Report. https://www.plannedparenthood.org/uploads/filer_public/b4/4b/b44b01ef-46d0-49ff-a2de-805a3cffd44a/digital-eng-pptnm-annualreport2024.pdf.

concerned that actions they have taken earlier in pregnancy, such as drinking or smoking, may have caused some damage to the fetus. Seeing normal development and a heartbeat in their fetus may give them reassurance and convince them to continue the pregnancy because the risk of loss is low after cardiac motion is documented.[140]

119. Ultrasound findings will reduce unwanted abortions. Many women obtain abortions even though they would prefer to give birth, under the assumption that no other options for support exist for them.[141] Studies document that seeing her unborn child on ultrasound will increase maternal bonding, which may motivate her to seek out other options.[142] Pregnancy center researchers and pro-abortion researchers alike have demonstrated that a woman is less likely to choose abortion after seeing an ultrasound.[143]

120. Thus, the Telemedicine Ban will improve the safety of women by facilitating pre-abortion screening tests and in-person verification of consent. This regulation requires a patient to take the first of the two medication abortion drugs "in the same room and in the physical presence" of the prescribing physician. The Plaintiffs attempt to portray telemedicine as equivalent to in-person medical care, but my extensive clinical experience has demonstrated that telemedicine is always inferior to face-to-face care.

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[140] Tannirandorn, et al. *Fetal loss in threatened abortion after embryonic fetal heart activity*. International Journal of Gynecology and Obstetrics 81 (2003) 263–266; Li, et al. *Predicting first-trimester outcome of embryos with cardiac activity in women with recurrent spontaneous abortion*. Journal of International Medical Research 2020;48(6):1–13.

[141] Reardon DC, Rafferty KA, Longbons T. *The effects of abortion decision rightness and decision type on women's satisfaction and mental health*. Cureus 2023;15(5): e38882.

[142] Fletcher and Evans. *Maternal Bonding in Early Fetal Ultrasound Examinations*. N Engl J Med 1983;308:392-393; Sedgmen. *The impact of two-dimensional versus three-dimensional ultrasound exposure on maternal– fetal attachment and maternal health behavior in pregnancy*. Ultrasound Obstet Gynecol 2006; 27: 245–251.

[143] Kimport K, Preskill F, Cockrill K, Weitz TA. *Women's perspectives on ultrasound viewing in the abortion care context.* Womens Health Issues. 2012;22(6):e513-7; Gatter M, Kimport K, Foster DG, et al. *Relationship between ultrasound viewing and proceeding to abortion.* Obstet Gynecol. 2014;123(1):81-87; Upadhyay UD, Kimport K, Belusa EKO, et al. *Evaluating the impact of a mandatory pre-abortion ultrasound viewing law: A mixed methods study.* PLoS One. 2017;12(7):e0178871; York AB, Bagwell LL. *Pregnancy Choices and the Role of Ultrasound Viewing*. J Christ Nurs. 2019;36(1):54-57.

121. Another important reason for Ohio's in-person mifepristone dispensing requirement is to prevent coercion. In-person dispensing ensures that mifepristone will be dispensed directly to the woman seeking abortion and allows in-person observation that she genuinely seeks this action and is not being coerced into the decision. And, of course, body language and other non-verbal cues can be more easily interpreted by a provider in the same room rather than observing over a video screen. This is equally true for what may be off screen as well.

VIII. Physician Requirement

122. Prohibiting Advanced Practice Clinicians (APC) from providing medication abortions will improve the safety of women by requiring abortion providers to have the clinical skills necessary to manage abortion complications. Handing out abortion drugs requires little skill, especially in the absence of pre-abortion testing that would require interpretation. But as previously noted, the FDA still requires mifepristone prescribers to have the "ability to intervene surgically if needed (or have an arrangement with a provider who could perform that intervention"). Optimally, the provider with whom a woman has established a provider-patient relationship would be available to provide the treatment of complications the drugs caused, something APCs are unable to do.

123. Neither Dr. Grossman nor Dr. Spetz, in their expert reports, allege that APCs have these skills. They both list procedures commonly performed by APCs, but conspicuously absent is surgical aspiration, the procedure needed when medication abortion fails. As noted by the University of Chicago, "Unlike our OB/GYN partners, midwives do not perform

surgeries."[144] This is true for all advanced practice clinicians, none of whom receive specific training in abortion provision or surgical aspiration in their clinical training programs.

124. The motivation behind APCs providing abortions is simple. Most Ob/gyns, the medical specialty that cares for women and their unborn children, do not want to perform abortions. Only 7-14% of practicing Ob/gyns say they would provide an abortion (surgical or medical) when requested by their patient,[145] and only 19% in another survey said they have prescribed abortion drugs. Another 24% of these doctors suggested they would be willing to prescribe the drugs if the "in-person" dispensing requirement were removed, because presumably they would be able to hide the fact that they were performing abortions, and they would be able to distance themselves from abortion provision as part of their medical practice. Even in this "ideal" situation, however, the majority of Ob/gyns are not willing to prescribe abortion drugs.[146] Most physicians recoil from abortion and view the fetus as another patient they have been trained to care for and protect. This ultimately causes staffing problems for clinics those who advocate for abortion "access" - that is, convenient and immediately available abortions. But staffing shortages cannot be elevated above the fundamental requirement of protecting patient safety.

125. Thus, pressure has been exerted on other types of physicians to provide abortions[147] to close staffing shortfalls when even Ob/gyns are unwilling to violate their Hippocratic Oath. This has also been unsuccessful, so the degradation of medical care has now been extended to

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[144] Midwives in hospital settings: *Understanding the benefits of choosing midwifery care*. https://www.uchicagomedicine.org/forefront/womens-health-articles/midwives-in-hospital-settings.

[145] Desai S, Jones R, Castle K. *Estimating abortion provision and abortion referrals among United States obstetricians and gynecologists in private practice*. Contraception 2018;97:297-302; Stuhlberg DB, Dude AM, Dahlquist I, Curlin FA. *Abortion provision among practicing obstetrician-gynecologists*. Obstet Gynecol 2011;118(3):609-614.

[146] Daniel S, Schulkin J, Grossman D. *Obstetrician-gynecologist willingness to provide medication abortion with removal of the in-person dispensing requirement for mifepristone*. Contraception 2021;104:73-76.

[147] Sager J, Rego E, Malhotra R, et al. *Abortion providers in the United States: expanding beyond obstetrics and gynecology.* American Journal of Obstetrics and Gynecology. 2023;May:1-6.

include APCs as the instrument of filling that gap and providing medication abortions despite their training and practice limitations.

126. In describing their reasons for objecting to Ohio's laws, the Plaintiffs say that "[t]he need for telehealth in reproductive and sexual health care is particularly acute given the scarcity of providers."[148] They also acknowledge that Planned Parenthood operates 22 clinics throughout the state but that only three are routinely staffed by physicians, thus the alleged need for telehealth and APC abortion provision.[149]

127. Doximity reports that there are 43,000 board certified Ob/gyns in the U.S.[150] If abortion were "necessary medical care", as proclaimed by many pro-abortion medical societies, there should be no difficulty finding Ob/gyns willing to perform a procedure needed by their patients. There would be no shortage of qualified physicians performing abortions and Planned Parenthood would have no difficulty staffing its clinics, easily fulfilling Ohio's legislative requirement. That this is not the case demonstrates the fallacy of this assertion.

128. The American College of Obstetricians & Gynecologists (ACOG) recommends that APCs be allowed to provide abortions, but their justification is that due to shortages of physicians willing to provide abortions, "APCs would provide much-needed access to abortion care."[151] ACOG also recommends opposing restrictions that limit abortion provision to physicians only.[152] These recommendations have been echoed by Physicians for Reproductive

[148] 2d Amended Complaint, ¶79.
[149] *Id*. ¶66-67.
[150] 2019 *Ob/Gyn Workforce Study*. https://press.doximity.com/articles/physician-shortage-hits-maternity-care.
[151] ACOG Issue Brief: *Advanced Practice Clinicians and Abortion Care Provision.* American College of Obstetricians and Gynecologists. https://www.acog.org/advocacy/abortion-is-essential/trending-issues/issue-brief-advanced-practice-clinicians-and-abortion-care-provision.
[152] ACOG Committee Opinion 612: *Abortion Training and Education*. 2014, reaffirmed 2019 and 2022. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;124(5):1055–1059.

Health, the American Public Health Association, and the World Health Organization. Apparently, "access" trumps "safety" in the economy of pro-abortion medical organizations.

129. The abortion industry proposes that abortion by non-physicians will not impact the risk of complications. For example, a 2020 ten-year retrospective review of almost 60,000 medication abortions concluded, "Outcomes of medication abortion provided by APCs in our study are well within published benchmarks for medication abortion effectiveness (95–99%) and safety (<1% complications) when managed by physicians." Of course, no particular skill is needed to hand women pills with which they will self-manage their own abortion at home in the absence of a medical provider. The authors chose to ignore the fact that outcomes were known in only 2/3 (64%) of the patients, nor did they remark on who performed the surgeries needed by 1.5% who experienced failed or incomplete abortions or 0.1% retrospectively diagnosed with ectopic pregnancy.[153] It is likely many of these women were dumped upon the emergency medical system because APCs cannot perform the needed interventions.

130. In April 2026, the Guttmacher Institute noted that 25 states (including District of Columbia) permit APCs to provide abortions, although 18 have limits on the type of abortions they may provide. Conversely 26 states do not permit APCs to provide abortions.[154] If Ohio continues to protect women by requiring physicians to perform abortions, they are not alone, as half of the states recognize this is poor quality care.

131. When an industry refuses to supervise itself, as we have observed with the abortion industry, and when politics prevents other supervisory organizations (like state and local health departments) from fulfilling their jobs, it is up to state governments to protect their citizens

[153] Lauren Porsch et al., *Advanced Practice Clinicians and Medication Abortion Safety: A 10-year Retrospective Review,* Contraception 2020;101:357.
[154] Guttmacher Institute: *Advanced Practice Clinicians Providing Abortion Care*. April 6, 2026.

from harm. Legislative regulations have been imposed on abortionists by the states because they often will not adhere to adequate medical standards of care without such oversight. The reality is that every state has some regulations related to abortion.[155] The question for Ohio is whether these regulations can be justified in the interest of protecting women.

132. Despite the political framework, abortion is a gynecologic procedure, and it should be subject to following the standards of care that all other medical procedures follow. In the absence of oversight, it is reasonable for Ohio to establish and maintain a minimum threshold for the standard of care in order to protect women from unsafe procedures and compromised providers.

[155] Guttmacher Institute. Interactive Map: *US Abortion Policies and Access After Roe.* https://states.guttmacher.org/policies.

Exhibit B

Ingrid Skop, M.D.

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Professional Summary:

I have over 30 years expertise in obstetrics and gynecology, encompassing delivery of over five thousand babies, high and low risk prenatal care, major and minor gynecologic surgeries, office-based procedures, well woman examinations and contraceptive management. Additionally, I have extensive experience in written and oral legal testimony, publishing peer and non-peer reviewed articles, op-eds, media interviews and oral presentations.

Work Experience:

- Charlotte Lozier Institute, Vice President and Director of Medical Affairs — March 2023-Current
- Charlotte Lozier Institute, Senior Fellow and Director of Medical Affairs — April 2022-March 2023
- OB Hospitalist Group, Obstetric Hospitalist — June 2022-Current
- Adjunct Clinical Faculty at the University of the Incarnate Word School of Osteopathic Medicine — March 2025-Current
- Baptist Hospital System, San Antonio, TX, staff appointment — July 1996-Current
- Northeast OB/GYN Associates, partner — July 1998-March 2022
- Northeast OB/GYN Associates, employed physician — July 1996-June 1998
- Northeast Baptist Hospital, Chairman, Department of OB/GYN — 2003-2005

Board Certification and Licensure:

- Texas Medical License J4524 — 1992-Current
- American Board of Obstetrics and Gynecology, Board Certified — 1998-Current
- American College of Obstetrics and Gynecology, Fellow — 1998-Current

Education:

- Obstetrics and Gynecology Postdoctoral Training — July 1992-July 1996
  University of Texas Health Sciences Center at San Antonio
  Chief Resident. July 1995-June 1996.
- Medical Doctorate — August 1988-May 1992
  Washington University School of Medicine
- Bachelor of Science, Physiology: — August 1984-May 1988
  Oklahoma State University

Peer-reviewed publications/Presentations/Professional

- Reviewer for peer-reviewed journals:
  - Annals of Internal Medicine
  - Issues in Law and Medicine
  - Cureus
  - Journal of Psychosomatic Obstetrics & Gynecology
  - BMC Women's Health and other BMC journals
  - Linacre Quarterly
- Texas Maternal Morbidity and Mortality Review Committee, member representing rural communities — 2024-current
- Maka Tsulukidze, Stuart W. Grande, and Ingrid Skop. Book Chapter: Decision Making in Health Care: *"If Only I'd Known then What I Know Now".* Decision-Making in Life and Work: Foundations, Strategies, and Current Neuroscience. Todd McElroy, Editor. Integrated Science, Volume 36. Springer. Switzerland. 2025.
- Studnicki J, Fisher JW, Cox T, et al. *Determining the Period Prevalence and Acuity of Emergency Department Visits Following Induced Abortion Mistakenly Identified as Spontaneous Abortion: An Analytic Observational Prospective Cohort Study*. J Family Med Prim Care Open Acc 2025;282(9):1-7.
- Studnicki J, Fisher JW, Cox T, et al. *Comparative Acuity of Emergency Department Visits Following Pregnancy Outcomes Among Medicaid Eligible Women, 2004-2015*. International Journal of Epidemiology and Public Health Research. 2024;5(2):1-4.

- Studnicki J, Cox T, Fisher JW, et al. *First Pregnancy Abortion or Natural Pregnancy Loss: A Cohort Study of Mental Health Services Utilization*. Issues in Law & Medicine 2024;39(2):
- Studnicki J, Skop I. *Is Induced Abortion Evidence-Based Medical Practice?* Medical Research Archives, (online) 2024;12(6):1-10.
- Skop I, Miller C, Duffy K. *United Kingdom Data Deficiencies Influencing U.S. FDA Decisions.* Issues in Law & Medicine. 2024;39(1):32-49.
- Harned M, Skop I. *Misleading Statements About "Life of the Mother" Exceptions in Pro-life Laws Require Correction*. Issues in Law & Medicine. 2024;39(1):76-81.
- Studnicki J, Longbons T, Reardon D, Fisher J, Skop I, et al. *A Cohort Study of Mental Health Services Utilization Following a First Pregnancy Abortion or Birth*. International Journal of Women's Health. 2023;15:955-963.
- Studnicki J, Longbons T, Reardon D, Fisher J, Harrison D, Skop I, et al. *The enduring association of a first pregnancy abortion with subsequent pregnancy outcomes: A longitudinal cohort study*. Health Services Research and Managerial Epidemiology. 2022;9:1-9.
- Skop I. *Chemical abortion: Risks posed by changes in supervision.* Journal of the American Association of Physicians and Surgeons. 2022;27(2):56-61.
- Studnicki J, Longbons T, Harrison D, Skop I, et al. *A post hoc exploratory analysis: Induced abortion complications mistaken for miscarriage in the emergency room are a risk factor for hospitalization.* Health Services Research and Managerial Epidemiology. 2022;9:1-4. (Retracted but disputed and in litigation, details @ https://assaultonscience.org/)
- Studnicki J, Harrison D, Longbons T, Skop I, et al*. Longitudinal cohort study of emergency room utilization following mifepristone chemical and surgical abortions, 1999-2015*. Health Services Research and Managerial Epidemiology. 2021;8:1-11. (Retracted but disputed and in litigation, details @ https://assaultonscience.org/)
- National Institute of Health Fetal Tissue Research Ethics Advisory Board, member. 2020.
- Marmion P, Skop I*. Induced abortion and the increased risk of maternal mortality*. Linacre Quarterly. 2020;87(3):302-310.
- Skop I. *Medical abortion: What physicians need to know*. Journal of the American Association of Physicians and Surgeons. 2019;24(4):109-113.
- Studnicki J, Reardon D, Harrison D, Fisher J, Skop I. *Improving the metrics and data reporting for maternal mortality: A challenge for public health surveillance and effective prevention.* Online Journal of Public Health Informatics. 2019;11(2):E17.
- Skop I. *Abortion safety: At home and abroad*. Issues in Law and Medicine. 2019;34(1):43-75.
- Studnicki J, Longbons T, Fisher J, Harrison D, Skop I, Mackinnon S. *Doctors who perform abortions: Their characteristics and patterns of holding and using hospital privileges*. Health Services Research and Managerial Epidemiology. 2019;6:1-8. (Retracted but disputed and in litigation, details @ https://assaultonscience.org/)
- "Complications and mortality from abortion." Oral presentation at the United Nations Global Commission on the Status of Women. March 2018.
- Texas Women's Healthcare Coalition, member. 2016-2019.
- San Antonio Maternal Morbidity and Mortality Task Force. 2016-2019.

Expert Witness Testimony:

- Johnson v Wyoming written expert witness testimony. April 2026.
- South Dakota Senate State Affairs Committee oral legislative testimony HB 1247. March 2026.
- Comprehensive Health of Planned Parenthood v Missouri written expert witness testimony, June 2025, preliminary injunction hearing, September 2025, trial consultant and oral trial expert witness. January 2026.
- Johnson v Wyoming written expert witness testimony. November 2025.
- Right by You v Missouri written expert witness testimony, June 2025.
- Poe v. Friedlander (Kentucky) written expert witness testimony, April 2025.
- Adkins v Idaho written and oral trial expert witness testimony, November 2024.
- U.S. Senate Committee on the Judiciary invited oral and written testimony, June 12, 2024.
- Cox v Texas written expert witness testimony, December 2023.
- Planned Parenthood South Atlantic v South Carolina written expert witness testimony, September 2023.
- Zurawski v Texas written and oral trial expert witness testimony. July 2023.
- Louisiana written legislative testimony. May 2023.
- U.S. Senate Committee on the Judiciary invited oral and written testimony. April 26, 2023.
- Wyoming written legislative testimony. March 2023.
- West Virginia written legislative testimony. February 2023.
- Nebraska oral and written legislative testimony. February 2023.

- Georgia written expert witness testimony and trial testimony case #2022-CV-367796. HB 481: Living infants' fairness and equality act. August 2022.
- Florida written expert witness testimony, deposition and trial testimony case #2022-CA-912. HB 5: An act relating to reducing fetal and infant mortality. June 2022.
- Ohio written legislative testimony. SB 260: An act to amend…and enact…regarding abortion inducing drugs. May 2022.
- Kentucky oral legislative testimony. December 2021.
- U.S. House Oversight Committee invited oral and written testimony. September 2021.
- Oklahoma written legislative testimony. SB 778: An act relating to OK abortion inducing drugs risk protocol act, SB 779: An act creating the OK abortion inducing drugs certification program act, HB 1904: An act relating to public health. September 2021.
- Texas oral legislative testimony. March 2021.
- South Carolina written legislative testimony. SB 1: South Carolina fetal heartbeat and protection from abortion act. February 2021.
- Montana oral and written legislative testimony. HB 136: An act adopting the MT pain capable unborn child protection act, HB 140: An act requiring…ultrasound. January 2021.
- Planned Parenthood v Utah written expert witness testimony and deposition. HB 136: An act…enacts and modifies provisions relating to abortion. 2020.
- Georgia written legislative testimony. HB 481: Living infants' fairness and equality act. 2020.
- Expert witness for the defense in medical malpractice lawsuit: Mary Ann De La Garza v. Carolina Praderio, M.D., Cause No. 2015DCV-3922-H (347th Judicial District Court). 2018.
- Vermont written legislative testimony. 2018.
- Texas oral legislative testimony. June 2013.

Charitable Organizations:

• Seton Home maternity shelter board member	2024-2025
• Save the Storks Medical Advisory Board	2023-current
• Impact San Antonio Women's Charitable Organization, founding member	2004-2024
• The Source, Houston and Austin, medical director.	2021-2022
• The Source, Texas, board member	2019-2022
• AWC Clinics, ob/gyn medical director	2020-current
• Any Woman Can, board member	2015-2022
• Any Woman Can, board chairman	2018-2022
• American Association of Pro-Life Obstetricians and Gynecologists, board member	2018-2020, 2025-current
• The Contraceptive Initiative, founding member and chairman	2015-2019
• Healthy Futures of Texas, board member	2016-2019
• Keystone School, board member	2014-2015
• Keystone School, Parent Teacher Organization president	2014-2015
• San Antonio AIDS Foundation, medical volunteer	2012-2016

CERTIFICATE OF SERVICE

I certify that the foregoing was served upon Plaintiffs' counsel via electronic mail this 1st day of May, 2026.

/s/ Amanda L. Narog
AMANDA L. NAROG (093954)
Assistant Attorney General

Exhibit B:

FDA Approval Letter (Jan. 3, 2023)

NDA 020687/S-026

SUPPLEMENT APPROVAL

Danco Laboratories, LLC
(b) (4), (b) (6)
P.O. Box 4816
New York, NY 10185

Dear (b) (4), (b) (6):

Please refer to your supplemental new drug application (sNDA) dated and received January 26, 2023, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mifeprex (mifepristone) Tablets.

This "Changes Being Effected" sNDA provides for revisions to your Prescribing Information and modification to the approved single, shared system (SSS) risk evaluation and mitigation strategy (REMS) for mifepristone 200 mg tablets, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. This SSS REMS is known as the Mifepristone REMS Program.

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The Mifepristone REMS Program, of which Mifeprex is a member, was originally approved on April 11, 2019, and the most recent REMS modification was approved on January 3, 2023. The Mifepristone REMS Program consists of elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS.

Your proposed modification to the REMS consists of revised Prescriber Agreement Forms to add space to allow for additional contact information on the forms, as well as a revision to the GenBioPro, Inc. Prescriber Agreement Form to correct a typographical error.

Your proposed modified REMS, received on January 26, 2023, and appended to this letter, is approved.

The Mifepristone REMS Program currently includes the products listed on the FDA REMS website[3].

[3] https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm

Other products may be added in the future if additional NDAs or ANDAs are approved.

The timetable for submission of assessments of the REMS remains the same as that approved on January 3, 2023.

There are no changes to the REMS assessment plan described in our January 3, 2023 letter.

We remind you that in addition to the REMS assessments submitted according to the timetable in the approved Mifepristone REMS Program, you must include an adequate rationale to support a proposed REMS modification for the addition, modification, or removal of any goal or element of the REMS, as described in section 505-1(g)(4) of the FDCA.

We also remind you that you must submit a REMS assessment when you submit a supplemental application for a new indication for use, as described in section 505-1(g)(2)(A) of the FDCA. This assessment should include:

a) An evaluation of how the benefit-risk profile will or will not change with the new indication;

b) A determination of the implications of a change in the benefit-risk profile for the current REMS;

c) *If the new indication for use introduces unexpected risks*: A description of those risks and an evaluation of whether those risks can be appropriately managed with the currently approved REMS.

d) *If a REMS assessment was submitted in the 18 months prior to submission of the supplemental application for a new indication for use*: A statement about whether the REMS was meeting its goals at the time of that last assessment and if any modifications of the REMS have been proposed since that assessment.

e) *If a REMS assessment has not been submitted in the 18 months prior to submission of the supplemental application for a new indication for use:* Provision of as many of the currently listed assessment plan items as is feasible.

f) *If you propose a REMS modification based on a change in the benefit-risk profile or because of the new indication of use, submit an adequate rationale to support the modification, including*: Provision of the reason(s) why the proposed REMS modification is necessary, the potential effect on the serious risk(s) for which the REMS was required, on patient access to the drug, and/or on the burden on the health care delivery system; and other appropriate evidence or data to support

the proposed change. Additionally, include any changes to the assessment plan necessary to assess the proposed modified REMS. *If you are not proposing REMS modifications*, provide a rationale for why the REMS does not need to be modified.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted.

Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA 020687 REMS ASSESSMENT METHODOLOGY
(insert concise description of content in bold capital letters, e.g.,
ASSESSMENT METHODOLOGY, PROTOCOL, SURVEY METHODOLOGIES, AUDIT PLAN, DRUG USE STUDY)

An authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission.

We remind you that section 505-1(f)(8) of FDCA prohibits holders of an approved covered application with elements to assure safe use from using any element to block or delay approval of an application under section 505(b)(2) or (j). A violation of this provision in 505-1(f) could result in enforcement action.

Prominently identify any submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 020687 REMS ASSESSMENT

or

NEW SUPPLEMENT FOR NDA 020687/S-000
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR NDA 020687/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED MAJOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR NDA 020687/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABELING CHANGES SUBMITTED IN SUPPLEMENT XXX

or

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 020687/S-000
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

Should you choose to submit a REMS revision, prominently identify the submission containing the REMS revisions with the following wording in bold capital letters at the top of the first page of the submission:

REMS REVISIONS FOR NDA 020687

To facilitate review of your submission, we request that you submit your proposed modified REMS and other REMS-related materials in Microsoft Word format. If certain documents, such as enrollment forms, or website screenshots are only in PDF format, they may be submitted as such, but Word format is preferred.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call (b) (6).

Sincerely,

{See appended electronic signature page}

(b) (6)

Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide
- REMS

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

(b) (6)

03/23/2023 11:54:00 AM

Exhibit C:

Dr. Daniel Grossman Deposition Transcript

CONFIDENTIAL

Transcript of Daniel Grossman, M.D.

Date: September 28, 2026
Case: Planned Parenthood Southwest Ohio Region, et al. -v- Ohio Dept of Health, et al.

Planet Depos
Phone: 888.433.3767
Email: clientservices@planetdepos.com
planetdepos.com
Michigan #8598 | Nevada #089F | New Mexico #566

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IN THE COURT OF COMMON PLEAS
FOR FRANKLIN COUNTY, OHIO

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, ET AL.,
Plaintiffs,
vs. : CASE NO. 2101148
OHIO DEPARTMENT OF HEALTH, ET AL.,
Defendants.

CONFIDENTIAL

STENOGRAPHIC DEPOSITION OF

DANIEL GROSSMAN, M.D.

SAN FRANCISCO, CALIFORNIA

MONDAY, SEPTEMBER 28, 2026

(Reported Remotely)

REPORTED BY: TANYA L. VERHOVEN-PAGE, CCR-B-1790

FILE NO. 652238

2

September 28, 2026

12:05 p.m.

Stenographic deposition of DANIEL GROSSMAN, M.D., held in San Francisco, California before Tanya L. Verhoven-Page, Certified Court Reporter (GA), Licensed Court Reporter (TN) and Certified Shorthand Reporter (TX).

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5

APPEARANCES OF COUNSEL

On behalf of Preterm-Cleveland and Women's Med Group Professional Corporation:

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ALSO PRESENT:

Matt Jackson, Technician

Lawrence Wallace, Technician

- - -

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I N D E X

WITNESS: DANIEL GROSSMAN, M.D.

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BY MS. NAROG	12

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SAN FRANCISCO, CALIFORNIA; MONDAY, SEPTEMBER 28, 2026
12:05 P.M.

P R O C E E D I N G S

THE TECHNICIAN: Thank you to everyone for attending this proceeding remotely, which we anticipate will run smoothly.

Please remember to speak slowly and do your best not to talk over one another. Please be aware that we are recording this proceeding for backup purposes. Any off-the-record discussions should be had away from the computer. Please remember to mute your mike for those conversations.

Please have your video enabled to help the reporter identify who is speaking. If you are unable to connect with video and are connecting via phone, please identify yourself each time before speaking.

We will provide a complementary unedited recording of this deposition

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with the purchase of a transcript.

I apologize in advance for any technical-related interruptions. Thank you.

Thereupon --

DANIEL GROSSMAN, M.D.,

called as a witness, having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MS. NAROG:

Q Good afternoon for me, morning for you, Dr. Grossman. My name is Amanda Narog, and I am with the Ohio Attorney General's Office. Pleased to meet you today.

I'm going to go over a couple of ground rules quickly before we get started, if that's okay.

So it's important that during this deposition only one of us speak at a time so that the court reporter can take down everything that we say. Therefore, if you let me finish my questions, I will certainly let you finish your answers.

The court reporter can only record words, so I need you to answer verbally. That means no

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nodding of your head or saying uh-huh or uh-uh. It's just much easier for her. If you don't hear or understand a question that I ask, please ask me to repeat it or rephrase it or restate. That's one you may need to remember because I sometimes can be very confusing in the way I ask a question. But otherwise, if you answer the question, I'm going to expect that you understood it and you're answering from that understanding.

If you need to take a break, just ask for one. I'll try to have a break every, you know, hour, hour and 15, as we go through the day, but if you do need one, just let me know. The only caveat would be is that, if there's a question pending, please answer the question before we take a break.

And are you taking any medications that affect your memory or would impair your ability to answer truthfully any of my questions today?

A I am not.

Q And one final note. Your lawyer is likely going to object to some of my questions during this deposition; but unless they direct you not to answer the question, you can still provide an answer to the extent that you're able.

Do we understand each other?

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A Yes.

Q All right. Great. Well, let's get started then. Can you please state your name for the record?

A Daniel Grossman.

Q And, Dr. Grossman, have you been deposed before?

A I have been.

Q And how often would you say that you have been deposed before?

A About ten times.

Q And they were in similar cases to the one we're discussing today? Meaning that they're abortion related?

A Yes.

Q Okay. What did you do to prepare for this deposition today?

MR. GUINEY: I would just like to caution the witness that you can answer this question, but please don't reveal any privileged communications.

THE WITNESS: I reviewed my -- the two reports that I prepared, and had discussions with my attorneys.

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BY MS. NAROG:

Q Okay. Did you speak with anyone besides your attorneys?

A I did not.

Q Did you review any documents?

A As I mentioned, I reviewed the two reports, my original report and rebuttal report.

Q Okay. Did you bring any documents with you today?

A I didn't bring any with me myself, but my attorneys printed out copies of my two reports that are here next to me.

Q And are those clean copies, no writing on them other than what you typed in your report?

A I haven't looked through them yet. I haven't written anything other than my --

Q Okay. Understood. You didn't speak -- and again, you didn't speak with anyone besides your attorneys in preparation for today's deposition?

A That's correct.

Q Okay. How did you come to be an expert witness in this case?

A I was asked by Planned Parenthood attorneys. I mean, I was involved in the earlier version of this case, but I believe in 2021, and --

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and then asked -- it was the end of 2025 or early 2026, to -- to be involved in this case.

Q And so you think that was back in 2021, the timeframe that you were contacted about this case originally?

A Yes.

Q Okay. How long did it take you to draft your report?

A The first report?

Q Yes. Your expert report.

A I would say perhaps about ten to 12 hours.

Q All right. And so are you currently employed?

A I am.

Q And where are you employed?

A I'm employed at the University of California San Francisco.

Q And what do you do there?

A I'm a professor in the Department of Obstetrics, Gynecology and Reproductive Sciences. I provide clinical care at San Francisco General Hospital, and I direct a research program called Advancing New Standards in Reproductive Health.

Q Are you currently providing abortion care

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to patients in Ohio?
A I am not.
Q And have you ever provided abortion care to patients in Ohio?
A I have not. Not in Ohio.
Q So you said that you provide abortion care. Is that through the hospital or the university?
MR. GUINEY: Objection. Vague.
THE WITNESS: I am a university employee and I provide care at the hospital. It's technically in a clinic setting adjacent to the hospital, San Francisco General Hospital.
BY MS. NAROG:
Q But is it all within your role as an employee of the university?
A That is correct.
Q Okay. Understood.
Are the physicians that perform abortions at San Francisco General Hospital employees or general contractors, other than yourself?
MR. GUINEY: Objection. Vague.
THE WITNESS: I don't think I know all of the details about everybody who

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provides abortion care at San Francisco General Hospital. I personally provide care in the OB/GYN department in a specific clinic called the Special Procedures and Abortion Clinic, but there are other clinicians that provide abortion care in primary care settings at the hospital. So I don't know all the details.
I also have to say, I don't know the details of all of the employees even who provide care in the clinic where I am. The physicians are all employees of University of California San Francisco. The advanced practice clinicians may vary.
BY MS. NAROG:
Q Okay. Do you provide abortion care in any other clinics?
A I do not currently.
(Grossman Deposition Exhibit A was marked for the record.)
BY MS. NAROG:
Q So let's talk about your expert report. I'm going to introduce what we'll mark as

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Exhibit A, which is the Grossman report.
MS. NAROG: I don't know how best you would like to handle the introduction of these exhibits. I put them in a file for the court reporters. So I don't know how best they would like to do that.
MR. GUINEY: I -- so I don't think that we necessarily have a preference. I think it's whatever is easiest for Dr. Grossman. If you're going to be referring to his opening and his rebuttal reports, maybe it makes sense for him to flip through the printout versions that we have, if that would be easiest.
MS. NAROG: Sure. That would work for me. So if you could just hand him his original report, expert report.
MR. GUINEY: Yeah.
THE WITNESS: I have it.
BY MS. NAROG:
Q Okay. So, Dr. Grossman, is this the report that you provided to your attorneys to provide to the State of Ohio in this case?
A Yes.
Q Do you have firsthand knowledge of

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everything in your report?
A Yes, I do.
Q And when you drafted your report, did you review the laws that are challenged in this case in preparation for that report?
MR. GUINEY: Objection.
THE WITNESS: I did read the laws, yes.
BY MS. NAROG:
Q And did you read each individual law or did you read just some of them? Do you recall which laws you reviewed?
MR. GUINEY: Objection. Compound.
THE WITNESS: I mean, I'm not sure that I remember the details of everything I reviewed, but I read through the laws pertinent to the three topics that I was asked to weigh in on in my report, and I had further discussions with my attorneys about the effect of these laws. So that was my -- how I became familiar with the laws.
MS. NAROG: Okay. So I would like -- if we could put in the Chat the exhibit that is marked 2919.123.

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THE TECHNICIAN: 2919.123?
MS. NAROG: Yes.
THE TECHNICIAN: It's in the Chat.
MS. NAROG: If you can open up that exhibit, which we'll have marked as Exhibit B.
(Grossman Deposition Exhibit B was marked for the record.)
MR. GUINEY: If you double click on the document, it should open it. Double click on it again and it should open right up.
THE WITNESS: Yes, I have the document now.
BY MS. NAROG:
Q Okay. Is this one of the laws that you reviewed?
A Yes.
Q And what do you understand this law to -- to do?
MR. GUINEY: Objection.
THE WITNESS: Again, forgive me. Since I'm not a lawyer, I'll try to explain it as --

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MS. NAROG: Of course.
THE WITNESS: -- as a physician.
My understanding is that this is what I refer to in my report as the evidence-based use ban that requires physicians providing medication abortion to follow the protocol described in the FDA-approved labeling.
BY MS. NAROG:
Q Do you know when this law was first passed by the Ohio General Assembly?
A I do not know.
Q Now, I'd like you to take a look at --
MS. NAROG: If we could put it in the Chat, the 2919.124, which we'll mark as Exhibit C.
(Grossman Deposition Exhibit C was marked for the record.)
THE TECHNICIAN: It's in the Chat.
MS. NAROG: And, Dr. Grossman, just let me know when you have that available.
THE WITNESS: Yes.
BY MS. NAROG:
Q Dr. Grossman, is this the statute that you reviewed when you were preparing your expert report in this case?
A Yes, it is.
Q And is this the statute that you referred to as the telemedicine ban?
A Yes.
Q And what is your understanding of what this law does?
MR. GUINEY: Objection.
THE WITNESS: Again, as a physician, my understanding is that this requires a physician to be physically present when the first dose of the medication abortion regimen is ingested by the patient and has the effect of prohibiting telemedicine-based medication abortion.
BY MS. NAROG:
Q You can set that aside now or take that off your screen.
I'm going to have you look, just for ease of access here, at your rebuttal report, which we'll mark as Exhibit D.
(Grossman Deposition Exhibit D was marked for the record.)

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BY MS. NAROG:
Q Please let me know when you have that in front of you.
A I do.
Q Is this the report you provided to the State of Ohio in this case?
A Yes.
Q And can you turn to Exhibit B, I believe, in that report and tell me what that is?
A This is my CV from May 29th of this year.
Q Is this CV still accurate?
A There's nothing incorrect here. I've had several other publications either accepted or published in peer-reviewed literature since then.
Q So in the last three months -- you would say -- how many have you had published?
A Perhaps two or three.
Q And what topics were those publications on?
A On medication abortion, telemedicine abortion.
Q Were any of the -- was any of the information that you had in those articles included in this report, your rebuttal report that we're looking at right now?

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A I didn't specifically cite to any of that information that was in those publications, no.
Q Let's talk about your background and qualifications. And that's why I wanted to go ahead get your CV in front of you in case you need to reference it.
Where did you go to college for your undergraduate degree?
A I went to Yale University.
Q What did you study there?
A Molecular biophysics and biochemistry.
Q And where did you go to med school?
A Stanford University.
Q And what time period was this that you were at Stanford University?
A I started in 1989 and graduated in 1994.
Q Did you train to perform abortions in medical school?
A I did not.
Q Where did you do your residency training?
A At the University of California San Francisco, in the Department of Obstetrics, Gynecology and Reproductive Sciences.
Q And were you trained to perform abortions during your residency?

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A I was.
Q And that was part of your residency program?
A Yes. It's also a requirement for all OB/GYN residents to get that training.
Q Is that requirement imposed by the State of California?
A No. It's imposed by like the national accreditation body.
Q For the school?
MR. GUINEY: Objection. Lacks foundation.
THE WITNESS: For the national accreditation body of -- essentially for the residency programs to be an accredited residency program in obstetrics and gynecology, the program must provide training in abortion care.
BY MS. NAROG:
Q So in the providing of abortions, you mean that and not miscarriage management, correct?
MR. GUINEY: Objection. Vague.
THE WITNESS: I mean abortion care.
BY MS. NAROG:
Q Okay. So the training was not elective

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then?
MR. GUINEY: Objection. Vague.
THE WITNESS: In -- at the time when I went through training at the University of California San Francisco, there was an option for people who did not want to participate. There were aspects of the care that they could decide to not participate in, but at least some part of the care they had to learn some of the basic skills.
I participated in all of the training that was offered.
BY MS. NAROG:
Q About how many abortions did you perform in your training?
A I don't know for sure.
Q Can you give me an estimated amount?
A The main rotation at the time was, I think, about six weeks long. And I'd say I performed perhaps about 60 abortions in total over that rotation. And so perhaps around an order of about 100 during my residency.
Q What were your other duties during residency?

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A So residency is -- this was part of my training. So the first year we have rotations in internal medicine, in the emergency department, in outpatient obstetrics and gynecology, on labor and delivery, in the operating room performing gynecologic surgeries.
In the subsequent years, it was also based on obstetrics and gynecology, and part of it was inpatient care, performing deliveries, performing surgeries and, in an outpatient setting, providing prenatal care and outpatient gynecologic care.
Q Did you have any other kind of training while you were in residency --
MR. GUINEY: Objection.
MS. NAROG: -- besides --
MR. GUINEY: Vague.
MS. NAROG: -- besides the residency program?
THE WITNESS: Can you just explain what you mean by "other kind of training?"
BY MS. NAROG:
Q I'm just curious if you were only receiving training during your residency through your residency program or were there any additional, you

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know, courses or education that you got that was outside of your residency program?

A I mean, we participated in kind of a continuing education course at least once a year where, you know, we were exposed to -- you know, often it was at another institution. And so we were exposed to other experts in the field and would get training in other different tropics.

And, of course, we had grand round speakers who would come from other institutions to the University of California San Francisco to talk on various topics.

Q How long did your residency program last?

A Four years.

Q And what did you do after residency?

A I worked at -- I was a physician at St. Luke's Women's Center in San Francisco, where I provided the full scope of obstetrics and gynecology as a generalist.

Q And what does that mean to be a generalist?

A That means I wasn't a subspecialist. So I was providing, again, obstetric care, prenatal care, doing deliveries, outpatient gynecologic care and performing gynecologic surgeries.

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Q And were you doing this -- you said a hospital setting, correct?

A No. It was -- I mean, I was an employee at -- of a clinic that was adjacent to a hospital. So we had an outpatient clinic that was next to the hospital. So I saw patients in the outpatient clinic, and then performed deliveries and surgeries in the hospital, as well as covered the emergency department.

Q I'm just trying to kind of understand the background, because I don't -- I'm not in the medical field.

So were you seeing -- were you seeing your own patients or were you seeing walk-ins? How does the clinic work?

A I mean, it was -- I was seeing my patients. I often had a continuity over years with patients at the clinic. And we also had walk-ins at times, so people could walk in. Sometimes they were my own patients and sometimes they were other patients.

Q So how long were you at St. Luke's then?

A I was there for about five years.

Q And then what did you do?

A I moved to Mexico and worked with the Population Council, which was their regional office for Latin America and Caribbean at the time, in Mexico City. I was not providing clinical care in Mexico. I did -- I still traveled back to San Francisco and provide some clinical care at St. Luke's.

But while I was in Mexico, I -- the main activity I was involved in was research.

Q And was that your first time doing research in your profession?

A No. I had training in research as -- during my residency. I had also done a different kind of research as a medical student and as an undergraduate. But I had had exposure and some training in -- in clinical and social science research related to women's health in residency. And then I got additional training when I was based with the Population Council in Mexico, and then led several studies there.

Q And what kind of studies were you leading there?

A They were on sexually transmitted infections and abortion, primarily the impact of unsafe abortion for people in Latin America, and some research on how people were using Misoprostol to self-manage abortion and to obtain access to legal abortion in Latin America.

Q So what is Misoprostol? Can you please give us a little description of that drug?

A Misoprostol is a prostaglandin that has the effect of softening and opening the cervix, the opening to the uterus, and it can also cause uterine contractions.

Q And is it used for anything other than abortion?

A Yes. It is used -- I mean, it's -- it was approved by the FDA for the treatment and prevention of gastric ulcers or stomach ulcers associated with the use of nonsteroidal antiinflammatory drugs, things like ibuprofen, but it's used very widely in obstetrics and gynecology.

It's used to induce labor with a term delivery. It's used to -- in the case of an intrauterine fetal demise in a second trimester, to deliver the fetus. It's used for -- before gynecologic procedures to soften and open the cervix for insertion of an intrauterine device or IUD. It's used before hysteroscopy, which is a procedure where you insert a small television camera inside of a uterus to look inside. It's used before a second

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trimester procedural abortion, again, to soften and open the cervix.

Q So you mentioned that you were trained in research while you were in Mexico. What was that training?

A I mean, part of it was like on statistical methods, part of it was on good clinical practice and kind of principles of research ethics in terms of how to obtain an informed consent, prepare informed consent documents and research protocol.

I mean, this wasn't through course work. It was all sort of like through mentored work that I was doing at the Population Council.

Q So would you consider it like an informal training program at the Population Council?

A Correct.

Q What did you do after you left Mexico?

A I joined a nonprofit research organization called Ibis Reproductive Health, and had several physicians with them, eventually becoming the vice president for research. And I was based in San Francisco. I did that during this period -- so for about the next ten years. I worked about 80-percent of my time with Ibis, and then did clinical work for the other 20-percent time.

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Some of that time I worked with St. Luke's and continued to do both inpatient and outpatient full scope obstetrics and gynecology, and part of that time I provided care with the Planned Parenthood affiliate here, which at the time was the Planned Parenthood Shasta Pacific, but it's now Northern California facility.

Q And what is Ibis?

A As I said, it's a nonprofit research organization.

Q And what do they research?

A They research a range of topics related to sexual and reproductive health, and certainly abortion is a big focus of the work. But also, one of the big studies that they led initially was focused on sexually transmitted infections, looking at impact of the diaphragm to prevent HIV transmission.

Q What was the focus of your research then when you were at Ibis?

A I mean, I was there for ten years. So there was -- I worked on lots of different things. We can look at my publications from that period.

So some of it was continuing the work that I was doing in Latin America, looking at the impact of unsafe abortion and access to Misoprostol. One of the areas of focus that I started researching around 2008 was telemedicine provision of medication abortion.

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I did work on -- another big focus of my research while at Ibis was on access to oral contraceptives and the possibility of being able to obtain oral contraceptives without a prescription or over-the-counter. So I collaborated with colleagues in Texas on a big National Institutes of Health funded study that was looking at people in El Paso, who border with Mexico, who were able to cross into Mexico and obtain oral contraceptives without a prescription.

My other work was focused on areas to accessing reproductive health services for people in the U.S. military.

Those were some of the main topics.

Q Okay. And so have you had any other employment since your time at Ibis in that ten-year period and now?

A I mean, my main position -- as I mentioned, during the time at Ibis I had -- I did clinical work at a few different places. Then I joined the faculty at UCSF in 2015, and I have not had any other employment since then.

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Q So when you were hired at UCF -- UCFS -- UCSF -- sorry -- what was your role when you were hired?

A I was hired as a professor in the Department of Obstetrics, Gynecology and Reproductive Sciences and to be the director of -- if I can use the acronym -- ANSIRH, Advancing New Standards for Reproductive Health, the research program I mentioned.

Q And is that the same role you have today?

A Correct. I am also the vice chair of advocacy in our department. And I believe I started that in -- let me check -- technically, I think it was around 2023.

Q And what does the vice chair of advocacy do?

A So I lead our advocacy strategy committee in department. Advocacy has always been one of the pillars of the obstetrics and gynecology department, a department that's deemed in our mission. And in this role I create opportunities to share the advocacy work that people are working on throughout the department and create training opportunities for faculty staff and learners to learn advocacy

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techniques and strategy, such as media advocacy, like providing support to help write an op ed or learning how to talk to the media, how to be an expert witness, things like that.

Q Do you do any political advocacy in that role?

A No.

Q And how long have you been in that role specifically, vice chair of advocacy?

A As I said, since 2023.

Q So about three years, a little over maybe?

A Yeah.

Q Okay.

A I'm not sure if I -- if I answered. I'm not entirely sure what you mean by "political advocacy." Certainly, some -- a piece of what we do is educating policymakers. And so we sometimes go to like Sacramento to talk to legislators about a specific bill where we're providing research evidence about a certain topic that we have expertise on.

Q So do you provide testimony information on proposed legal initiatives in California then?

A I have been asked to testify in legislative committee meetings, hearings about bills

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and where I have expertise that is relevant to the bill, yes.

Q Are you being paid for your expert opinion in this case?

A I'm being paid for the work that I'm doing as an expert witness, yes.

Q Are you a member of any professional organizations?

A I am.

Q And what are those organizations?

A I am a Fellow of the American College of Obstetricians and Gynecologists. I am a member of the Society of Family Planning. I'm a member of the American Public Health Association. I'm a member of the American Medical Association. Those are the main ones that I've been most active in.

Q Other than your medical license, do you hold any other licenses?

A I do not.

Q Are you engaged in the advanced training of students at the medical school? Clinical training, I should caveat that.

A I'm involved in clinical training of medical students, yes.

Q And what do you train at medical school

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clinically?

MR. GUINEY: Objection. Vague.

THE WITNESS: So I work with medical students in all the work that I do. So in the outpatient gynecology clinic I am working with students and train them in outpatient gynecology, including procedures -- the provision of -- of outpatient procedures.

I also work with medical students in the abortion clinic and train them in clinical aspects of abortion care.

BY MS. NAROG:

Q So what percentage of your current practice is clinical in nature?

A It's about 10 percent.

Q And of that 10 percent, how much of that is not related to abortion care?

MR. GUINEY: Objection. Vague.

THE WITNESS: It's about one-third abortion care, two-thirds outpatient gynecologic care.

BY MS. NAROG:

Q And just so that I can understand.

What kind of outpatient abortion

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gynecological care do you provide that's non-abortion-related in the clinic?

MR. GUINEY: Objection. Vague.

THE WITNESS: Can you please restate the question? Because you said abortion twice and so I just want to make sure I understand.

BY MS. NAROG:

Q What -- what kind of gynecologic care do you provide in the clinic that is not abortion related?

A I see patients for kind of routine preventive care, like cervical cancer screening for Pap smears. I see people for, you know, evaluation of complaints like heavy menstrual bleeding or pelvic pain. I provide family planning-related care, so counseling about contraception and providing contraceptive methods, including long-acting reversible contraceptives, like the implant for intrauterine device. I provide miscarriage management.

I see post menopausal patients who may have, you know, symptoms that reflect a gynecologic problem. I see patients with post menopausal bleeding that require endometrial biopsy.

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Those are some of the kinds of things I see.

Q So I know we kind of talked about this earlier with a similar program that you're working with.

But do you see patients that are your own patients or are they mostly patients that present at the clinic? How does that work?

A You know, as I said, I'm only providing care 10 percent of the time. So I don't have a lot of continuity with my patients because I'm not there that much. But -- so maybe about a third of the patients or so I've seen before and I'm seeing in follow-up care, and the rest are new patients who are just coming into the clinic for the first time.

Q Okay. So since you returned from Mexico or, you know, continued your, you know, patient care after working at the organization in Mexico, how much of your practice has been related to clinical treatment of patients?

A When I first started in 2015, about 20 percent of my time was clinical, and in the more recent years that's been reduced to about 10 percent.

Q And about how long would you say it's been about 10 percent?

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A The past three years.

Q Okay. So can you tell me what the general restrictions are in abortion care under California law where you practice?

MR. GUINEY: Objection. Foundation.

THE WITNESS: The general restrictions on abortion care in California. I mean, abortion care needs to be provided by a licensed clinician. Up until recently, both physicians and advanced practice clinicians, they still can't provide abortion care up until recently, and currently there is a limit for advanced practice clinicians to provide abortion care in California, up to about 12 weeks or so.

A law was just recently passed just this legislative session that will allow advanced practice clinicians to perform abortion care, with sufficient training, past that limit.

The -- there are restrictions in terms of the upper limit of abortion care that can be provided. That's generally linked to viability. And so an abortion can't be performed past viability without -- there are certain names. There are exception to say that.

I think those are the main restrictions that I'm aware of.

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BY MS. NAROG:

Q So are you able to provide medication abortion over telemedicine in California?

A Yes.

Q And do you provide telemedical abortion care in California?

A Do I personally provide it?

Q Yes.

A Where I am at San Francisco General Hospital, we provide telehealth follow-up visits for patients who have received medication abortion in the clinic, but we have not yet started offering kind of a full telehealth service. There's a plan to do that in the coming year, but that hasn't yet started.

Q So can you tell me, now, how do you see your patients that are seeking an abortion through medication -- the medication route in California today if you see a patient?

MR. GUINEY: Objection. Vague,

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compound.

THE WITNESS: I see medication abortion patients who come into the clinic to receive medication abortion care.

BY MS. NAROG:

Q And what happens during that clinic appointment?

A Patients receive counseling from a trained counselor. They often, although not always, receive an ultrasound. They are -- I meet with them and go through the informed consent process. They receive medications instructions and then sign all the required forms. They're not required to take medications -- to take them for the first time at the clinic. They can take that home with them to start the process when they want.

Patients are offered a range of different regimen options that are evidence-based and may differ from the protocol described in the FDA labeling. So we offer patients, for example, to shorten the interval between Mifepristone and Misoprostol to -- when you administer the Misoprostol vaginally.

We are also currently offering medication

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abortion to 77 days, but in certain instances we offer it up to 84 days, and we have a plan to a plan to extend the gestational duration fully up to 84 days. And then patients are generally scheduled for some sort of follow-up, either to come back to the clinic or an evaluation to have -- or they may have blood testing with a regimen of serum human chorionic -- chorionic gonadotropin or HCG levels, or they may have a telehealth visit to check on their symptoms after a week, and then they do a home urine pregnancy test after about four to five weeks.

Q So you mentioned -- go ahead.

A Just to say, I mentioned that I work in a clinic with students, and also with residents, and with advanced practice clinicians. And in some keys cases I'm directly providing the care myself without any of those other people, but sometimes I am supervising those other people who are providing care.

Q Okay. You mentioned that most, but not all, receive an ultrasound.

What kind of situations would -- would lead to not having an ultrasound?

A So in our clinic, it's set up in a way -- I mean, there are, like, five ultrasound machines in

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the clinic. People have been trained in ultrasound. So it's very accessible. And so if someone hasn't had an outside ultrasound, generally they have an ultrasound in our clinic.

That -- so if someone has -- has had an -- had -- I'm sorry -- an ultrasound that was performed elsewhere that we have documentation of, then we don't perform ultrasound.

This is not standard everywhere. At San Francisco General Hospital and at the family health center where we work closely with our colleagues there, medication abortion is performed without routine use of ultrasound.

Q What other testing do patients have done when they come into the clinic for their abortion appointment?

MR. GUINEY: Objection. Vague.

THE WITNESS: They have whatever testing is indicated, but for most people -- I'm sorry. Was your question specifically about medication abortion?

BY MS. NAROG:

Q Yes, medication abortion.

A For medication abortion, there is no routine testing that's done. For patients that have

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a history that is suggestive of anemia or symptoms that are suggestive of anemia, we will check the hemoglobin. For -- I guess I mentioned we're not doing medication abortion past 12 weeks. So we're not doing testing for RHD status.

Q So do you -- are most of your patients that come in for medication abortion provided with a pregnancy test?

A Not standardly. If we're not doing an ultrasound, we would generally do a pregnancy test. In cases where we can't see the pregnancy on ultrasound, which is not uncommon, which is called a pregnancy of unknown location, we do a pregnancy test.

Q What percentage would you say of the patients seen in the clinic receive an ultrasound?

MR. GUINEY: Objection. No foundation.

THE WITNESS: At our clinic, it's probably currently over 90 percent.

BY MS. NAROG:

Q You also said that an HCG level is performed at a follow-up generally.

What does that mean, HCG or HGC? I can't recall what you said.

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A Sorry. Perhaps I misspoke. But it's -- so it stands for human chorionic gonadotropin, or the hormone in pregnancy. And one way to confirm completion of a medication abortion is to check an HCG level like on the day someone starts taking the medications, and then to do a follow-up test at some point later, generally five days or seven days later. And you'd expect to see a specific decline in the level of HCG. So that's one way the completion of the medication abortion can be documented.

Another way is for patients to come back and have an ultrasound. Another way is for patients to come back and have a physical examination. And another way, which is the most common way that we do follow-up, is we generally schedule a telehealth visit for about a week after they've taken the medications. I'd say, you know, many people we're not able to contact at that week, but we try to contact them and check on their symptoms.

And then they're told to do a home urine pregnancy test after about four to five weeks, which we would -- it takes that long for the hormone level to get low enough for the urine test to be negative.

Q Who meets with the patient in these telehealth follow-up appointments?

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MR. GUINEY: Objection. Vague.
THE WITNESS: So the -- I mean, as I mentioned, I mean, we're in a learning environment. So it may be a medical student resident, a complex family planning fellow, or an attending physician like myself, or possibly an advanced practice physician who has that telehealth visit with the patient.
BY MS. NAROG:
Q Okay. So it would be a clinician either that's advanced practice or some type of physician; is that correct?
A Yes.
MR. GUINEY: Objection. Misstates testimony.
BY MS. NAROG:
A Okay. Understood. So you had mentioned earlier that you right now are prescribing medication abortion from 77 to 84 days gestation, and you said that not everyone gets to go to the 84-day limit, and I was wondering why.
What would disqualify a patient from getting, you know, the medication up to 84 days?
MR. GUINEY: Objection. Compound.

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THE WITNESS: As I said, we're -- we're working on it, changing the protocol in the clinic so that it's available to everyone. At the moment, the protocol has just been up to 77 days and -- but certainly there are patients who, you know, when they're scheduled, people think -- thought that they were about 77 days and they're found to be 79 days. Really that doesn't make any difference in the care. And we will provide service because, again -- even though there isn't yet a standardized protocol in the clinic, we also have a protocol that we provide evidence-based medicine and can provide up to 84 days in those specific cases.
But we're not like -- if someone calls the clinic and says that they're 83 days clinic -- 83 days pregnant, we generally don't say that we offer medication abortion to that point.
BY MS. NAROG:
Q Okay. So what is the basis for the 77 days that has been adopted by the clinic?

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A I mean, there's a great deal of published literature about the safety and effectiveness of medication abortion up to 77 days and up to 84 days. The data on 84 days is more recent. And so -- and the most recent guidelines from the National Abortion Federation endorse provision of medication abortion up through 13 weeks and six days. I think it's 96 days -- 97 days. Sorry.
But again, sort of a -- historically, the evidence had been more in support of up to 77 days and that had been our date, and we're working on extending it.
Q Do you know about when the clinic started using 77 days as its standard?
MR. GUINEY: Objection. Lack of foundation.
THE WITNESS: I am not sure, but it's been more than five years. Certainly during the time -- by 2020, I believe we were already offered to 77 days.
BY MS. NAROG:
Q So when -- when would you say the clinical literature -- the clinical and research literature started suggesting that beyond 70 days was

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safe for provision of medication abortion?
A Beyond 70 days?
Q Yes.
A I -- I mean, there has been evidence for a while about the safe and effective use of Mifepristone, Misoprostol throughout the first trimester, and even to the second trimester, for a while.
The systematic review by Nathalie Kapp was published in I think 2019. We can check. I believe I cite to that in my report. But so certainly by that time there was a body of evidence indicating that medication abortion could be performed in what sometimes is referred to as the later part of the first trimester.
Q So how long after that evidence, you know, became available in the research did you -- did your clinic make the change to 77 days, approximately?
A Yeah, again, I -- this is really quite approximate because, you know, I'm not part of a leadership of -- of the abortion clinic at San Francisco General Hospital. I don't write the protocols or provisions there. So I'm kind of basing this on my vague memory of what I was providing over

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the last 11 years that I've been providing care there.

So I guess I would say, you know, if we started providing in 20- -- I guess -- thinking back on this, I think, you know, when the FDA updated the Mifepristone labeling in around 2016 and extended gestational duration limit to 70 days, already at that time there was a -- you know, there was a body of evidence indicating that medication abortion could be past -- could be performed past 70 days.

So I guess I might say, it took four to five years before that got implemented into the clinic.

Q And do you know generally in California how long abortion providers will provide medication abortion, what gestational limit most other use -- or abortion providers provide?

MR. GUINEY: Objection. Vague.

THE WITNESS: So, again, as I think I refer to in my report, Dr. Ushman Upadhyay is one of my colleagues at ANSIRH. He leads a project called the Abortion Facility Database where they contact -- attempt to contact every abortion provider in the country.

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And I think the most recent published report, if I recall correctly, is from 2023, and I believe that the median upper limit of the provision of medication abortion nationally was 11 weeks, and I believe it was 11 weeks in California, as well.

BY MS. NAROG:

Q Okay. You mentioned that the National Abortion Federation has changed its guidelines recently about the gestational limits for medication abortion.

What was the date that you said that they were providing?

A The guidance says that medication abortion can be provided in an outpatient setting up through 13 weeks, six days.

Q Is that for all patients?

A I mean, all patients who are deemed eligible.

Q Are there any restrictions on providing the medication in their guidance to that 13 week, six day limitation?

MR. GUINEY: Objection. Vague.

THE WITNESS: I mean, they -- the guidance kind of reviews the medical contraindications to the provision of medication abortion, but those don't differ by gestational duration.

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BY MS. NAROG:

Q Okay. Are there other medical organizations that differ from this 13 week, six days opinion on guidance for providing medication abortion?

MR. GUINEY: Objection. Vague.

THE WITNESS: I mean, the current -- the current American College of Obstetricians and Gynecologists practice bulletin is focused on provision up through 70 days; although there is also mentioned in the protocol -- I mean, in the -- in the document about evidence-based protocols that can be used past that.

I know that there -- that document is currently being updated in collaboration with the Society of Family Planning. And I know that because I'm part of the writing team developing that guidance.

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Planned Parenthood guidance, I believe, endorses medication abortion up through 84 days, I believe.

That's sort of standard, but clinics can kind of apply for waiver, I believe, to perform past that, but I don't know the details because I'm not currently providing care, if that makes sense.

BY MS. NAROG:

Q Okay. Makes sense.

MS. NAROG: All right. So we've been going for about an hour and ten minutes. Do you want to take a short break? Does that make sense for you?

MR. GUINEY: That would be great.

MS. NAROG: Okay. Let's -- we'll come back just a little before -- is like 15 minutes good? Is that enough?

MR. GUINEY: Yeah, we can probably do ten, even if that. That's fine.

MS. NAROG: Yeah, I think ten would be. Okay. Let's just come back at -- we'll come back at 1:25. Split the difference.

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MR. GUINEY: Okay.
MS. NAROG: Okay.
(Brief pause.)
BY MS. NAROG:
Q All right. Let's talk a little bit about your expert qualifications.
I think we talked earlier that you've acted as an expert witness before in other legal cases, correct?
A Yes.
Q And you said about ten, you think, cases in which you were an expert?
A I believe I said there were about ten times I was deposed. I think I've been involved in about 12 cases or so.
Q Okay. And were all those cases about abortion-related issues?
A Yes.
Q Have you ever served as an expert in other types of cases?
A I have not been involved as an expert in cases that were not related to abortion.
Q Did you write an expert report in those 12 cases that you think you acted as an expert?
A Yes, I did.

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Q And how many of those cases did you provide a rebuttal report in?
A I really don't remember.
Q And you've never submitted an expert report in any other kind of legal matter other than an abortion case?
A I have not.
Q So if we turn back to your expert report, if you would -- if you could grab that copy that you have -- does this report contain your entire expert opinion about the matters at issue in this specific case?
A Sorry. Can you please repeat the question for me?
Q So does this report contain your entire expert opinion about the matters involved in this specific case?
A I guess, yes, it is -- this is my expert opinion generally. I think, even since I've prepared this report, there have been additional peer-reviewed articles published that, if I were to write this report again today, I would add those citations and those would be also informing my current assessment. It doesn't change my overall expert opinion.
Q And how did you reach your opinion? What did you base your opinion upon?
MR. GUINEY: Objection. Compound.
THE WITNESS: I based my opinion on my training, on my clinical experience, on my -- the research that I performed and my review of other published research on the topics that I was asked to opine on.
BY MS. NAROG:
Q Let's turn to Paragraph 4 in your report, and let me know when you have that.
A I do.
Q Okay. You state in this paragraph that your research has been supported by grants from Federal agencies and private foundations; is that accurate?
A Yes.
Q What kind of foundations, private foundations, have funded your research?
MR. GUINEY: Objection. Vague.
THE WITNESS: Are you asking for the names of foundations?
BY MS. NAROG:
Q What kind of foundations. Yes, names is fine, or descriptions would work, as well.

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A Private foundations that give funding in the area of research in reproductive health are the types of foundations that have supported my work.
Q And can you give me the names of those foundations?
A The Hewlett Foundation, the Packard Foundation, Grohne Foundation. Those are a few.
Q Does Planned Parenthood ever fund any of your research?
A They do not fund my research.
Q Do any other abortion advocacy organizations fund your research?
MR. GUINEY: Objection. Vague.
THE WITNESS: Can you tell me what is an abortion advocacy organization?
BY MS. NAROG:
Q An organization that advocates on behalf of abortion.
MR. GUINEY: Objection. Vague.
THE WITNESS: I don't know what that means.
BY MS. NAROG:
Q You're the leader of advocacy at your college and you teach students how to advocate. You don't understand what it means to advocate on behalf

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of abortion?
MR. GUINEY: Objection. Vague.
THE WITNESS: It's one thing to say to engage in advocacy activities. It's another thing to be titled an advocacy organization. So -- and specifically an abortion advocacy organization.
If you could give me -- tell me what you mean, I can tell you if they funded it.
BY MS. NAROG:
Q We'll move on. I -- it doesn't -- I don't think it's that difficult to understand.
I just want to know if any other abortion organizations that, you know, that advocate on behalf of abortion procedures, have funded your research.
MR. GUINEY: Objection. Vague.
BY MS. NAROG:
Q That doesn't necessarily mean that the organization must be deemed an advocacy organization.
A I don't understand.
Q It's fine. We'll move on.
What Federal agencies have funded your research?
A The National Institutes of Health have

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funded my research.
Q Are there any other Federal agencies?
A That have funded my specific research, no.
Q Okay. It says here that you also have published 260 articles in peer-reviewed journals and that you're a member the editorial board of the Journal of Contraception; is that correct?
A That is correct.
Q How many of your peer-reviewed articles are specifically on the topic of abortion?
A I do not know. But I have provided a list in my CV as of May 29th, so we could count them.
Q What percentage would you say, approximately, of your peer-reviewed articles are specifically on the topic of abortion?
A I would really have to count them. Would you like me to do that?
Q No, it's not necessary to count. I'm just asking for a general estimation.
A I do not know.
Q How many of your articles relate to medication abortion?
A The majority of the articles that I've written on abortion are related to medication

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abortion, I believe.
Q How many of your articles consider the abortion practices of clinicians in other states, besides California?
MR. GUINEY: Objection. Vague.
THE WITNESS: Again, I can look at my CV, but several of my studies are based on national samples, and so we use data from every states. In particular -- in addition, I have done some research that specifically recruited patients in specific states. And sometimes patients travel from other states to obtain care in the states where we recruited.
BY MS. NAROG:
Q Have you conducted research specifically about patients in Ohio?
MR. GUINEY: Objection. Vague.
THE WITNESS: I mean, as I said, some of the research that I've done has included national samples and included people from Ohio, and in some of our research in -- where we recruited in the Midwest, some patients may have traveled from Ohio.

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BY MS. NAROG:
Q But have you conducted any research that was specifically based in Ohio, related to Ohio patients?
A I have not.
Q What responsibilities do you take on when you're writing a research paper for publication with other co-authors?
MR. GUINEY: Objection. Vague.
BY MS. NAROG:
Q Generally.
A What responsibilities. It depends on what kind of research paper it is, whether I'm leading the research or not. I mean, I may have a role -- I'm sorry. Maybe you could be a little more specific about what you're asking because I could go on and on about my roles in creating a research paper.
Q So how many -- how often do you act as the lead author in a research study?
A I mean, over the past ten years, as a director of my research program, I'm often the senior author of papers. Not always, but often.
Q So in that capacity, what responsibilities do you usually take on when you're

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writing a research paper for publication and there are other co-authors?

A I mean, so, again, if we're talking about the research that I have -- where it's my team that is leading the research, I am involved in every aspect of the research. That means that I'm involved in developing a proposal for the funding of the research, getting the funding for the research, developing the research protocol for the institutional review board, developing the study instruments, piloting the study instruments, identifying the sites where we will be doing the data collection, negotiating contracts with those sites to perform data collection, supervising the data collection, supervising the data management and data cleaning, supervising the statistical analysis, supervising and actively participating in writing the manuscript, and getting feedback from co-authors on the manuscript, and eventually submitting the manuscript to a journal.

Q What approach do you take to finding and selecting, you know, studies to review when you're looking at, say, a systematic review? How do you determine which studies you'll consider and which you won't?

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MR. GUINEY: Objection. Vague, compound.

THE WITNESS: You're talking about for a systematic review?

BY MS. NAROG:

Q Right.

A I mean, there's a very detailed and established way that you -- I mean, as part of a research team, it's never done with just an individual researcher -- identify the question that the review is aimed to answering, and then creating a list of inclusion and exclusion criteria for the articles. There's then a sequential process that first involves creating the search and ensuring that you create search terms and use search terms that are sufficiently broad so that you'll capture a large number of articles, understanding that many of the articles won't be relevant, but increasing the likelihood that all of the relevant articles will be captured.

So that's -- I think that answers your question.

Q So how do you come up with ideas for, you know, research that you are going to conduct in the future? How do you come up with ideas for new

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research?

MR. GUINEY: Objection. Compound.

THE WITNESS: Sometimes it's because prior research that I've done has raised a question about something that's not fully answered, so we want to do the follow-on study that will help to answer that question.

Sometimes there's a service delivery advance that is being implemented and we have an opportunity to evaluate that change in service delivery to try to understand how that service is being rolled out and how patients are affected by that change.

Sometimes it's due to a policy change that occurs that may either restrict access to care or expand access to care and we want to document what the effect of that policy change is.

Those are some of the things.

BY MS. NAROG:

Q So you mentioned service delivery advance. What is that?

A So, like in 2008, I was at a National

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Abortion Federation Conference meeting and heard about the Planned Parenthood affiliate in Iowa that started to offer abortion care -- medication abortion by telemedicine. That was the first time I had ever heard about that.

So that's an example of a service delivery advance that then motivated me to develop a research project to study it.

Q Now, in your report, if we could turn back to that, in Paragraph 5, you say here that you're -- you are also a board certified subspecialist in complex family planning.

What does it mean to be a subspecialist in complex family planning?

A There are several subspecialties in the field of obstetrics and gynecology, including complex family planning. Many -- there's -- and there's a fellowship in complex family planning that people can do after completing residency. And then, after completing the fellowship, they go through the required board certification process to become a complex family planning subspecialist.

When this became a recognized subspecialty in the field of obstetrics and gynecology, there was a process where other experts

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who did research and provided clinical care in complex family planning could be grandparented into the subspecialty by taking a written examination, which I did -- I believe in 2023, I think -- and became a subspecialist, a boarded subspecialist.

Q Okay. So does that mean you didn't take the fellowship, you weren't involved in any fellowship training?

A Correct.

Q Okay. And so what kind of patients does a complex family planning specialist see?

A They care for people through -- who have complex medical conditions and are seeking contraception. They may have more complex conditions related to family planning, for example, intrauterine devices that are difficult to remove or subdermal contraceptive implants that are difficult to improve. The subspecialist will receive additional training to provide that type of care. Again, medical conditions that require consideration in selecting a contraceptive method.

And complex family planning specialists also provide abortion care, including later abortion care.

Q Okay. So you mentioned contraception and abortion care.

So would you provide genetic counseling for patients that have health conditions that they, you know -- that they may or may not be concerned about in potentially having a family?

MR. GUINEY: Objection. Vague.

THE WITNESS: I mean, that's not the focus of what I do. That's generally not the -- I mean, there are genetic counselors. I certainly collaborate closely with genetic counselors that do that -- that kind of work.

BY MS. NAROG:

Q Okay. I'm just trying to understand, you know, exactly what a complex family planning specialist does because I've like not heard of it before I read your report. So I was just curious to know what kind of -- what the scope of your treatment and practice was.

Okay. Let's go to Paragraph 8, which is just on the same page. Do you see Paragraph 8?

A I do.

Q Okay. So this -- you just say here that: I understand that Senate Bill 260 requires that a physician who prescribes abortion-inducing medication to a patient be physically present at the location and at the time the patient takes the first dose of the medication in the abortion regimen.

I'm curious about what you mean when you say, I understand. Could you tell me what that means, I understand that Senate Bill 260 does these things?

MR. GUINEY: I would just caution the witness to avoid revealing any privileged communications in your answer, but if you could do so without providing privileged information, you can do so.

THE WITNESS: That is my understanding of the bill -- of the law.

BY MS. NAROG:

Q Is that based on your own reading of the -- the statute?

MR. GUINEY: Same caution.

THE WITNESS: That is based on my -- again, I'm not a lawyer, as you know. That is my understanding as reading it as a physician and in discussions with my attorneys.

BY MS. NAROG:

Q Okay. Let's turn to Page 12 or -- sorry -- Paragraph 12. Let me know when you have that.

A I do.

Q Here you say: It is my opinion that the evidence-based use ban restricts clinicians in Ohio from providing evidence-based care. It arbitrarily limits access to medication abortion with no medical benefit and contrary to the best medical evidence.

Did I read that correctly?

A Yes.

Q Okay. What do you mean when you say there is no medical benefit?

A There is no medical benefit to a patient to only being able to access medication abortion according to the protocol described in the FDA-approved labeling of Mifepristone.

Q And what do you base that reasoning on?

A I mean, my own clinical practice, my -- the research that I have performed, and the research that I have read.

Q So is it your opinion that there's no medical benefit to the restrictions that are provided in the REMS program for Mifepristone?

MR. GUINEY: Objection. Misstates testimony, vague.

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THE WITNESS: The statement that I just made previously was about the protocol described in the FDA-approved labeling, which includes both the label and -- I believe when you said REMS, you were referring to the risk evaluation and mitigation strategy.

I do not believe that there is medical benefit to a patient to be limited to all of those things.

BY MS. NAROG:

Q And what specific things do you think they should not be limited to that there's no medical benefit for?

MR. GUINEY: Objection. Vague, compound.

THE WITNESS: At a high level, I believe that patients should be allowed to receive medical care based on the best available medical evidence, and that includes the use of medications that are approved by the Food and Drug Administration, but used off-label, because that use reflects the best available medical evidence.

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I believe that's true across the board in all various medicine, and I don't think it is in patient's interest to be restricted in this case regarding the use of Mifepristone.

If you'd like me to detail the specific problems that I see related to Mifepristone, I can certainly do that.

BY MS. NAROG:

Q Yes, please. That's what my question was kind of getting at.

A Again, I guess I just want to start by saying I can tell you what I see currently, but the scientific evidence is going to continue to evolve. And, again, patients in Ohio, if this law were being enforced, would be denied access to that medical progress.

But currently, some of the things that I see as problematic are the fact that this -- the evidence use ban would prohibit -- again, if it were enforced currently, would prohibit shortening the interval between Mifepristone and Misoprostol. As I mentioned before, I see a significant number of patients who are very eager to move forward with the medication abortion process as quickly as possible,

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and may allow them to shorten that interval to six hours and use vaginal administration of Misoprostol.

Also, as I have said, provide medication abortion past 70 days. There are, again, a significant number of patients that I see that present past 70 days and feel very strongly that they want to have a medication abortion. And patients in Ohio, if this law were being enforced, would not be able to access that.

The -- we also use medication abortion -- we use -- I'm sorry -- use Mifepristone and Misoprostol commonly for miscarriage management. Which, again, is an off-label use of Mifepristone, because it's the most effective medication regimen for people who have a miscarriage or the pregnancy has not remained in the past.

We've also use Mifepristone as an option for cervical priming before a procedural abortion. Another off-label use.

Q So what do you define as the best medical evidence? What does that mean to you?

A Medical evidence that has -- often in the context when we're referring to it here and related to abortion care, it's evidence that has been incorporated into guidelines that have come from

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organizations that focus on this area, including guidelines from the National Abortion Federation, from Planned Parenthood, from the Society of Family Planning, from the American College of Obstetricians and Gynecologists. The evidence that has -- there are cases when there are several studies that are published in well-regarded peer-reviewed literature -- peer-reviewed journals.

That's the kind of evidence, obviously, that I would look to.

Q All right. Let's turn to Paragraph 24, please. Let me know when you've gotten there.

A I am there.

Q Okay. So right here at the top of Paragraph 24, you say: Abortion is one of the one of the safest treatments in contemporary medical practice.

Did I read that correctly?

A Yes.

Q How do you define "safe" in the context of medical care?

A Something that has a very low risk of having a serious adverse event.

Q And how did you determine that abortion is one of the safest treatments in all contemporary

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medical practice?
A I don't say all, but I say contemporary. I mean, this is my opinion, I think. It's generally recognized as a very safe treatment with a very low rate of serious adverse events. It's something that has been incorporated into primary care provision in many settings. It can be provided by clinicians who are not physicians. A lot of evidence that it's very safe.
Q And, again, I recognize that you state here, the safest treatments in contemporary medical practice, but is that compared to, you know, other obstetrical treatments or is that to other outpatient procedures? How did you -- how do you make that statement that it is one of the safest treatments?
MR. GUINEY: Objection. Compound.
THE WITNESS: Again, I think this is a -- let me remember my grammar correctly. It's something like a topic sentence of my paragraph. And I then kind of go on to talk about all the data. And we just have a lot of evidence that this is a very safe treatment. So that's how I made that assessment.

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BY MS. NAROG:
Q Okay. And I -- and I understand that you do provide a lot more information here, but I'm just curious.
You say it's one of the safest, and so I'm just wondering what you compared that to, to determine that it's one of the safest.
MR. GUINEY: Objection. Asked and answered.
MS. NAROG: Not that it's just safe.
THE WITNESS: Again, I'm comparing it to the treatments that I have provided or observed as a physician in medical school, in residency and in practice.
I also think about this in the context of the training that I do and the -- you know, yeah, what sort of training is required to perform different kinds of procedures and the amount of studying that someone needs to do to prepare to be able to provide this to competency and safely.
And I think I provide data in my report documenting the safety.

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BY MS. NAROG:
Q So I wanted to ask something about what you testified to earlier.
You talked about how you might be up performing abortions in the second trimester; is that correct?
MR. GUINEY: Objection. Misstates testimony.
THE WITNESS: Maybe if you could pull it up. I don't remember where I said that.
BY MS. NAROG:
Q You were talking -- and it doesn't -- I can just ask you the question.
Do you perform abortions in the second trimester as part of your clinical treatment of patients?
A I do.
Q And what does it mean to be in the second trimester?
A Generally, that's taken to mean abortion care after about 14 weeks or so.
Q And how -- what is the gestational limit for providing procedural abortions in your practice?
MR. GUINEY: Objection. Vague.

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THE WITNESS: Could you clarify. Do you mean at the clinic where I provide care, or what do I personally provide to --
BY MS. NAROG:
Q Personally provide in your practice.
A I mean, generally I provide procedural abortion up to about 18 weeks or so.
Q Eighteen weeks. Have you provided abortion care beyond 18 weeks in your past?
A I have.
Q And up to -- to what gestational limit have you provided abortions for in those contexts?
MR. GUINEY: Objection. Vague.
THE WITNESS: About 23 weeks.
BY MS. NAROG:
Q And when -- when were you providing abortions to 23 weeks?
A That was part of my training as a resident in obstetrics and gynecology.
Q And how many abortions beyond 18 weeks have you provided in your career?
MR. GUINEY: Objection. Vague.
THE WITNESS: I don't know.

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BY MS. NAROG:
Q And is that part of what qualifies you as a specialist -- subspecialist in complex family planning?
A I'm providing second trimester care as part of the scope of practice of a complex family planning specialist, yes.
Q That's what I think we discussed and that's what I was trying to ask about and I kind of got off track there. So thank you for returning to that for me.
Okay. So let's talk about if there's any limitation in the research data. So you say that there are multiple, multiple studies that show that abortion is very safe. Are there any that say that abortion may not be perfectly safe?
MR. GUINEY: Objection. Vague.
THE WITNESS: I -- can you say a little bit more about what you're asking? I'm not sure I understand what you're asking.
BY MS. NAROG:
Q So do all of the relevance sources of research support your, you know, opinion that abortion is safe?

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A I believe that the -- I mean, I know that the vast majority of research on abortion and all of the large studies that have -- you know, that are well done and we have representative samples document safety of abortion, yes.
Q Is there any evidence that there might be some inaccuracies related to the reporting of maternal deaths related to abortion care?
MR. GUINEY: Objection. Vague.
THE WITNESS: I -- I'm not aware of that.
MS. NAROG: So I'm going to go ahead and just put in the Chat because I think it will make it a little bit easier. I'm going to mark this as Exhibit -- are we on D?
THE TECHNICIAN: We are on E.
MS. NAROG: E. Okay.
(Grossman Deposition Exhibit E was marked for the record.)
MS. NAROG: And I'm going to go ahead and have you open that. It did not send. I'll send it again. It's the blog article, if you can try to put it in the Chat, too.

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THE TECHNICIAN: From 2016?
MS. NAROG: Yes. It's telling me that the network is disconnected. So at any rate, if you could put that in the Chat, I'd appreciate it.
BY MS. NAROG:
Q Dr. Grossman, let me know when you've managed to open that.
A Yes.
Q Okay. Are you familiar with this -- this article?
A I am not.
Q I'll give you a second to just go ahead and give it a quick review before I ask you some questions about it.
A I mean, do you want me to take the time so review the entire article?
Q I just want to give you a chance to take a look and then I was going to ask if you recalled reviewing this study before.
A Did I cite to this study in the report?
Q I don't believe so.
A I have not -- I don't believe I've reviewed this paper before.
Q And are you familiar with this journal

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called BJOG?
A I am.
Q And what is this journal?
MR. GUINEY: Objection. Vague.
THE WITNESS: It's the British Journal of Obstetrics and Gynecology and it's a peer-reviewed journal.
BY MS. NAROG:
Q So this article is peer-reviewed then?
MR. GUINEY: Objection. Lacks foundation.
THE WITNESS: Yeah, I believe so, since this is published there. And you're -- I can't do a detailed review of this article.
BY MS. NAROG:
Q No, no, that's okay.
Just generally, if it's published in the journal, would it be then peer reviewed?
A Not everything that appears in any journal is peer reviewed. This appears to be a research study. So at first look, I would guess that this was peer reviewed, but I cannot be 100-percent sure.
Q Okay. So let's -- I'm going to have you

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turn to Page 1 -- or 1652, which is near the end of the document. It should be -- it should say Interpretation at the top of the page.

A Yep.

Q So the second paragraph, it says: The above findings have implications for policymakers, planning and resource allocation. Inaccurate reporting of cause of deaths limits the validity and usefulness of mortality indicators for policy research and applied public health decisions.

Accurate cause of death attribution is considered to be increasingly important to guide national and international efforts aimed at reducing maternal deaths in the post millennium development goal agenda. Inconsistencies across countries makes it difficult to correctly plan mortality reduction strategies and are also a concern if they are incorrect but used to inform planning at national and international levels.

It is also of concern that this could -- that this could mean that policy decisions globally, as well as locally, are based on intrinsically faulty data.

Did I read that correctly?

A Yes, I believe so.

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Q So according to their website, the journal published this article -- that published this article has over 4.65 million full text downloads per year, with an impact factor of 4.663.

What is this an impact factor?

A An impact factor is a way to assess like for how many times a particular -- generally, impact factors refer to the journal and would refer to how often the articles in that journal are cited.

Q And so what does an impact factor of 4.663 indicate?

MR. GUINEY: Objection. Lack of foundation.

THE WITNESS: I can't tell you off the top of my head how that number is actually calculated. I would say that's kind of a medium impact journal in our field.

BY MS. NAROG:

Q So what are the ranges of numbers for high impact to medium to low, in your field?

A I mean, there are some journals that have an impact factor of one to two, and -- I mean, there are other more general medical journals that have impact factors I think even the size 100.

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Q So you think that 4.66 is more medium -- medium and not lower impact factor?

A I mean, specifically -- and I'm sorry, were you telling me that this was the impact factor of the British Journal of Obstetrics and Gynecology?

Q Yes.

A Yeah. I would categorize this as a medium impact factor journal in the field of obstetrics and gynecology.

Q Is that based off of that 4.66 number or just what your experience is?

A Both.

Q Okay. So in your opinion, is it -- is it possible that reporting of abortion-related deaths in the broader category of maternal mortality is widespread?

MR. GUINEY: Objection. Vague, lack of foundation.

THE WITNESS: Can you please repeat the question?

BY MS. NAROG:

Q So I'm asking if, in your opinion, is it possible that reporting of abortion-related deaths in the broader category of maternal mortality is widespread?

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MR. GUINEY: Same objection.

THE WITNESS: No. It is my opinion that that is incorrect.

BY MS. NAROG:

Q What is your opinion on the reporting of maternal mortality then?

A That wasn't your question.

Q What is your opinion of the reporting of maternal mortality then? Like, what is your opinion? Do you feel it's accurate?

A I believe your question was about abortion reporting related -- or abortion-related deaths in the context of maternal mortality. Did I misunderstand your question?

Q No. I'm asking a different question.

So I'm asking what is your opinion of the reporting of maternal mortality then, especially as it impacts abortion, but in your research and your experience?

MR. GUINEY: Objection. Vague.

THE WITNESS: I'm really having a hard time following you. Are you asking me a question about abortion mortality or are you asking me a question about maternal mortality overall?

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BY MS. NAROG:
Q I would say overall, but then also in the context of abortion -- of abortion care.
MR. GUINEY: Objection. Compound.
THE WITNESS: Okay. I am not an expert in maternal mortality overall, and do recognize that there are challenges with reporting of maternal mortality generally, including related to some of the issues that you highlighted in this article that have also been highlighted in other research related to how -- how maternal deaths are recorded on death certificates.
I don't believe that, that -- those same issues apply to abortion mortality because there is a great deal of scrutiny applied to abortion and abortion-related deaths in our country.
And up until 2024 when the U.S. Centers for Disease Control were kind of completely gutted by the current administration and there was a robust group there in the division of reproductive health, there was very

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active surveillance of abortion-related deaths that relied on a variety of sources that went beyond simply evaluating death certificates.
BY MS. NAROG:
Q So I recognize you have not reviewed this article, but does this give you any concern about the reliability of some of the maternal mortality data that has gone into the calculation that abortion is safe?
MR. GUINEY: Objection. Vague.
THE WITNESS: Based on what I just said and the several minutes you allowed me to review this paper has since not changed my opinion about the reliability of the data that we have on abortion safety in the United States.
BY MS. NAROG:
Q Okay. I'm going to turn to a different study, if I can find it.
MS. NAROG: So could you drop in the Chat the Global Causes of Maternal Death article.
THE TECHNICIAN: One moment. It should be in the Chat.

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MS. NAROG: And that I'm going to mark for identification as Exhibit E.
THE TECHNICIAN: Exhibit F.
MS. NAROG: Or F. Sorry.
(Grossman Deposition Exhibit F was marked for the record.)
BY MS. NAROG:
Q Let me know when you have that.
A I do.
Q Okay. And have you reviewed this article before?
A I have seen this article in the past, yes.
Q Can you tell us what it's about?
A I really -- I can just tell you that I've seen it. I would need some time to review it if you want to give me some time.
Q Yeah, I'll give you a couple of minutes to review it.
A So this is -- I'm sorry. Was your question about what the article was about?
Q Yes. If you could just give us a general idea of what this article is about?
A It's a review of available data to identify causes of maternal deaths worldwide.

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Q And is this a peer-reviewed article?
A Yes.
Q And what were the general findings of this review?
A You're asking me to take a look at a paper and summarize a paper in three minutes. Is that the question.
Q I was just asking generally, but if you refer, I can just read part of the -- part of the findings.
Did you consider this article when you came to your expert opinion in this case?
A I not did. I mean, I have reviewed this paper in the past and it certainly informs my general views. I did not -- I don't believe I cited this paper in my report.
Q So on Page E-331, top heading is Abortion. When you see that, let me know.
A Yes.
Q Okay. So in the second half of that first paragraph, it starts: Even where induced abortion is illegal, religious and cultural perceptions in many countries mean that women do not disclose abortion attempts, and relatives or high care professionals do not report that as such.

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Under-registration of deaths might be the result of stigmatization of abortion affecting what information is reported by relatives and informants or potential misclassification by providers when abortion is restricted.

Did I read that correctly?

A You did.

Q What does it mean to say that it might be misreported or misclassified?

MR. GUINEY: Objection. Foundation.

THE WITNESS: So this is a global study that's reporting on a variety of settings where -- and certainly during this period before there were robust electronic health records, where abortion is legally restricted and may only be available from clandestine providers. I don't believe these findings are applicable to the United States.

BY MS. NAROG:

Q Did they consider information from the United States in this study, to your recollection?

MR. GUINEY: Objection. Foundation, lack of relevance.

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THE WITNESS: I do not see evidence that they considered or were specifically referring to the United States when they wrote these sentences.

I can't quite see what the footnote is to the sentence, but the specific footnote is to a paper we're looking at, review of existing methods to measure unsafe abortion and the associated mortality with that; which, fortunately, is not an issue in the United States.

So the only citation to the sentences that you've read are completely -- is completely irrelevant to the context in the United States.

BY MS. NAROG:

Q So that part of the -- of the study is not relevant to the United States then?

MR. GUINEY: Objection. Foundation. I'd also just like to note for the record the witness has only had three minutes with this document and he hasn't had the adequate opportunity to review it before being asked to analyze or opine on it.

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MS. NAROG: If he would like more time, that's absolutely fine, if that's what he'd like to do. I just was trying to get his general knowledge about these studies.

THE WITNESS: The citations that are in -- even the ones in this paragraph focused on unsafe abortion, which, as I said, fortunately is a very uncommon phenomenon in the United States. Unfortunately, it may be becoming more common in places where -- in states where abortions have been restricted, but I don't know if that's the focus of what you're asking.

There is nothing that is cited to in this paragraph that indicates that they used source material from the United States to substantiate these conclusions.

BY MS. NAROG:

Q Okay. So, again, this -- this article you had reviewed before, but you didn't use it as a basis for your opinions in this case, right?

A That's correct.

Q Okay. Let's -- you can go ahead and set

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that aside.

So can you -- let's talk a little bit about the REMS program that was developed for Mifepristone. And I think you gave us a little bit of background on Mifepristone and its use as abortion medication in the United States, but can you talk to us a little bit about the REMS program and what it required?

MR. GUINEY: Objection; vague.

THE WITNESS: Sure. When Mifepristone was approved by the U.S. Food and Drug Administration in 2000, it was approved with several restrictions on its distribution. Later, when the FDA established the REMS program or, as we said, the Risk Evaluation and Mitigation Strategy, those distribution limits were sort of incorporated into a REMS.

BY MS. NAROG:

Q And do you remember -- do you recall what those limitations were when they were first incorporated into the REMS program?

A There is -- again, this is -- I have to look at my report where it summarizes this, but based on my recollection, these include a requirement for

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prescribers that they sign a prescriber agreement form. There is a -- there was a requirement, and still is, for patients to sign a patient agreement form, and at the time of approval, there was also an in-person dispensing requirement.

Q Do you know when the in-person dispensing requirement was removed from the REMS?

A It was initially removed in 2021, and then was kind of finally -- like formally codified into modified REMS in 2023.

Q So what are the requirements for prescribing Mifepristone listed in the REMS program?

MR. GUINEY: Objection. Vague.

THE WITNESS: Can I refer to -- I mean, I can tell you some of the things off the top of my head. I'm not sure I can list everything. There's quite a few things that are in that.

MS. NAROG: Okay. So let's -- can we -- can you place in the Chat the REMS -- 2011 REMS document so that he can review it.

(Grossman Deposition Exhibit G was marked for the record.)

THE WITNESS: Yes, I have it.

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BY MS. NAROG:

Q If you'd like to just open that, and if you can tell us what this document is.

A This looks like the REMS for Mifepristone as of June 2011.

Q Is that the first REMS document that we have? Isn't that what you said in your testimony, that they had incorporated the original requirements into a REMS program about this time?

A I believe so, and I see this also says Initial. I'm not entirely sure if this was the very first one. It was a REMS --

Q Okay. And what does this require for physicians to prescribe Mifepristone?

A First of all, it says Healthcare Providers. They have to review the prescribing information of Mifepristone and complete the prescriber agreement form, which I referred to. And in that form, by signing it they agree that they have the following qualifications, including the ability to assess the duration of pregnancy accurately, the ability to diagnose atopic pregnancies, the ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and

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ability to assure patient access to medical facilities equipped to provide blood transfusion and resuscitation if necessary, and then that they would follow the guidelines for the use of Mifepristone.

Q So that requirement that they will follow the guidelines, that would not include prescribing off-label?

MR. GUINEY: Objection. Vague.

BY MS. NAROG:

Q Is that your understanding?

A I -- my understanding as a physician -- again, I'm not a legal expert -- was that there was nothing in the REMS, even at this time, that prohibited off-label use of Mifepristone.

Q So the fact that they provided gestational limitation, is it your testimony then that, that would not be barred by this REMS program to provide it outside of 70 days or beyond 70 days gestation?

MR. GUINEY: Objection. Vague, misstates testimony.

THE WITNESS: I'm not a legal expert. I am not a regulatory expert.

I can tell you that, at the time when -- first of all, you just -- you

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said something about 70 days at the time in 2011. The labeled indication for Mifepristone was to 49 days.

But I would just also would like to have a little bit more time to just review exactly which V.I through V are.

I don't see anything in there about following any specific protocol. So I -- reading this as a physician, I would not -- I don't see anything in here that would prevent off-label use.

BY MS. NAROG:

Q So you -- you said that the -- the gestational limit at that time, when this was the REMS program that was in effect, was 49 days, correct?

A That is my recollection, yes. I'm sure we could pull up the label from 2011, if you would like.

Q So there's nothing in this part of the agreement, though, that would prohibit you from prescribing beyond the 7 -- or the 49 days?

MR. GUINEY: Objection. Vague.

THE WITNESS: Perhaps it would just be helpful to read into the record where

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it says: They will follow the guidelines of use of Mifepristone, see V.ii-v below, that includes, as a condition of certification, healthcare providers must follow the guidelines for use of Mifepristone prescribed below.
Review the patient agreement form with the patient and fully explain the risks and benefits of the treatment regimen, answer any questions the patient may have prior to receiving Mifepristone.
Two, sign the patient agreement form and obtain the patient's signature on the form.
Three, provide the patient with a copy of the patient agreement form and the medication guide.
Four, place the signed patient agreement form in the patient's medical record.
Five, record the serial number from each package of Mifepristone in each patient's record.
I don't see anything in there describing anything about the protocol

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that's being used.
BY MS. NAROG:
Q Okay. When was the gestational limit changed, to your recollection, in the REMS program?
MR. GUINEY: Objection. Vague.
THE WITNESS: My recollection is that the FDA updated the labeling for Mifepristone in 2016 to change the indication for use up through 70 days gestation.
BY MS. NAROG:
Q Okay. Was there in-person requirements for prescribing in 2011, to your recollection?
MR. GUINEY: Objection. Vague.
THE WITNESS: There was an in-person dispensing requirement, as we see here in No. 2: Mifepristone must be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices and hospitals, by or under the supervision of a certified prescriber.
BY MS. NAROG:
Q And when did they dispense with that requirement in the REMS program, to your

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recollection?
A As I believe I said a few minutes ago, that was first changed -- I mean, it was changed briefly in 2020, I believe, in the context of a lawsuit, but it was changed then in 2021. The FDA issued some initial guidance around that, and then there was a final codification of the change with the REMS modification in 2023.
Q Are there any other -- have there been any other changes to the REMS program since the original REMS program in 2011, to your knowledge?
A Again, I'm a little confused, because sometimes you're saying things that are in the labeling, but you're referring to them being in the REMS.
So I just want to note that there were several changes made to the labeling in 2016, some of which we mentioned and some of which we haven't mentioned. The main change to the REMS was removal of the in-person dispensing requirement.
MS. NAROG: Okay. Before I turn to the next section, do you want to take a quick ten-minute break, and then we can come back and try to do another hour or so before lunch?

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MR. GUINEY: So it's 11:30 here. Dr. Grossman, would you like to maybe go for a little bit longer, take a lunch now, or would you like maybe another session before lunch?
THE WITNESS: I'm happy to take a another session before lunch. We can take a short break now then.
MR. GUINEY: That works for us and works for you.
MS. NAROG: We'll come back at -- you know, let's do 2:45.
(Brief pause.)
BY MS. NAROG:
Q Dr. Grossman, before we took our break, we were talking about the FDA REMS program, and we were talking a little bit about the Mifepristone label. And I think it is worthwhile to just discuss the difference -- the difference between the two.
So what is the Mifepristone drug label?
A The drug label was approved by the FDA initially in 2000 for Mifepristone, and it includes information, for example, about the indication for use, medical contraindications, warnings, information about recommended protocol that was used in the

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studies that led to the approval, and other potential risks and warnings.

MS. NAROG: I was going to ask if you could please drop into the Chat the Mifeprex drug label.

MR. GUINEY: Just for my own record keeping, this will be Exhibit H; is that right?

MS. NAROG: I believe so.

THE TECHNICIAN: I just want to be sure, Counsel --

MS. NAROG: Let me see here. I couldn't hear you very well there.

It should say Mifeprex Label. That's what it should be.

THE TECHNICIAN: Oh, yeah. Sorry.

MS. NAROG: That's okay.

(Grossman Deposition Exhibit H was marked for the record.)

THE TECHNICIAN: It is up in the Chat.

BY MS. NAROG:

Q And, Dr. Grossman, let know when you have it open.

A I do have it.

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Q So is this the most recent Mifeprex drug label that you know of, that you're aware of?

A Yeah, it looks like this is the version revised in January 2023, which I believe is the most recent.

Q And what major changes were proposed in this drug label as opposed to the prior drug label, if you recall?

A Can you just clarify what you mean by prior? What two do you want to try to compare?

Q We just discussed the fact that the label -- this is the most recent drug label.

So prior to 2023, when this label was adopted, what changes were made from prior to this label to this label? So the 2016 label to this current one.

A I believe that this label was updated in the context of the modification of the REMS. I -- I'm not sure I can specifically identify what changes -- I honestly don't know what prior -- if you want to -- do you want me to tell you changes that happened between 2016 and 2023? Is that your question?

Q Yes. Yes.

A And you mean after the 2016 changes?

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Q Correct.

A Okay. One of the changes that was made -- I'm not sure it's exactly the timing -- is that all -- any reference to physician was eliminated. And so I believe they either use healthcare provider or possibly they say clinician, but there's no longer a specific reference to a physician.

I don't remember exactly here in the label where it refers to the -- if there's any -- had been previously any reference to the in-person dispensing requirement. That was removed since that was the main change to the REMS.

Honestly, I don't remember other -- what other specific changes were made between 2016 and 2023 to the label.

Q Okay. But the two are distinct, correct, the REMS program and the label, or are they incorporated somehow?

A Yeah, I don't -- speaking as a clinician, they're distinct, distinct documents.

Q Okay. So the prescribing requirements on the label are not actually what is enforced by the REMS program in your understanding or position, because we had a discussion, you know, just before

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the break about, you know, whether off-label was allowed under the REMS program.

So is the -- is the label -- would it allow for off-label prescription of Mifepristone for other uses or not?

MR. GUINEY: Objection. Vague, compound.

THE WITNESS: So you haven't shown me the current REMS. I think it might be helpful to pull up the current REMS and see if there's any language there that -- I will say, in practice, it has never been -- I'm not aware of any limitation in the REMS that prohibits off-label use of Mifepristone.

MS. NAROG: So if you could put in the Chat the Mifepristone_2023_03_23 REMS, that would be helpful. And that will be Exhibit I.

(Grossman Deposition Exhibit I was marked for the record.)

THE TECHNICIAN: I'm sorry. Can you tell me the --

MS. NAROG: It should say Mifepristone_2023_03_23, and it should

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say REMS, R-E-M-S, underscore, Full.
THE TECHNICIAN: I do not have that file.
MS. NAROG: All right. Let me see if I can -- I'm seeing it listed here, but let me know if you still need me to try again.
While we're waiting, does somebody have a -- a notification on their computer that's been dinging? I keep hearing it and I'm not sure -- I was kind of worried that it was me.
THE TECHNICIAN: I haven't heard anything.
MR. GUINEY: I haven't, either.
MS. NAROG: I don't know where that's coming from. Thank you.
THE TECHNICIAN: The file is now in the Chat. Thank you very much, Counselor.
BY MS. NAROG:
Q Okay. So we were talking about the 2023 REMS program, and you said that you would like to take a look at that. So I'll give you a moment to review it. All right?

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A May I review the same relevant part --
Q Okay, yeah.
A -- related to the prescriber agreement form.
Q Yes.
A And there's one additional point, but -- sorry. I've now reviewed it, yes.
Q So we were talking about whether or not the label allows for the off-label prescription of Mifepristone for abortion or for other uses. And that's when you said you would like to review the 2023 REMS.
But did you identify other changes made to the REMS that you had not identified earlier?
MR. GUINEY: Objection. Vague.
THE WITNESS: I mean, this REMS is different. Do you want me to go through all the differences between this REMS and the 2011 REMS?
BY MS. NAROG:
Q We had -- you've already discussed many of them, but -- part of the fact that you wanted to review them was so that you could see if there was anything that you had missed that was relevant to the question of whether off-label use of Mifepristone and

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prescription of Mifepristone is allowable under the label or the REMS.
A I am not aware of anything in the label or REMS that prohibits off-label use of Mifepristone. And reviewing this again, the components of the prescriber agreement form are generally the same as what I read into the record before, and there's one additional point under B.
But again, reading that, I don't see anything there that prohibits off-label use of Mifepristone.
Q So what is that additional point that you're talking -- that you're referring to, under B?
A I think it's the point -- it relates to -- so it's -- it's Roman numeral two, capital A.1.b, little B, dot small Roman numeral 6: If Mifepristone will be dispensed by a certified pharmacy, one, provide the certified pharmacy assigned prescriber agreement form; two, assess appropriateness of dispensing Mifepristone when contacted by a certified pharmacy about patients who will receive Mifepristone more than four calendars days after the prescription was received by the certified pharmacy; three, obtain the NDC and lot number of the package of Mifepristone the patient

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received in the event the prescriber becomes aware of the death of the patient.
I believe these are new and -- yeah.
Q So let's turn to your expert report. You might want to keep some of these documents handy in case you want to review them.
But Paragraph 52 in your report, if you can turn there and please let me know when you have that.
A Yes.
Q You state here -- let me find it. It is on -- actually, it's Page 53 -- or Paragraph 53. I'm sorry. I didn't write that down correctly.
It says: Since Mifepristone was approved in 2000, an additional layer of regulatory scrutiny was applied to the drug that has limited its distribution. This is currently codified in the drug's risk evaluation and mitigation strategy.
Did I read that correctly?
A Yes.
Q So what constitutes a drug's risk evaluation and mitigation strategy? Is it just the REMS program or does it include other things --
MR. GUINEY: Objection.

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BY MS. NAROG:
Q -- meaning, from the drug label?
MR. GUINEY: Objection. Vague, compound.
THE WITNESS: As I said before, my understanding as a clinician is that those are two distinct documents.
BY MS. NAROG:
Q Okay. So could you tell me why a drug gets a REMS program?
MR. GUINEY: Objection. Lack of foundation.
THE WITNESS: The FDA makes a determination about whether a drug needs a REMS program to try to balance the potential risks of a drug against its benefits.
And, generally, the main component of the REMS are these elements to ensure safe use that the FDA believes are necessary to ensure the safe use of the drug.
BY MS. NAROG:
Q So would you say that the FDA found that Mifepristone needed to have a REMS program because

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there is some risk to safety?
MR. GUINEY: Objection. Vague, compound and lack of foundation.
THE WITNESS: The FDA made that determination -- again, as we talked about, the distribution requirements or distribution restrictions that were imposed at the time of FDA approval in 2000 were then later codified into the REMS when that program was established.
So these -- this is based on an assessment that the FDA did in 2000. That was definitely the view that the FDA took a quarter century ago.
BY MS. NAROG:
Q Have they reevaluated the REMS since it was first -- since Mifepristone was first approved in 2000 or since the first REMS program was published in 2011?
MR. GUINEY: Objection. Compound, lack of foundation.
THE WITNESS: Elements of the REMS have been examined in 2016, and again in 2021. In 2016, there was a recommendation by the FDA division staff

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to remove the patient agreement form because it was duplicative of consent forms that the patient already signed at the clinic. That was overruled at a higher level. That part of the review is redacted, so that's all I know.
And then, of course, the components related to the in-person dispensing were reviewed in 2021.
BY MS. NAROG:
Q Okay. So even though they've reviewed some of the components, they haven't reviewed the entire program; is that what your understanding is?
MR. GUINEY: Objection. Lacks foundation.
THE WITNESS: Some other aspects -- I don't know that they did a comprehensive review of the REMS. I believe -- it's also not -- there is not clear guidance about what the process is to have a REMS removed once it's established. At the very -- you know, it would generally require a request from the sponsor to -- to do so. And I'm not sure that that has been done.

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So, again, I think -- what I can say for sure is that it was the view of the FDA in 2000 at the time of approval that this REMS was necessary.
BY MS. NAROG:
Q Okay. And when you say "sponsor," the sponsor would have to ask to have it removed, what is that? What do you mean by sponsor?
A The sponsor is the drug company that holds the new drug application, in this case Danko.
Q What are some of the side-effects of Mifepristone?
A Whenever it's used or --
Q Well --
A -- are we talking specifically about medication abortion?
Q I would say for any use. Because even if you're using it for medication abortion, there would be side-effects that could be -- could be experienced by a patient, correct, with the use of that drug for any purpose?
MR. GUINEY: Objection. Vague.
THE WITNESS: As you know, medication abortion involves a regimen that includes two drugs. And so we --

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usually when we're talking to patients about the possible side-effects that they will experience, we're talking about side-effects related to the entire regimen and the entire process. Because some of the symptoms that they will experience are also inherent to having an abortion and less related to the drugs themselves.

So my question is whether you're asking about Mifepristone used in isolation for anything or in the context of the regimen used for medication abortion?

BY MS. NAROG:

Q Well, let's start with just use for anything. What are some of the side-effects of Mifepristone?

A Mifepristone may cause some gastrointestinal side-effects, such as nausea and vomiting. It may cause some bleeding, depending on where someone is in their menstrual cycle. We're talking about a female person and whether they might be pregnant.

Q And these are just generally for all

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patients, just to clarify, right?

A Correct.

Q And what specific adverse side-effects does Mifepristone or can Mifepristone cause for medication abortion?

A So medication abortion involving Mifepristone together with Misoprostol result in a number of symptoms. Again, some of these are inherent to the medication abortion process itself, and some related to the medications.

If anyone -- whenever someone has a successful medication abortion, they will have some bleeding and some cramping or pain. So those are common symptoms. Nausea, vomiting, diarrhea, chills, fever, these are all possible symptoms or side-effects that people may experience with medication abortion.

Q So give me one second. I'm just trying to find where that -- okay.

Let's look at the patient agreement form in the 2023 REMS, which is -- looks like it is -- oh, boy, it's not listed. I don't have a number on it. It's near the end of the document.

A Sorry. Do you want me to open a document I already have?

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Q Yes. So it's in the REMS, 2023 REMS, the most recent, Exhibit I.

A Yes.

Q So if we look at the Patient Agreement Form No. 6, do you see that?

A Yes.

Q It tells the patients that two out of seven -- I believe -- two to seven of 100 women who use the treatment will experience some type of adverse event.

Is that -- do you feel like that's a low number or is that pretty -- pretty true to your experience?

A That is not what that says. Can I read what it says?

Q Yes.

A I know that in some cases the treatment will not work. This happens in about two to seven out of 100 women who use this treatment. If my pregnancy continues after treatment with Mifepristone and Misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy.

So it's talking about the risk of failure.

Q Okay. Yeah. Got you. And is that -- is

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that considered a pretty low number for risk of failure?

MR. GUINEY: Objection. Vague.

THE WITNESS: So this is -- also reflects outdated data, which is one of the problems with the patient agreement form. There had been an older study that showed that when a regimen of Mifepristone 200 milligrams followed by 24 to 48 hours later Misoprostol, 800 micrograms administered buckly in a single dose, that the overall success rate was about 93 percent or 7 percent would have incomplete abortion or ongoing pregnancy.

There is more recent data that I cite to in my report showing that when a second dose of Misoprostol is used -- and this is specifically people who are nine weeks of pregnant or later. When a second dose of Misoprostol is used in those cases, the success rate is over 97 or 98 percent.

So, first, I would say that these numbers are incorrect. But, yes,

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overall, the success rate of medication abortion is very high. And this is a critical piece of counseling that we do with patients when they're considering their options for abortion method, and they understand what potential risk of failure is.

And, in my experience talking to patients who, you know, strongly want to have a medication abortion, they're willing to take that 3 to 5-percent risk that it may not work, understanding there's about a 95-percent chance that it will work and they'll avoid having a procedure.

BY MS. NAROG:

Q So how often do you recommend that patients have a surgical intervention for a failed medication abortion?

MR. GUINEY: Objection. Vague.

THE WITNESS: That was a difficult wording to understand. Do you mind just repeating the question for me?

BY MS. NAROG:

Q How often do you recommend a surgical

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procedure following a failed medication abortion?

MR. GUINEY: Same objection.

THE WITNESS: Whenever a patient has an ongoing pregnancy after taking Mifepristone and Misoprostol for medication abortion, I have -- and this is my patient -- I have a detailed discussion with them, again, about their desires for the pregnancy, the risks and benefits of continuing the pregnancy versus proceeding with termination.

And in my experience, almost all patients decide to proceed with a procedure to terminate an ongoing pregnancy after using medication abortion. Some people might choose that they're still within the gestational duration limit, they might choose to repeat the course of Mifepristone and Misoprostol, and a very, very small number of people might decide to continue the pregnancy.

BY MS. NAROG:

Q So what would you say the -- the percentages are between the surgical after a failed

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medication abortion and repeating the medication abortion regimen in your patients?

A Again, most people decide procedural abortion. In my experience, I would say it's, you know, 80 percent or more.

Q Are there any additional risks in repeating the medication abortion cocktail a second time?

MR. GUINEY: Objection. Vague.

THE WITNESS: We call it a regimen. There are the same risks that it has the first time, which is that there's a risk that it may not work. I mean, of course, every patient, of course, is unique and we need to evaluate a patient who has an ongoing pregnancy after Mifepristone and Misoprostol.

There may be a reason for that, including one thing that is being identified more and more is -- it's still a very rare condition -- but a patient who might have had a prior Cesarean section who has what's called a Cesarean scar pregnancy -- Cesarean scar ectopic pregnancy, and that can be a reason why

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the medication abortion doesn't work. So we would want to carefully evaluate the patient before deciding to just repeat medications.

BY MS. NAROG:

Q So re-prescribing the same drugs again shouldn't -- or hasn't been found to pose a greater risk to the patient after a failed medication abortion?

MR. GUINEY: Objection. Vague.

THE WITNESS: There is no evidence of increased risk to the patient who is still under 84 days pregnant at the time they're identified to have an ongoing intrauterine pregnancy after one treatment of Mifepristone and Misoprostol.

As I said, though, most patients at that point just want to get the abortion completed as soon as possible and will opt to have a procedure. And, as I also mentioned, a very small number of patients decide that their opinions about pregnancy have changed and that, given this new information, decide to continue

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the pregnancy.
BY MS. NAROG:
Q Okay. So how frequently do your patients -- I'll retract the question. I don't want to delve into that too much further.
So what other -- I know ectopic pregnancy is one of the risks with the medication abortion protocol. Why is it a risk?
A I would not say that it is a risk. People who are pregnant may have an intrauterine pregnancy or an ectopic pregnancy. An ectopic pregnancy occurs generally among all pregnant people in about 2 percent of all pregnancies. It appears to be less common among those seeking abortion where it's generally less than 1 percent.
It's important, you know, whatever anyone is planning to do with their pregnancy, whether they're planning to have an abortion or planning to continue the pregnancy, to identify an ectopic pregnancy as quickly as possible because it can be life-threatening. An ectopic pregnancy most commonly develops in the fallopian tube and, if it continues to grow, can cause the fallopian tube to rupture and the pregnant woman to have massive internal bleeding. There's a risk even of death.

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So in the context of early pregnancy care, we need to identify people who have ectopic pregnancies, including if they're presenting for abortion care.
Q So the manufacturer has on the drug label and also in the REMS that the clinician must be able to diagnose ectopic pregnancy as one of the reasons -- as one of the requirements for being able to prescribe.
Why is it listed specifically in the REMS program and on the label?
MR. GUINEY: Objection. Lack of foundation, vague.
THE WITNESS: Again, because it's -- this is -- it says that the prescribers agree that they have the ability to diagnose ectopic pregnancy. So the provision of medication abortion occurs early in pregnancy. It may be the first time a pregnant person is having contact with the healthcare system. So it's important to be able to identify people that have ectopic pregnancies.
The medications that we're talking about here, Mifepristone and Misoprostol,

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we don't have evidence that they treat an ectopic pregnancy. And so it's important in the context of this early pregnancy care to be able to identify people who do have ectopic pregnancies.
BY MS. NAROG:
Q So if I have an ectopic pregnancy, it just needs to be identified, it's -- would they still be a candidate for medication abortion?
A I just said, these medications don't treat an ectopic pregnancy. So, no, people need different kind of treatment if they have an ectopic pregnancy.
Q And why don't they treat ectopic pregnancy as opposed to a standard pregnancy, intrauterine pregnancy?
A That's actually a very good question, and it's something that some researchers are beginning to look at. There is some evidence that they might have some effect on a very early ectopic pregnancy in the same way that Mifepristone works to block the progesterone receptor, which ends up having an effect to cause the pregnancy to separate from the lining of the uterine wall. It may have that effect in the lining of the tube, as well. That just hasn't been

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clearly shown.
But implantation site in a tube or elsewhere of an ectopic pregnancy is just different from the lining of the uterus. So we don't have clear evidence that it has that effect.
Q And is that why it's considered contraindicated for ectopic pregnancy, because it doesn't seem to be as effective, at least, with --
A It isn't the approved treatment. I mean, there are identified treatments for ectopic pregnancy, and it's important to identify an ectopic pregnancy and make sure people get timely treatment of those ectopic pregnancies.
Q And how is -- how is an ectopic pregnancy treated differently than medication abortion or patients that need to end their pregnancy because it's ectopic?
A An ectopic pregnancy may be treated with medications such as intramuscular Methotrexate. It made be treated with surgery to remove the ectopic pregnancy. In some cases, it may be possible to simply closely monitor an ectopic pregnancy that is in some ways almost like having a spontaneous miscarriage, like dissolving spontaneously.
But regardless, whenever these treatments

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are provided, patients need very careful follow-up, particularly with medications or in cases where they're being carefully monitored to show that the hormone level -- the hormone of pregnancy that I mentioned earlier, the HCG, is falling appropriately.

Q Okay. I think I understand the difference then. Okay. So I think we can probably put aside the Mifepristone REM label for the time being. So let's look at another document.

MS. NAROG: It is going to be J. Are we at Exhibit J?

MR. GUINEY: I believe so, yeah.

MS. NAROG: Thank you. Exhibit J. This is going to be marked as the -- let me find it. It's going to be Nature Medicine 2024.

(Grossman Deposition Exhibit J was marked for the record.)

THE TECHNICIAN: Stand by.

MS. NAROG: Let me know when you have that pulled up from the Chat. It's Nature Medicine 2024.

THE TECHNICIAN: Got it. It is in the Chat for you, and it is indeed Exhibit J.

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MS. NAROG: Okay.

THE WITNESS: I have it.

BY MS. NAROG:

Q Have you seen this document before?

A Yes, I have.

Q Can you tell us generally what it's about?

A This is a part of a large cohort study of patients who are undergoing telehealth medication abortion in the United States, using both synchronous and asynchronous models of telehealth care.

Q And are you familiar with the methodology that was used in this study then?

MR. GUINEY: Objection. Lack of foundation.

THE WITNESS: I'm generally familiar with it, yes.

BY MS. NAROG:

Q Okay. And did you happen to rely on this as part of the scientific basis for the opinion that a no-test telehealth medication abortion is safe for appropriately selected patients?

A Yes.

Q Can you describe in your own words the primary question the study was designed to answer?

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A I mean, it was designed to estimate the risk of serious adverse events occurring with telehealth medication abortion, as well as effectiveness of telehealth medication abortion, and look at differences in these two outcomes between synchronous and asynchronous models of care.

Q So what was the basic stuff you designed for this trial?

MR. GUINEY: Objection. Lack of foundation.

THE WITNESS: I mean, this was a cohort study. I believe it was a prospected cohort study where the researchers developed relationships with various telehealth providers to capture information about the clinical care that they provided, and obtained information about effectiveness and safety outcomes.

BY MS. NAROG:

Q So was it an observational type study or was it like a randomized clinical trial?

A This was an observation study.

Q Okay.

A A cohort study is an observation study.

Q Okay. Thank you.

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So can you explain how the patients that received the telehealth care were screened for medication abortion eligibility in this study?

MR. GUINEY: Objection. Lack of foundation.

THE WITNESS: I didn't conduct the study, so you're going to have to give me a few minutes.

BY MS. NAROG:

Q Take any time you need to review the document.

A So it says that: As per the published protocol, patients were evaluated for medical eligibility based on recorded medical history. Pregnancy duration at intake was primarily based on self-reported date of last menstrual period or ultrasonography, if available. Some patients had already had ultrasonography before contacting the virtual clinic.

Additionally, patients were referred for pre-abortion ultrasonography if they had any risk factors for or symptoms of ectopic pregnancy or were potentially beyond the gestational limit of the virtual clinic. Some of these patients returned to the virtual clinic after their eligibility was

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confirmed by ultrasonography and obtained a telehealth abortion, thus they were included in the study. Others opted for in-person care and thus were excluded.

Q So is it correct then that the telehealth model like relied primarily on information the patient provided about their medical history, rather than an actual physical examination?

MR. GUINEY: Objection. Vague, lack of foundation.

THE WITNESS: In general, that is -- that's true. This was -- that is how this telehealth services operate.

BY MS. NAROG:

Q And what types of medical information did the patient's self-reporting -- like what did they -- what did the -- what types of medical information did patients self-report during the screening?

MR. GUINEY: Objection. Lack of foundation.

BY MS. NAROG:

Q So, for example, like was it last menstrual period, pregnancy symptoms, medical histories?

A What they specifically go into detail

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here is about the assessment of gestational duration, which seems like they've primarily relied on last menstrual period. I mean, I'm familiar with these telehealth abortion providers that the authors worked with, all of which essentially follow the no-test protocol that I believe is another reference in my report in which I co-authored.

Q Did the telehealth clinicians independently verify any of the patient reported information, you know, such as gestations age or last menstrual period that they were provided?

MR. GUINEY: Objection. Lack of foundation.

THE WITNESS: I don't know how you independently corroborate a last menstrual period.

BY MS. NAROG:

Q Do you agree that the telehealth model depended substantially on the accuracy of that patient's self-reporting?

MR. GUINEY: Objection. Vague.

THE WITNESS: As I describe in my report, we now have several studies, including several that have been led by my colleague, Dr. Lauren Ralph,

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looking -- that examine the accuracy of patient's self-assessment of gestational duration.

And we have a lot of evidence indicating that people can very accurately assess their gestational duration based on asking them questions about their last menstrual period, how many weeks pregnant they are. And if they don't know those things, the date that they think they got pregnant.

Some people, of course, can't answer those questions or have other symptoms that need in-person evaluation. And as they did in this study, as I just read, some people were referred for in-person care.

BY MS. NAROG:

Q Understood. But in the telemedicine model that this study employed, it relied substantially on the accuracy of patient's self-reporting? Regardless of whether that reporting was correct or not, it relied on patient's self-reporting in determining whether they were an adequate candidate for medication abortion; is that

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correct?

MR. GUINEY: Objection. Vague, lacks foundation.

THE WITNESS: When you're saying -- I don't know exactly when you mean by self-reporting. They also state that some people did obtain outside ultrasound and then they reported on what that ultrasound showed, and sometimes they submitted that actual -- actual report.

But, yes, most people were able to easily answer the questions about pregnancy dating, and the telehealth providers relied on that self-reported -- that self-reported information to assess gestational duration.

BY MS. NAROG:

Q Were there any other methods that were employed to determine gestational age for patients receiving medication abortion through telehealth in this study besides ultrasound and besides self-reporting?

MR. GUINEY: Objection. Lack of foundation. I'd also just like to note for the record that Dr. Grossman did not

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author this study.
MS. NAROG: I would just like to note for the record that he is relying on it in his report in Ohio. We do not allow the admission of these types of studies and articles, for the record, at trial, so that's why I need him to talk about them now.
THE WITNESS: They talk about that the patients were sometimes referred for ultrasonography in the study. I don't believe that they -- they don't mention that they referred some people to have a physical exam alone to assess for gestational duration and rely on that.
That said, that's another option for assessing gestational duration.
BY MS. NAROG:
Q So I think you just said this.
But ultrasounds were not routinely used then in the telehealth model?
MR. GUINEY: Objection. Lack of foundation, vague.
THE WITNESS: In this telehealth model, as you said, I think several times

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now, most patients -- most patients were dated based on their last menstrual period, and some also reported an ultrasound report.
BY MS. NAROG:
Q So what risks exist if a patient is mistaken or uncertain or isn't -- is not accurate about her last menstrual health period when gestational age is determined via telehealth?
MR. GUINEY: Objection. Vague.
THE WITNESS: So as I think we've said before or as I have said before, and as I certainly delineate in my report, the no-test protocol is a screening protocol for eligibility and patients are asked a series of questions.
And so those -- since you mentioned those who are unsure of their last menstrual period, those people wouldn't be able to answer those questions. And so they would be screened out by the protocol and referred for in-person care to be -- to have an ultrasound or a physical examination to confirm their gestational duration.

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Your other question about what happens if people are wrong, I think that's what you were saying, or they misestimate based on their -- their last menstrual period. Again, the evidence that we have now from thousands of patients indicates that, in the United States, if people can answer these questions, they are -- can be -- they're very accurate in assessing how far along they are.
In fact, only -- depending on the questions, less than 2 percent of people misestimate their gestational duration. And if they do, they misestimate it by a very small amount of time, like a week or less.
So these are just very accurate. It's a -- people are -- in the United States who are seeking abortion care generally are very accurate to assess their gestational duration.
BY MS. NAROG:
Q So does this study compare the telehealth group to any in-person cohorts in which gestational

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age was verified by ultrasound rather than the patient's report?
MR. GUINEY: Objection. Lack of foundation.
THE WITNESS: This particular study does not, but I include other studies in my report that do.
BY MS. NAROG:
Q So what information does this study provide regarding the margin of error associated with self-reporting of a last menstrual period?
MR. GUINEY: Objection. Vague, lack of foundation.
THE WITNESS: As we just said, this paper doesn't compare. I mean, it might be helpful to pull up other papers that I refer to in my report that do, do what you're asking, but this paper, since everybody did not have an ultrasound, they weren't able to compare gestational duration assessment by the patient themselves to compare that to an ultrasound.
BY MS. NAROG:
Q So that would be how they would have to

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be compared with the patients that get ultrasounds and the patients that don't to be able to determine whether there was a margin of error associated with self-reported LMP?

MR. GUINEY: Objection. Vague, misstates testimony.

THE WITNESS: No. Perhaps it would be useful to pull up a paper by Dr. Lauren Ralph that I referred to. In that paper, it's -- it reports on a large cohort of patients who all were asked a series of questions about the dating of their pregnancy before they had the ultrasound. Then they had an ultrasound, and then they were able to make a direct comparison about the accuracy of that self-assessment with the very same patients.

BY MS. NAROG:

Q Okay. That's -- that's a different paper entirely than what we're talking about right now?

A Yes. This paper reports on the overall effectiveness and safety from a very large cohort of people obtaining telehealth medication abortion in the United States and finds that the regimen is very

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effective and also very safe and consistent with all the other prior literature on this topic, including the studies that are cited in the Mifepristone label.

Q So this study also, you know, reports ectopic pregnancies occurring within the telehealth cohort.

Are you able to recall how many ectopic pregnancies this study identified?

MR. GUINEY: Objection. Lack of foundation.

THE WITNESS: No, but I can try to find it. They say, overall, there were six patients that had an ectopic pregnancy in the cohort, which was 0.16 percent.

BY MS. NAROG:

Q Did the report -- did it report -- does this study report any ruptured ectopic pregnancies that required surgical intervention?

A They say three ectopic pregnancies were -- three were suspected ectopic pregnancies treated with Methotrexate. One was an ectopic pregnancy treated with unknown treatment. One was a Cesarean scar ectopic pregnancy, treated with an unknown treatment. And one as a ruptured ectopic

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pregnancy, treated with salpingectomy.

Q How were the ectopic pregnancies identified in this telehealth model?

MR. GUINEY: Objection. Lack of foundation.

THE WITNESS: In their -- they say that patients who had any risk factors for or symptoms of ectopic pregnancy or were potentially beyond the gestational limit of the clinic were referred for pre-ultrasound ultrasonography.

Let me look at the -- they say that: The effectiveness and safety outcomes were determined from all information collected in the medical records and surveys.

BY MS. NAROG:

Q So it's not clear whether that information was based on the patient's self-reporting of symptoms or imaging?

MR. GUINEY: Objection. Vague.

THE WITNESS: I mean, they obtained -- they obtained records about whether a patient -- I mean, the clinic obtained information about whether a

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patient was like admitted to a hospital and obtained treatment for ectopic pregnancy, and then that was in the data that the researchers obtained in this analysis.

BY MS. NAROG:

Q Does this study conclude that a history-based screening alone is sufficient to rule out ectopic pregnancy?

MR. GUINEY: Objection. Lack of foundation.

THE WITNESS: I mean, this study demonstrates the safety and effectiveness of telehealth provision of medication abortion as it's currently being implemented at the -- was being implemented at the time in the real world.

BY MS. NAROG:

Q So is it possible for a telehealth screening models to miss ectopic pregnancy if the patient does not accurately report symptoms or is not aware of the clinically meaningful symptoms of ectopic pregnancy?

MR. GUINEY: Objection. Vague.

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THE WITNESS: I'm not sure that this is the best -- I'm not sure if you're asking this question generally or in the context of this paper or --

BY MS. NAROG:

Q I'm asking generally if telehealth screening methods for ectopic pregnancy might miss an ectopic pregnancy if the patient does not accurately report symptoms or is unaware of what those symptoms might be?

MR. GUINEY: Objection. Vague, compound.

THE WITNESS: So in the no-test protocol that telehealth providers use, there are recommended screening questions about those symptoms that are direct questions that are asked of all patients, including questions about risk factors like a history of an ectopic pregnancy, history of surgery on the fallopian tube, getting pregnant when an intrauterine device is in place, as well as about certain symptoms, in particular things like pelvic pain on one side more than the other.

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And the recommendation is for those people to then be referred for further evaluation, which may involve an ultrasound, may involve blood testing or other interventions. So I don't believe it's an issue that we're not just relying on patients spontaneously reporting these things. These are direct questions that are asked of patients.

I think that -- but it is true that some people who have ectopic pregnancies don't have those risk factors and don't have any symptoms.

What we see from the evidence that has been published on telehealth medication abortion is that starting the medication regimen does not worsen the outcomes of an ectopic pregnancy. As we said, these medications don't treat an ectopic pregnancy, but they also don't make the outcomes worse. They don't make the pregnancy grow and rupture. They don't have any effect on the ectopic pregnancy.

And so what we see in one of the other papers that I cite to in my report by Aiken from the United Kingdom showed that, after the telehealth medication abortion was implemented in the United Kingdom during the COVID-19 pandemic, they showed that medication abortion was very safely provided using the telehealth protocol, but more of the ectopic pregnancies were identified after the medications were given, instead of before the medications were given, but it didn't increase the serious adverse events. There wasn't -- they didn't see any evidence of increased risk of rupture.

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In fact, sometimes giving the medication is actually -- helps us to diagnose an ectopic pregnancy because people don't have any bleeding after they take the medications. And so that's something -- that's a way that we can help to identify an ectopic pregnancy and get someone in to be further evaluated to see if they might have an ectopic.

BY MS. NAROG:

Q So if a patient has an ectopic pregnancy, they won't experience bleeding if they take the medication abortion protocol?

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A They may have a small amount bleeding or no bleeding. They don't generally have the expected amount of bleeding, no.

Q And what evidence do you have for that -- for that claim? What study were you referencing there --

MR. GUINEY: Objection. Vague.

BY MS. NAROG:

Q -- that relates to the lack of bleeding?

MR. GUINEY: Same objection.

THE WITNESS: That's my clinical experience. There is also a -- a published abstract by Biggs, et al., that documents this in a small sample of ectopic pregnancies after a telehealth medication abortion.

BY MS. NAROG:

Q How small was the sample size of the Biggs, et al.?

A I believe it's about 35 ectopic pregnancies, which is -- comes from a large population of people because ectopic pregnancy is so rare. But it's, I think, 35 ectopic pregnancies.

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But this is also something -- I mean, this is something that I believe it's even in the clinical guidance that exists from the National Abortion Federation. It's in the no-test protocol.

If someone is being evaluated after taking a medication abortion and they have minimal bleeding, if they have no other symptoms, it may be reasonable to repeat the dose of Misoprostol to see if that works. But certainly if they have any symptoms or if that additional dose of Misoprostol doesn't cause more bleeding, we generally recommend the patient be evaluated soon to rule out an ectopic pregnancy.

Q So what are the serious adverse events that can happen with the use of medication abortion as identified in this particular study?

MR. GUINEY: Objection. Vague.

THE WITNESS: I mean, they say in the methods that serious adverse events include blood transfusion -- blood transfusion, abdominal surgery, including salpingectomy, laparotomy, laparoscopy to treat an ectopic pregnancy, hospital admission requiring overnight, or death.

Those are the serious adverse

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events that are included as potentially included in their methods. And then what they say is that there were -- out of this piece of the analysis that included 4,454 patients, 99.7 percent had no major abortion-related adverse event, and there were 15 major abortion-related adverse events. This included six blood transfusions, one surgery, including the ectopic pregnancy that we mentioned, and ten hospital admissions.

MR. GUINEY: And, Ms. Narog, I just wanted to flag, I think we've been on the record for approaching an hour and 15 since our last break. Would this be a good time to break for lunch?

MS. NAROG: Yeah, we can do that now. You'd like to take an hour?

MR. GUINEY: We can --

MS. NAROG: Or do you want less than that?

MR. GUINEY: Probably less. Maybe half an hour? Does that work for you, Dr. Grossman?

THE WITNESS: Yeah.

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MR. GUINEY: So maybe we circle back at -- that would be, I think, about 1:20 our time, probably about 4:20 your time.

MS. NAROG: Yeah, that's fine. That will work for me.

(Brief pause.)

BY MS. NAROG:

Q All right. Dr. Grossman, we're back from a break, and I'm going to show you another document. This is going to be titled Comparison of No-Test Telehealth.

MS. NAROG: If you could put that in the Chat, please, and we'll mark that for identification as Exhibit K.

(Grossman Deposition Exhibit K was marked for the record.)

THE TECHNICIAN: Stand by. It is in the Chat.

BY MS. NAROG:

Q Dr. Grossman, just let me know when you have that open.

A Yes, I do.

Q Do you recognize this document?

A I do.

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Q Can you tell us what it is?

A It's an article titled Comparison of No-Test Telehealth and In-Person Medication Abortion. It was published in JAMA 2024.

Q And what is this -- what does this document tell us?

MR. GUINEY: Objection. Vague.

THE WITNESS: This is a peer-reviewed article on a study that I was the senior author for. It's an observational cohort study, prospective cohort study, where we recruited patients within the same clinic system who were obtaining apparently either telehealth medication abortion or in-person medication abortion, and compared outcomes related to effectiveness and safety.

BY MS. NAROG:

Q What was the finding of this research?

A The main finding of this research was that, with regard to effectiveness, that telehealth provision of medication abortion with mailing of medications was not inferior to in-person provision with ultrasound.

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We also showed that serious adverse events were uncommon in all patients across the groups.

Q So did it rely entirely on patient reporting for LMP for the gestational dating of the telehealth arm then?

MR. GUINEY: Objection. Vague.

THE WITNESS: It was similar to the other study in that patients undergoing telehealth did not have an ultrasound within that clinic system. They might have had an outside ultrasound at a different facility. But for most of the people, they were deemed to be eligible for the no-test protocol because they were able to give information to date their pregnancy.

BY MS. NAROG:

Q And this was an observational study, correct?

A That is correct.

Q Completion rates of 94.4 versus 93.3 met a non-inferiority margin, but that doesn't show equal protection in all clinical scenarios, right?

MR. GUINEY: Excuse me. Objection.

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And if you're reading from the document, can you point me to where you're reading that from? I just want to make sure I'm following along.

MS. NAROG: I was not reading from the document.

MR. GUINEY: Oh, apologies.

THE WITNESS: I don't understand what you mean by equal protection.

BY MS. NAROG:

Q It doesn't -- those completion rates don't show equal protection in all clinical scenarios, right?

MR. GUINEY: Objection. Vague.

BY MS. NAROG:

Q It doesn't protect equally in all clinical scenarios?

A I'm sorry. I'm really struggling to understand what you mean. That's not a medical term that we would use, so maybe it means something for you from a legal perspective, but I don't know what you mean by "protect."

Q So what does a -- what does a non-inferiority margin mean?

A So the analysis that we undertook with this study was what's called a non-inferiority analysis, where we aimed to demonstrate that the telehealth arm was not inferior to the in-person arm study within a 5-percent margin. And that -- it's a little bit more complex than that in terms of the analysis because it also takes into account the margin of error. But we mean, even including that margin of error, that it's within the pre-specified 5-percent non-inferior -- non-inferiority margin.

And we actually found that, as you can see, the overall effectiveness in the no-test and mail group was a little bit higher than the in-person group with ultrasonography, and it met the 3-percent non-inferiority margin.

Q So both groups met that margin that you set prior to completing the study?

A So when you say "both groups," what do you mean by both groups?

Q Your telehealth arm and your in-person arm?

A So it's not that both groups met that. It's that we're looking at this as the in-person provision of care with ultrasonography as sort of the reference group that we're comparing it to. And the thing that we're asking, is it inferior to that reference group, we're asking that about the telehealth group.

So the question was whether the telehealth group met that prespecified 5-percent non-inferiority margin, and it did. It was not inferior to the group that we were comparing it to, which was the in-person group.

Q Okay. So the study mentions Lost to Follow-up. What is that?

A It's people who did not -- we were not able to obtain a final outcome assessment of work.

Q And what does this -- what was the lost follow-up of this study?

MR. GUINEY: Objection. Vague.

THE WITNESS: Lost follow-up was very low in this study, but I want to quote you the exact number.

So abortion outcome data were available for 91.8 percent of this. So lost to follow-up was 8 to 2 percent.

BY MS. NAROG:

Q And you don't consider that to be a large percent of patients that you were not able to evaluate?

A No. In the medical literature, that's a

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small amount.
Q And how might missing safety data, such as this lost to follow-up, affect the interpretation of a -- of a study?
MR. GUINEY: Objection. Vague.
THE WITNESS: I also just want to clarify, for this study we also used widely accepted statistical method to account for missing observation, which is called imputation.
So, as it says -- I'm not sure what page this is, but -- since you don't have the original article. But we say that: In sensitivity analyses rerunning models with imputed missing observations with application of inverse probability of treatment weights, with adjustment for clustering observations by organization, results were consistent and demonstrated non-inferiority with no test model.
BY MS. NAROG:
Q But can this kind of missing information affect the interpretation and the outcome of a study?
MR. GUINEY: Objection. Vague.

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BY MS. NAROG:
Q Even if it's a small percentage?
MR. GUINEY: Same objection.
THE WITNESS: Missing data and having high rates of lost to follow-up and not using accepted techniques to account for missing data can lead to biases in interpreting results.
I do not believe that that's a critique of this paper, which has low lost to follow-up, and does use techniques to account for missing data.
BY MS. NAROG:
Q This study, though, did not evaluate identity verification, coercion detection, or who actually ingests the medication that's provided to the patient, correct?
MR. GUINEY: Objection. Vague, compound.
THE WITNESS: Can you just -- would you mind asking me each one of those one at a time?
BY MS. NAROG:
Q Sure. The study did not evaluate identity verification of the patient, did it?

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A For this study for these clinic sites, they -- at the time, for this particular model of telehealth, it involved asynchronous telehealth visit. So people had a visit with the clinician that involved either video or telephone interaction. And people also have to provide ID as part of their clinic visit. So the clinic was verifying identification.
Q Did it evaluate coercion detection?
A All of these clinic partners that we work with have standard protocols to identify patients who are at risk of intimate partner violence or family violence with standard questions that are part of their intake that are either part of their in-person clinic assessments or the telehealth assessments.
We didn't report on that for this paper, but I am familiar with their clinic protocols and know that to be the case.
Q Well, I was asking about this study specifically. Like it didn't evaluate coercion detection protocols in this study, did it?
MR. GUINEY: Objection. Vague.
THE WITNESS: We also in this study survey participants, and asked participants a wide variety of questions

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about their abortion experience and the support that they were also receiving, certainly emotional support they were receiving. And there were also many opportunities for patients to -- in open-ended responses, to identify whether they were a victim of coercion. And no participant in this study reported that.
BY MS. NAROG:
Q Understood. I'm asking, though, if this study evaluated the protocols used for coercion detection in --
A I'm telling you --
MR. GUINEY: Objection. Asked and answered, vague.
THE WITNESS: No participant reported coercion in this study.
BY MS. NAROG:
Q But did you evaluate the procedures that were used to detect coercion before the, you know, medication abortion was actually prescribed to the patient? That's all I'm asking.
MR. GUINEY: Objection. Asked and answered.
THE WITNESS: All I can answer is

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that no patient reported coercion.
BY MS. NAROG:
Q Okay. So was the purpose of the study to evaluate coercion detection protocols used by telehealth clinics?
A No. As I said earlier, the purpose of this study was to determine whether telehealth medication with mailing of medication abortion was not inferior to in-person provision with ultrasound. We also looked at a variety of other outcomes and have some reported outcomes on satisfaction, on psychosocial burdens that patients reported, including questions about whether they were able to tell people that they cared about, about the abortion.
So we asked about a lot of things in this study and no patient reported coercion.
Q Okay. Did the study evaluate the identity of the person who actually ingests the medication?
A We asked patients in a survey, Did you take this medication and, if so, at what date and time. And so we did collect information about who took the medication and when.
Q And how reliable is data that's collected

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through surveys?
MR. GUINEY: Objection. Vague.
THE WITNESS: I believe that women are very able to answer a question about whether they took a medication and when. Yes, I do believe that actually can be very accurately reported.
BY MS. NAROG:
Q In the scientific literature, however, in scientific medicine, when you look at the various types of evidence you can have for a proposition, how does survey responses rank among all of those types of research?
MR. GUINEY: Objection. Vague.
THE WITNESS: I don't know what you're referring to. So a survey that is specifically performed with a cohort of patients that has a 92-percent response rate about a very simple question about did you take a medication, that is something that would be considered an accurate piece of data.
BY MS. NAROG:
Q Right. But don't -- aren't most scientific findings, research studies, aren't they

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ranked amongst themselves as being more reliable, less reliable, more likely to have errors and less likely to have errors?
MR. GUINEY: Objection. Vague.
THE WITNESS: What kind of scientific medical information and studies are you talking about?
BY MS. NAROG:
Q When we're talking about various levels of evidence for a proposition, there are more reliable studies than others; is that not true?
A Yes.
Q And aren't they usually ranked in a specific level based on their scientific rigor and the reliability of the evidence that's been collected?
A A prospective cohort study, especially with very low follow-up, is a very highly accurate type of scientific study in terms of observational studies.
Q In terms of -- so where does observational studies rank in this, you know, framework of a bunch of scientific research studies? How is it ranked among, say, randomized trials or, you know, evaluations of all -- a bunch of research

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studies that are done in one area of medicine? How does that rank among those?
MR. GUINEY: Objection. Vague.
THE WITNESS: Again, this really depends on the context. In this particular context we were talking about a particular type of abortion service delivery model. It's very hard to perform a randomized controlled trial of telemedicine because you have to have a group of people who are essentially signing up for a study who are willing and likely to be eligible for telehealth or in-person, and then they get randomly assigned to one of the two treatment arms.
That's not very generalizable to the whole population of people who might be seeking abortion care because, for many people, they have a preference about one of those models of care or one of those models of care might -- there might be other reasons that they might be seeking the model of care, such as it's much easier for them to access telehealth

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medication abortion compared to an in-person medication abortion.
BY MS. NAROG:
Q So you're familiar with the pyramid of evidence, correct, the pyramid of the standards of evidence?
MR. GUINEY: Objection. Vague.
THE WITNESS: If there's something you'd like me to review, I'm happy to take look at it.
BY MS. NAROG:
Q It's just a question.
Are you familiar with the pyramid of the standards of evidence for research, scientific research?
MR. GUINEY: Objection. Vague.
THE WITNESS: I haven't heard of it referred in this way, so I'm not entirely sure what you're referring to.
BY MS. NAROG:
Q What have you heard it referred to as? There's a pyramid of evidence.
A What you say "it," I don't know what you're talking about. I would really request that you show it to me.

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Q I don't think the utility of me showing it to you.
I'm just asking, as a researcher, are you familiar with the pyramid of the standards of evidence that lists at the top, systemic reviews and meta analyses, all the way to the bottom that says, background information and expert opinion?
MR. GUINEY: Objection. Vague, compound.
BY MS. NAROG:
Q Are you familiar with that?
A First of all, I believe you misread it. It's not systemic reviews. They're systematic.
Q Systematic. You're right. I'm sorry.
A I would really like to be able to review what you're looking at. It seems like a very simple question I'm asking. I wish that you would comply with this.
Because I can't just talk about this in the abstract. Again, it really depends on the context. I've talked to about you about the reason why randomized control trials are often referred to as sometimes a gold standard in scientific and medical evidence. But there are also reasons why randomized controlled trial may not be the best --

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give us the most meaningful evidence to answer a specific medical question because the findings will not be generalizable to the larger population.
Q And I understand that entirely. But, based off of this -- this kind of hierarchy of evidence, which I understand is very widely accepted within scientific research circles, that case reports and self-reporting of patients or of people that are involved in these studies is not as reliable as some of these other methods. That's all I was trying to ask about.
MR. GUINEY: Objection. Vague.
THE WITNESS: Is there a question in what you just said?
BY MS. NAROG:
Q I was asking about whether or not self-reporting is considered to be less reliable than these other methods of clinical data that you can get, research data that you can get from conducting research studies. That's all I was asking.
A You're moving your hands and pointing to a screen that indicates that you're looking at something. I don't know what you're looking at. I'm asking for you to show me what you're looking at when you say "these studies."

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If you want to read them all out to me again and ask me to compare one to the other, I'm happy to. Otherwise, I cannot read your mind.
Q How reliable is self-reporting against a meta analysis? How reliable -- how much -- how much can we put our faith in self-reporting of patients versus a meta analysis of all of the studies in a field? What is more reliable?
MR. GUINEY: Same objection.
THE WITNESS: It -- these are -- you're asking me to compare cherries to watermelons. I mean, these are like two different things. I don't understand what your question is.
There may be times when -- I mean, for some things, the information -- you're also asking me to talk about information we are obtaining in a clinical setting compared to a meta analysis.
Obviously, these are different kinds of ways to collect information. Sometimes the information that we obtain from a patient, the only way to get that is to ask them a question and have them

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report it. There are other questions that we need to answer as a medical field that can only be answered through meta analysis.

BY MS. NAROG:

Q So one is not better than the other or more authoritative than the other? They're all equal?

A When you say "they," a meta analysis is not equal to a patient-reported event.

Q Does one carry more weight?

A Where?

Q Does one -- does a meta analysis have more information to provide that is reliable than does self-reporting of patients?

MR. GUINEY: Objection. Vague.

THE WITNESS: Okay. Are we talking about -- when we're comparing -- you're talking about comparing published articles in a peer -- in the peer-reviewed literature? Is that what you're asking about?

BY MS. NAROG:

Q I'm talking about, yes, the type of evidence that a study might provide is a meta

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analysis that can give you information and comes to conclusions, is that more reliable or less reliable than self-reported observational studies of patients?

A I cannot answer this question in the abstract. If you're asking about a specific question, I can answer this question. I cannot answer this in the abstract.

Q So you don't -- you don't have any knowledge about whether or not these -- generally, meta analyses carry more weight in the scientific literature than does observational studies of patient reporting?

MR. GUINEY: Objection. Vague.

THE WITNESS: Again, it depends on what kind of -- what is the question that we're aiming to answer, what is the -- what the methods that were used for each of these studies, what -- the data that were included or excluded in the meta analysis.

I can't just say across the board that a meta analysis is always more reliable, no. I refuse to say that.

BY MS. NAROG:

Q Is there anything you would be willing to

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say about the difference between a meta analysis or a systematic review versus observational patient self-reporting?

MR. GUINEY: Objection. Vague.

THE WITNESS: For some medical questions or questions that we encounter in medicine, a randomized controlled trial is the most reliable -- has sort of the highest level of evidence that can be provided. That said, not all randomized controlled trials are equally strong and you have to look at the specific study and how it was done, and particular how generalizable the findings are.

And then when you go to the level of meta analysis, especially meta analysis that only includes randomized trials, again, it depends what trials were actually included in that meta analysis and which ones were excluded, again, to be able to interpret the findings and understand how generalizable they are.

BY MS. NAROG:

Q So this specific study, while it does

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show that there is some greater ability to, I guess, patient-report their LMP in telelmedical application, does that -- is that the finding of the study, that telemedicine prescription of Mifepristone is better than in-person?

MR. GUINEY: Objection. Vague.

THE WITNESS: I'm sorry. I think that you're not really understanding the study. The study is primarily focused on effectiveness.

So what the study found was that there was a higher proportion of people in the telemedicine arm who had -- were found to have an effective medication abortion compared to the in-person group. However, that difference was not statistically significant.

And, in terms of the way the analysis was designed, telehealth was not inferior to in-person care with regard to effectiveness.

BY MS. NAROG:

Q But it doesn't show the inverse, either, correct, that in-person is inferior to telehealth, right? That's what I'm just trying to understand.

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A That wasn't the way the study was designed. So no, as I said, there was no statistically significant result.
Q Okay.
MS. NAROG: Let's -- if you could put in the Chat, please, this is -- this will be marked as Exhibit L. Let me look at it and tell you what it's called. This is -- it's going to be Mail Order Pharmacy Dispensing.
THE TECHNICIAN: Yes. The file name is Mail-O Fill To 1, correct?
MS. NAROG: No, I've got -- I can put it in the -- I'll upload it again if that's a problem. I've got Mail-O-R-D-E-R. But if you don't have that, that may be a problem. Let me see.
THE TECHNICIAN: I might have. I just wanted to be sure.
MS. NAROG: Okay. That's fine with me. Okay. I just uploaded it again.
THE TECHNICIAN: Yes, stand by. Thank you. It is in the Chat, Exhibit L.
(Grossman Deposition Exhibit L was marked for the record.)

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BY MS. NAROG:
Q Dr. Grossman, if you can just let me know when you're able to open that.
A Yes, I have it.
Q Okay. Do you recognize this document?
A I do.
Q Can you tell us what it is?
A It's an article entitled Mail Order Pharmacy Dispensing Mifepristone Medication Abortion After In-person Screening, that was published in JAMA Internal Medicine.
Q And what does this study -- what did it look at?
A This was a prospective cohort study of patients who were seeking medication abortion up through 63 days gestation, and were evaluated in-person for eligibility, and have the medications, including Misoprostol, dispensed through a mail order pharmacy.
Q So they were screened in-person. Does that mean they received an in-person evaluation by the physician or clinician?
A Correct.
Q So it did not test for the safety of remote prescribing without an in-person evaluation;

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is that right?
MR. GUINEY: Objection. Form.
THE WITNESS: We just said it did have an in-person evaluation.
BY MS. NAROG:
Q I'm just trying to be clear on what exactly what the study says and what it doesn't say. That's all I'm asking.
So it did not actually test the safety of remote prescribing without in-person evaluation, correct?
A Maybe we can just back up and explain a little bit about medication.
Q Okay.
A There are a few sort of steps in the protocol. The first step involves evaluation for eligibility. That can be done in-person or that can be done remotely using telehealth. That can be done using testing, including an ultrasound, or it can be done based primarily on history-based screening or using the test protocol.
Then there's the provision or dispensing of the medications. Those can be provided or dispensed in-person at the facility, or they can be mailed to the patient from the clinic. Or they can

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be provided through a pharmacy, either a brick and mortar pharmacy, or using a mail order pharmacy.
So I'm not sure exactly what you meant by pre remote prescribing, because in this study, the evaluation component, the evaluation for eligibility was performed in-person, but then the medications were remotely prescribed through a mail order pharmacy to be sent to the patient.
Q They were remotely prescribed, but the doctor -- I guess the confusion is that the doctor or clinician that evaluated the patient prescribed the medications, but it was filled by a remote pharmacy, correct?
A The prescription was transmitted to the mail order pharmacy, and then the patient took the medications after they received them in the mail.
Q Okay. Not --
A Not in the physical presence of the physician.
Q Okay. So the study reports completion rates of 98.7 percent and satisfaction levels and low adverse events, and it seems to support mail order dispensing of the medication, but it doesn't actually promote the elimination of the in-person meeting with the physician; is that recollect?

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A So it addresses this question whether patients need to be in the physical presence of the prescribing clinician to safely have a medication abortion, which is my understanding what Senate Bill 260 in Ohio does. So, in fact, this is looking exactly at some of the issues that are related to what's of interest in Ohio.

Q Right, and I understand that. And I'm just trying to make clear based on what the study actually looked at, what it actually says and what it doesn't say.

And so that's all I was asking about is it doesn't -- it doesn't purport to say that eliminating the in-person meeting with the clinician is advisable or would lead to better results; is that correct?

A It does not look at -- again, I'm trying to use the same language based on -- that I just used. It is not looking at testing different ways to evaluate for eligibility because everybody got in-person evaluation for eligibility.

Q All right. Let's look at the -- a different document here.

MS. NAROG: I just need to find the right one. This would be marked for

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identification -- give me one moment. I just need to fix something on my computer. There we go. This will be marked for identification as Exhibit M.

(Grossman Deposition Exhibit M was marked for the record.)

MS. NAROG: I'm still waiting for it to open. Give me one moment, please.

THE TECHNICIAN: Sorry. I missed the name of that file.

MS. NAROG: It would be -- I'm trying to -- give me one moment. Can we go off the record for like a minute?

MR. GUINEY: Yeah, sure thing.

(Brief pause.)

BY MS. NAROG:

Q So, Dr. Grossman, we were talking a bit about gestational dating before we had our little issue. So I'm going to ask that you open what is marked as -- should be marked as Comparison of Pregnancy Dating, and we'll mark that as -- I'm not sure I know now. Is that M?

MR. GUINEY: I have it as M, yes.

THE TECHNICIAN: What was the name of that file?

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MS. NAROG: It's Comparison of Pregnancy Dating.

THE TECHNICIAN: I've got it.

MS. NAROG: Okay.

THE TECHNICIAN: It should be there.

BY MS. NAROG:

Q Dr. Grossman, let me know when you're able to open this document.

A Yes.

Q Are you familiar with this document?

A I am not.

Q It's a study called Comparison of Pregnancy Dating by Last Menstrual Period, Ultrasound Scanning and Their Combination.

Did I read that correctly?

A You read the title correctly. This is not the whole paper. I am just seeing an abstract.

Q It's just an abstract. And so I just wanted to know if you had -- if you had seen this before.

And without having the full study in front of you, what does the study purport to conclude?

MR. GUINEY: Objection. Vague.

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THE WITNESS: I cannot assess a study if you're not providing me the study.

BY MS. NAROG:

Q In the Conclusion, I'll read from the abstract: Last menstrual period estimates of the duration of gestation are subject to both random error and a systematic tendency to overstate the duration of gestation, most likely because of delayed ovulation.

Is that -- did I read that correctly?

A You read those words correctly, yes.

Q So why would delayed ovulation potentially lead to errors in LMP estimates?

MR. GUINEY: Objection. Vague.

THE WITNESS: I believe what they are getting at here is that, if people had delayed ovulation, they would actually be less pregnant -- their pregnancy duration would truly be less than they self-assess it based on their last menstrual period. So they would overestimate and determine that they were further along in pregnancy than they truly were.

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BY MS. NAROG:
Q Okay. And you don't -- and I think you testified earlier that an error in estimation typically is not an issue because a couple of days to a week don't matter that much when you're using the medication protocol; is that correct?
MR. GUINEY: Objection. Misstates testimony.
THE WITNESS: I mean, this -- from what you've shown me, this is actually very consistent. I mean, anything that supports the conclusion that self-assessment about eligibility -- or self-assessment of gestational duration eligibility for medication abortion is likely to have a small proportion of false negatives, meaning that it's less likely for people to underestimate their gestational duration.
In fact, this paper shows that they're more likely to overestimate. So there would be more likely to think -- to report a date that would make them ineligible for medication abortion, and then they would be referred for

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in-patient care or in-person care, and then have an ultrasound or physical examination to determine whether they're eligible.
MS. NAROG: You can take that exhibit down if you'd like. Then I'd like you to open -- let's see, where is it marked?
So this is marked Determination for Eligibility for Medication. If you could put that in the Chat. We're going to mark this as Exhibit N.
(Grossman Deposition Exhibit N was marked for the record.)
THE TECHNICIAN: It should be in the Chat.
BY MS. NAROG:
Q Let me when you're able to open that.
A Yes.
Q Are you familiar with this article?
A I am.
Q And what does this article -- what does it study?
A I mean, the title of the article is Self-Determination of Eligibility of Medication

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Abortion without Ultrasonography, Using a History-Based Tool called LMP-SURE. I have not committed to memory the paper. So if you have a copy of the full paper, I'd be happy to review it.
Q I don't have a full copy of the paper. I guess we have to have an affiliation with a group in order to have this.
But I was just curious if you were aware of it and what it purports to find.
MR. GUINEY: Objection. Compound, vague.
THE WITNESS: Perhaps I can read the results: We consented 1,026 participants, 781 met eligibility requirements and completed the tool. Using the LMP-SURE Tool, we identified 493 participants, 65.1 percent eligible for medication abortion without an ultrasonogram.
The LMP-SURE Tool sensitivity (the ability to correctly identify the patient ineligible for medication abortion) was 83.8 percent. The specificity was 70 percent, the confidence interval likelihood ratio was 0.23 and percentage

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of false-negatives was 1.5 percent.
Only 11 patients who met eligibility for medication abortion without an ultrasound by the LMP-SURE Tool were found ineligible for medication abortion on their ultrasound -- ultrasonogram. Of those with conflicts, six had a gestational age -- or 0.8 percent had a gestational age beyond 77 days. The two participants (0.3%) diagnosed with ectopic pregnancies, both required ultrasounds by LMP-SURE.
I would say, overall, this study supports both the accuracy and feasibility of using this screening tool to screen people for medication abortion.
BY MS. NAROG:
Q Did you cite to this study in your expert report?
A I believe I did. I'm not 100 percent sure. I'd have to go back and check.
Q Does your telehealth model independently verify LMP with patients that have menstrual regularity or irregularity?
MR. GUINEY: Objection. Vague.

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THE WITNESS: What do you mean by "your telehealth model"?
BY MS. NAROG:
Q The telehealth model that you have suggested, the no -- I can't think of it -- it just went right out of my head.
The telehealth model that you talked about, can it independently verify LMP and take into account factors like menstrual regularity or irregularity?
MR. GUINEY: Objection. Compound, vague.
THE WITNESS: I mean, we can -- I'm sure you have the paper, the test protocol paper. We can look at the questions it includes. We do have some questions in the protocol about asking history of regular menses. And certainly some clinic systems have incorporated the no-test screening protocol to include questions about history of regular menses.
In fact, in some of our analyses we've done using the data from papers led by Dr. Lauren Ralph have shown that

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including those questions about regularity of menses don't really affect -- don't improve the accuracy of the assessment of gestational duration, and it ends up kind of excluding a bunch of people who otherwise would be eligible for medication abortion.
So I actually don't advise to include questions about menstrual irregularity.
BY MS. NAROG:
Q So if the patient is uncertain about their last menstrual period or they report irregular cycles, what would a clinician do?
A If they cannot adequately answer the questions about gestational duration, then they would be referred for in-person care.
Q And is that a widely accepted model throughout the United States in the provision of medication abortion care?
MR. GUINEY: Objection. Vague.
THE WITNESS: I mean, that is the standard of care for -- if people are implemented telehealth services, they are following -- the standard of care would

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be to follow the no-test protocol, which means screening people with these questions.
And if they cannot get adequate answers to date the pregnancy or if they have symptoms that are risk factors that are concerning for an ectopic pregnancy, that they would be referred for in-person care, usually for an ultrasound.
BY MS. NAROG:
Q And you -- you just mentioned standard of care. So it is the accepted standard of care to do no -- you know, no assessment, no evaluation, prescription of Mifepristone, now in the United States?
MR. GUINEY: Objection. Vague, misstates testimony.
BY MS. NAROG:
Q In-person, I guess I should say.
MR. GUINEY: Same objections.
THE WITNESS: Can you ask me the question again? I don't -- I'm not recalling it.
BY MS. NAROG:
Q That's okay. You mentioned standard of

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care that is the standard of care. So the no-testing protocol, is that now the standard of care in the United States? Is that your contention?
A It is a standard of care that's described in the National Abortion Federation's guidelines. It's also in the Planned Parenthood standards and guidelines. It's in guidance from the Society of Family Planning.
So that is a standard of care to do a -- use the no-test protocol to screen for eligibility for medication abortion using telehealth, but also in-person. That is being implemented in clinics across the country.
Q So it is still the standard of care, as well, for in-person evaluation of patients before prescribing Mifepristone and Misoprostol for abortion care?
MR. GUINEY: Objection. Vague, misstates testimony.
THE WITNESS: Again, as I just said, these are kind of two separate things, whether we're talking -- one issue that you're referring to is the place where the evaluation for eligibility occurs. It can occur

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in-person in a facility, a medical facility, or it can occur via telehealth. It can use testing, including ultrasound, or it may not involve testing including ultrasound.

Either of those can be incorporated with either a telehealth evaluation or an in-person evaluation. So I guess I'm trying to clarify that, in some facilities, people are being evaluated in-person using the no-test protocol.

BY MS. NAROG:

Q Okay. But you said that the no-test protocol is a standard of care, which seems to imply that there are more than one standard of care in this particular provision of care; is that accurate?

A Yes. It is also appropriate to use ultrasound to assess for eligibility for medication abortion.

Q And is the use of ultrasound to assess for the eligibility for medication abortion, is that safe?

A Yes.

Q And has it been proven effective?

A You mean is medication abortion effective

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with use of ultrasound?

Q Is ultrasound as a screening tool for the eligibility for medication abortion, is that an effective screening tool?

A I'm not sure what you mean by "effective." It does not -- I mean, there are errors with assessment of gestational duration with ultrasound. There are also errors in identification of intrauterine versus ectopic pregnancy that can occur with ultrasound.

So it's a reasonably effective modality. It's not 100-percent effective.

Q Would you say that the no-test protocol without ultrasound or any other testing, is that reasonably effective, or how would you describe that -- that protocol's effectiveness in determining eligibility for medication abortion?

A Again, we don't usually use the term "effectiveness" in this context. We might compare the accuracy to some other standard.

So if we can look at the accuracy of assessment using no-test protocol to in-person assessment with ultrasound, that accuracy is very high, yes.

Q Is one -- does one have a higher accuracy

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than the other?

A I would -- in terms of what?

Q In --

A I don't know what you mean.

Q So we were just talking about the accuracy of two different screening tools for eligibility for medication abortion.

Is the no-test protocol more or less accurate than ultrasound, or vice versa, in determining eligibility for medication abortion?

A Compared to what?

Q Compared to each other. Is one more accurate in determining whether a patient is eligible for a medication abortion?

A I don't -- we're -- we compare the no-test protocol to in-person protocols with ultrasound. That's sort of how these studies have been done. So there is an error associated with both ultrasound assessment of gestational duration and with self-assessment of gestational duration. Neither can pinpoint precisely the exact day of gestational duration.

That error is less with ultrasound compared to self-assessment overall, I would say. However, in most cases, that doesn't have a

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meaningful impact on overall eligibility for medication abortion.

Q Okay. I'm just -- all I was trying to do is get to they're both standards. Is one preferable to the other or not? And that's -- that was the only purpose of that question.

Let's go to -- as kind of a separate subject, are you aware of any circumstances where patients have been given abortion medications against their will?

A In my personal medical practice or in -- in my personal medical practice, I'm not aware of that.

Q Are you aware of any other cases in which people have been given abortion medications against their will?

A I have heard of cases in the media, yes.

Q Are you familiar with any such cases that have happened in Ohio?

A I do not know the details of the case in Ohio.

MS. NAROG: I'm going to ask that you put in the Chat what is called Toledo Surgeon. We'll mark that for identification as Exhibit -- I'm on O, I

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think.
MR. GUINEY: Yeah, we're on O.
(Grossman Deposition Exhibit O was marked for the record.)
THE TECHNICIAN: Stand by.
BY MS. NAROG:
Q Once you're able to open that, if you can let me know.
A I have it open.
Q Would you quickly just review this article?
A I've finished reading it.
Q Okay. This article tells a story of an Ohio doctor that force fed Mifepristone pills to his girlfriend, using another woman's identity to obtain them via telemedicine, correct?
A I believe it was one Mifepristone pill with 12 Misoprostol pills. That's what's reported here.
Q Okay. But the intended recipient of the medication did not want an abortion, correct?
A Right, I don't believe so. This is a horrible case.
Q And remote systems had no method of detecting identity misuse in this case, did they?

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MR. GUINEY: Objection. Vague.
THE WITNESS: I don't know -- I don't see anything here about where the person -- where the medications were obtained from, whether they were obtained by a U.S. licensed provider. So I don't know anything about what --
BY MS. NAROG:
Q So it says here -- and I'll just read from the paragraph on the second page. It says: Inside the Medical Board's Allegations. In a November 5th, 2025 notice, the State Medical Board of Ohio says Abbas used his estranged wife's name, birth date and driver's license number to order one 200-milligram Mifepristone pill and 12 200-mcg Misoprostol tablets from an out-of-state telemedical provider -- telemedicine provider.
Sorry. Did I read that accurately?
A That's what it says, yes.
Q But he was able to obtain the pills through a telemedical provider according to this article, right?
MR. GUINEY: Objection. Vague.
THE WITNESS: That's what the article says. It does not say that this

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came from a licensed U.S. clinician.
MS. NAROG: So let's take a look at another exhibit here. We'll mark that one as P. It is going to be the Ohio Medical Board suspension document. If you can put that in the Chat, please.
(Grossman Deposition Exhibit P was marked for the record.)
THE TECHNICIAN: Stand by. It is in the Chat.
BY MS. NAROG:
Q Dr. Grossman, if you could take a look at this document and let me know when you have it open.
A Okay.
Q Have you had a chance to review this document?
A I just read through it quickly right now, yes.
Q And what is this document, as you understand it?
A I mean, I believe these are the documents related to the suspension of medical license, I believe, for this physician who was accused of assaulting his partner and forcing her to ingest Mifepristone and Misoprostol.

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Q And his medical license was suspended, correct?
A I believe so, yes.
Q And, again, down where it says Notice of Summary Suspension and Opportunity for a Hearing, which is I think the third page, fourth page, do you see that page?
A Yeah.
Q It, again, references in Subparagraph 1, that the medication was obtained from an out-of-state telemedical provider; is that correct?
A Yes, and again, it does not specify though whether this was from a licensed clinician or potentially came from out of the country. It doesn't say that.
Q Well, I think -- that's fair. Although I think if it was out of the country, it would say it was an out-of-the-country telemedical provider.
But, however, it was sent through the mail, correct?
MR. GUINEY: Objection. Lack of foundation.
THE WITNESS: It says that the medication was delivered to their address -- to his address.

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BY MS. NAROG:
Q Okay. So he was able to obtain this medication under his ex-wife's name and provide it to a patient that did not wish to receive it, correct?
MR. GUINEY: Objection. Lack of foundation.
THE WITNESS: I mean, this is what he -- this is what he allegedly did.
It's a horrible case.
BY MS. NAROG:
Q Does your telemedical model or the no-test model provide safeguards against this kind of abuse?
MR. GUINEY: Objection. Vague.
THE WITNESS: Telehealth is used throughout medicine to provide a wide range of services and, yes, there are accepted ways to screen for intimate partner violence in the context of a telehealth visit. And, in fact, the American College of Obstetricians and Gynecologists specifically says that telehealth is a perfect modality to screen for victim partner violence.

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BY MS. NAROG:
Q Do you believe that the medication abortion protocol can be prescribed without meeting with the patient via telemedicine or telehealth?
MR. GUINEY: Objection. Vague.
THE WITNESS: Are you asking about asynchronous models of care?
BY MS. NAROG:
Q If that's what -- if that's how you refer to it. I mean without actually having a teleconference or a video conference with the patient before a prescription is given.
A Yes, asynchronous telehealth is also an accepted modality for providing a wide range of healthcare services, and there's evidence, including the paper that we looked at earlier, that was published in Nature Medicine by Upadhyay, showing that synchronous compared to asynchronous models of telehealth provision of medication abortion had similar rates of effectiveness and serious adverse events.
Q So similar rates of effectiveness in completed abortion?
A Yes.
Q But did it test for the safety of

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providing the medication without meeting with the patient in-person, at least via telephone or video conferencing?
MR. GUINEY: Objection. Vague.
THE WITNESS: Yes. We already looked at this paper. It looked -- it included over 6,000 patients, and I think it was about half of them who received -- had asynchronous telehealth visit with either a telephone or video visit, and others who had an asynchronous assessment where they responded to a series of questions using like an on-line portal or survey.
And in that paper it showed similar overall effectiveness and similar safety results.
BY MS. NAROG:
Q So describe -- tell me how an asynchronous model works.
A An asynchronous model involves a patient entering information about their health history, through a secure on-line portal generally, answering a series of targeted questions about their eligibility for medication abortion and also other

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general health history. And those are then reviewed by a clinician.
In some cases, people are clearly ineligible for medication abortion and they would be referred for an in-person care. Some people require some sort of synchronous interaction, so they would schedule a video or telehealth consultation to get further information about some of the information that was shared. And others may be deemed eligible after the clinician reviews the answers to those questions.
And then those people for whom -- who are deemed eligible are then prescribed medication that's mailed to them through a mail order pharmacy.
Q So how does an asynchronous model identify -- like verify independently the identity of the person seeking the medication?
A The -- I mean, I think different services may go about that differently. Some might require, you know, submitting their -- like an ID and picture or video of them. I have -- since I'm not providing that model of care, I don't know the details of all the ways that people are doing that, but that's one potential way that people might use.
Q And have you advocated for any of those

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based on your research to protect against the misuse of identification or identity in obtaining these pills through an asynchronous model?
MR. GUINEY: Objection. Vague.
THE WITNESS: I mean, when you say "advocate for any of these," what do you mean?
BY MS. NAROG:
Q Any of these protections that can ensure that these telemedicine asynchronous platforms aren't misused to obtain these medications?
MR. GUINEY: Same objection.
THE WITNESS: The problem of intimate partner violence is really very, very serious, and I think that I certainly advocate for -- as does the professional organizations that I'm part of, including the American College of Obstetricians and Gynecologists and Society of Family Planning, advocates in its guidance to screen people for intimate partner violence. And those -- that can be -- that screening can be done through remote technology.
I have not particular -- I have not

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been specifically advocating one way or another to specifically identify the patient who receives telehealth care.
BY MS. NAROG:
Q So as far as coercion goes, aside from this case, how can a telemedical clinician screen for coercion when they're not in the presence of the patient?
MR. GUINEY: Objection. Vague.
THE WITNESS: As I've just said, they can screen for coercion using screening tools that are widely used and accepted that allow patients to answer a series of questions about -- to identify risk of coercion and intimate partner violence.
In my personal experience, as well as in the published literature, it is much more common for patients to be coerced to continue the pregnancy than it is for them to be coerced to end the pregnancy.
BY MS. NAROG:
Q So how can -- let me think about this for a second, how I want to ask this question.

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How can asynchronous telemedical models protect against one person obtaining the medications for someone else to take?
A I think I just described one way that they can try to do that. Do you want me to say that again?
Q No. If there's another way that they can do that, that's fine, if you feel like you've already testified adequately as to that.
A I mean, I described one way that that can be done. Again, I -- so I think I already said.
Q So, for example, we have an older sister who sets up a telemedical appointment. She fills out the information for herself, claims that she is only eight weeks along and obtains the medication, only to give them to her younger sister, who is still a minor, and was not evaluated by the clinician at all.
How can telemedicine protect against that kind of abuse?
MR. GUINEY: Objection. Vague.
THE WITNESS: I mean, you're giving me a hypothetical question that is very difficult to assess. So when you say -- what part of this -- what is the abuse? Can you tell me more about this case?

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Does the minor want to obtain the abortion? Is the minor truly contraindicated or indicated to obtain a medication abortion? Is -- is the minor doing this out of their own free will and consent?
BY MS. NAROG:
Q That's the issue, isn't it, though? Because that's what I'm trying to get at.
We don't know those things because she didn't actually meet with the telehealth physician. This other party did under the guise of being pregnant, but because there's this asynchronous model where they don't actually have to have testing and they don't actually have to prove their identity, that they can obtain the medication and give it to their younger sister who's a minor, who may or may not want the medication abortion, may or may not have issues -- medical health issues that would make her not an acceptable candidate.
How can we protect against those types of abuse in order to protect patients?
MR. GUINEY: Objection. Vague, compound.
THE WITNESS: So even in settings

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where there is an in-person dispensing requirement, it's possible that that older sister could go into a clinic, get evaluated, get the medications and take them home and give them to the younger sister. So the in-person dispensing requirement doesn't adequately prevent this.

BY MS. NAROG:

Q Well, in Ohio, our law requires that -- that the patient take the medication in the presence of the physician. Would that adequately protect against having this kind of abuse?

A Not really, because --

MR. GUINEY: Objection.

THE WITNESS: -- actually, the rest of the Misoprostol pills that the sister would have gotten is also a very effective abortication and the sister could take those Misoprostol tablets home to the sister to use if they had researched about how to use Misoprostol for medication abortion.

BY MS. NAROG:

Q So it may not protect entirely, but it

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will at least prevent the patient from getting the Mifepristone?

A I mean, it's also possible the person -- I mean, someone who's clearly very motivated to -- again, you're giving me lots of hypotheticals, so we can scheme up all sorts of things.

But it could be possible the sister could put the pill in her mouth, pretend to swallow. It doesn't dissolve immediately. Leave the room and then take -- spit it out and then give it to her sister when she gets home.

Q Would it at least provide the assurance that that patient, at least from all available evidence, took the medication in the presence of the physician if he witnessed her taking the medication, even if she put it in the side of her cheek and not all of the medication was ingested?

MR. GUINEY: Is there a question there?

MS. NAROG: Yes.

THE WITNESS: What is the question?

BY MS. NAROG:

Q The question is, isn't it true that it would at least protect against the -- the patient getting all of the Mifepristone if the patient

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ingests the medication, puts it in her mouth while she's in the presence of the physician?

MR. GUINEY: Objection. Vague.

THE WITNESS: With five minutes in someone's mouth, very little, I think, Mifepristone would be absorbed. So I think it's likely the patient could get -- again, in a hypothetical situation of a very motivated pair of sisters, they could make this work.

BY MS. NAROG:

Q But it is at least an obstacle, is it not, to have the patient put the medication in their own mouth and the physician attempt to see them ingest the medication?

MR. GUINEY: Objection. Vague, also asked and answered.

THE WITNESS: Yeah, I think I answered that.

BY MS. NAROG:

Q Does in-person evaluation of a potential abortion medication abortion candidate put them at any greater risk than does telemedical evaluation of any kind of adverse outcome?

MR. GUINEY: Objection. Vague.

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THE WITNESS: For some patients, it is difficult for them to get to an in-person visit, to get to a facility that provides in-person medication abortion care. It may be a long distance from where they live, it may be difficult for them to get off time from work or school. It may be difficult for them to obtain child care for the children that they take care of.

And because of that, they may face delays accessing abortion care if they -- if the only option is for them to obtain it in-person. Those delays may push them past the limit for which they would be eligible for medication abortion. So if they had a preference for obtaining medication abortion, that is no longer available.

In some cases, the delays may be so much that they're pushed into the second trimester and face the increased risks associated with the second trimester procedural abortion, which is very safe, but it does have a higher risk of

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complications for the patient. There -- it's also a more involved procedure. It may involve -- it may involve multiple days. It's also more expensive for patients.

And, for some patients, it may just be impossible to overcome those obstacles to getting to in-person care and they would be forced to continue their pregnancy to term.

So, yes, I do believe there are harm's associated with making in-person provision of medication abortion the only option for patients.

BY MS. NAROG:

Q And I understand those harms, but are they put at greater medical risk if they are evaluated in-person rather than through telemedical evaluation, and I mean medical risk, than just that they may be delayed in receiving care?

MR. GUINEY: Objection. Vague, asked and answered.

THE WITNESS: Yes, I believe I answered this question already by saying clearly that, if that delay forces them

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to have a second trimester abortion, they are forced medically to obtain -- to undergo increased risks associated with second trimester abortion. And if they're forced to continue the pregnancy to term, they're forced to undergo the medical risks of continuing a pregnancy to term, which are at least significantly higher compared to having an abortion.

MS. NAROG: Okay. Let's -- let's take a 15-minute break and then we'll try to get back and finish this up. I don't have a lot left. And then we can, you know, call it a day. Does that sound okay?

MR. GUINEY: Sounds great.

MS. NAROG: I just need to get some food. It's getting late here in Ohio for me. So let's take like a 15-minute break. We'll come back at like 6:15. Okay?

(Brief pause.)

BY MS. NAROG:

Q Dr. Grossman, we talked a little bit about some misuses of telehealth in obtaining

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medication abortion prescriptions, and you have testified that you had -- were not really aware of any of those in your clinical practice; is that accurate?

A That's correct.

Q So other than the one we've already discussed that occurred here in Ohio, are you aware of any others?

A Not that I can recall off the top of my head.

Q Did you happen to hear about a case in England where a woman took Mifepristone that she obtained via telehealth through a friend when she was 30 to 32 weeks LMP?

A I did not -- I don't know which case you're talking about, no.

Q Is Mifepristone safe to take when a woman is 30 to 32 weeks pregnant?

MR. GUINEY: Objection. Vague.

THE WITNESS: I don't know the details of this case, about what happened, but certainly it's not -- it is not an evidence-based protocol to use Mifepristone at that stage of pregnancy.

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BY MS. NAROG:

Q If she had been evaluated in-person, would she have been given the medications here in the United States?

MR. GUINEY: Objection. Vague.

THE WITNESS: I didn't -- I don't know the details of this case. I thought you just said she got them through a friend who obtained them.

BY MS. NAROG:

Q She got them through a friend who obtained them via telemedicine for her. So neither person was met in-person or evaluated by a physician or clinician.

A So, again, I don't know the details of this situation, but it's possible that the friend could have been evaluated in-person in U.S. and be given the medications.

MS. NAROG: So let's look at an article that I'd like to have placed in the Chat. It's called -- I think it's Weibe, W-E-I-B-E, study. And is this Exhibit Q?

MR. GUINEY: I have Exhibit Q, yeah.

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MS. NAROG: Okay.
(Grossman Deposition Exhibit Q was marked for the record.)
BY MS. NAROG:
Q And let me know when you're able to open that up.
A Yes, I have it opened.
Q Okay. Dr. Grossman, are you familiar with this document?
A I am familiar with this article.
Q And what is it about?
A Sorry. I was just --
Q No, you're fine.
A So this article is reporting findings from a clinic in British Columbia, Canada, comparing telemedicine to in-person provision of medication abortion with Misoprostol and Mifepristone.
Q Do you recall if you cited this in your expert report?
A I don't recall if I did or not.
Q If you would look on Page 2, there's a paragraph that starts Table 2, and then there is Table 1, as well, on that page.
Do you see those two? Do you see the paragraph that starts Table 2?

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A Table 2 shows the proportions. That one?
Q Yeah, that's the one.
A Yes.
Q A little more than halfway down, it says: Unscheduled communications with office assistants were greater in the telemedicine patients than in-person patients.
Did I read that correctly?
A Yes.
Q Okay. And it -- I'm not a mathematician, but it seems to say that 46.2 percent of the telemedicine patients had unscheduled communications with office assistants; is that correct?
A I believe so, yes.
Q Okay. And that is contrasted with 21.6 percent of in-person patients, right?
MR. GUINEY: Objection. Lack of foundation.
THE WITNESS: That is correct. That is the way I read this.
BY MS. NAROG:
Q All right. And then if you look down at Table 1, just below there, it says: Demographics of in-clinic and telemedicine patients requesting abortion at one clinic in British Columbia in 2017 to 2018.
Did I read that correctly?
A Yes.
Q And it seems to say that telehealth patients received ultrasound 18.1 percent of the time versus the 100-percent ultrasound usage with in-person patients or in-clinic patients; is that correct?
A Yes.
Q When a patient receives telehealth medication abortion, how is -- how are emergencies or emergency symptoms cared for?
MR. GUINEY: Objection. Vague.
THE WITNESS: Patients are, you know, given the same counseling and information in-person as they're given through the context of a telehealth visit, including the symptoms that are considered normal with the medication abortion and the considers -- what we would call warning signs or signs that require further evaluation. These are things like the amount of bleeding, the amount of pain, whether someone has fever. Those would be considered warning signs.
And, I mean, generally, if a patient has, you know, any serious warning signs, they're told to seek urgent care, like an emergency department. And that's the same whether they're receiving the medication in a facility or through a telehealth service.
MS. NAROG: Okay. I'd like you to put into the Chat what was marked Updated AJO -- AJOG -- it may be ACOG, is what I might have -- 2025 study. And we'll mark this for identification as Exhibit R.
(Grossman Deposition Exhibit R was marked for the record.)
BY MS. NAROG:
Q And, Dr. Grossman, if you're able to let me know when you're able to open that, I'd appreciate it.
A Yes.
Q Are you familiar with this document?
A I'm familiar with this article that's called Effectiveness and Safety of Medication Abortion With Versus Without Screening Ultrasonography or Pelvic Examination.

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Q What did this study look at?
A Sorry. I just need to refresh my memory. Okay. So this is a retrospective cohort study of medication abortion where they abstracted clinical information of patients receiving medication abortion, including a group that underwent screening using the no-test protocol --
Q Okay.
A -- and those who had a test, an ultrasound.
Q And what did this -- what did this study find?
A I mean, they reported on the demographics of the -- of these patients. I think some of the things that are interesting were the patients who received medication abortion without -- through the no-test protocol were less likely to reside in urban areas and they were more likely to pay out-of-pocket for the abortion.
The study found similar effectiveness in the two groups and also similar safety findings. They -- I think those are the main findings.
Q Did the study show that ultrasound identified risk factors that were not captured by the history-only screening?

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MR. GUINEY: Objection. Lack of foundation.
THE WITNESS: I mean, they saw -- they found no difference in their safety analysis. I'm going to have to read through the paper in more detail to try to answer your specific question. If there's a part of the article you'd like to point me to, to save some time late in the day, I'm happy to do that.
Otherwise, I'll keep reading.
BY MS. NAROG:
Q I think it might be reflected in the figure in -- Figure 1, I think, is --
A Sorry. It's been a while since you asked the question. Would you mind restating the question so I can answer it?
Q Sure. Isn't it true that this study shows that ultrasound identified risk factors that were not captured in the history-only screening provided to some patients?
MR. GUINEY: Objection. Lack of foundation.
THE WITNESS: Can you just clarify, risk factors for what?

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BY MS. NAROG:
Q Risk factors for the procedure, for medication abortion provision.
MR. GUINEY: Objection. Vague, lack of foundation.
THE WITNESS: I'm not seeing that in the paper, and in fact I'm seeing that the proportion with a major abortion-related adverse event was similar in the two groups and not statistically significant.
BY MS. NAROG:
Q So were there any ultrasound findings that were -- that were better for the patients that received them as opposed to those that were not in this study?
MR. GUINEY: Objection. Vague, lack of foundation.
THE WITNESS: I don't know what it means for an ultrasound result to be better from someone who doesn't receive an ultrasound.
BY MS. NAROG:
Q Were the results of the ultrasounds in the screening for risk factors for any of the

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potential risk factors more effective than they were for the patients that were not screened by ultrasound?
MR. GUINEY: Objection. Lack of foundation, vague.
THE WITNESS: Again, if there's a specific part of the paper you want me to look at in Figure 1 to point to a risk factor, I don't see a risk factor identified in Figure 1.
BY MS. NAROG:
Q Give me one moment. So if you look at the Methods, sectio, I think that's where it is. Let me -- well, let's move on from this -- from this example. I can't find the reference.
So is clinical management usually adjusted if the ultrasound reveals some contraindications for medication abortion if the person receives an ultrasound?
MR. GUINEY: Objection. Vague, compound.
THE WITNESS: Is the clinical management altered? Is that what you said? Or adjusted?

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BY MS. NAROG:
Q Yes. Adjusted.
A So if on ultrasound a patient is found to be past their gestational duration limits, for example, past 84 days if that's the limit, then, yes, the patient would be counseled on the abortion method available to them would be procedural abortion. If the ultrasound identifies an ectopic pregnancy, then the management would be altered to provide treatment for an ectopic pregnancy.
Q So are there any studies that look at telehealth provision of medication abortion that evaluated identity verification of the patient?
MR. GUINEY: Objection. Vague.
THE WITNESS: All of the studies that involve synchronous provision of medication abortion involve identity verification. I do not know specifically about all the studies of asynchronous telehealth medication abortion provision.
BY MS. NAROG:
Q So in all the studies that looked at synchronous provision of medication abortion provision via telehealth, they all looked at identity verification as a feature of that provision of care?

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MR. GUINEY: Objection. Vague.
THE WITNESS: It was an inherent component of the service delivery model because patients were required to provide identification, a government ID, and they had a video visit.
BY MS. NAROG:
Q Do you know of any synchronous models that did not require, you know, a government ID?
A I do not.
Q But there could be certain synchronous models that would not include an identity verification protocol, correct?
A Again, you're asking me a hypothetical question. Is that possible to --
Q Yes.
A -- design a model like that? I suppose it is, and it is also possible to have an in-person model of care, as we discussed, where somebody could come in and pretend to be the pregnant person seeking medication abortion and then give those medicines to someone else.
Q So do any studies evaluate the telehealth provision of abortion medication that evaluated coercion detection in either asynchronous or

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synchronous models?
MR. GUINEY: Objection. Vague, compound.
THE WITNESS: There is an ongoing study, I know, with -- it's called the MAP, Master Abortions Project, where they are directly asking patients about questions related to coercion. And so far have reported, you know, disturbing but not surprising, because the report is literally the proportion of patients who are in a situation at risk of intimate partner violence, and where they are reporting pressure to continue the pregnancy.
And they certainly are equipped to also identify cases of coercion. So far I have not heard that they have identified any.
As I also said, in our study, the prospective cohort study of telehealth, we ask detailed questions about psychosocial burden, mental health, about satisfaction with the abortion, about their social situation around the

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abortion, and no patient identified being coerced.
BY MS. NAROG:
Q Are there any telehealth studies that evaluate the provision of medication abortion that looked at the third party control issue?
MR. GUINEY: Objection. Vague.
THE WITNESS: Please define the third party control issue.
BY MS. NAROG:
Q So the fact that -- let me ask this a different way.
Have any telehealth abortion care provision studies looked at forced ingestion of the abortion medications by patients --
MR. GUINEY: Objection.
BY MS. NAROG:
Q -- that did not want to have an abortion?
MR. GUINEY: Same objection.
THE WITNESS: As I have said -- I think this might be the fourth time I've said this -- in our prospective cohort study of telehealth, medication abortion compared to in-person care, we asked detailed questions about psychosocial

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burden, mental health, social situation, acceptability around the abortion, experience with the abortion, social situation, including asking and allowing patients opportunities to give open-ended responses, and no patient reported that.

BY MS. NAROG:

Q And how large was the study that you're referencing?

A It's the Ralph study from -- it was published in JAMA in 2024. You pulled it up precisely.

Q And were you an author on that study?

A I was.

Q Are there any telehealth, you know, evaluation studies that looked at the misrepresentation of medical history that patients -- in patients that are seeking medication abortion?

MR. GUINEY: Objection. Vague.

THE WITNESS: Can you explain what you mean?

BY MS. NAROG:

Q So are there any studies that looked at whether or not patients might misrepresent their medical history in the provision of telehealth

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abortion care?

MR. GUINEY: Objection. Vague.

THE WITNESS: There are studies that look at the accuracy of patient's self-reported responses to eligibility screening questions compared to a clinician's assessment, now with thousands of patients. Including studies led by Dr. Lauren Ralph that I was the senior author on. And so that would include patients who incorrectly report their medical history, patients who don't understand the questions and therefore can't answer the questions correctly.

And I think to your point, if you actually believe that some patients may lie in the context of a medical visit, it would include those, too.

And taken all together, we find that patients are quite accurate in their self-assessment of eligibility compared to a clinician.

BY MS. NAROG:

Q Are there any studies that have shown that in-person evaluation prior to medication

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abortion is not adequate care for a patient?

MR. GUINEY: Objection. Vague.

THE WITNESS: Adequate care sounds like a very subjective assessment. I think I already answered this when I talked about the potential risks of restricting or limiting access to telehealth provision of medication abortion and making it so that in-person provision is the only way that patients can access that care.

I can go through what those potential harms are to the patient, but for that reason I believe it is inadequate to only offer in-person services for medication abortion.

BY MS. NAROG:

Q And just to be clear, your testimony earlier was that there was -- that it had been studied and found that that was not adequate care or not effective care to only have an in-person model or was -- I thought that testimony was based on your opinion?

MR. GUINEY: Objection.

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BY MS. NAROG:

Q I had asked about -- I had asked about any study had shown that in-person evaluation prior to medication abortion has been found not to provide adequate care for patients referred to --

MR. GUINEY: Objection. Sorry about that. I cut you off.

THE WITNESS: Sorry. Please repeat the question one more time.

BY MS. NAROG:

Q Okay. So are there any studies or research that's been conducted that found that in-person evaluation of patients prior to medication abortion does not provide effective care to patients?

A There are studies. There's a study from Iowa that I authored showing that when telehealth medication abortion was introduced in Iowa, I think there was a significant reduction in second trimester abortion overall across the current system where it was introduced.

I believe that that is a study that shows that only offering in-person care is harmful to patients because it increases the risk of needing to have a second trimester abortion.

Q And that's the Iowa study that you

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mentioned?
A Yes.
Q Was that an actual conclusion of that study?
A Yes.
Q Are there any studies that show that ultrasounds prior to a medication abortion is less effective in evaluating patients for risk factors related to Mifepristone and Misoprostol use for medication abortion?
A Than what?
Q Is not effective or is not as adequate a care model to evaluate patients.
A Than what? You're saying it's not as something.
Q Not adequate -- is not an adequate care model for patients. So let me -- let me rephrase.
Are there any research studies or articles that have concluded that ultrasound does not provide adequate care in assessing patients for risk factors for medication abortion prescription?
A There is research showing -- I don't know what you -- adequate to identify risk factors. Ultrasound is an adequate way to screen for eligibility. We have said several times that that is

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a standard of care. It is not -- does not perfectly identify everybody who is truly ineligible, in particular because it doesn't -- it doesn't identify everybody who has an ectopic pregnancy. But it is an accepted standard of care.
Q So what role, in your opinion, does legislation play in setting proper standards for abortion provision to patients in Ohio or anywhere in the United States?
MR. GUINEY: Objection. Vague.
THE WITNESS: Can you say more about what -- what kind of legislation you're talking about?
BY MS. NAROG:
Q Well, any kind of legislative enactment that would somehow set standards for the provision of abortion in any given jurisdiction, but Ohio specifically.
What role does the legislature have in providing some kind of safeguards for abortion provision within a state?
A I believe that the legislature has -- should play the same role in determining how abortion is provided, as any medical care.
So to the extent that the legislature is

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involved in making decisions about who can be licensed, what is considered, you know, within the scope of practice for a physician, if they're doing it across medicine generally, perhaps that has a role.
I don't believe that there's a role generally for the legislature to dictate the practice of medicine. I think that that should be left to the medical professionals.
Q So if, for example, this case ends in a permanent injunction of the laws at issue, would the General Assembly have any role in creating safety guardrails around the provision of telehealth medication abortion here within the state?
MR. GUINEY: Objection. Vague, lack of foundation.
THE WITNESS: Yeah, I think you're really asking questions that go beyond my area of expertise. I know that here in California we -- there are very few legislative restrictions on provision of abortion care. There are -- there -- I mean, we've talked about some of them. And clinicians are providing abortion care safely and effectively consistent

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with medical guidance according to the standard of care.
And people who -- there are mechanisms for clinicians who are operating outside of the standard of care to be sanctioned by a medical board, in the context of malpractice litigation, and otherwise, and that seems to be working well here in California.
BY MS. NAROG:
Q So, for example, if the General Assembly decided to require that a telehealth provider verify identity through a government-issued driver's license or identity card, would that be an acceptable limitation placed on telehealth medication or would that not be acceptable and the medical industry should do its own regulation on that issue?
MR. GUINEY: Objection. Compound, lack of foundation.
THE WITNESS: I mean, I don't know. I would really have to see what the restriction is, I mean, how that would be actually implemented. There are challenges for many people in this country to obtain a government ID. Does

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that mean they're not eligible for obtaining this service? Might there be other ways that they could document their identity?

So there -- I would need to have a lot more information to be able to answer this question.

BY MS. NAROG:

Q And what about in the situation that we discussed earlier with the -- the physician who force fed his girlfriend Mifepristone? Is the legislature unable to regulate those kind of abuses other than through the medical system?

MR. GUINEY: Objection. Lack of foundation.

THE WITNESS: I mean, that's a really horrifying case and it's particularly horrifying to read that it was a physician who would do something like that. And also just imagining all the other medications that would be at that person's disposal that they could have used to poison to try to end the pregnancy of their -- I guess, as you said, it was their ex-partner, if they

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didn't have access to Mifepristone and Misoprostol.

It's an absolutely horrifying case, and that person, I would say, deserves a whole lot more than having their medical license revoked or suspended.

I am not kind of a criminal justice expert. I don't know all of the ways that -- you know, the potential ways that that person could be, you know, punished. I don't feel like there's more than I can say about that question.

BY MS. NAROG:

Q But we can agree that no one should have an abortion that they don't want, correct?

A I do believe that, and I also believe that no one should be forced into a pregnancy that they don't want, either, by a partner, by a family member or by the state.

Q And you do understand that we have an abortion amendment to our constitution here in Ohio that allows for pre-viability abortion and it's a protected right in our constitution, correct?

A I do understand that.

Q And so Ohioans and people who come to

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Ohio for abortion care can get it here in Ohio up to the point of viability?

MR. GUINEY: Objection. Lack of foundation.

THE WITNESS: I mean, having that in the constitution is one thing, and ensuring that everybody has access to that is another thing.

BY MS. NAROG:

Q And do you know that people are not able to have access to abortion care here in Ohio?

A I didn't say -- I said those are two different things and we -- there are a number of reasons why people may not be able to access want an abortion. I know that from my clinical experience, I know that from research I've conducted, and I know that from research that my colleagues have conducted.

Q Do you know how telehealth is provided in the abortion space, medication abortion specifically, in Ohio?

A I don't know the details of how it's currently provided. I've heard -- I know it's sort of evolved over the period of time during this period of this injunction. There are other laws that have come into play, including related to the waiting

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period and state mandated counseling. I don't know the details of how it's currently provided.

Q Have you spoken to any abortion providers in Ohio regarding telemedical provision of medication abortion care?

A Ever?

Q In the context of this case, yes.

A Not in the context of this case. I have -- I read the report from Dr. Kumar.

Q And -- let me see here. Do you have any evidence that Ohio's physical presence requirement lacks a medical or safety value for patients?

MR. GUINEY: Objection. Vague.

THE WITNESS: Can you repeat the question, please?

BY MS. NAROG:

Q So do you have any evidence, be it scientific from a study or research, that Ohio's physical presence requirement, meaning that personal in-person evaluation, lacks medical or safety value for patients?

MR. GUINEY: Objection. Vague.

THE WITNESS: Lacks medical or safety -- I mean, we spent several hours reviewing the evidence about the safety

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and effectiveness of telehealth evaluation compared to in-person evaluation, and we reviewed several studies, even more studies I reviewed in my report, that clearly shows no benefit to an in-person evaluation. So I think I've answered that question several times.

BY MS. NAROG:

Q So you're saying there's no benefit to an in-person requirement as opposed to a telehealth provision of abortion care?

MR. GUINEY: Objection. Misstates the testimony.

THE WITNESS: There's no benefit in terms of either telehealth evaluation for eligibility or remote provision of the medication with mailing to the patient's home and ingestion at the patient's home, compared to an in-person assessment for eligibility and in-person dispensing of medications.

MS. NAROG: Okay. I think we can take like a ten-minute real quick. I'm just going to check and make sure I

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didn't miss anything and I think we can conclude. Okay?

MR. GUINEY: Sounds good. And also, can I just -- when we get back, can I just have a time check for how much time has been on the record.

(Brief pause.)

MS. NAROG: Back on the record.

BY MS. NAROG:

Q I just wanted to clarify one thing before we end the deposition.

So based on your research and your view of the available information, is medication abortion as safe and effective for termination of pregnancy as surgical abortion?

MR. GUINEY: Objection. Vague.

THE WITNESS: Medication abortion is somewhat less effective than procedural abortion. That is a feature of the abortion method that is explained to patients when they're considering their options and that patients understand when they make a decision to have a medication abortion as compared to the procedural abortion.

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In terms of safety, I mean, the overall risk of serious adverse events is comparable between the two options.

BY MS. NAROG:

Q And just to -- just to make sure we're talking about the same thing.

In Ohio, we don't refer to it in our law as procedural abortion. We refer to it as surgical abortion. So what do you mean when you say "procedural abortion"? Just so we make sure we understand each other.

A By procedural abortion, I mean vacuum aspiration, either electrical vacuum aspiration or manual vacuum aspiration. I assume we're talking about an aspiration that's similar to a gestational period up to 12 weeks.

Q Yes.

MS. NAROG: I think that's all I have for you today, Dr. Grossman.

MR. GUINEY: Thank you. I think we might just want one or two minutes very quickly just to see if we have any questions to ask. So could we just go off the record and we'll be right back.

MS. NAROG: Yes, that's no problem.

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MR. GUINEY: Thank you.

(Brief pause.)

MR. GUINEY: Okay. Thank you so much. No -- no redirect from us, Dr. Grossman. Thank you so much for your time today.

THE WITNESS: Thank you.

(Thereupon, the deposition was concluded at approximately 7:12 p.m.)

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CERTIFICATE

I, Tanya Verhoven-Page, CCR, LCR, CSR, do hereby certify that the witness was duly sworn by me and that I was authorized to and did report said proceedings.

I further certify that the foregoing transcript is a true and correct record of the proceedings; that said proceedings were taken by me stenographically and thereafter reduced to typewriting under my supervision; that reading and signing was requested; and that I am neither attorney nor counsel for, nor related to or employed by, any of the parties to the action in which this deposition was taken; and that I have no interest, financial or otherwise, in this case.

IN WITNESS WHEREOF, I have hereunto set my hand this 29th day of September, 2026.

_____
Tanya L. Verhoven-Page,
Certified Court Reporter,
CCR-B-1790, CSR-12254
and LCR-991.

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CERTIFICATE OF DEPONENT

I, DANIEL GROSSMAN, M.D., hereby certify that I have read the foregoing pages, numbered 1 through 240, of my deposition of testimony taken in these proceedings on Monday, September 28th, 2026 and, with the exception of the changes listed on the next page and/or corrections, if any, find them to be a true and accurate transcription thereof.

Signed: _____
Name: DANIEL GROSSMAN, M.D.
Date: _____

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ERRATA SHEET FOR THE TRANSCRIPT OF:
Case Name: Planned Parenthood v. Ohio Department
Dep. Date: September 28, 2026
Deponent: Daniel Grossman, M.D.

CORRECTIONS

Pg.	Ln.	Now Reads	Should Read	Reason

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CORRECTIONS

Pg.	Ln.	Now Reads	Should Read	Reason

_____
Signature of Deponent
SUBSCRIBED AND SWORN BEFORE ME
This the_____ day of_____, 2026.
_____
(Notary Public) My Commission Expires:_____

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