IN THE DISTRICT OF JOHNSON COUNTY, KANSAS
CIVIL COURT DEPARTMENT

HODES & NAUSER, MDs, P.A., on behalf of itself, its patients, physicians, and staff; TRACI LYNN NAUSER, M.D.; TRISTAN FOWLER, D.O.; and COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, on behalf of itself and its patients, physicians, and staff, Plaintiffs, v. KRIS KOBACH, in his official capacity as Attorney General of the State of Kansas; STEPHEN M. HOWE, in his official capacity as District Attorney for Johnson County; MARC BENNETT, in his official capacity as District Attorney for Sedgwick County; MARK A. DUPREE SR., in his official capacity as District Attorney for Wyandotte County; SUSAN GILE, in her official capacity as Executive Director of the Kansas Board of Health Arts; and RONALD M. VARNER, D.O., in his official capacity as President of the Kansas Board of Healing Arts, and JANET STANEK, in her official capacity as Secretary of the Kansas Department of Health and the Environment Defendants.	Case No. 23CV03140 Division No. 12 K.S.A. Chapter 60

DEFENDANTS ATTORNEY GENERAL KRIS W. KOBACH AND DISTRICT ATTORNEYS STEPHEN M. HOWE, MARC BENNETT, AND MARK A. DUPREE SR.'S RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION FOR TEMPORARY INJUNCTION AND/OR TEMPORARY RESTRAINING ORDER

(Pursuant to K.S.A. Chapter 60)

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Constitutional Provisions

INTRODUCTION

"Abortion is a unique act." *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 884, 112 S. Ct. 2791, 120 L.Ed.2d 674 (1992), overruled in part by *Dobbs v. Jackson Women's Health Org.*, ___ U.S. ___, 142 S. Ct. 2228 (2022). "[I]t seems unexceptionable to conclude some women come to regret their choice to abort the infant life they once created and sustained. Severe depression and loss of esteem can follow." *Gonzales v. Carhart*, 550 U.S. 124, 159, 127 S. Ct. 1610, 167 L.Ed.2d 480 (2007) (citations omitted). Abortion also is "fraught with consequences . . . for the life or potential life that is aborted," *Casey*, 505 U.S. at 852, in whom the State may have a significant interest, *Gonzales*, 550 U.S. at 158. And without adequate informed consent, pregnant women will not be able to meaningfully consider the impact of abortion on themselves or their unborn child.

Plaintiffs are unlikely to succeed on their challenge to the commonsense measures that found in the aptly named Woman's Right to Know Act ("the Act"), first enacted in 1997. Such provisions have been widely upheld for decades by state and federal courts, including the Supreme Court, and understandably so. Kansas, like every other state, has authority to regulate the medical profession as part of its inherent powers to preserve the health, safety, and welfare of its citizens. It is *women*, not self-interested abortionists like Plaintiffs, who will suffer harm if this Court enjoins the reasonable informed consent requirements of the Act. Further, Plaintiffs have an adequate legal remedy of which they can take advantage through the normal course of litigation. Plaintiffs concede they have complied with all but one of the challenged provisions for decades, without issue. They are not entitled to extraordinary, emergency relief.

Further, an injunction would be against the public interest, because it would usurp the democratic process and strip the State of its essential role in ensuring that women undergoing a significant medical procedure do so only after being fully

informed and giving their voluntary consent. These duly enacted laws enjoy a presumption of constitutionality, and an injunction would radically disrupt the longstanding status quo. Plaintiffs cannot overcome their high burden, and this Court should reject their attempt to undermine constitutionally sound statutes designed to inform and protect the very women Plaintiffs claim to serve.

SUMMARY OF FACTS

The Woman's Right to Know Act ensures that women who seek an abortion have received all information necessary from a doctor to inform their decision. This information includes facts about the nature of the abortion procedure; the medical risks of carrying a child to term; the inherent risks of abortion procedure; alternatives to abortion; information about fetal development; the restrictions that may apply depending on whether the child is viable; contact information for prenatal and perinatal medical assistance; and any need for anti-Rh immune globulin therapy. K.S.A. 65–6709(a)(2)–(8), (d), (m)(1); 65–6710.

The woman must be told of the legal and financial obligations of the child's father, as well as her right to withdraw consent to abortion. K.S.A. 65–6709(b). Further, she must be offered the opportunity to view a sonogram and listen to the baby's heartbeat, both of which she may decline. K.S.A. 65–6709(e)–(f), (h)–(i).

Informed consent necessarily requires deliberation, and the statute builds in a brief 24-hour period between the doctor providing the written information to the woman and performing an abortion on her. K.S.A. 65–6709(c). The woman is also ensured she will meet the doctor, likely for the first time, 30 minutes before the abortion, giving her a chance to ask any questions. K.S.A. 65–6709(a). A doctor is always free to share his own views and offer a critique of the State's materials.

The Act also reasonably requires abortion providers to share information about their professional background. That includes disclosing disciplinary action, a loss of any clinical privileges at a hospital, the names of local hospitals where he has clinical

privileges, whether he has malpractice insurance, the year he obtained his medical degree, how long he has worked at the abortion facility, and whether he is a resident of Kansas. See K.S.A. 65–6709(a)(1)(D)–(E), (G).

Any abortion facility must place a sign in a "conspicuously post[ed]" place so that it is "clearly visible to patients." It must be in legible, boldfaced type and inform the woman that she cannot be forced to have an abortion; that she may change her mind at any time; that the father must provide child support; that if she decides against an abortion, the State can help finance the costs of childbirth; and that State agencies are available to assist with the process. K.S.A. 65–6709(k). Abortion facilities must also place on the home page of their website a link to the informed-consent information at the Kansas Department of Health and Environment's website. K.S.A 65–6709(l).

Similarly, the 2023 amendment requires medical facilities that dispense mifepristone to "post a visible sign" disclosing that: (1) mifepristone "alone is not always effective in ending a pregnancy"; (2) "[i]t may be possible to reverse its intended effect if the second pill or tablet has not been taken"; and (3) a woman can "get immediate help by accessing available resources" if she changes her mind about continuing the pregnancy soon after taking mifepristone. L. 2023 Ch. 88, § 1. The notice must include information about the State's pregnancy resources website and "other relevant telephone and internet resources containing information on where the patient can obtain timely assistance to attempt to reverse the medication abortion." L. 2023 Ch. 88, § 1. The Act provides that 90 days after the effective date of the Reversal Amendment, the State Department of Health and Environment will publish materials "designed to inform women" of the availability of information pertaining to abortion pill reversal." L. 2023 Ch. 88, § 1(e). The parties have stipulated to an agreed temporary restraining order against enforcement of this provision. (Doc. 32). The provisions of the Act are severable. L. 2023 Ch. 88, § 1(j). 1

LEGAL STANDARD

Legislation that has been duly enacted through the democratic process is "cloaked in a presumption of constitutionality," *Leiker v. Gafford*, 245 Kan. 325, 363-64, 778 P.2d 823 (1989). Injunctive relief "is an extraordinary and drastic remedy, one that should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion." *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (emphasis in original); see also *Winter v. Nat'l Res. Defense Council, Inc.*, 555 U.S. 7, 24, 117 S. Ct. 1865, 138 L.Ed.2d 162 (2008) ("[A]" preliminary injunction is an extraordinary remedy never awarded as of right.").

A party cannot successfully challenge the status quo and obtain injunctive relief unless it can show all five factors:

> (1) a substantial likelihood of eventually prevailing on the merits; (2) a reasonable probability that the plaintiff will suffer irreparable injury without an injunction; (3) the lack of an adequate legal remedy, such as damages; (4) the threat of injury to the plaintiff outweighs whatever harm the injunction may cause the opposing party; and (5) the injunction will not be against the public interest.

Downtown Bar & Grill, LLC v. State, 294 Kan. 188, 191, 273 P.3d 709 (2012). Litigants must also "exercise reasonable diligence" to be entitled to injunctive relief. *Noble v. Butler*, 25 Kan. 645, 651 (1881).

ARGUMENT

The Woman's Right to Know Act helps to ensure a pregnant woman is fully informed before a doctor aborts her unborn child. Plaintiffs invoke the Kansas Constitution to avoid these common (and commonsense) requirements on their medical practice, but they do so by invoking a *woman's* fundamental right to abortion, which they do not share. They co-opt this right because they have none of their own. What they *do* have is a legal and ethical obligation to disclose and explain information

the woman needs to decide whether to carry her child to term. And the Act serves that purpose by providing minimal disclosure requirements that do not infringe on the right to abortion, but instead respect a woman's autonomous right to make a fully informed decision. Even if Plaintiffs could vicariously invoke a woman's right to abortion, the challenged provisions are narrowly tailored to further at least three compelling State interests: (1) protecting maternal health; (2) protecting unborn life; (3) preventing fetal pain; and (4) regulating the medical profession.

Plaintiffs' invocation of speech rights also fails because the Act regulates their *conduct* as medical professionals, not their speech. The State has broad authority to ensure that all doctors fully inform their patients, and it has done so through the Act, the provisions of which are reasonably designed with the best interests of women in mind. This Court should reject Plaintiffs' extraordinary request to suspend the basic health-and-safety protections this statute has afforded to women for decades and allow these reasonable requirements to remain in force during this litigation.

I. Plaintiffs do not have a substantial likelihood of prevailing on the merits of their claims.

Plaintiffs invoke three constitutional protections as the basis for their request for temporary injunction: a woman's right to an abortion, as well as the free speech and due process guarantees of the Kansas Bill of Rights. But they do not have standing to assert a right that belongs exclusively to a third party—not to mention that the *right* to abortion is not implicated by the Act, which only provides reasonable requirements. Further, their free speech claim mischaracterizes regulation of medical conduct as "speech," in contravention of clear U.S. Supreme Court precedent. Lastly, their vagueness claim is a premature challenge to a statute directing rules to be promulgated by the Kansas Department of Health and Environment; those provisions will not be published until October 1, 2023, and there is no basis for a vagueness challenge to provisions yet to be determined.

A. Plaintiffs cannot establish third-party standing.

Plaintiffs come to this Court as medical professionals who are regulated under a commonplace state statute protecting women's health that they say is interfering with their business model. Yet abortion providers have no "freestanding right to perform abortions." *Planned Parenthood of Greater Ohio v. Hodges*, 917 F.3d 908, 912 (6th Cir. 2019). Recognizing this, Plaintiffs repeatedly invoke their "*patients'* fundamental right to abortion" as a basis for their request for an injunction. (Doc. 4 at 1; 11; 11–18.) But Plaintiffs cannot assert the rights of third-party patients without meeting the requirements for third-party standing.

"Generally, standing must be based on a violation of a plaintiff's personal rights, not a violation of a third party's rights. See *Powers v. Ohio*, 499 U.S. 400, 410–11, 111 S. Ct. 1364, 113 L.Ed.2d 411 (1991). In limited circumstances, courts have permitted litigants to bring suit on behalf of a third-party. To satisfy the requirements for third-party standing, a plaintiff: (1) must have suffered an "injury in fact," giving him a "sufficiently concrete interest" in the outcome of the issue in dispute; (2) must have a "close relation to the third party" and (3) "there must exist some hindrance to the third party's ability to protect his or her own interests." 499 U.S. at 411. And even if a plaintiff has a "sufficiently concrete interest" in the outcome of a dispute, 499 U.S. at 411, it may not assert third-party standing where its interests "are not parallel and [are] . . . potentially in conflict" with the third party, *Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 15, 124 S. Ct. 2301, 159 L.Ed.2d 98 (2004).

In a case decided before *Dobbs*, the Kansas Supreme Court held that abortion providers had third-party standing "to assert their patients' rights." *Alpha Med. Clinic v. Anderson*, 280 Kan. 903, 921, 128 P.3d 364 (2006). But that case does not apply here, where Plaintiffs interests conflict with those of their patients. In fact, the extraordinary relief they are seeking works *against* their patients' right to informed

consent. See *Cameron v. EMW Women's Surgical Ctr., P.S.C.*, 664 S.W.3d 633, 652–53 (Ky. 2023) (where conflict of interest cases that permitted abortion providers to invoke third-party standing have now been "strongly, and rightfully, discredited" by *Dobbs*.

Critically, Plaintiffs here do not allege that they satisfy *any* of the requirements for third-party standing—they say nothing about the closeness of any brief encounter they have with women, nor do they claim women are hindered from suing. And the facts demonstrate a clear conflict of interest that precludes financially motivated abortion providers from raising the rights of third parties to overturn statutes designed to protect them.

At the outset, third-party standing requires a close "*existing* relationship," which is "quite distinct from a *hypothetical*" relationship. See *Kowalski v. Tesmer*, 543 U.S. 125, 131, 125 S. Ct. 564, 160 L.Ed.2d 519 (2004) (emphases in original). Accordingly, in *Dobbs*, the Supreme Court condemned the presumption that abortion providers were entitled to third-party standing. See 142 S. Ct. at 2275. The Court reasoned that, if abortion providers can vicariously represent the interests of a client they hardly know, standing requirements are essentially meaningless whenever abortion is at issue. 142 S. Ct. at 2275. Other courts have noted the brevity and impersonal nature of an abortion procedure. The Kentucky Supreme Court recently concluded that abortion providers did not possess a "close relationship" to their patients because "the evidence demonstrate[s] their consultations [are] fleeting and the procedures require[] little to no follow up." *Cameron,* 664 S.W.3d at 652–53.

Plaintiffs' own arguments and admissions demonstrate the lack of a close relationship here. Plaintiffs promise prospective patients that the procedure will take

"only about a minute," or at the most "3 to 5 minutes."[1] Further, the crux of Plaintiffs' complaint is that Kansas requires them to spend *too much time* with their patients and personally provide information necessary to their informed consent. The statutory provisions they seek to eviscerate will *reduce* their interactions with future abortion patients. Plaintiffs should not be allowed to invoke third-party standing to turn a brief encounter of minutes into an even shorter and more impersonal interaction.

Plaintiffs cannot get around the "blatant conflict of interest" that is inherent to their objection to the Woman's Right to Know Act. *June Med. Servs. L.L.C. v. Russo*, ___ U.S. ___, 140 S. Ct. 2103, 2167 (2022) (Alito, J., dissenting). Plaintiffs openly complain that they are incurring business losses because of the informed-consent requirements of the Act. (See Doc. 4 at 29 (explaining how they have been "forced to turn away" new clients). (Doc. 4 at 29). By outlining minimal informed-consent disclosures, the Act deters abortion providers from rushing a patient through the procedure without relevant information or full consent. This case demonstrates the importance of this safeguard. For example, Plaintiffs deride the "onerous requirements" of a statute they have complied with for decades because it requires them to meet with patients beforehand and interferes with their profit margins. (Doc. 4 at 23–24). But the purpose of the requirements Plaintiffs seek to avoid is "to ensure [the patient] has an adequate opportunity to ask questions of and obtain information from the physician concerning the abortion," K.S.A. 65–709(c)).

While claiming to be concerned about "delaying time-sensitive care," (doc. 4 at 16), Plaintiff Hodes & Nauser demands on its website that patients "**Bring** enough funds to pay for the procedure. . . . **Patients unable to pay in full will be**

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[1] See Center for Women's Health, *Pregnancy Termination/Abortion* at https://www.hodesnauser.com/services/procedures-services/pregnancy-termination-abortion (last visited June 28, 2023).

rescheduled."[2] With Plaintiffs imposing a (potentially permanent) delay on patients who cannot pay in full upfront, their "harmful delay" accusations about the Act ring hollow. The interests of Plaintiffs' business and their customers are very much "in conflict." *Elk Grove Unified Sch. Dist.*, 542 U.S. at 15.

Plaintiffs must but cannot establish "some hindrance to the third party's ability to protect his or her own interests." *Powers*, 499 U.S. at 410–11. Case after case has been brought by women capable of challenging abortion restrictions—often using pseudonyms to protect their privacy. *See June Med. Servs.*, 140 S.Ct. at 2169 (2020) (Alito, J., dissenting) (citing cases); *Singleton v. Wulff*, 428 U.S. 106, 126, 96 S. Ct. 2868, 49 L.Ed.2d 826 (1976) (Powell, J., concurring) ("Our docket regularly contains cases in which women, using pseudonyms, challenge statutes that allegedly infringe their right to exercise the abortion decision."). In short, Plaintiffs meet none of the requirements for third-party standing.

B. Plaintiffs are not likely to succeed on their claim that the Act violates abortion patients' right to personal autonomy.

i. The Act does not infringe any fundamental right.

Section 1 of the Kansas Constitution Bill of Rights provides that "[a]ll men are possessed of equal and inalienable natural rights, among which are life, liberty, and the pursuit of happiness." Kan. Const. Bill of Rights, § 1. In 2019, the Kansas Supreme Court held that "[a]t the core of the natural rights of liberty and the pursuit of happiness is the right of personal autonomy, which includes the ability to control one's own body, to assert bodily integrity, and to exercise self-determination." *Hodes & Nauser, MDs, P.A. v. Schmidt*, 309 Kan. 610, 636, 440 P.3d 461 (Kan. 2019). Relying in part on *Roe v. Wade*, 410 U.S. 113, 93 S. Ct. 705, 35 L.Ed.2d 147 (1973), and in part on *Roe*-era cases from other state supreme courts, the Kansas Supreme

[2] See Center for Women's Health, *Pregnancy Termination/Abortion* at https://www.hodesnauser.com/services/procedures-services/pregnancy-termination-abortion (last visited June 28, 2023) (bold in original).

Court further held that this "right of personal autonomy" is broad enough to include a "right to decide whether to continue a pregnancy." *Hodes*, 309 Kan. at 649. It then rejected the undue burden test of *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 112 S. Ct. 2791, 120 L.Ed.2d 674 (1992), in favor of *Roe*'s strict scrutiny standard. *Hodes*, 309 Kan. at 665—66.

It is unclear whether, under *Dobbs*, *Hodes*' holding that the Kansas Constitution includes a fundamental right to abortion remains good law. 142 S. Ct. at 2242. Regardless, *Hodes* did not create an unqualified right to abortion on demand. On the contrary, "not every law which makes a right more difficult to exercise is, ipso facto, an infringement of that right" so "before a court considers whether a governmental action survives [strict scrutiny], it must be sure the action actually impairs the right." *Hodes*, 309 Kan. at 672. *Hodes* went on to find that a law prohibiting D&E abortions, the most common abortion procedure in the second trimester infringed the right. 309 Kan. 672.

Plaintiffs do not argue that the Act prevents women from exercising their right to abortion. Instead, Plaintiffs argue for strict scrutiny because the Act "targets abortion care, patients, and providers for an additional layer of intrusive regulation." (Doc. 4 at 12). But nothing in *Hodes* prevents the State from imposing commonsense regulations of abortion that do not infringe the right itself. See *Casey*, 505 U.S. at 887 (upholding 24-hour informed consent waiting period because "it cannot be classified as an interference with the right *Roe* protects"). Plaintiffs bear the burden—but have not met it—to "prove[] an infringement" of the right to personal autonomy before strict scrutiny attaches. *Hodes*, 309 Kan. At 668.

Because the Act does not prevent women from exercising their right to personal autonomy, but instead "facilitates the wise exercise of that right," it does not trigger strict scrutiny. *Casey*, 505 U.S. at 883, 887.

ii. The Act is rationally related to legitimate interests.

The State has legitimate interests in "respect for and preservation of prenatal life at all stages of development, . . . the protection of maternal health and safety[,] … the preservation of the integrity of the medical profession[,] [and] the mitigation of fetal pain." *Dobbs*, 142 S. Ct. at 2284. The Act advances each of those interests by accurately informing women about the consequences of abortion. See *Casey*, 505 U.S. at 882–83. Plaintiffs argue the Act is irrational because (1) it delays abortion when a patient is sure in her decision, (2) the font and color requirements are "absurd and arbitrary," and (3) some information must be provided more than once. (Doc. 4 at 18).

First, the legislature could have rationally concluded, like many other states, that a 24-hour informed-consent period and 30-minute reflection period would advance the State's interests in fetal life and maternal health by giving women time to fully consider the consequences of their abortion decision. Even a woman choosing abortion cannot give informed consent without being informed of the medical, physical, and psychological consequences to her and her unborn child. Ex. # Curlin Decl. ¶ 43. It is rational to conclude that a patient cannot *instantaneously* process such significant details—especially when, as Plaintiffs recognize, it is a "difficult decision."[3] With informed consent, "the State furthers the legitimate purpose of reducing the risk that a woman may elect an abortion, only to discover later, with devastating psychological consequences, that her decision was not fully informed." *Casey*, 505 U.S. at 882.

Second, the legislature could rationally conclude that the font and color requirements would make the informed-consent information easier to understand. For some people, it is easier to read information in print rather than online. And specifying that the font must be of a legible size and color is rational, because it

[3] Center for Women's Health, *Pregnancy/Abortion*, at https://www.hodesnauser.com/services/procedures-services/pregnancy-termination-abortion (last check July 5, 2023).

ensures the text is legible. These requirements are rationally related to the State's interests in protecting fetal life and women's health by facilitating an understanding of the nature of abortion and available alternatives.

Third, the legislature could rationally conclude that requiring women receive certain information both orally and in writing ensures that women receive the information in a form suited to their individual learning style. Studies show that while some people receive information best by listening, others receive information best by reading. Ex. # Curlin Decl. ¶ 44. Thus, a combination of oral and written informed-consent requirements is rationally related to the State's interest in ensuring that a woman's abortion decision is fully informed.

iii. The Act passes strict scrutiny.

Although strict scrutiny is inappropriate here, the Act passes that test because it is narrowly tailored to advance a compelling state interest.

a. Kansas has compelling interests in protecting fetal life, women's health, the integrity of the medical profession, and in preventing fetal pain.

The State has compelling interests in protecting fetal life, women's health, and the integrity of the medical profession. First, *Hodes* acknowledged that "promoting or protecting fetal life . . . ha[s] been court-recognized as [an] interest[] that may be compelling." 440 P.3d at 501. Plaintiffs rely heavily on the U.S. Supreme Court's long-discredited decisions in *City of Akron v. Akron Center for Reproductive Health*, 462 U.S. 416, 103 S. Ct. 2481, 76 L.Ed.2d 687 (1983), and *Thornburgh v. American College of Obstetricians & Gynecologists*, 476 U.S. 747, 106 S. Ct. 2169, 90 L.Ed.2d 779 (1986), to discount this interest. But *Casey* overturned *Akron* and *Thornburgh* to the extent that they prevent "the giving of truthful, nonmisleading information about the nature of the procedure, the attendant health risks and those of childbirth, and the 'probable gestational age' of the fetus." 505 U.S. at 882. It did so because those cases undervalued the State's "important interest in potential life." *Hodes* acknowledged

that "promoting or protecting fetal life and patient safety[] have been court-recognized as interests that may be compelling." 309 Kan. at 677. And it cited with approval the Iowa Supreme Court, *Planned Parenthood of the Heartland v. Reynolds*, 915 N.W.2d 206, 241 (Iowa 2018), which held that "[t]he State indeed has a compelling interest in promoting potential life and in helping people make informed choices in life." *Hodes*, 309 Kan. at 666. While the *Hodes* concurrence warned that the majority's strict-scrutiny test would bring back "[p]re-*Casey* federal strict scrutiny jurisprudence," including *Thornburgh*, 309 Kan. at 509 (Biles, J., concurring), the majority rejected this argument, clarifying that "the State is certainly free to assert any interests it believes compelling and show how S.B. 95 is narrowly tailored to those interests," 309 Kan. at 503.

Second, *Hodes* acknowledged that "promoting or protecting . . . patient safety ha[s] been court-recognized as [an] interest[] that may be compelling." 309 Kan. At 677. And Plaintiffs admit that "the State may have a compelling interest in protecting patient health." (Doc. 4 at 16).

Third, the State has a compelling interest in regulating and protecting the integrity of the medical profession. See Dobbs, 142 S. Ct. at 2284 (recognizing State's interest in "the preservation of the integrity of the medical profession"); *Gonzales*, 550 U.S. at 157 ("There can be no doubt the government 'has an interest in protecting the integrity and ethics of the medical profession.'" (quoting *Washington v. Glucksberg*, 521 U.S. 702, 731, 117 S. Ct. 2258, 138 L.ED.2d 772 (1997))). Plaintiffs do not even acknowledge this interest.

Fourth, the State has a compelling interest in "the mitigation of fetal pain." See *Dobbs*, 142 S. Ct. at 2284; see also *Comprehensive Health of Planned Parenthood of Kan. & Mid-Mo., Inc. v. Templeton*, 954 F. Supp.2d 1205, 1215–17 (D. Kan. June 30, 2013) (holding that abortion providers were not likely to prevail on the merits of claim that fetal pain provision violated strict scrutiny). It provides information about

when fetuses are able to feel pain, thereby discouraging women from having an abortion that will cause pain to their unborn child. Once again, Plaintiffs do not even mention this interest, even though the fetal pain provisions of the Act directly advance it. K.S.A. 65-6709(a)(6), 65-6710(a)(2).

b. The Act is narrowly tailored.

Plaintiffs are wrong that the Act does not advance a compelling state interest merely because "other legal and ethical standards already require health care providers to obtain informed consent," or because the Act allegedly "delay[s] time-sensitive care and interfer[es] with the provide-patient relationship." (Doc. 4 at 14–17). Neither assertion undercuts the State's valid interests.

First, even under *Roe*, courts have long held that the state may impose abortion-specific regulations because "[a]bortion is inherently different from other medical procedures, because no other procedure involves the purposeful termination of a potential life." *Harris v. McRae*, 448 U.S. 297, 325, 100 S. Ct. 2671, 65 L.Ed.2d 784 (1980). Plaintiffs argue that the Act for "is meant to 'influence' and 'persuade'" women to "'withhold [informed consent] altogether.'" (Doc. 4 at 15) (quoting *Akron*, 462 U.S. at 443–44). But a State may constitutionally "persuade" a woman "to choose childbirth over abortion" so long as it does not infringe the woman's ultimate right to make the decision. *Casey*, 505 U.S. at 878.

Moreover, the Act is consistent with medical ethics. Dr. Farr Curlin, a physician and bioethicist at the Duke University School of Medicine, notes that abortion is "ethically sui generis" because it "terminates the life of a whole, separate, unique, living, human being." Ex. 1 ¶ 13. Thus, it is reasonable for the State to discourage abortion even absent a universal consensus on fetal personhood. Ex. 1 ¶ 25.

Second, the Act's waiting periods benefit women by ensuring that they have a "sufficient opportunity to consider" their decision, Ex. 1 ¶ 44, especially important

where that decision concerns ending a human life. Ex. 1 ¶ 44. Due to the gravity, many patients will be uncertain, and some may change their minds. Ex. 1 ¶ 69. Medical interventions like abortion or physician-assisted suicide are "characteristically regulated in ways that do not apply to other interventions." Ex. 1 ¶ 49.

The Act also does not undermine the physician-patient relationship because nothing in the Act prevents the physician from telling the patient that the "physician disagrees with the state disclosures." Ex. 1 ¶ 79. And the physician can make clear that the Woman's Right to Know Act information comes from the State.

Plaintiffs rely on two long-overruled cases to argue that the Act "is 'plainly underinclusive' because there is no patient for whom all the state-mandated information is relevant." (Doc. 4 at 17) (quoting *Thornburgh*, 476 U.S. at 762). But those cases are inconsistent with the Kansas Supreme Court's recognizing compelling interests in "protecting fetal life and patient safety." *Hodes*, 309 Kan. at 678.

Regardless, it would be impossible for the State to determine in advance which patients might find relevant each particular piece of information, such as that "the father of your child is legally responsible to assist in the support of the child" or that "the law permits adoptive parents to pay the costs of prenatal care, childbirth and neonatal care." K.S.A. 65-6710(a)(3). And nothing in the Act prevents a physician from "tailor[ing] the content and timing of informed-consent conversations to patients' needs," (Doc. 4 at 17). Indeed, some provisions of the Act invite such tailoring, requiring "a description of risks related to *the proposed abortion method*" and "the probable gestational age of the unborn child *at the time the abortion is to be performed*." K.S.A. 65-6709(a)(3), (4) (emphasis added).

Second, Plaintiffs argue that the Act "is also underinclusive" because "there are patients, including obstetrical patients carrying to term, for whom some of the mandated information might be relevant." (Doc. 4 at 18). But, as explained above, the

State may regulate abortion differently than other medical procedures, see *Harris*, 448 U.S. at 325, and failure to enact permissible informed-consent laws for OB patients does not make informed consent to abortion impermissible, *Williams-Yulee v. Florida Bar*, 575 U.S. 433, 449, 135 S. Ct. 1656, 191 L.Ed.2d 570 (1955) (even under strict scrutiny, "[a] State need not address all aspects of a problem in one fell swoop; policymakers may focus on their most pressing concerns").

C. The Act does not violate free speech rights.

Informed-consent laws in the medical context are widespread and routine, and they have been consistently upheld by the U.S. Supreme Court, even under *Roe* and *Casey*. As statutes regulating professional *conduct*, laws like the Act permissibly govern health and safety, even if they incidentally sweep in speech pertinent to the regulated conduct. Plaintiffs' contrary argument should be rejected.

The Kansas Constitution provides that "all persons may freely speak, write or publish their sentiments on all subjects, being responsible for the abuse of such rights," Kan. Const. Bill of Rts., § 11, a guarantee "generally considered coextensive" with the federal First Amendment, *State v. Russell*, 227 Kan. 897, 900, 610 P.2d 1122, (Kan. 1980). It does not shield Plaintiffs from complying with statutes governing the way they practice medicine.

For starters, the Act does not regulate based on content or viewpoint but instead regulates Plaintiffs' "professional conduct, . . . [which] incidentally involves speech," *Nat'l Inst. of Fam. & Life Advocs. v. Becerra* (*NIFLA*), ___ U.S. ___, 138 S. Ct. 2361, 2372 (2018) (citing *Casey*, 505 U.S. at 884 (plurality op.).[4] These laws, like

[4] Plaintiffs argue, "Even if the [Act] is an informed-consent requirement, it fails under the standard of review applicable to regulations of conduct that incidentally burden speech." Br. at 24 (citing *United States v. O'Brien*, 391 U.S. 367, 377 (1968)). Plaintiffs' citation to *O'Brien* is unhelpful to them. *O'Brien* recognized that legislatures can "regulate conduct that may have a communicative component" as long as it does so "for reasons unrelated to the communication of ideas," *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 569 (2001) (citing *O'Brien*, 391 U.S. at 382). To the degree the Woman's Right to Know Act impacts communication, it is incidental to the Act's purpose: to ensure informed consent to medical procedures.

those in *Casey*, merely "regulate the conduct of [Plaintiffs'] profession." *Capital Associated Industries, Inc. v. Stein*, 922 F.3d 198, 207–08 (4th Cir. 2019) (using, as a specific example, informed consent for abortion procedures).

Kansas regulates professional conduct under the State's legitimate authority. As the Kansas Supreme Court has held, "[A] state has a right to regulate, through its agencies, the practice of medicine." *Corder v. Kansas Bd. of Healing Arts*, 256 Kan. 638, 654, 889 P.2d 1127 (1994). Put differently, "the practice of the healing arts is a privilege[,] [and the] State has the right to regulate, through its agencies, the practice of medicine and this authority is broad in scope." 256 Kan. at 654 (citing *Brinkley v. Hassig*, 130 Kan. 874, 879, 289 P. 64 (1930)).[5] It also has the right to "require[] that medical professionals alert patients to laws that affect medical choices." *Doe v. Rokita*, 54 F.4th 518, 520–21 (7th Cir. 2022).

The Court in *NIFLA* acknowledged that "drawing the line between speech and conduct can be difficult," but held that laws that "facilitate informed consent to a medical procedure" are conduct-based because they regulate speech "only 'as part of the practice of medicine, subject to reasonable licensing and regulation by the State.'" *EMW Women's Surgical Ctr., P.S.C. v. Beshear*, 920 F.3d 421, 432 (6th Cir. 2019) (citing *NIFLA*, 138 S. Ct. at 2373–74). Three requirements must be met for a regulation to constitute an informed-consent requirement, and thus part of the medical "conduct": (1) The regulation must be "tied to a procedure"; (2) the procedure must be "sought, offered, or performed"; and (3) the regulation must carry information about the "risks or benefits of those procedures." *NIFLA*, 138 S.Ct. at 2372–73.

Here, the provisions of the Act (1) are tied to a procedure (abortion) (2) that Plaintiffs offer or perform, and (3) provide information about the "risks and benefits" of the procedure. 138 S.Ct. at 2372–73. The State has a rational basis for imposing

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[5] The Kansas State Board of Healing Arts enforces the Woman's Right to Know Act. Kan. Stat. Ann. §§ 65-2812, 6712.

its "truthful and not misleading" disclosures, which "further the legitimate purpose of reducing the risk that a woman may elect an abortion, only to discover later, with devastating psychological consequences, that her decision was not fully informed." *Casey*, 505 U.S. at 882.

i. Brief waiting periods give a woman an opportunity to consider key information.

Whenever a woman is making this highly consequential decision, she needs time. Even Plaintiffs acknowledge as much on their website on which they caution women who "are still unsure" about getting an abortion: "do not rush to make a decision."[6] They also say, "It is helpful to talk to someone—such as your parents, a close friend, a minister or other professional counselor—in addition to your husband or boyfriend."[7] The 24-hour period gives a woman a day to consider information about the risks, consequences, and alternatives to abortion before making this momentous decision. K.S.A. 65–6709(a)–(b). It also gives her an opportunity to discuss the decision with those who know her best. And the 30-minute requirement serves a similar purpose, providing an opportunity to speak to the doctor, to ask questions, to obtain any remaining information she needs, and to fully evaluate her decision in light of that information. K.S.A. 65–6709(c).

ii. Basic information about the abortion doctor is essential to a woman's ability to assess the risks.

To facilitate informed consent, Kansas requires doctors to disclose truthful and nonmisleading professional information like prior disciplinary action, medical malpractice coverage, and residency. *See* Summary of the Facts, *supra*. This information is relevant for evaluating the physician who will perform the abortion—

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[6] Center for Women's Health, *Patient Resources*, https://www.hodesnauser.com/patient-resources#what-if-even-after-talking-to-a-provider-i-am-still-unsure (last visited on June 30, 2023).
[7] Center for Women's Health, *Pregnancy Termination/Abortion*, https://www.hodesnauser.com/services/procedures-services/pregnancy-termination-abortion (last visited on June 30, 2023).

that he is experienced, has not had his professionalism questioned, can compensate her for any injuries he inflicts, and has a connection to the area where he practices. This is essential because this information may very well demonstrate that the woman cannot and should not trust the doctor who will perform the abortion.

iii. The printing requirement ensures that women receive the relevant information in a readable format.

Plaintiffs claim that patients are burdened by the requirement that informed-consent information come on a legible printed form. (Doc. 4 at 5, 29). But the statute applies to *abortion* providers, not women, to "provide" the relevant information "in writing" "on white paper in a printed format in black ink with 12-point times new roman font." K.S.A. 65–6709(a). Although Plaintiffs apparently shift the burden onto their patients to print the form properly, (doc. 4 at 5, 17), no such requirement is found in the statute. Plaintiffs can—as the statute contemplates—provide the formatted information by mail or overnight carrier to all patients, without any inconvenience to women and regardless of whether they have access to a printer. To the degree their patients are struggling with the printing requirement, it is because Plaintiffs have placed that burden on them.

iv. The sign requirements aid informed consent.

The Act requires abortion facilities to place certain essential information on a sign where every patient can see, including information about the woman's rights, the availability of financial and other support, and the effects of mifepristone. *See* Statement of the Facts, *supra*. Abortion facilities must also put a link on their website's homepage to the State's informed consent website.

Plaintiffs rely on *NIFLA* to challenge this requirement, but they draw the wrong conclusion. (Doc. 4 at 22–23). In *NIFLA*, California required licensed pregnancy centers to post signs in their waiting rooms advertising free abortions. 138 S. Ct. at 2370. But the signs had nothing to do with informed consent, because those

centers did not provide abortions, and therefore informed consent was not necessary. 138 S. Ct. at 2373–74.

Here, the notice regards abortion and goes to the heart of informed consent: that abortion cannot be forced; and that if as an alternative a woman chooses to carry her baby to term, financial assistance is available. And unlike *NIFLA*, where the mandated signs would reach only a tiny fraction of the State's intended audience (all pregnant women), here, the Act requires notice in abortion facilities.

v. The information requirements provide an array of information facilitating informed consent.

The Act guarantees a comprehensive list of information that is available to all women. See Summary of the Facts, *supra*.[8] This works in tandem with the requirement that the woman be given the opportunity to view her baby with a sonogram and listen to the baby's heartbeat, both of which she may decline. See K.S.A. 65–6709(e)–(f), (h)–(i); see also *EMW Women's Surgical Ctr.*, 920 F.3d, 422–23 (stating, "[O]ne can hardly dispute the relevance of sonogram images for twenty-first century informed consent."). With the sonogram-offer requirement, the statute recognizes the scientific fact that a pregnant woman is carrying a human being; and that, for a mother, the very real possibility of her baby feeling pain might be a factor in her decision. See *Casey*, 505 U.S. at 882 (plurality) (stating that it cannot "be doubted that most women considering an abortion would deem the impact on the fetus relevant, if not dispositive, to the decision").

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[8] Many other states have statutes that contain similar provisions as those found in the Act. See, e.g., Ala. Code § 26-23A-4; Alaska Stat. § 18.16.060; A.R.S. § 36-2158; A.C.A. § 20-16-1703; A.C.A. § 20-16-2503; Fla. Stat. § 390.0111(3); O.C.G.A. § 31-9A-3; Idaho Code § 18-609; Burns Ind. Code Ann. § 16-34-2-1.1; Iowa Code § 146A.1; K.S.A. § 65-6709; KRS § 311.725; La. R.S. § 40:1061.16; 22 M.R.S. § 1599-A; MCLS § 333.17015; Minn. Stat. § 145.4242; Miss. Code Ann. § 41-41-33; § 188.027 R.S.Mo; 50-20-104, MCA; R.R.S. Neb. § 28-327; N.C. Gen. Stat. § 90-21.82; N.D. Cent. Code, § 14-02.1-02; ORC Ann. 2317.56; 63 Okl. St. § 1-738.2; 18 Pa.C.S. § 3205; S.C. Code Ann. § 44-41-330; S.D. Codified Laws § 34-23A-10.1; Tenn. Code Ann. § 39-15-202; Utah Code Ann. § 76-7-305; W. Va. Code § 16-2I-2; Wis. Stat. § 253.10(3).

The information is truthful, not misleading, and "relevant to a patient's decision to have an abortion, even if that information might also encourage the patient to choose childbirth over abortion." *Planned Parenthood Minn. v. Rounds*, 530 F.3d 724, 735 (8th Cir. 2008) (en banc). Contrary to Plaintiffs' claims, the language used in the statute reflects scientifically supported data.

a. It is a fact that an embryo or fetus is a human being.

The Act refers to a human embryo or fetus as an "unborn child." K.S.A. 65-6709, 65-6710. The word "fetus" is Latin for "little one" and is used by medical professionals to refer to "a developing human from usually two months after conception to birth." [Cite Curlin.] Similarly, an "embryo," is "the developing human individual from the time of implantation to the end of the eighth week after conception." [Cite Curlin.] In other words, a human fetus or embryo is, quite literally, an unborn child.

Plaintiffs argue that "unborn child" is not a medical term. (Doc. 1. ¶ 66). But the touchpoint for informed-consent disclosures is whether they are truthful and non-misleading. See *Casey*, 505 U.S. at 882. If anything, the term "unborn child" would be *easier* to understand for a lay person without specialized knowledge of embryonic and fetal development. Dr. Robin Pierucci, a practicing clinical neonatologist, notes that "[u]sing scientific jargon such as embryo or fetus obfuscates the medical fact that a human baby is being discussed." Ex. 2 ¶ 12. Indeed, Plaintiffs Hodes & Nauser, Nauser, and Fowler repeatedly use the term "baby" to describe an embryo or fetus in utero.[9]

Plaintiffs also challenge "the statement that 'the abortion will terminate the life of a whole, separate, unique, living human being.'" (Doc. 1 ¶ 64 (citing K.S.A. 65-

[9] https://www.hodesnauser.com/services/obstetrics/prenatal-care (noting that during prenatal care, Plaintiffs will "assess the baby's heart", "[a]ssess the baby's age and size," and "ensure the well-being of ... your baby throughout your pregnancy") (last visited July 5, 2023)

6709(b)(5), 65-6710(a)(2), (3))). The Act defines "human being" as "an individual living member of the species of homo sapiens, including the unborn human being during the entire embryonic and fetal ages from fertilization to full gestation." K.S.A. § 65-6709(m)(1). While Plaintiffs complain that "[t]here is no universal consensus on the philosophical and ideological question of when human life begins," (doc. 1 ¶ 67), they do not allege that these statements are medically inaccurate. Nor could they. "[F]rom the moment of sperm-egg fusion, a new human being with identifiable DNA that is different than either of the contributing parents exists." Ex. 2 ¶ 6.[10]

b. Abortion poses risks of premature birth and breast cancer.

The Act requires disclosure of "risks related to the proposed abortion method, including risk of premature birth in future pregnancies, risk of breast cancer and risks to the woman's reproductive health." K.S.A. 65-6709(a)(3). Plaintiffs object to the disclosures about premature birth and breast cancer risks.

Plaintiff Nauser states that she "spend[s] time dispelling myths like . . . the impact of a previous abortion on future preterm birth," without citing a single source explaining why the risk of premature birth is a "myth." (Doc. 3, Ex. 1 ¶ 38). But Dr. Monique Chireau Wubbenhorst, an obstetrician-gynecologist with over 20 years clinical experience who has done extensive research on women's health, testified that "[m]uch evidence indicates that abortion is associated with future preterm birth." Ex. 3 ¶ 116.

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[10] Numerous states include provisions in their informed consent statutes requiring that the woman must be informed that "the abortion will terminate the life of a whole, separate, unique, living human being"; and that "by no later than 20 weeks from fertilization, the unborn child has the physical structures necessary to experience pain." See, e.g., Ala. Code § 26-23A-4; A.R.S. § 36-2158; A.C.A. § 20-16-1703; A.C.A. § 20-16-2304; A.C.A. § 20-16-2503; Fla. Stat. § 390.0111(3); O.C.G.A. § 31-9A-3; Idaho Code § 18-609; Burns Ind. Code Ann. § 16-34-2-1.1; Iowa Code § 146A.1; K.S.A. § 65-6709; KRS § 311.725; MCLS § 333.17015; Minn. Stat. § 145.4242; Miss. Code Ann. § 41-41-33; § 188.027 R.S.Mo; 50-20-104, MCA; R.R.S. Neb. § 28-327; N.C. Gen. Stat. § 90-21.82; N.D. Cent. Code, § 14-02.1-02; ORC Ann. 2317.56; 63 Okl. St. § 1-738.2; 18 Pa.C.S. § 320; S.D. Codified Laws § 34-23A-10.1; Tenn. Code Ann. § 39-15-202; W. Va. Code § 16-2I-2; Wis. Stat. § 253.10(3).

Plaintiff Nauser also claims "[t]here is no scientific backing for . . . the increased risk of breast cancer after abortion," but once again, she cites nothing for that claim. (Doc. 3, Ex. 1 ¶ 37). On the contrary, Dr. Joel Brind, a biologist who has extensively researched the connection between abortion and breast cancer, testified that "[t]he peer-reviewed medical literature is replete with scores of studies documenting increased risk of breast cancer after abortion." (Ex. 4 ¶ 13). Dr. Nauser also ignores the specific language of Kansas's informed consent handbook, which does not state irrefutably that abortion increases the risk of breast cancer, but instead that "[t]here are . . . studies that have found an increased risk of breast cancer after abortion, but other studies have found no risk." (Ex. 5 at 26).

Dr. Brind also testified that the handbook's statements that "[i]f you have carried a pregnancy to term as a young woman, you may be less likely to get breast cancer in the future" and that "[p]regnancy and breast feeding also cause breast cells to mature in order to produce milk, and some researchers hypothesize that those cells are more resistant to cancer," (ex. 5 at 26), "have been long recognized as established by decades of research." (Ex. 4 Brind Decl. ¶ 17).

And while a panel organized by the U.S. National Cancer Institute (NCI) concluded that "[i]nduced abortion" did not have an "independent effect" on "breast cancer risk," (ex. 4 ¶ 19), "the writers of the Kansas handbook for patients did a masterful job of clarifying the findings of the NCI panel so that it actually produces useful information to women." (Ex. 4 ¶ 20).

c. A child may feel pain at 20 weeks' gestation.

The Act also requires informing the woman that "by no later than 20 weeks fertilization, the unborn child has the physical structures necessary to experience pain." K.S.A. 65-6709(a)(6). The disclosure further explains that "[t]here is evidence that by 20 weeks from fertilization unborn children seek to evade certain stimuli in a manner that in an infant or adult would be interpreted to be a response to pain"

and that "[a]nesthesia is routinely administered to unborn children who are 20 weeks from fertilization or older who undergo prenatal surgery." K.S.A. 65-6709(a)(6).

Plaintiffs' expert Dr. Alsaden states that "there is a consensus in the medical community . . . that it is not possible for a fetus to feel pain before at least 24 weeks LMP." (Doc. 3, Ex. 2 ¶ 58). 24 weeks LMP is 22 weeks after fertilization. Dr. Maureen L. Condic, a neurobiologist who has done extensive research on fetal pain, testified that that a fetus evades painful stimuli as early as eight weeks post-fertilization. (Ex. 6 ¶ 24). And as the Act states, anesthesia is routinely administered to fetuses less than 20-weeks old. (Ex. 6 ¶¶ 30, 34).

Dr. Pierucci testified that she has personally witnessed a fetus at 22-weeks LMP (20-weeks post-fertilization) make faces that "in response to an indisputably painful injections" that would be interpreted "in older human beings" as "consistent with responding to uncomfortable, undesirable, or distinctly painful stimulations." (Ex. 2. ¶¶ 55, 56). And a fetus has the physical structures necessary to experience pain even earlier. "[T]he first evidence for an intact nociceptive system," which is "the nervous system's processing of noxious stimuli," "emerges at about 8 weeks." (Ex. 2 ¶ 28). Plaintiffs have not provided "objective scientific evidence" to rebut Dr. Pierucci. And because, "at this point in the litigation, [this] is an unresolved question of fact, plaintiffs have not made a substantial showing of a substantial likelihood of success on the merits with regard to the fetal pain requirement." *Comprehensive Health of Planned Parenthood of Kan. and Mo. v. Templeton*, 954 F. Supp. 2d 1205, 1217 (D. Kan. 2013).

d. A fetal heartbeat is a key indicator of viability.

The Act requires disclosing "that less than 5% of all natural pregnancies end in spontaneous miscarriage after detection of cardiac activity, and a fetal heartbeat is, therefore, a key medical indicator that an unborn child is likely to achieve the capacity for live birth." K.S.A. 65-6710(a)(2). Dr. Alsaden claims this statement "is

factually incorrect" because "[t]he overall risk of miscarriage may be as high as 26 percent of all pregnancies." (Doc. 3, Ex. 2 ¶ 60). But the statement does not refer to "all pregnancies"—only those in which a fetal heartbeat has been detected. The rate of miscarriage after detection of a fetal heartbeat is only 3%. [Cite Dr. Wubbenhorst]. And while "[t]he risk of miscarriage is based on a number of patient-specific variables," (doc. 3, Ex. 2 ¶ 60), the absence of a heartbeat after about 7-weeks' gestation is clear evidence that the unborn child is not viable. [Cite Dr. Wubbenhorst.]

e. The information about embryonic and fetal development is truthful, relevant, and not misleading.

The Act requires disclosing information on fetal development, including specific weekly milestones. KSA. 65-6710(a)(3). Plaintiff Nauser claims that "[e]xperts in human anatomy who examined the state-published printed materials in 2013 found that over 40 percent of its statements on embryonic and fetal development were medically inaccurate." (Doc. 3, Ex. 1 ¶ 37). In support of that proposition, she cites a website called the "Informed Consent Project." But that website neither discloses the identity of its "experts" nor identifies which specific statements its "experts" believe are "scientifically incorrect or misleading," or why.[11] Nor do Plaintiffs. Regardless, Dr. Mulcaire-Jones testified that "[t]here are no inaccuracies" in the handbook's "present[ation of] the anatomic, physiological, and behavioral features present at successive gestational ages." [Mulcaire-Jones cite].

f. The information about mifepristone-effects reversal is truthful, relevant, and not misleading.

The 2023 Amendment requires performing physicians to inform women, in writing, that "it may be possible to reverse the intended effects of a medication abortion that uses mifepristone, if the woman changes her mind, but that time is of

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[11] Informed Consent Project, Kansas, https://informedconsentproject.com/states/kansas/. (last visited . . .)

the essence," and that "information on reversing the effects of a medication abortion that uses mifepristone is available on the department of health and environment's website . . . and other relevant telephone and internet resources containing information on where the patient can obtain timely assistance to attempt to reverse the medication abortion." L. 2023 Ch. 88, § 1(c)(1).

Plaintiffs' experts claim that "[t]here is no medically acceptable or reliable evidence proving that progesterone can reverse the effects of any abortion-inducing drugs, including mifepristone." (Doc. 3, Ex. 1 ¶¶ 49–56); (Doc. 3, Ex. 2 ¶¶ 51–56); (Doc. 3, Ex. 4 ¶¶ 26, 35). On the contrary, Dr. Jonathan Scrafford, a Kansas obstetrician-gynecologist and abortion pill reversal (APR) provider, testified that "[t]he best available clinical research demonstrates that using progesterone to counter the effects of mifepristone and to stop the medication abortion process is safe and effective." (Ex. 8 ¶ 9). "As of 2022, "the APR protocol has been used in all 50 states and in 86 countries and data indicates that it has resulted in over 4,000 lives being saved from the fatal effects of medication abortion on the living human fetus." (Ex. 8 ¶ 8). And Dr. Scrafford has personally administered APR to three women who went on to deliver healthy babies. (Ex. 8 ¶ 11).

Plaintiffs' own expert acknowledges that mifepristone and progesterone have an antagonistic relationship, one offsetting the other. (Doc. 3, Ex. 2 ¶ 17). Regardless, "[m]edical uncertainty does not foreclose the exercise of legislative power in the abortion context." *Gonzalez*, 550 U.S. at 164. Plaintiffs' appeal to a purported medical consensus is unavailing: The U.S. Supreme Court has upheld "abortion regulations that were directly contrary to alleged medical-profession custom and that certain medical groups did not consider to be necessary." *EMW Women's Surgical Ctr.*, 920 F.3d at 438 (citing cases). These include the informed-consent requirements in *Casey*, which were a "substantial departure from the ordinary medical requirements of

informed consent." 920 F.3d at 438.[12] The question is "whether the mandated disclosures are truthful, non-misleading, and relevant to the medical procedure—and not necessarily whether the law is consistent with medical-profession custom or views of certain medical groups." 920 F.3d at 439.

Plaintiffs' proffered experts never directly or specifically identify any provision of the Act that is untruthful, misleading, or irrelevant to the abortion procedure—let alone establish it to a level of medical certainty. Rather, Plaintiffs' egregious request of this Court—on a motion for extraordinary relief and in the face of portions of the Act being in effect for more than two decades—"would essentially be concluding that women must be shielded and protected from this . . . information, that women are unable to or should not be required to process it." 920 F.3d at 444. Simply because "this information might persuade a woman to change her mind does not render it suspect under the First Amendment. It just means that it is pertinent to her decision-making." 920 F.3d at 430.

All the Act requires of Plaintiffs is giving patients the full benefit of informed consent, furthering "the legitimate purpose of reducing the risk that a woman may elect an abortion, only to discover later, with devastating psychological consequences, that her decision was not fully informed." *Casey*, 505 U.S. at 882. Given the gravity of the woman's choice, she is entitled to "truthful, non-misleading, and relevant information aimed at informing a patient about her decision to abort unborn life" as a basic matter of health, safety, and welfare. *EMW Women's Surgical Ctr.*, 920 F.3d at 432 (citing *Casey*, 505 U.S. at 882–84; *Tex. Med. Providers Performing Abortion Servs. v. Lakey*, 667 F.3d 570, 577–78 (5th Cir. 2012)). The State of Kansas is squarely within its authority to protect its citizens in this way.

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[12] As for Plaintiffs' appeal to the expertise of the American College of Obstetricians and Gynecologists ("ACOG"), (doc. 4 at 8), the Supreme Court has accepted the validity of opinions that contradicted ACOG—twice. See *EMW Women's Surgical Ctr.*, 920 F.3d at 438 (citing *Casey*, 505 U.S. at 884); see also *Gonzalez*, 550 U.S. at 180 (Ginsberg, J., dissenting).

D. The Woman's Right to Know Act does not include unconstitutionally vague language.

Plaintiffs' vagueness challenge attacks a provision that has yet to be promulgated by the Kansas Department of Health and Environment ("KDHE"). (Doc. 4 at 25) (citing L. 2023 Ch. 88, § 1(b)(1), (e)). Their argument is premature. The State has agreed not to enforce this provision until, as the Act directs, KDHE provides the specific content, 90 days after its effective date. (See Doc. 32). And until KDHE has specified the "other relevant telephone and internet resources containing information on where the patient can obtain timely assistance to attempt to reverse the medication abortion," Plaintiffs cannot adequately allege that the to-be-determined terms are vague. See generally *Texas v. United States*, 523 U.S. 296, 300, 118 S.Ct. 1257, 1259, 140 L.Ed.2d 406 (1998) ("A claim is not ripe for adjudication if it rests upon " 'contingent future events that may not occur as anticipated, or indeed may not occur at all.") (cleaned up).

II. There is not a reasonable probability that Plaintiffs will suffer irreparable injury without an injunction.

If Plaintiffs are going to make a case for suffering irreparable injury without an injunction, they have a lot of explaining to do. The Woman's Right to Know Act became law in 1997 and has since been amended five times. All Plaintiffs concede they have complied with the Act for years. (Doc. 3, Ex. 1 ¶ 23); (Doc. 3, Ex. 2 ¶ 37). Their ability to comply with the Act for decades and their delay in bringing this suit foreclose emergency relief here.

At the outset and as explained above, the challenged provisions do not infringe Plaintiffs' or their patients' constitutional rights. As a result, Plaintiffs' near-absolute reliance on cases finding irreparable harm from ongoing constitutional violations are inapropos. Plaintiffs are not entitled to emergency relief because they cannot show irreparable harm from provisions of law they have uncomplainingly complied with for decades.

"A delay in seeking a preliminary injunction of *even only a few months*—though not necessarily fatal—militates against a finding of irreparable harm." *Wreal, LLC*, 840 F.3d at 1248 (emphasis added). And a temporary injunction cannot be used to remedy past injury. *Wichita Wire, Inc. v. Lenox*, 11 Kan. App. 2d 459, 464, 726 P.2d 287 (1986). Accordingly, "[a] long delay by plaintiff after learning of the threatened harm [] may be taken as an indication that the harm would not be serious enough to justify a preliminary injunction." 11A Wright & Miller, Federal Practice and Procedure: Civil § 2948.1 (2013).

Here, Plaintiffs have offered no explanation why they cannot continue to comply with existing law. The State is not beholden to reflect the decisions made by other state legislatures in response to *Dobbs*, (doc. 4 at 29), much less respond to what Plaintiffs have deemed to be an emergency.

Further, Plaintiffs have sat on these claims. An injunction is an equitable remedy that requires Plaintiffs to have exercised reasonable diligence. "Courts of equity require that persons shall themselves exercise reasonable diligence in the protection of their rights, and that they shall not depend slothfully upon the action of courts of equity." *Noble v. Butler*, 25 Kan. 645, 651 (1881); accord *Tr. Women Found. Inc. v. Bennett*, 509 P.3d 599 (Kan. Ct. App. 2022). Plaintiffs have not acted diligently here—all but one of the informed consent provisions they target have been in effect between 6 and 26 years. In the event the Court finds any provision to be unconstitutional, the statute contains a severability provision. L. 2023 Ch. 88, § 1(j).

III. Plaintiffs have an adequate legal remedy.

Plaintiffs do not argue that they lack an adequate remedy at law which dooms their emergency application for relief. To justify emergency relief, Plaintiffs are required to demonstrate "the lack of an adequate legal remedy." *Downtown Bar & Grill, LLC v. State*, 294 Kan. 188, 191, 273 P.3d 709, 713 (2012). Plaintiffs' failure to even argue this point demonstrates that their complaints can be adequately

addressed through the normal course of litigation and bars the extraordinary relief they request.

IV. The balance of harms greatly favors the State of Kansas and is in the public interest.

Enjoining the Act's informed-consent provisions—even temporarily—will cause immediate and obvious harm to the State: its ability to regulate licensed medical conduct will be handcuffed, its citizens' policy preferences on health and safety through duly enacted legislation will be blocked, and its people—especially pregnant women in Kansas—will be deprived of critical information before undergoing the life-altering decision to have an abortion.

If this Court enjoins state law that has long existed to protect pregnant women in Kansas, it will leave self-interested and financially motivated abortion providers like Plaintiffs as the gatekeepers of the information for women considering abortion. But Plaintiffs want to withhold the essential information guaranteed by the Woman's Right to Know Act, as well as even a brief time for the woman to ensure she is decided. (Doc. 4 at 15, 17–18, 23–24).

Given that Plaintiffs complain about being required to discuss the procedure and its risks with patients themselves rather than through a surrogate and lament an even 30-minute delay in getting as many women through their doors as quickly as possible, (doc. 4 at 15, 17–18, 23–24), there is every reason to think patients will be rushed towards a decision to abort their child. Pregnant women will be deprived of the crucial information they are currently guaranteed by the Woman's Right to Know Act.

Plaintiffs say they are protecting "patient autonomy," (doc. 4 at 30), and yet the purpose of their lawsuit is to deprive patients of information. As the Supreme Court observed in *NIFLA*, "in the fields of medicine and public health . . . information

can save lives." 138 S. Ct. at 2374 (internal quotation marks omitted) (quoting *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 566, 131 S. Ct. 2653, 180 L.Ed.2d 544 (2011)).

Plaintiffs do not allege *any* fact indicating harm to pregnant women that will result during the litigation of laws that have largely been in place for years—they only cite their concerns with the *new* provision. Indeed, Plaintiffs identify no public interest or harm from informing a woman that she may be able to reverse an abortion. (Doc. 4 at 30). Instead, in the event a woman "report[s] feeling angry, sad, or guilty," after an abortion, the facility will merely give a referral to a counselor or support group.[13] But what they will not do is provide the full range of information to a woman, including that it may be possible to reverse the abortion and save her child's life. In the years to follow, the woman may very well learn the full range of information she should have learned from the abortionist when she came for her appointment. These harms cannot be undone, and the Act currently guards against them.

For much the same reason, it is in the public interest to allow the Woman's Right to Know Act to remain in effect. Otherwise, pregnant women in Kansas will be deprived of the information they need to make an informed choice about abortion. And the State will be deprived of its interest in enforcing democratically enacted laws designed to protect the health, welfare, and safety of its citizens, and its authority to preserve the integrity of the medical profession. Even where a right to abortion exists, the public interest warrants informed-consent disclosures to further a state's "profound interest in potential life" and "to persuade the woman to choose childbirth over abortion." *Casey*, 505 U.S. at 878. The State should therefore be allowed to continue protecting women's right to be fully informed when considering the life-altering decision to abort their child, while this litigation proceeds.

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[13] See Center for Women's Health, *Pregnancy Termination/Abortion*, https://www.hodesnauser.com/services/procedures-services/pregnancy-termination-abortion (last visited, June 29, 2023).

CONCLUSION

For the foregoing reasons, Defendants Attorney General Kobach and District Attorneys Steven M. Howe, Marc Bennett, and Mark A. Dupree Sr. respectfully request that the Court deny Plaintiffs' requests for a temporary restraining order and/or temporary injunction.

Respectfully submitted this 7th day of July, 2023.

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This is the certify that on this 7th day of July, 2023, I filed the above and foregoing with the Clerk of the Court, and served electronically to all counsel of record:

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EXHIBIT # 1

IN THE DISTRICT OF JOHNSON COUNTY, KANSAS
CIVIL COURT DEPARTMENT

HODES & NAUSER, MDs, P.A., on behalf of itself, its patients, physicians, and staff; TRACI LYNN NAUSER, M.D.; TRISTAN FOWLER, D.O.; and COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, on behalf of itself and its patients, physicians, and staff, Plaintiffs, v. KRIS KOBACH, in his official capacity as Attorney General of the State of Kansas; STEPHEN M. HOWE, in his official capacity as District Attorney for Johnson County; MARCH BENNETT, in his official capacity as District Attorney for Sedgwick County; SUSAN GILE, in her official capacity as Executive Director of the Kansas Board of Health Arts; and RONALD M. VARNER, D.O., in his official capacity as President of the Kansas Board of Healing Arts, Defendants.	)	Case No. 23CV03140 Division No. 12 K.S.A. Chapter 60

EXPERT DECLARATION OF FARR A. CURLIN, M.D.

I, Farr A. Curlin, M.D., pursuant to the provisions of Kan. Stat. Ann. § 53-601, do hereby declare as follows:

1. I am of at least 18 years of age, and I am competent to testify.

I. PROFESSIONAL BACKGROUND

2. I am the Josiah C. Trent Professor of Medical Humanities in the Trent Center for Bioethics, Humanities, and History of Medicine, and Professor in the Department of Medicine, at Duke University. I am also Co-Director of the Theology, Medicine, and Culture Initiative at Duke Divinity School and Senior Fellow in Duke University's Kenan Institute for Ethics. Prior to joining the Duke University faculty in 2014, I served on the faculty of the University of Chicago.

3. I am licensed to practice medicine and maintain medical licensure in the State of North Carolina. I am a general internist with board certification in Internal Medicine, as well as subspecialty board certification in Hospice and Palliative Medicine. From 2001 to 2013, I practiced general internal medicine, maintaining an outpatient primary care clinic from 2001 to 2008, and attending on the inpatient wards at the University of Chicago Hospitals from 2003 until I moved to Duke University at the end of 2013. Since January 2014, I have served as a palliative medicine consultant and hospice physician at Duke University.

4. I completed a fellowship in clinical medical ethics at the University of Chicago, and I have served on the medical ethics faculties of the University of Chicago and Duke University for 19 years, providing clinical ethics consultations (at the University of Chicago), attending regular ethics case conferences, teaching medical ethics, and completing research studies and other scholarly work regarding medical ethics. In addition, I was named to the Greenwall Foundation Faculty Scholars Program in Bioethics, through which, over the subsequent decade, I met numerous times with a community of leading scholars in bioethics.

5. My work on medical ethics has included peer-reviewed publications, invitations to lecture at universities nationwide and internationally, and being asked to speak as an expert before national advisory bodies and to serve as an expert witness regarding medical ethics questions at stake in litigation. I have received awards in bioethics. My training, research, and experience give me familiarity with professional ethical norms regarding both clinical medicine and research, as well as the application of those norms to particular scenarios, including the scenarios at issue in the present litigation.

6. In addition, I completed a 2-year postdoctoral fellowship in health services research at the University of Chicago, and I have spent a substantial portion of my time since then conducting and publishing empirical research, including research on physicians' attitudes and practices regarding abortion. This training and experience give me added expertise in interpreting and applying scientific data to clinical contexts.

7. This report presents my independent, expert opinions based on my study, training, and experience as a physician, bioethicist, and health services researcher; my review of relevant scholarly literature; and my discussions over the years with colleagues in medicine and bioethics. I do not speak herein for Duke University, nor is the affidavit intended to represent the opinions or policies of Duke University.

8. My most recent curriculum vitae, which lists my publications, is attached to this report as exhibit A.

9. As part of my preparation of this report, I have reviewed the following materials related to this action:

a) Petition filed by the Plaintiffs June 6, 2023 ("Complaint")

b) Stamped Motion for Temporary Injunction ("Motion for TI")

c) House Bill No. 2264 ("HB 2264")

d) K.S.A. 65-6709

e) K.S.A. 65-6710

f) Declaration of Dr. Traci Nauser

g) Declaration of Dr. Iman Alsaden

h) Declaration of Nadia Sawicki

i) Declaration of Dr. Matthew Wynia

j) The references cited below in my report

10. I have been asked to provide an analysis of the current dispute with respect to biomedical ethics,[1] because the Plaintiffs allege that what the Kansas statutes require contradicts medical ethics norms regarding bodily integrity, autonomy, and informed consent.[2] What follows reflects my expert opinions regarding this case.

II. SUMMARY OF OPINIONS

11. The statutes require providing the woman considering abortion more information than the state requires for other interventions, but this difference is not arbitrary. Rather, the difference reflects the unique characteristics of abortion, and particularly the fact that it involves killing another human being. This fact, which has made abortion enduringly controversial and ethically problematic, gives the state a rational basis for discouraging abortion and for making sure a woman has every opportunity to consider what is at stake in abortion before consenting to it. The Plaintiffs' allegations about violating medical ethics depend on ignoring the fetus and any regard owed to it, but medical ethics does not countenance ignoring the human beings directly affected by an action. In light of what abortion does, the disclosures mandated by the statutes provide factual and relevant information that the Plaintiffs otherwise would withhold.

12. Contrary to the Plaintiffs' claims, it is demonstrably true that mifepristone "alone is not always effective in ending a pregnancy" and that "[i]t may be possible to reverse its intended effect if the second pill or tablet has not been taken or administered." The truth of these statements is made plain by the studies relied

[1] The term "biomedical ethics" lexically bridges *bioethics* (the broader category—the ethics of actions involving biological research and the application of its findings, including medicine) and *medical ethics* (the ethics of medicine). I am an expert in each of these categories, and my analysis in this report does not depend on any distinctions between these terms.

[2] *See, e.g.*, Compl. ¶¶ 107, 108, 115.

on by the Plaintiffs, when those studies are described and interpreted fairly.[3] This information is especially relevant to any woman who has taken mifepristone and then regrets her decision and wishes to avoid completing the abortion. Without the statutes, a woman who regrets her abortion will not be able to consider all of the legitimate options a reasonable person in her situation would want to know. She might even mistakenly take misoprostol that not only carries its own adverse side effects but also, in such circumstance, is directly contraindicated—potentially killing the fetus she now hopes will live.

III. OPINIONS

The state's informed consent requirements for abortion are not arbitrary.[4]

13. It is true that the state requires more information be provided regarding abortion than it requires for other interventions, and if abortion were like other interventions in all relevant respects, such requirement would be arbitrary. Elective abortion, however, is unlike any other intervention offered by medical professionals, insofar as it appears to involve intentionally killing another (albeit small) human being. This unique characteristic of abortion gives the state a rational basis for requiring more information be provided.

14. The Plaintiffs completely ignore the central ethical problem of abortion. They never mention the effects of abortion on the fetus, and they never acknowledge the reasons given by the many otherwise reasonable persons (including the representatives of the people of Kansas), both historically and in the present, who have concluded that abortion involves unjustified killing.

15. It is malpractice for a trained medical ethicist like Dr. Wynia to advance claims *as an ethicist* while ignoring the well-known (to any moderately educated person, and all the more to any ethicist) counterfactuals and arguments that, if valid, contradict his claims.[5] Dr. Wynia and Ms. Nawicki both proceed as if they are unaware that abortion might be ethically problematic. The Plaintiffs could have acknowledged why many ethicists and laypersons alike conclude that abortion is unjust to the fetus. They then could explain why they believe this conclusion is based on faulty premises or invalid arguments. They could make a case that regard for the fetus is trumped or outweighed by other factors, such as concern for women's autonomy. Instead, the Plaintiffs ignore the fetus entirely, suggesting a tacit

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[3] Including the following "Advocacy" report and the reports cited by it: Am. Coll. Obstetricians & Gynecologists, Facts Are Important: Medication Abortion "Reversal" Is Not Supported By Science, https://www.acog.org/advocacy/facts-are-important/medication-abortion-reversal-is-not-supported-byscience (last visited July 3, 2023).

[4] Despite the Plaintiffs repeatedly alleging so. *See, e.g.*, Compl. ¶124.

[5] To give just one painfully ironic example, Dr. Wynia invokes the Hippocratic principle, *do no harm*, but he ignores entirely the centuries of consensus that abortion contradicts this principle.

acknowledgement that their claims cannot stand once the relevant counterfactuals and arguments are in view.

16. Because they ignore the obvious, I will outline here at the outset why so many find elective abortion ethically problematic. I then will consider the Plaintiffs' claims in the light of these ethically relevant characteristics of abortion.

17. As reflected in the law, abortion has long been regarded as ethically problematic. In the *Dobbs* decision, the U.S. Supreme Court noted that, "At common law, abortion was criminal in at least some stages of pregnancy and was regarded as unlawful and could have very serious consequences at all stages," and that until *Roe v. Wade*, most U.S. states likewise had laws prohibiting abortion except in narrow circumstances.[6] These laws reflect centuries of ethical consensus that abortion contradicts a universal norm—*do not kill the innocent.* This norm is a starting point for further ethical reasoning, so foundational that not even those who advocate for abortion challenge it.

18. It is an uncontroversial scientific holding that an organism is: "a living thing that has an organized structure, can react to stimuli, reproduce, grow, adapt, and maintain homeostasis."[7] In their popular biology textbook, Miller and Levine write, "Every organism has a particular pattern of growth and development. During development, a single fertilized egg divides again and again. As these cells divide, they differentiate, which means they begin to look different from one another and to perform different functions."[8] All human organisms began in this way.

19. Moore and Persaud, in their embryology textbook state what is again established science:

> Human development begins at fertilization when a male gamete or sperm (spermatozoon) unites with a female gamete or oocyte (ovum) to produce a single cell—a zygote. This highly specialized, totipotent cell marked the beginning of each of us as a unique individual …. The unicellular zygote divides many times and becomes progressively transformed into a multicellular human being through cell division, migration, growth, and differentiation.[9]

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[6] *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228, 2248 (2022).

[7] Organism. (n.d.) In *Biology online dictionary*. Retrieved from https://www.biology-online.org/dictionary/Organism (last visited July 3, 2023).

[8] Miller KR, Levine JS. *Miller & Levine biology, Student Edition*. Boston, MA: Pearson; 2010:18.

[9] Moore KL, Persaud TVN. *The developing human: Clinically oriented embryology* (7th ed.). New York: Saunders; 2003:16.

20. As for humans, scientifically speaking, "organism" and "being" are used interchangeably, as being implies *existence* (a human *being* is a human that exists),[10] and humans exist as organisms. In this respect, in defining a human being as "an individual living member of the species homo sapiens, including the unborn human being during the entire embryonic and fetal ages from fertilization to full gestation", and in affirming that "abortion will terminate the life of a whole, separate, unique, living human being,"[11] the statutes point to simple facts of human biology and embryology.[12]

21. The Plaintiffs allege that it is problematic for the state to refer to the fetus as the "unborn child," because the latter "is not a medical term."[13] If by "medical term" the Plaintiffs mean terms that are specific to medicine, then thankfully, good physicians do not limit themselves to medical terms when talking to patients. If they did, it would be hard to foster understanding necessary for the patient to give informed consent. Indeed, we physicians are taught to communicate to patients using the most plain, everyday language possible. Moreover, medical practitioners depend on all kinds of terms that are not specific to medicine, including child, offspring, unborn, harm, ethics, informed consent, risk, benefit, and countless more.

22. Even *fetus* and *embryo* are terms that are not specific to medicine. The Oxford English Dictionary defines fetus as "the offspring of a human or other animal during its development within the uterus or egg" and defines *embryo* as "[t]he unborn human offspring, esp. during the early stages of development."[14] As a matter of convention, medical practitioners usually use the term *embryo* to refer to the developing human being through the 8th week of pregnancy and use *fetus* thereafter. Both terms refer to the offspring of the pregnant woman, a synonym for which is *child,* as the phrase "with child" indicates, referring to the state of being pregnant). As such, the human embryo or human fetus is literally an unborn child.

23. Moreover, when pregnant women see their doctors in any context other than abortion, few doctors will talk about the woman's "fetus", much less refer to the fetus as the "pregnancy." Rather, they talk about the woman's "baby" or "child." A

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[10] See: https://www.merriam-webster.com/dictionary/being?utm_campaign=sd&utm_medium=serp&utm_source=jsonld.

[11] 2011 Kansas Laws Ch. 44 (H.B. 2035).

[12] The advent of technologies such as 3D ultrasound images of the fetus has made this fact even harder to ignore. Dr. Wynia wonders how the fetus can be described as "separate" from the pregnant woman. But "separate" does not mean "separated". For example, twins are separate organisms long before they are separated. That fetuses and their mothers are separate organisms long before they are separated is another fact of human biology—nowhere disputed by embryologists.

[13] Compl. ¶¶ 66–67.

[14] Oxford English Dictionary, available by subscription at: www.oed.com. (last visited July 3, 2023).

quick search indicates leading medical institutions, including the Mayo Clinic and Johns Hopkins Medicine, follow this ordinary pattern of human language in their patient-facing materials.[15] The language of "unborn child" is straightforward, accurate, and commonsense. Note the Plaintiffs make no argument to show that the fetus is *not* the child of the woman, much less that the fetus is other than unborn.

24. The Plaintiffs rely on the "ACOG Guide to Language and Abortion,"[16] which allegedly is "designed to help inform language choice for those writing about reproductive health to use language that is medically appropriate, clinically accurate, and without bias." In my professional judgment, the ACOG guide is an Orwellian attempt to discredit plain language when plain language exposes facts ACOG apparently does not want exposed. The report is anything but "without bias." For example, it alleges that the term "chemical abortion" should not be used, because "[t]his is a biased term designed to make medication abortion sound scarier than the safe, effective medical intervention it is." In fact, ACOG's preferred term, "medication abortion" is an obvious euphemism (for that reason I put the term in quotes throughout my report). In the case of abortion, the drugs mifepristone and misoprostol act not as medications—they are not intended to preserve or restore health—but instead to disrupt the healthy functioning of the woman's reproductive system. ACOG likewise alleges that the term "dismemberment" is an inflammatory way of referring to the "disarticulation" that occurs with D&E abortion, despite the fact that what happens in such abortion is literally dismemberment and not merely disarticulation. ACOG goes on to allege that clinicians should not refer to "elective abortion" because the motivation for an abortion "should not be judged." All of this smacks of the "newspeak" in George Orwell's novel, *1984*, where the dystopian regime forbids people from using plain language to speak the truth, instead requiring euphemisms that hide reality.

25. The Plaintiffs allege that the state-mandated statements about the fetus are invalid, because "there is no universal consensus on the moral status of a pregnancy,"[17] but the statements say nothing about *moral status*, which is a moral rather than scientific concept. (I address this concept and its twin, *personhood*, below.) By the same illogic, the Plaintiffs might seek to rebut the claim that abortion kills a fetus by saying that there is no consensus regarding *citizenship*. To make a reasonable judgment regarding moral status or personhood or citizenship, one begins

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[15] Johns Hopkins Medicine defines fetus as "An unborn baby from the 8th week after fertilization until birth." (https://www.hopkinsmedicine.org/health/wellness-and-prevention/anatomy-fetus-in-utero). The Mayo Clinic refers repeatedly to the embryo and fetus as "your baby." (https://www.mayoclinic.org/healthy-lifestyle/pregnancy-week-by-week/in-depth/prenatal-care/art-20045302) (last visited July 3, 2023).

[16] Am. Coll. Obstetricians & Gynecologists, ACOG Guide to Language and Abortion, https://www.acog.org/contact/media-center/abortion-language-guide (last visited July 4, 2023).

[17] Compl. ¶ 121.

with the scientific facts, including the fact that the fetus is a human organism, a human being.[18]

26. Some people do argue that although a human being, the human fetus is not yet a *person*, where achieving *personhood* marks a point at which what formerly was a mere human being (which may be killed) obtains sufficient "moral status" to have a claim against being killed.

27. What changes a mere human being into a *person* with moral status? In an essay published more than thirty years ago titled, "Personhood in the Bioethics Literature,"[19] philosopher and bioethicist Ruth Macklin (who does not oppose abortion) observed that the literature on personhood already was "enormous" and that proposals for the criteria of personhood varied widely, from simply being a human being (one conceived by human parents), to having detectable brain waves of the sort a six-week-old fetus has, to displaying an array of reasoning and choosing capacities that early fetuses lack but which also are lacked by many patients with dementia, brain injuries, or cognitive disabilities.

28. As Macklin demonstrates in some detail, "personhood" is not a scientific concept, nor even a descriptive one, but instead an evaluative concept. Macklin further notes that the great majority of efforts to define personhood have occurred within debates about abortion, where those who support abortion justify it by defining personhood in such a way that fetuses do not have it.[20]

29. In their textbook, *The Principles of Biomedical Ethics*, Beauchamp and Childress describe five different and incompatible bioethical theories of *moral status*,[21] and they note that appeals to moral status have been used repeatedly over history to justify discrimination against vulnerable groups:

> The worry today is that some groups, especially vulnerable groups, may still be in a discriminatory social situation: They fail to satisfy criteria of moral status precisely because the dominant criteria have been tailored specifically to deny them partial or full moral status. Discussion in biomedical ethics has focused principally, though not exclusively, on whether the following are vulnerable groups of this description: *human embryos, human fetuses*,

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[18] There is universal consensus among embryologists and biologists on this point.

[19] Macklin R. Personhood in the bioethics literature. *The Milbank Memorial Fund Quarterly. Health and Society*. 1963;61(1): 35-57.

[20] Macklin, R. (1983). Personhood in the bioethics literature. *The Milbank Memorial Fund Quarterly. Health and Society*, *61*(1), 35-57. doi: 10.2307/3349815.

[21] Beauchamp, T. L., & Childress, J. F. (2012). *Principles of biomedical ethics* (7th ed.). New York: Oxford University Press. See pages 62–100.

anencephalic children, research animals, and individuals in a persistent vegetative state.[22]

30. Two conclusions follow from all of the above: First, regardless of the "moral status" of the fetus, it remains true that "abortion will terminate the life of a whole, separate, unique, living human being." The ethical principle of informed consent supports disclosing this fact. Second, unless it can be shown that fetuses differ from other human beings in ways that justify doing to them what we would not tolerate being done to any other class of human beings, then abortion appears to involve invidious discrimination leading to unequal treatment with respect to a human right of bodily integrity. The Plaintiffs have not alleged much less argued for any differences that would justify treating one class of human beings in this way.

31. Apart from the general ethical problems with abortion, the weight of medical tradition has long seen abortion as incompatible with medicine, because it seems not only to involve killing the innocent but also to involve physicians directly contradicting their professional obligation to heal only and never (intentionally) to harm. For more than two millennia, there was medical consensus that the commitment to do no harm, often referred to now as the *principle of nonmaleficence*, includes refusing to cause an abortion: From the Hippocratic reform movement in ancient Greece until shifts in some quarters starting in the 1960s, medical oaths and codes consistently condemned elective abortion as contradicting physicians' constitutive professional commitment to never intentionally damage or destroy the health of another. The ancient Hippocratic Oath states, "I will not give to a woman an abortive remedy."[23] The World Medical Association's Declaration of Geneva, adopted in 1948 in response to corrupt uses of medicine during the Second World War, includes the promise, "I will maintain the utmost respect for human life, from the time of conception, even under threat."[24]

32. It is true that today several prominent medical professional organizations either have a policy of neutrality toward abortion or claim, as the American College of Obstetricians and Gynecologists (ACOG) does, that abortion is an essential part of healthcare. Such policies, however, mask persistent opposition to abortion among a

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[22] Beauchamp, T. L., & Childress, J. F. (2012). *Principles of biomedical ethics* (7th ed.). New York: Oxford University Press. See page 79. Emphasis added.

[23] Edelstein L. The Hippocratic Oath: Text, translation and interpretation. In Temkin O, Temkin CL, eds. *Ancient Medicine*. Baltimore: Johns Hopkins University Press; 1967: 3-63, reprinted in Lysaught MT et al, eds. *On Moral Medicine, 3rd edition*. Grand Rapids: Eerdmans; 2013: 223.

[24] As abortion became more widely practiced, the phrase "from the time of conception" was changed to "from its beginning" and then dropped. See Declaration of Geneva, original version (Declaration of Geneva. Adopted by the 2nd General Assembly of the World Medical Association, Geneva, Switzerland, September 1948) as well as subsequent versions, all available at: https://www.wma.net/policies-post/wma-declaration-of-geneva/.

large proportion of U.S. physicians, including members of these professional organizations. Indeed, in a large representative study of U.S. obstetrician gynecologists, my colleagues (including colleagues that practice abortion) and I found that only one in seven (14%) ever performs abortions,[25] while 41% morally object to elective abortion in a typical case (failed contraception) at six weeks gestation.[26] Among U.S. physicians from all specialties, half (52%) objected to abortion in the context of failed contraception.[27]

33. Moreover, even those physicians who support elective abortion do not disregard the fetus in other contexts. For instance, physicians caring for women routinely take great care not to harm the developing fetus. They sometimes refuse to prescribe medicines that are known to cause birth defects unless the patient is willing to commit to using contraceptives. They use careful shields against radiation when taking radiographic images, or even use alternative imaging modalities to avoid radiation altogether. Whenever possible, when caring for pregnant women they choose medication alternatives that are less risky to the health of the fetus. Physicians have even developed methods for performing surgeries on the fetus in utero to preserve and restore the fetus's health.[28] Elective abortion contradicts physicians' characteristic practices of treating the fetus with moral regard.

34. The medical profession's historic opposition to abortion does not mean it forbade doing what is necessary to preserve a woman's life and health. On the contrary, physicians have always distinguished between intentionally harming a another, which they should never do, and accepting the unintentional harms that often follow as side effects of healing interventions (so long as there is proportionate reason), which they often must do. Physicians routinely make such judgments under the ethical *rule of double effect*.[29] The statutes align with this ethical norm by allowing for abortion in cases of medical emergency, defined as "a condition that, in reasonable medical judgment, so complicates the medical condition of the pregnant

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[25] Stulberg DB. Dude AM, Dahlquist I, Curlin FA. Abortion provision among practicing obstetrician gynecologists. *Obstetrics and Gynecology*. 2011;118(3):609-14.

[26] Harris L, Cooper A, Rasinski KA, Curlin FA, Lyerly AD. Obstetrician-gynecologists' objections to and willingness to help patients obtain an abortion. *Obstetrics and Gynecology*. 2011;118(4):905-912.

[27] Curlin FA, Lawrence RE, Chin MH, Lantos JD. Religion, conscience, and controversial clinical practices. *New England Journal of Medicine*. 2007;356(6):593-600.

[28] Antiel R, Collura C, Flake A, Johnson M, Rintoul N, Lantos J, Curlin F, Tilburt J, Brown S, Feudtner C. Physician views regarding the benefits and burdens of prenatal surgery for myelomeningocele. *Journal of Perinatology*. 2017;37(9):994-998; Antiel RM, Flake AW, Collura C, Johnson M, Rintoul N, Lantos J, Curlin FA, Tilburt J, Brown SD, Feudtner C. Weighing the social and ethical considerations of maternal-fetal surgery. *Pediatrics*. 2017;140(6).

[29] Sulmasy DP, Pellegrino ED. The rule of double effect: clearing up the double talk. *Archives of Internal Medicine*. 1999;159(6):545-50.

woman as to necessitate the immediate abortion of such woman's pregnancy to avert the death of the woman or for which a delay necessary to comply with the applicable statutory requirements will create serious risk of substantial and irreversible physical impairment of a major bodily function."[30]

35. So far, we have seen that abortion has long been recognized as ethically problematic because it appears to fail to show the basic moral regard we owe to all human beings. Instead of attempting to show why the fetus is not in fact a human being, or not an unborn child, or otherwise not deserving of moral regard, the Plaintiffs instead ignore the fetus entirely. It is not reasonable for the state or the court to do likewise. Put simply, one cannot assess the ethics of an action (e.g., elective abortion) by ignoring the human beings directly affected by that action. Nor can a woman give informed consent to an action (elective abortion) without understanding its effects on the human being (her fetus/unborn child) most affected by that action. These facts must be taken into account when considering whether the Kansas statutes are ethically justified.

36. Importantly, the Plaintiffs have not shown that the state's claims about abortion (e.g., that it kills another human being) are false. Instead, they have complained that there is no "universal consensus" about moral status—which, as noted above, is just a euphemism for saying there is no universal consensus about whether elective abortion is ethical. There are two problems here. First, the Plaintiffs are using a double standard: if "universal consensus" is required to justify a claim, then the Plaintiffs' entire case falls, as the case includes a number of claims about which there is no universal consensus. Second, the state never claims universal consensus about abortion. Rather, the state reasonably claims the fetus is a human being and based on that claim, takes a posture toward abortion that has a rational basis recognized in law, philosophy, and ethics for centuries.

37. With all of the above in view, the Plaintiffs' allegations must be considered in light of the state's rational holding that abortion kills another human being. Because the Plaintiffs have not even begun to show that claim to be false (they have ignored rather than contested it), and because, if true, that fact has decisive ethical implications, we must consider whether the statutes are ethically justified *if that claim is true.*

Do the statutes contradict the principle of informed consent?

38. Medicine and medical ethics affirm a right of bodily integrity as a right to refuse any medical intervention. This right is respected through the medical doctrine of informed consent, perhaps the most firmly established norm of medical ethics. For medical practitioners, respecting this right of refusal is straightforward. It is clear to

[30] H.B. 2264.

whom it applies—every competent adult. It is clear when it applies—always.[31] The right of refusal is fundamental and comprehensive in its scope.

39. The landmark 1979 *Belmont Report* identifies respect for persons as the first ethical precept relevant to human subjects research and adds that, "Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them."[32] The principle of informed consent was specified as following from respect for persons, and soon after it was applied to clinical medicine in another landmark government report, *Making Health Care Decisions*.[33] Since then it has been uniformly established across the domain of healthcare,[34] often linked to respect for patient *autonomy*.[35] The principle of informed consent requires clinicians to give patients the information they need to understand what the clinician proposes to do and what can be expected as a result, so that the patient can freely consent to or decline the clinician's proposal.

40. How much information must the clinician give? The most widely endorsed ethical standard is the *reasonable person standard*.[36] That is, a clinician must provide information that a reasonable person in the patient's position would want to know. When in doubt about whether particular information is material (relevant), the ethical principle of informed consent emphasizes giving more information rather than less. Put differently, although it is true that giving irrelevant information to a patient can hinder the patient's understanding, the ethical emphasis with respect to informed

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[31] In rare circumstances, concern about public health has led states to trump the otherwise comprehensive right of refusal. This was seen, for example, with respect to COVID vaccine mandates. Importantly, even in these cases in which the state attaches a coercive penalty to refusing what the state mandates, medical practitioners only intervene on patients who give their consent.

[32] U.S. Department of Health, Education, and Welfare, *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, 44 Fed. Reg. 76, 21392–97 (Apr. 18, 1979).

[33] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. *Making Health Care Decisions: The Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship* (1982).

[34] Beauchamp and Childress write (p121), "Virtually all prominent medical and research codes and institutional rules of ethics now hold that physicians and investigators must obtain the informed consent of patients and subjects prior to a substantial intervention."

[35] "We think that respect for autonomy does provide the primary justification of rules, policies, and practices of informed consent. . . . At a minimum, personal autonomy encompasses self-rule that is free from both controlling interference by others and limitations that prevent meaningful choice, such as inadequate understanding." Beauchamp & Childress, 101.

[36] Beauchamp & Childress, 126.

consent is on giving *sufficient* information, not on making sure to give only the minimum required.

41. Here we see a problem with Ms. Sawicki's argument. Sawicki rightly observes that the state requires the provision of more information regarding abortion than it requires for other interventions. She then concludes that the statutes therefore are "inconsistent with" legal precedent. The relevant ethical question, however, is not whether the statutes are consistent with what the state requires for other procedures. Rather, the relevant question is whether what the state requires in this case violates the ethical principles of informed consent and the right to bodily integrity that the law is meant to uphold. In my judgment, it does not, for the following reasons.

42. One can reasonably set a different bar for demonstrating that informed consent has occurred if doing so is necessary to honor the moral goods that the principle (and the law) is intended to protect. This happens regularly at the level of the clinician and the patient. If a patient is considering a major medical intervention that is risky and burdensome, a physician reasonably takes more time to be sure the patient understands all that is at stake before proceeding. Physicians often insist on doing so even if the patient would rather just proceed without hearing more.

43. On that note, the Plaintiffs say the information is irrelevant because most women are certain of their decision before receiving any of the state-mandated information. Physicians, however, characteristically go through an informed consent process regardless of how "sure" a patient is when they inquire about a procedure. Without doing so, the physician cannot know whether the patient's consent is adequately informed. That is to say that physicians cannot absolve themselves of disclosing relevant information by saying, "the patient was certain of her decision in advance." Rather, the clinician must ensure that the patient knows enough to be reasonably informed before granting consent.

44. Given the unique ethical characteristics of abortion (especially that it involves intentionally killing another human being), the state reasonably requires the provision of more information regarding abortion than it requires for other interventions. It reasonably takes extra measures to ensure that those considering abortion have every opportunity to understand what is at stake in that decision and to consider alternatives. It reasonably requires information be given in multiple formats (e.g., verbally and in written form, in a pamphlet and on conspicuous signage), recognizing that not all patients are literate and that different people process information in different ways (e.g., visual vs. auditory processors). It reasonably requires a waiting period to give patients time to digest the information before undergoing abortion. Such waiting periods neither insult women nor tell them they have not thought long enough or well enough.[37] Rather, the requirements merely indicate that the state wants to ensure that all women have sufficient opportunity to

[37] Compl. ¶¶ 51, 62.

consider carefully what is at stake in abortion. Similarly, the requirements do not perpetuate demeaning views or prejudicial stereotypes regarding women.[38] Rather, they merely reflect the uniquely grave character of abortion—that it involves killing another human being, the offspring of the pregnant woman.

45. The state reasonably requires such disclosures also because the state cannot rely on the Plaintiffs to give pregnant women the information the state believes (reasonably) is necessary for consent to abortion to be duly informed. For example, the Plaintiffs have made clear they will not acknowledge to patients that abortion kills a human being.

46. It is important to clarify that informed consent does not require or imply other things the Plaintiffs allege: First, informed consent is fully compatible with hearing arguments and judgments regarding what should or should not be done. Physicians regularly give their advice to patients. Doing so in no way vitiates informed consent. As such, Dr. Wynia wrongly alleges that, "When advising on a preference-sensitive medical decision, physicians have an ethical obligation to avoid expressing judgment about the patient's choice."[39] Likewise when he holds up "judgment free advice" as an ideal.[40] Indeed, "judgment free advice" is an oxymoron, and the right of bodily integrity (a right of refusal) with its corollary principle of informed consent require that *all* medical decisions are "preference sensitive" insofar as all involve the patient making a judgment regarding whether she prefers to give or withhold consent to what the clinician proposes.

47. Indeed, although a full discussion goes beyond the scope of this report, several prominent scholars of medical ethics from across the ideological spectrum have critiqued the way that the ideas Dr. Wynia asserts prioritize patient autonomy so much so that they treat patients as if they are mere consumers and medical practitioners as if they are mere "providers of services."[41] Beauchamp and Childress, authors of the most widely influential framework for teaching medical ethics,

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[38] Compl. ¶ 125.

[39] Wynia ¶ 47.

[40] Wynia ¶ 48.

[41] *See, e.g.*, Siegler, M. (1981). Searching for moral certainty in medicine: A proposal for a new model of the doctor-patient encounter. *Bulletin of the New York Academy of Medicine*, *57*(1), 56-69.; Quill, T. E., & Brody, H. (1996). Physician recommendations and patient autonomy: Finding a balance between physician power and patient choice. *Annals of Internal Medicine*, *125*(9), 763-769. doi: 10.7326/0003-4819-125-9-199611010-00010; Schneider, C. (1998). *The Practice of autonomy: Patients, doctors, and medical decisions*. New York: Oxford University Press.; Emanuel, E. J., & Emanuel, L. L. (1992). Four models of the physician-patient relationship. *Journal of the American Medical Association*, *267*(16), 2221-2226.; Thomasma, D. (1983). Beyond medical paternalism and patient autonomy: A model of physician conscience for the physician-patient relationship. *Annals of Internal Medicine*, *98*(2), 243-248. doi: 10.7326/0003-4819-98-2-243. See also Curlin, F.C., & Tollefsen, C (2021). *The Way of Medicine: Ethics and the Healing Profession*. South Bend: Notre Dame University Press.

emphasize that respect for patient autonomy should not be elevated above other ethical concerns in this way.[42] They note, "The principle of respect for autonomy does not by itself determine what, on balance, a person ought to be free to know or do or what counts as a valid justification for constraining autonomy."[43] Contrary to Dr. Wynia's claim, hearing the judgments (and the basis for such judgments) of others, whether clinician, family member, or the state, allows a patient to make a more informed decision. It enhances rather than contradicting patient autonomy.[44]

48. Second, requiring a patient to affirm receiving information before undergoing an intervention does not coerce the patient. It is routine for states and hospitals and clinicians to insist on patients receiving information and affirming such receipt as a condition of undergoing an intervention. This happens every day when patients are asked to sign informed consent documents that include information that a patient (and/or her clinician) may believe is irrelevant, poorly worded, or worse. In some states, surgeons are required by law to use specific informed consent scripts for specific surgeries, regardless of whether the surgeon considers some or part of those scripts to give extraneous or irrelevant information.

49. When an intervention has grave and irreversible effects on someone who cannot benefit directly from the intervention, the regulation characteristically requires more information to be given and more documents signed. For example, before a patient can participate in a clinical research trial, the patient typically must receive and sign a lengthy informed consent form, authorized by an institutional board, whether or not the patient and/or the physician considers some of the information in that form to be extraneous or irrelevant (which they often do). Similarly, before a person can donate an organ (such as a kidney) for transplantation, they typically must go through a highly regulated process to make sure they fully understand what is at stake. In such cases, the patient retains the right of bodily integrity and even retains the right to refuse the information, though doing so may mean foregoing the intervention. As such, the statutes are not coercive unless the everyday practices of documenting informed consent are themselves coercive.

50. Moreover, the contexts of clinical research and transplantation highlight the way that authorities often do not leave the informed consent process to the discretion of the clinician. And for good reason. A physician mentor once taught me, "You go to Midas, you get a muffler." His point was that those who believe in and offer particular interventions or technologies (whether mufflers or gutter guards, hip

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[42] Beauchamp, T. L., & Childress, J. F. (2012). *Principles of biomedical ethics* (7th ed.). New York: Oxford University Press. See page 57.

[43] Beauchamp, T. L., & Childress, J. F. (2012). *Principles of biomedical ethics* (7th ed.). New York: Oxford University Press. See page 64.

[44] Quill, T. E., & Brody, H. (1996). Physician recommendations and patient autonomy: Finding a balance between physician power and patient choice. *Annals of Internal Medicine*, *125*(9), 763–69.

surgeries or chemotherapy, lipodissolve[45] or abortions) often are not reliable reporters of all that is at stake in such interventions or of alternatives a patient might consider. For this reason, government agencies and healthcare institutions often require clinicians and researchers to report their conflicts of interest. For the same reason, living organ donor candidates sometimes are paired with patient advocates whose job is to make sure the patient hears the reasons why they might *not* want to donate an organ. This basic principle also undergirds our system of law, in which verdicts in antagonistic proceedings are not rendered after hearing from the plaintiff(s) but only after also hearing from the defense.

51. Abortion is deeply contested, and those who provide abortions obviously come down on one side of the ethical debate. One need not allege bad faith on the part of abortion providers to assume that their judgments about the ethics of abortion will shape how they talk to patients. Similarly, an organization like ACOG, which has long been committed to abortion advocacy and has consistently opposed any regulation of abortion (even opposing the partial birth abortion ban), cannot be relied on to give impartial information regarding abortion. Below I will illustrate further how ACOG fails to interpret data fairly. The statutes ensure that women considering abortion have a chance to receive in-depth information from another perspective. If a woman consents to abortion after reading some or all the information given, her consent will be better informed than it otherwise would have been.

52. Certainly, informed consent depends on truth telling. If the information in the state-mandated disclosures is offered in bad faith, then the statutes are specious and unethical. If the information includes factual errors, those must be corrected. The Plaintiffs repeatedly alleged that the state is acting in bad faith and that the disclosures include information that is false, irrelevant, and misleading, but repeating that claim does not make it so, and in my judgment, they have failed to demonstrate what they claim on any specific point.

53. Indeed, in attempts to discredit the state-mandated information, the Plaintiffs sometimes twist and misinterpret that information. To give one example that stood out to me, Dr. Alsaden alleges the state's claim that "less than five percent of pregnancies 'end in spontaneous miscarriage after detection of cardiac activity' . . . is factually incorrect."[46] To support her allegation she notes that "risk of miscarriage is based on a number of patient-specific variables" and that "the overall risk of miscarriage may be as high as 26 percent of all pregnancies." Dr. Alsaden here compares apples to oranges to generate a nonsequitur. The state does not make a claim about the *overall* risk of miscarriage. Rather, the state made a claim about the risk of miscarriage *after* detection of cardiac activity, recognizing that the great majority of miscarriages occur early in pregnancy. The state's claim is supported by a reputable scientific study, the findings of which neither Dr. Alsaden nor any of the

[45] The Plaintiffs note that Kansas requires a specific informed consent script for those offering lipodissolve. See Complaint ¶ 110.

[46] Alsaden ¶¶ 60, 65.

other Plaintiffs contradicts.[47] Similarly, the Plaintiffs allege that the statement, "a fetal heartbeat is . . . a key medical indicator that an unborn child is likely to achieve the capacity for live birth" is false, yet they give no data to support this allegation, which is contradicted by the same study.

It is ethical to inform patients that it may be possible to reverse the intended effects of a "medication abortion" if the woman changes her mind before taking misoprostol.

54. The statutes require that women considering a "medication abortion" receive, prior to giving valid consent, information that includes the statement, "Mifepristone, also known as RU-486 or mifeprex, alone is not always effective in ending a pregnancy. It may be possible to reverse its intended effect if the second pill or tablet has not been taken or administered. If you change your mind and wish to try to continue the pregnancy, you can get immediate help by accessing available resources." The provider must also inform the patient, "that it may be possible to reverse the intended effects of a medication abortion that uses mifepristone, if the woman changes her mind, but that time is of the essence."

55. In my opinion, this disclosure requirement is ethically justified if three conditions hold: a) the statements have a factual basis, b) the statements provide information that a reasonable person might want to consider, and c) patients otherwise would not likely receive this information.

Do the statements have a factual basis?

56. The Plaintiffs claim, "The statement that 'it may be possible to reverse the intended effects of a medication abortion that uses mifepristone' is false and deceptive." They add, "There is no credible scientific evidence that a medication abortion using mifepristone can be 'reversed.'"[48] Scientific evidence does not interpret itself, and all data have limits. Because abortion is so contested, stakeholders scrutinize clinical data that has implications for abortion, as well as any claims made regarding those implications. The Plaintiffs have scrutinized and critiqued the studies that provide the basis of the state's statements. Such critiques are part and parcel of scrutinizing reports published in the medical literature, and if the state claimed that the available evidence *establishes unequivocally* or *proves* that the effects of mifepristone can be avoided, ceased, or reversed, then the Plaintiffs would have more grounds for opposing the required disclosures. That is not, however, what the required disclosure claims.

57. Moreover, although the Plaintiffs and their experts allege repeatedly that the required statements are false, the scientific reports on which the Plaintiffs

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[47] Mukherjee S, Velez Edwards DR, Baird DD, Savitz DA, Hartmann KE. Risk of miscarriage among black women and white women in a U.S. Prospective Cohort Study. *American Journal of Epidemiology*. 2013;177(11):1271-8.

[48] Compl. ¶ 101.

themselves rely demonstrate plainly that that the statements required by the statutes are true. In their efforts to discredit and discount the studies led by Delgado, the Plaintiffs contradict themselves while misinterpreting ethical norms and the norms for evaluating evidence.

58. The Plaintiffs themselves note, "Taken alone, mifepristone administered as part of a medication abortion will terminate a significant percentage of pregnancies, but not all."[49] Confirming this fact, the American College of Obstetricians and Gynecologists (ACOG) practice bulletin on "medication abortion," on which the plaintiffs rely, includes a table of possible "medication abortion" regimens, all of which include misoprostol.[50] There is no reasonable way to interpret these statements except to conclude that it may be possible to reverse the intended effects of a medication abortion that uses mifepristone, even if only by not taking misoprostol and thereby allowing the body to recover from the effects of mifepristone.

59. The ACOG bulletin claims, "There is no evidence that treatment with progesterone after taking mifepristone increases the likelihood of the pregnancy continuing,"[51] but this claim is directly contradicted by the two papers the bulletin cites as the basis for the claim. In the first,[52] published in the *New England Journal of Medicine*, Grossman and White review a case series published by Delgado and colleagues (hereafter, Delgado study) that included 547 women worldwide who underwent treatment with progesterone to attempt to reverse the effects of mifepristone.[53] The case series found that women who had received either intramuscular progesterone or high dose oral progesterone had ongoing pregnancy rates (64% and 68%, respectively) much higher than would have been expected based on previous studies of patients who received mifepristone alone (in which continuing pregnancy rates ranged from 8% to 25%).

60. Grossman and White pointed out limitations of the Delgado study and argued that if one focused only on the women in the study who took 200mg of mifepristone (the current standard in the US) at or before 7 weeks gestation and compared them to one small study in which women received one 200mg dose of mifepristone, then the differences in continuing pregnancy rates were no longer statistically significant. Grossman and White did not acknowledge, however, that even in this post-hoc subgroup analysis the effect size for progesterone remained

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[49] Compl. ¶ 103.

[50] Am. Coll. of Obstetricians & Gynecologists. *Medication Abortion Up to 70 Days of Gestation: ACOG Practice Bulletin*, 225 Obstetrics & Gynecology 136, e35 (2020).

[51] *Id.* at e33.

[52] Daniel Grossman & Kari White, *Abortion "Reversal"—Legislating Without Evidence*, 379 New Eng. J. Med 1491, 1493 (2018).

[53] George Delgado et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone*. 33 Issues L. & Med. (2018).

large—pregnancy continuation rates were still roughly twice as high for those who took progesterone compared to those who did not.

61. Neither did they acknowledge how sensitive the p-values (a proxy for "statistical significance") they reported are to the number of subjects in the control group. The concept of statistical significance communicates the likelihood that a difference of the measured magnitude would occur if there were no actual association, assuming the study and control samples are equal except for the studied variable. In other words, if progesterone had no effect on continuation of pregnancy, how likely is it that one would find a difference in pregnancy continuation rates of the magnitude recorded? Properly understood, statistical significance is always a matter of degree, but by convention many clinical studies consider $p<.05$ to be "statistically significant", meaning that one would expect a difference of the measured magnitude to occur "by chance" in fewer than 5% of trials. Even in Grossman and White's post hoc analysis, which itself is limited and subject to reasonable critique, they found that one would expect a difference of the magnitude found in the Delgado study to occur "by chance" in fewer than 8% of trials, approaching the conventional 5% threshold for "statistical significance."

62. Again, statistical significance is highly sensitive to the sample size, and Grossman and White chose a control group that included only 30 patients. According to my calculations, had the control group included as few as four more patients with the same measured pregnancy continuation rates, then even their post-hoc analysis would have found Delgado et al.'s findings to be statistically significant at $p<.05$.[54] In sum, the data from the Delgado report gave real evidence that taking progesterone increased the likelihood of the pregnancy continuing.

63. This is not to say that the Delgado report *proves* that the progesterone regimens fully account for the fact that the measured pregnancy rates were higher than had been reported with mifepristone alone. As with all evidence that suggests a clinical effect, it would be helpful to have more data, to make sure that the control and study populations are as similar as possible, etc. Whether and when the evidence is sufficient to justify attempting or continuing a treatment is a matter of clinical judgment, not of appeal to some algorithmic cut-off. The clinical judgment depends on how safe the treatment is, how compelling the physiological rationale is, how grave are the potential consequences for not treating, how important it is to the patient considering the treatment, and any number of other factors. Grossman and White cite an earlier systematic review they had published (the second article cited by ACOG), in which they reviewed Delgado's earlier case series of seven patients[55] and concluded that "[i]n the rare case that a woman changes her mind after starting

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[54] This is based on using a chi-square statistic and the data found in Grossman and White's table under "Gestational age ≤7 wk" but stipulating that the control group included 34 total pregnancies and 8 continuing pregnancies (rather than 30 and 7, respectfully).

[55] George Delgado & Mary L. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone.* 46 Annals Pharmacotherapy e36 (2012).

medical abortion, evidence is *insufficient* to determine whether treatment with progesterone after mifepristone results in a higher proportion of continuing pregnancies compared to expectant management."[56] I agree with their conclusion in that case. After the publication of data from more than 500 patients, however, even if one thinks the data remains insufficient to firmly establish that progesterone works as intended, one cannot reasonably deny that credible evidence suggests it does.

64. It also matters that treatment with progesterone is not a shot in the dark, scientifically speaking. Rather, it reflects longstanding scientific and clinical familiarity with progesterone, as well as knowledge of how both mifepristone and progesterone interact with the progesterone receptor. It is common knowledge among physicians that continuing pregnancy depends on the actions of progesterone. Mifepristone is a competitive antagonist (inhibitor) of the receptor for which progesterone is the relevant agonist (activator).[57] It is well known among biologists and physicians that, in principle, "[t]he action of a competitive antagonist can be overcome by increasing the dose of the agonist (i.e. the block is surmountable)."[58] Delgado et al cite an animal study that bore out the effects of high dose progesterone on reversing the effects of mifepristone. Indeed, the ACOG Practice Bulletin reports, "Concern has been raised that the immediate use of hormonal contraception that contains progestins could theoretically interfere with medication abortion efficacy. . . . In a randomized trial that evaluated the effects of DMPA [a long-acting progesterone-based contraceptive] injection timing on medication abortion outcomes, ongoing pregnancy was more common among those randomized to receive DMPA injection on the day of mifepristone administration compared with those who received DMPA at a follow-up visit."[59] All of this gives further evidence to support the claim that the effects of mifepristone may be avoided or reversed.

65. The Plaintiffs' interpretations of the scientific evidence appear untrustworthy insofar as they deploy double-standards and cherry-picking to support their conclusions. After claiming that the Delgado report of data from 547 women provides "no credible evidence," they then appeal to a study of just twelve patients (Creinin et al) to allege that the interventions used by Delgado and colleagues are dangerous because "[t]his randomized controlled clinical trial was terminated early due to safety risks to the participants after three of the twelve participants

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[56] Daniel Grossman et al., *Continuing Pregnancy After Mifepristone and "Reversal" of First-Trimester Medical Abortion: A Systematic Review*, 92 Contraception, 206, 206–11 (2015) (emphasis added).

[57] *See Mifepristone*, § 8.8, PubChem, https://pubchem.ncbi.nlm.nih.gov/compound/Mifepristone#section=Mechanism-of-Action.

[58] *See* DG Lambert, *Drugs and Receptors*, 4 Continuing Educ. in Anesthesia, Critical Care & Pain 181, 183 (2004).

[59] Am. Coll. of Obstetricians & Gynecologists, at e38-39.

experienced severe hemorrhage requiring hospital transport."[60] The Plaintiffs fail to note that only one of the three patients in that study had received progesterone, nor do they acknowledge that she was found to have a completed abortion and did not require further treatment—contradicting the description of her bleeding as "severe."[61] They do not mention that both of the women who experienced severe bleeding after *not* receiving progesterone required uterine aspiration, nor that one of these two had dangerously low blood pressure and required blood transfusion. The Plaintiffs do not mention that the study's authors concluded, "patients who receive high dose oral progesterone treatment do not experience side effects that are noticeably different than placebo."[62]

66. The Plaintiffs likewise ignore the findings of the Creinin study which give more evidence to suggest that the effects of mifepristone can be avoided or reversed by administering progesterone: First, the only patient in the Creinin study who did not experience any bleeding or spotting was the patient with the highest baseline progesterone level, consistent with the idea that higher progesterone levels more effectively compete with mifepristone at the progesterone receptor. Second, the study's authors report: "Overall, four of six patients in the progesterone group and two of six patients in the placebo group had continuing pregnancies at 2 weeks. Excluding the two patients who did not finish treatment, these rates are four of five and two of five, respectively."[63] The Plaintiffs completely ignore the fact that this randomized controlled trial of abortion reversal found that two weeks after treatment, 80% of those who took progesterone had continuing pregnancy, compared to 40% of those who did not. Yes, these are small numbers of participants, and so any estimates from these numbers are, as analysts put it, "unstable." But it cannot be that small numbers are important only if the results favor one's conclusions, and unimportant if they do not.

67. In the end, the Plaintiffs demonstrate double standards, cherry-picking of data, and misleading interpretations of the evidence they review. They emphasize findings that seem to support their conclusions, while ignoring those findings that do not. Their claim that the mandated information is scientifically inaccurate is not substantiated. Their claim that there is "no credible scientific evidence" [64] to support the mandated statements is contradicted by the very studies they cite.

68. Finally, the Plaintiffs allege that the Creinin study suggests it may be dangerous to attempt to reverse the effects of mifepristone because these three

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[60] Compl. ¶ 106; *see also* Alsaden ¶ 54; Nauser ¶ 51.

[61] Mitchell D. Creinin et al., *Mifepristone Antagonization with Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial*, 135 Obstetrics & Gynecology 158, 160–61 (2020).

[62] *Id.* at 162.

[63] *Id.* at 160.

[64] Compl. ¶ 101.

women experienced bleeding after not receiving misoprostol. Their allegations obscure what must be made plain: no one is suggesting that women take mifepristone as a stand-alone treatment. But if a woman changes her mind about abortion after taking mifepristone, then in that case taking misoprostol is directly contraindicated, both medically and ethically. Such women are in a bona fide medical emergency—the continuation of their pregnancy and the life of their unborn (and now wanted) child are directly and imminently threatened by the effects of a drug (mifepristone) that, from the perspective of what they now want and choose, is a poison.[65] Such women have two plausible medical options: 1) watchful waiting—hoping that the mifepristone will fail to cause a completed abortion, or 2) taking a medication (progesterone) for which there is some evidence to suggest it may counteract and mitigate the effects of mifepristone. The Plaintiffs have shown no data to suggest that option 2) is riskier than option 1),[66] much less that option 2) is so risky that it should not be offered to women who are trying to preserve the lives of their unborn children. On the contrary, the reports on which the Plaintiffs rely make plain that progesterone is quite safe, certainly no riskier than "medication abortion" itself. How can it be ethical to offer women an elective intervention ("medication abortion") that both kills the fetus and carries real medical risks, but unethical to offer women an emergency intervention (progesterone) that both intends to preserve the life of the fetus and has fewer risks? This seems a plain double standard regarding the clinical significance of risks and the importance of supporting patient autonomy.

Is this information that a reasonable person would want to know?

69. It seems plain that this is information a reasonable person would want to know. Most women are firm in their decisions to pursue abortion, but not all.[67] Some change their minds about abortion after taking mifepristone and before taking misoprostol. Women are not obligated to take misoprostol just because they took mifepristone. Indeed, patients can consent to a multi-step treatment plan and still withdraw their consent at any step. This frequently happens in the practice of medicine. "Medication abortion," insofar as it involves two discrete steps separated by 24 hours, is unlike tubal ligation or vasectomy. Contra Dr. Wynia's assertion,[68] a physician who tells a patient that "medication abortion" is irreversible after taking mifepristone is not telling the truth.

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[65] See: https://www.merriam-webster.com/dictionary/poison.

[66] Indeed, the Creinin study suggests the opposite.

[67] The Plaintiffs report that "in rare cases" patients express doubt or ambivalence about abortion at their appointments (Compl. ¶ 34). They report that "most people seeking abortion are certain of their decision" (Compl. ¶ 128). The state does not contest those claims, but it has a reasonable interest in the women, however few, who are undecided or do change their minds.

[68] Wynia ¶ 35.

70. The Plaintiffs allege that the disclosures regarding possible reversal may encourage patients to proceed with "medication abortion" before they are firm in their decisions based on the mistaken belief that they can reliably reverse the effects of mifepristone. Nothing in the statutes prevents abortion providers from counseling the patient to prevent this potential misunderstanding, and they are obligated to do so if they genuinely see it as a risk, just as they are obligated to ascertain whether the woman is firm in her decision. Misunderstanding can be avoided if the abortion provider gives adequate information before asking for the patient's consent. The principle of informed consent obligates abortion providers to do their best to make sure the woman understands how the two drugs work, how likely they are to cause the abortion, etc.

71. Clinicians should never withhold relevant information from a patient just because the clinician is worried the information might lead the patient to make a choice that the physician disagrees with. We saw during the COVID pandemic how when experts withhold information, however laudable their motivations, it destroys trust. Moreover, withholding this information could result in irreparable harm for women who change their mind about abortion after taking mifepristone but are unaware that the effects of mifepristone might be avoided or reversed. The Plaintiffs here again are deploying a double standard.

72. Imagine a woman who regrets attempting abortion and now hopes desperately that her fetus will not die. It strains credulity to suggest that it would not be relevant to her to know about the evidence for the possibility of sustaining the pregnancy using a medication that has long been considered safe by the medical community, and to know how to access more information about that treatment urgently.

73. Or consider this hypothetical: A woman has preterm threatened labor. The best evidence suggests that without further intervention there is only a 25% chance that she will continue the pregnancy until the point that the baby can survive outside the womb. Now suppose there is a medication regimen that is based on well-known physiology, has been used in thousands of women for other indications and found to have no long-term adverse effects, and has been found in an analysis of data from >500 similarly situated women to result in continued pregnancy rates of >50%. In my expert opinion, a physician who knew about such data and did not disclose the information to such a patient would be failing in his ethical obligations to the patient. The patient in such a case would not be sufficiently informed to give valid consent to a strategy of watchful waiting.

74. The gravity of what is at stake in a decision influences what a reasonable person would want to know. Few situations, if any, have more at stake than these, since whether the woman knows of the possibility of avoiding or reversing the effects of mifepristone may be a matter of life or death for her child. There is manifest evidence that women who are pregnant treat the threatened death of their fetuses as a grave matter. Many women readily undergo significant interventions, such as caesarean-section or even fetal surgery, to marginally reduce the risk of their unborn

child being injured or dying. Clinicians characteristically support women in such choices. In the case of women who regret starting a "medication abortion," the Delgado study makes clear that some will want to do what they can to prevent the abortion from being completed, even under conditions of significant uncertainty about whether the reversal intervention will work. In my opinion, it is inconsistent to affirm the importance of women's reproductive autonomy and then withhold from women the information included in the required statement.

75. Moreover, abortion providers have an obligation to provide this information if for no other reason than because it may help women avoid the serious adverse side effects of misoprostol. Women are under no obligation to take misoprostol even after they have taken mifepristone. If a woman believes mistakenly that after having taken mifepristone the abortion will invariably follow—that the fetus cannot possibly survive—then if she changes her mind about the abortion, she may unwittingly take a drug (misoprostol) that is medically contraindicated for her and brings an array of adverse side effects. The ACOG Practice Bulletin notes, "Adverse effects commonly associated with misoprostol use include nausea (43–66%), vomiting (23–40%), diarrhea (23–35%), headache (13–40%), dizziness (28–39%), and thermoregulatory effects such as fever, warmth, hot flushes, or chills (32–69%) (26–29)."[69] Misoprostol is also known to cause serious birth defects. The ACOG Bulletin adds, "No evidence exists to date of a teratogenic effect of mifepristone. However, misoprostol can result in congenital anomalies, such as limb defects with or without Möbius' syndrome (i.e., facial paralysis), when used during the first trimester."[70] Misoprostol also causes pain, leading ACOG to recommend pharmacological pain management.[71] Women need to know that if they are not trying to complete an abortion, they no longer have reason to take misoprostol. Indeed, they have several reasons *not* to take misoprostol.

Without the state's requirement, will those considering "medication abortion" receive this information?

76. If abortion providers already consistently provided the required information in their own way, then the state would not have reason to require them to do so in a prescribed way. The Plaintiffs are clear, however, that without the state mandates they would not disclose to their patients this information.

77. In sum, in my expert opinion the state has a rational basis for requiring abortion providers to give women considering abortion the information about possible reversal of mifepristone. This information is material (relevant) under a reasonable person standard for women considering "medication abortion," and women will not have the opportunity to consider this information without the statute. As such the principle of informed consent, respect for patient autonomy, and obligations to protect patients from unwittingly taking a drug (misoprostol) that is not medically

[69] Am. Coll. of Obstetricians & Gynecologists, e32.

[70] *Id.* at e33.

[71] *Id.* at e37.

indicated—not to mention obligations to preserve the life of an unborn baby insofar as reasonably possible—all support providing the information.

The statutes do not undermine the physician-patient relationship.

78. Contrary to the Plaintiffs' claims, the statutes do not undermine the physician-patient relationship by making physicians agents of the state who must act as if they believe what they do not believe. Wynia claims that the statutes make clinicians the state's "mouthpieces"[72] who are "required to advance the state's ideological value judgments as though they are their own beliefs."[73] The plaintiffs also allege that by requiring disclosure of information the clinician disagrees with, the disclosure requirement "compels physicians to personally lie to their patients."[74]

79. Not so. First, nothing in the statute prevents clinicians from making clear, as they presumably do already, that they are required by law to give the patient the state-mandated information. If abortion providers disagree with the state's information, they are free to say as much and explain why. The statute no more compels the clinician to lie than states compel surgeons to lie by requiring a particular informed consent form be used for a particular surgery (knowing full well that some surgeons will disagree with some of the wording on that form). Surgeons in such case, and abortion providers in the present case, are free to qualify the mandated information as they see fit to avoid anticipated misunderstandings. Any such qualifications, assuming they are offered in good faith and have a sound basis, will further enhance the patient's autonomy by giving the patient more information to consider before they either consent to or decline abortion.[75]

80. The Plaintiffs are deploying double standards regarding transparency and autonomy. Wynia writes, "Among the core principles that guide our profession are shared promises related to truth-telling and transparency."[76] Yet by withholding from patients information about what abortion does, the Plaintiffs are not being transparent. By withholding the fact that the effects of mifepristone might be avoided if one does not take misoprostol, they keep from women the choice of looking into that evidence and potentially availing themselves of a reversal therapy. Even the ACOG bulletin concedes, "Most individuals with a continuing pregnancy opt to complete the abortion, but patients should be supported in their choice of how to proceed."[77] Yet patients cannot be supported in their choice of how to proceed if they do not know

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[72] Wynia ¶ 45.

[73] Wynia ¶ 3.

[74] Compl. ¶ 107.

[75] Timothy E. Quill & Howard Brody, *Physician Recommendations and Patient Autonomy: Finding a Balance Between Physician Power and Patient Choice*,125 Annals Internal Med. 763, 763-769 (1996).

[76] Wynia ¶ 29.

[77] Am. Coll. of Obstetricians & Gynecologists, e33.

what choices are available. Whether abortion is an ethically justifiable choice is a point of enduring dispute and disagreement among the public, clinicians, and medical ethicists. But I am not aware of anyone arguing that women should not have the choice of continuing their pregnancies and availing themselves of any treatments that physicians might offer to help them preserve the life of their fetus when that life is threatened. The Plaintiffs are on thin ice, ethically speaking, in arguing that somehow women need not know about these latter options.

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

This declaration was executed on July 5, 2023.

Farr A. Curlin, MD

EXHIBIT A

CURRICULUM VITAE

Farr A. Curlin, MD

PERSONAL INFORMATION

Office: Trent Center for Bioethics, Humanities & History of Medicine
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Home: 8705 Gleneagles Dr
Raleigh, NC 27613

Spouse: Kimberly Curlin Children: David, Andrew, Caroline, and Gigi

EDUCATION AND TRAINING

College: University of North Carolina at Chapel Hill, BA with distinction, Biology, 1992
Medical School: University of North Carolina School of Medicine, MD, 1998
Residency: University of Chicago Hospitals in Internal Medicine, 1998 – 2001
Fellowship: Robert Wood Johnson Clinical Scholar, The University of Chicago, 2001-2003
Fellowship: MacLean Center for Clinical Medical Ethics, University of Chicago 2003-2004
Summer Institute for Survey Research Methods, University of Michigan – 2006
Program in Palliative Care Education and Practice, Harvard University – 2008

BOARD CERTIFICATION

Diplomate American Board of Internal Medicine 204781, 2001, 2011, 2022
Hospice and Palliative Medicine Certification (ABIM), 2010, 2022

MEDICAL LICENSURE

North Carolina License No: 2013-01944

MEMBERSHIPS

American Medical Association
American Society for Bioethics and Humanities

ACADEMIC APPOINTMENTS:

Duke University

2014 -	Josiah C. Trent Professor of Medical Humanities, Trent Center for Bioethics, Humanities & History of Medicine
2014 -	Professor of Medicine, Center for Palliative Care, Section of General Internal Medicine, Department of Medicine
2014 -	Professor and Co-Director, Theology, Medicine, and Culture Initiative, Duke Divinity School (tmc.divinity.duke.edu)
2017 -	Senior Fellow, Kenan Institute for Ethics

The University of Chicago:

2003 – 2005	Instructor of Medicine, Section of General Internal Medicine
2003 – 2006	Associate Faculty, Robert Wood Johnson Foundation Clinical Scholars Program
2004 – 2013	Faculty, the MacLean Center for Clinical Medical Ethics

2005 – 2010 Assistant Professor of Medicine, Section of General Internal Medicine
2009 – 2013 Co-Director, Program on Medicine and Religion (pmr.uchicago.edu)
2010 – 2013 Associate Professor of Medicine, Section of General Internal Medicine

HONORS, AWARDS, SCHOLARSHIPS (selected)

1989 Valedictorian, Jackson Central Merry High School, Jackson, TN
1989 William Richardson Davie Scholar, University of North Carolina
1992 Phi Beta Kappa, University of North Carolina – Chapel Hill
1995 Herbert H. Fritz special merit award for scholastic excellence, UNC School of Medicine
1995 North Carolina Albert Schweitzer Fellowship Award
1995 Foreign Fellowship Award, UNC School of Medicine
1997 Alpha Omega Alpha Honor Medical Society, UNC School of Medicine
1998 Heusner Pupil Award, for showing "a great capacity to grasp the principles of science, to heal the sick, to comfort the troubled, to be humble before God." UNC School of Medicine
1998 Cecil G. Sheps Award in Social Medicine – chosen by the Department of Social Medicine as the graduating student who most embodies the department's ideals, UNC School of Medicine
1998 Terri Brenneman Award - for "the graduating student who has most demonstrated a commitment to the underserved." UNC School of Medicine
1998 Merck Award – chosen by the UNC faculty as one of four graduating students to be honored for their contributions to the medical school community, UNC School of Medicine
2000 Norris L. Brookens Award – chosen by the state chapter of the American College of Physicians as the Most Outstanding Internal Medicine Resident in Illinois
2003 John A. Oremus Memorial Scholar – MacLean Center for Clinical Medical Ethics, The University of Chicago
2006 Greenwall Foundation Faculty Scholar in Bioethics (2006-2009)
2007 Outstanding Physician Scientist Award. Central Society of Clinical Research and the Midwestern Section of the American Federation for Medical Research
2008 Early Career Development Award. Central Society for Clinical Research
2011 Arnold P. Gold Foundation Humanism in Medicine Award Nominee. Pritzker School of Medicine student body
2012 David B. Larson Fellowship in Health and Spirituality, The Library of Congress
2012 White Coat Ceremony Keynote Speaker, Pritzker School of Medicine, August 5
2014 Gold Humanism Honor Society Induction Ceremony Keynote Speaker, Pritzker School of Medicine, Chicago, IL. March 13
2017 Inaugural Robert D. Orr, MD, Lecture in Medical Ethics, University of Vermont, October 27
2018 The Steve Thorney Career Award for Spiritual Care, MD Anderson Cancer Center
2018 Paul Ramsey Award for Excellence in Bioethics, Paul Ramsey Institute
2019 Pellegrino Medal for Healthcare Ethics, Samford University
2021 Inaugural Lisio Family Lecture (medical ethics). Columbia University
2022 Educator of the Year, Christian Medical and Dental Associations
2023 Englehardt Award (bioethics), The Ohio State University Center for Bioethics and Medical Humanities

REVIEW AND EDITORIAL EXPERIENCE

Ad hoc journal and book review

Academic Medicine, American Journal of Bioethics, AJOB – Empirical Bioethics, American Journal of Hospice and Palliative Medicine, American Journal of Law and Medicine, American Journal of Psychiatry, Annals of Family Medicine, Annals of Internal Medicine, Archives of Internal Medicine, British Medical Journal, BMC Medical Education, Cancer, CHEST, CMAJ, Elsevier, Explore, Georgetown University Press, Harvard University Press, Health Affairs, International Journal of

Psychiatry in Medicine, Johns Hopkins University Press, Journal of Christian Bioethics, Journal of Clinical Oncology, Journal of General Internal Medicine, Journal of Medical Ethics, Journal of Medicine and Philosophy, Journal of Oncology Practice, Journal of Pain and Symptom Management, Journal of Religion and Health, Journal of the Scientific Study of Religion, Lancet, Medical Care, Mayo Clinic Proceedings, Medical Journal of Australia, New England Journal of Medicine, Oxford University Press, Pediatrics, Perspectives in Biology and Medicine, Plos One, Social Science & Medicine, Southern Medical Journal, Stanford University Press, Theoretical Medicine and Bioethics, Zygon

Editorial experience

2008	Guest editor of special issue of *Theoretical Medicine and Bioethics*, focused on conscience and clinical practice, published 2008
2014 -	Editorial Board, *Perspectives in Biology and Medicine*
2016	Guest editor of special issue of *Christian Bioethics*, focused on setting the medicine in the context of a good and faithful life
2019	Guest editor of special issue of *Theoretical Medicine and Bioethics*, focused on defining and measuring death
2019	Guest editor of special issue of *Perspectives in Biology and Medicine*, focused on disputes about conscience in medicine
2023	Guest editor of special issue of *Christian Bioethics*, focused on moral and theological questions raised by medicalizing risk

CLINICAL PRACTICE

2001 – 2003	Primary Care Internist, Lawndale Christian Health Center
2003 – 2008	Primary Care Physician, University of Chicago Primary Care Group
2003 – 2013	General Internal Medicine attending physician. University of Chicago Hospitals.
2004 – 2013	Ethics consult service, University of Chicago
2008 – 2013	Associate Medical Director – Horizon Hospice Care, Chicago, IL
2008 – 2013	Palliative Medicine Consult Service. University of Chicago Hospital
2014 –	Attending physician. Duke Hospice and Palliative Care

ADMINISTRATIVE LEADERSHIP / COMMITTEE WORK (selected)

2000 – 2003	Best Practices Project Steering Committee. The US Bureau of Primary Health Care and the Christian Community Health Fellowship
2003	Working group on the ethics of spirituality in medicine. George Washington Institute for Spirituality and Health and the Association of American Medical Colleges
2006 – 2008	Ethics Research Group. Division of Standards and Survey Methods. Joint Commission on Accreditation of Healthcare Organization
2008 – 2013	Founding Co-Director (with Daniel Sulmasy, MD, PhD), Program on Medicine and Religion, The University of Chicago. https://pmr.uchicago.edu
2010 – 2015	The Witherspoon Council on Ethics and the Integrity of Science. Member.
2012 – 2015	Bioethics and Christian Theology Affinity Group, Founding Co-Director (with Jeffrey Bishop). American Society for Bioethics and Humanities
2014 –	Co-Director (with Warren Kinghorn, MD, ThD), Theology, Medicine, and Culture Initiative (TMC), Duke Divinity School. https://tmc.divinity.duke.edu
2017 – 2020	Founding Director, Arete Initiative, Kenan Institute for Ethics, Duke University

INVITED PRESENTATIONS (selected)

Intramural

1. Should physicians prescribe prayer? Internal Medicine Residency Medical Ethics Conference, The University of Chicago Hospitals. September 22, 1999. Chicago
2. Strangers or friends? A proposal for a new spirituality-in-medicine ethic. MacLean Center for Clinical Medical Ethics Annual Conference. Chicago, November 15, 2003.
3. Physician religiosity and approaches to spirituality in medicine. Medicine Grand Rounds – The University of Chicago. January 6, 2004.
4. Finitude: Defining Death in the Public Sphere. [Panelist] The University of Chicago Divinity School. April 8, 2005.
5. An honored but humble servant: The right relationship of empirical research to moral deliberation. MacLean Center for Clinical Medical Ethics Annual Conference. The University of Chicago, November 12, 2005.
6. The Ethics of Plastination and Display of Human Bodies. [panelist] AMA student chapter. The University of Chicago. April 20, 2007.
7. Much ado about conscience, practice, and the possibility of clinical ethics. Annual Conference, MacLean Center for Clinical Medical Ethics. Nov 9, 2007
8. Religion, conscience and controversial practices in sexual and reproductive health care. Section of Family Planning Grand Rounds. University of Chicago. Dec 4, 2007.
9. Grand rounds. Department of Pediatrics. University of Chicago. March 6, 2008.
10. Do the goals of sedation 'terminate' at palliation? Annual Conference, MacLean Center for Clinical Medical Ethics. Nov 13, 2009.
11. The goals and limits of palliative sedation: Attitudes and practices of US physicians. Annual Conference, MacLean Center for Clinical Medical Ethics. November 13, 2010.
12. Religious traditions in death and dying: What the student/clinician needs to know. University of Chicago Chapter of the Arnold P. Gold Foundation Humanism Honor Society. March 8, 2011
13. "Palliative Medicine" or "Palliative Care"? Ethical implications of two ways of framing a new discipline. Annual Conference, MacLean Center for Clinical Medical Ethics. November 16, 2013.
14. #DyingInAmerica: A panel discussion on Narratives, Policies and Law at the End of Life. Duke University Consortium on Social Equity. October 9, 2014
15. Duke University Geriatrics Grand Rounds. April 8, 2015
16. Living well and dying faithfully: How can hospice and palliative medicine help? 2015 Convocation & Pastor's School. Duke Divinity School. October 12-13, 2015
17. Anglican Episcopal House of Studies Study Day. Duke Divinity School. April 11, 2016
18. Being Present: Why Health Care Needs Theology and the Church. 2016 Convocation & Pastor's School. Duke Divinity School. October 10-11, 2015

Extramural

1. Wabash College. February 23, 2004. Crawfordsville, IN
2. Loyola University School of Law. March 21, 2004. Chicago, IL
3. Christian Community Health Fellowship Conference (keynote). Atlanta, GA, May 21, 2004.
4. Spirituality and Healthcare Dialogue. The University of Texas Medical Branch. March 30, 2005. Galveston, TX.
5. God in the clinic: Religion, medicine, and the dilemmas of "patient-centered care." Lee University, Cleveland, TN, October 4, 2005.
6. Getting below the surface: The ethics of religious/spiritual interaction in the clinical encounter. Duke University, Durham, NC. October 6, 2005.
7. Program in Genetic Counseling. Northwestern University, February 6, 2006.
8. Duke University Center for Theology and Medicine, Durham, NC, June 22, 2006.

9. Annual Faith in Medicine Conference, (keynote) The Faith and Medicine Institute, Boston, MA, September 2, 2006.
10. Spirituality/Medicine Interface Conference (keynote). Southern Medical Association. Atlanta, GA, September 14-16, 2006.
11. Sr. Alice Potts Endowed Lectureship for Spirituality and Medicine, MD Anderson Cancer Center, Houston, TX, October 30, 2006.
12. 4th Annual Vincent C. DeStefano Memorial Conference. Memorial Hospital. South Bend, Indiana. June 13, 2007.
13. University of Michigan Ethics Conference, Ann Arbor, March 11, 2008.
14. Louise Kingston Endowed Lectureship in Spirituality and Medicine. Princeton University Medical Center, Princeton, NJ. April 1, 2008.
15. American Medical Association, Division of Medical Ethics. Chicago. May 30, 2008.
16. Christian Medical and Dental Associations National Conference (keynote). Bloomingdale, IL. June 19, 2008.
17. Patient Rights vs. Doctor Conscience. DeVos Medical Ethics Colloquy. (keynote, along with R. Alta Charo). Grand Rapids, MI. September 8, 2008.
18. Conscience and clinical practice. President's Council on Bioethics. September 11, 2008. https://bioethicsarchive.georgetown.edu/pcbe/transcripts/sept08/session3.html
19. The Role of Conscience in Medicine. (keynote) Center for Law, Health & Society, Georgia State University. Atlanta, GA. October 9, 2008
20. Religion, Science, and the Moral Life of Medicine. (keynote) Sentara 2008 Ethics Conference. Williamsburg, VA. November 7, 2008.
21. Controversial Bodies: How to View and Think about Plastinated Corpses. (keynote) University of Kansas Medical School and Center for Practical Bioethics. Kansas City, MO. December 5, 2008.
22. Medicine Grand Rounds, University of Saskatchewan College of Medicine, Saskatoon, CA. January 9, 2009.
23. David Larson, MD, Memorial Lecture, Society for Spirituality, Theology and Medicine Annual Conference. Durham, NC. June 5, 2009.
24. Veritas Forum. Mayo Clinic, Rochester, MN. September 23, 2009.
25. 8th Annual Contemporary Catholic Healthcare Ethics Conference. Stritch School of Medicine at Loyola University. October 9, 2009. Chicago, IL
26. Florida Hospital Annual Conference on Spirituality and Medicine. March 25, 2010. Orlando, FL
27. Spirituality and Medicine Conference. Brody School of Medicine. April 1, 2010. Greenville, NC
28. The Lupina Centre for Spirituality, Healthcare and Ethics at Regis College, University of Toronto. October 15/16, 2010
29. Children's of Minnesota Westgate Pediatric Ethics Forum, Minneapolis, MN. November 12, 2010
30. Grand Rounds. Methodist Hospital, and Lecture in the Religion and Public Life Program. James Baker Institute for Public Policy. Houston, TX. December 3, 2010.
31. International Institute of Restorative Reproductive Medicine (IIRRM). Dublin, Ireland. March 26, 2011.
32. Terminal Sedation and Active Euthanasia: What are the Boundaries? 3rd Annual Bioethics Symposium. (keynote) University of Wisconsin. Madison, WI. April 7, 2011
33. Where Religion, Policy, and Bioethics Meet: An Interdisciplinary Conference on Islamic Bioethics and End-of-Life Care. (keynote) University of Michigan. Ann Arbor, April 10, 2011
34. Religion, Spirituality, and Mental Health (keynote). Loyola University Chicago. April 12, 2012
35. Kluge Center, United States Library of Congress, Washington, DC. June 28, 2012

36. 26th Annual A. Kurt Weiss Lecture in Biomedical Ethics, University of Oklahoma Health Sciences Center. September 27, 2012
37. Turner Conference on Faith and Medicine (keynote), Muncie, IN. October 10, 2012
38. Allen M. Boyden, M.D, Memorial Lecture. Providence St. Vincent Medical Center. Portland, OR. November 8, 2012
39. Speaking About the End of Life, Spiritual, Religious and Community Conversations (keynote). Mount Sinai Medical Center & Greater Miami Jewish Federation. December 4, 2012
40. Ethics Grand Rounds. Loyola University Medical Center. January 8, 2013
41. Workshop on Comparative Studies of Religion and Values among Healthcare Professionals. Freiburg Institute of Advanced Studies. Germany. February 20-22, 2013
42. 28th Annual Notre Dame Medical Ethics Conference. Notre Dame, IN. March 8-10, 2013
43. Trent Center Lecture on Medical Humanities, Duke University. Durham, NC, April 17, 2013
44. Reverend Edward J. Drummond, S.J. Lecture, Medicine Grand Rounds, Saint Louis University. May 10, 2013
45. Association of Professional Chaplains national webinar journal club. May 14, 2013
46. Institute of Medicine. Committee on Approaching Death: Addressing Key End of Life Issues. Houston. July 22, 2013
47. Spirituality and Ethics in Health Care (keynote speaker). Catholic Health Partners. Cincinnati, OH. October 3, 2013
48. Institute for Ethics and Culture Annual Conference. Notre Dame University. November 9, 2013
49. Loyola University Annual Medical Ethics Conference. March 13, 2014
50. Notre Dame Annual Medical Ethics Conference. March 21-23, 2014
51. Physician Well-Being Conference. Adventist Health Care. Jacksonville, FL. April 11, 2014
52. 4th European Conference on Religion, Spirituality and Health (Keynote). Malta. May 23, 2014
53. Harvard Lecture Series on Spirituality and Medicine, Harvard University. November 17-18, 2014
54. Medicine Grand Rounds. Medical College of Virginia. Richmond, VA, February 19, 2015
55. Institute for Faith and Learning. Baylor University. Waco, TX. September 11, 2015
56. Annual Conference. MacLean Center for Clinical Medical Ethics. November 14, 2015
57. 2016 Conference on Medicine and Religion. Houston, TX. March 4, 2016.
58. Reimagining Medicine Conference. Denver Institute for Faith and Work. April 6, 2016
59. Hagop S. Mekhjian Lecture. The Ohio State University. Columbus, OH. September 15, 2016
60. Ohio State University Center for Bioethics Annual Conference. September 16-17, 2016
61. The Basil Society. UT Southwestern. Dallas, TX. September 24, 2016
62. What is the place of sedation in care at the end of life? (symposium). The University of Chicago. October 14, 2016
63. 2016 MedConference. Florham Park, NJ. October 15, 2016
64. Medical Ethics Grand Rounds. UNC School of Medicine. Chapel Hill, NC. November 3, 2016
65. Schiltz Lecturer in the Medical Humanities, University of Kansas School of Medicine. Wichita, KS. January 12-13, 2017
66. Weston Lecture. Augustine College. Ottowa, ON. March 16, 2017
67. 35th Annual MacLean Center Interdisciplinary Seminar Series on Reproductive Ethics. The University of Chicago. April 26, 2017
68. Z. Stanley Stys Memorial Lecture. Princeton University Medical Center. May 23, 2017
69. Robert D. Orr, MD, Lectureship. University of Vermont. October 27, 2017
70. Grand Rounds, Department of Pediatrics. University of Illinois. Chicago, January 5, 2018
71. Grand Rounds, Department of Medicine, Medical College of Georgia. January 9, 2018
72. The Steve Thorney Life Career Award and Lecture in Spiritual Care, MD Anderson Cancer Center, Houston, TX, February 9, 2018
73. Provonsha Lecture. Loma Linda University. March 2, 2018
74. Thomistic Institute. Harvard University. April 23, 2018

75. Grand Rounds, Department of Obstetrics and Gynecology, Vanderbilt University. May 5, 2018
76. Holy Friendship Summit, Bristol, TN. May 18-19, 2018
77. Commencement Address. Trinity Academy of Raleigh. Raleigh, NC. May 26, 2018
78. Grand Rounds, Department of Medicine, Texas Tech University. November 8, 2018
79. Physician Assisted Suicide and Euthanasia: Theological and Ethical Responses (symposium): Georgetown University. November 9, 2018
80. Affirming Ethical Options for the Terminally Ill. Heritage Foundation. Washington, DC. March 11, 2019
81. Bioethics Grand Rounds. National Institutes of Health. April 3, 2019
82. Grand Rounds. Biomedical Ethics Research Program. Mayo Clinic. April 30, 2019
83. Center for Ethics and Culture, Notre Dame University. May 13, 2019
84. HEAL Institute, Samford University Center for Faith and Culture, September 6, 2019
85. King Institute for Faith and Culture, King University, Bristol, TN, September 16-17, 2019
86. 88th Annual Educational Conference. Catholic Medical Association. Nashville, TN. September 26, 2019
87. Thomistic Institute. Queen's University School of Medicine. Kingston, Ontario. October 9, 2019
88. Lehman Lecture in Medical Ethics. Allegheny College, Meadville, PA. February 18, 2020
89. Carol Carfang Nursing & Healthcare Ethics Conference. Tampa, FL. February 28, 2020
90. School of Civic and Economic Thought and Leadership. Arizona State University. June 15, 2020
91. McDonald Centre for Theology, Ethics & Public Life. Oxford University, UK. September 4, 2020
92. Hoover Lecture, York Hospital. York, PA. September 17, 2020
93. Program in Medical Ethics, Humanities, and Law. Western Michigan University Homer Stryker M.D. School of Medicine. October 7, 2020
94. 2021 Scholar in Residence. Union University. March 8-12.
95. Character and the Professions Conference (panelist). Wake Forest University. March 13, 2021
96. Inaugural Lisio Family Endowed Lectureship. Columbia University School of Medicine. September 20, 2021
97. Thomistic Institute, Yale University. November 3, 2021
98. MacLean Conference on Clinical Medical Ethics, University of Chicago, November 13, 2021
99. Thomistic Institute, Johns Hopkins Medical Institute, November 15, 2021
100. Maurice B. Siegel, M.D., Lecturer in Humanism and Medicine. Cedar's Sinai. January 19, 2022
101. John Collins Harvey Lecture, Pellegrino Center for Clinical Ethics, Georgetown University, February 25, 2022
102. Foglio Lecturer, Michigan State University School of Medicine. March 22-23, 2022 (rescheduled—now pending new date)
103. Celebrating and Defending the Freedom to Care, Christian Medical and Dental Associations, Washington, D.C. January 2023 (upcoming)

PEER-REVIEWED PRESENTATIONS AT SCHOLARLY MEETINGS

1. Holism or Evangelism? A consideration of religion in medicine. [Special session]. Robert Wood Johnson Clinical Scholars Program National Conference. Ft Lauderdale, FL, November 22, 2003.
2. Religion and Health: Theological Limits and Concerns. [Panel presentation] American Society for Bioethics and Humanities. National Conference. Denver, CO. October 27, 2006.
3. Religion, Conscience, and Controversial Clinical Practices. Central Society for Clinical Research/Midwestern Section American Federation for Medical Research. [Chosen as the top observational science abstract.] April 13, 2007. Chicago, IL.

4. Does Conscience Have a Place in the Healthcare Encounter? [Panel presentation] American Society for Bioethics and Humanities. National Conference. Washington, DC. October 19. 2007
5. Social and Ethical Implications of Supporting or Limiting a Right of Conscientious Refusal for Health Care Providers. [Panel presentation] American Society for Bioethics and Humanities. National Conference. October 15, 2009. Washington, DC.
6. Whose outcomes? Which notion of health? Ethical issues in the measurement of religious experience and its relation to health. [Panel presentation] American Society for Bioethics and Humanities. National Conference. Washington, DC. October 18, 2009.
7. Empirical research in bioethics: A toolkit for beginners. Pre-conference workshop. American Society for Bioethics and Humanities. National Conference. San Diego, CA. October 21, 2010
8. Serving two masters? [Panel presentation] American Association for Hospice and Palliative Medicine Annual Assembly. February 11,2011
9. Representing death, anticipating the corpse [Panel presentation]. American Society for Bioethics and Humanities. National Conference. Washington, DC. October 19, 2012
10. Towards a new art of dying [Panel session]. 2013 Conference on Medicine and Religion. Chicago, IL. May 29, 2013
11. Is traditional inpatient bioethics suited to outpatient settings? [panel] American Society for Bioethics and Humanities. National Conference. Atlanta, GA. October 26, 2013.
12. Among all physicians, is there a physician? Irony and the practice of medicine. American Society for Bioethics and Humanities. National Conference. Atlanta, GA. October 26, 2013.
13. "Do not be anxious ... about your body." Assessing contemporary primary care in light of the Sermon on the Mount. 2014 Conference on Medicine and Religion. Chicago, IL. March 8, 2014
14. Pharmacist on the execution team [panel]. American Society for Bioethics and Humanities. National Conference. San Diego. October 18, 2014.
15. Project on the Good Physician: Relevance of the Rationalist-Intuitionist Debate for Ethics and Professionalism in Medical Education. American Society for Bioethics and Humanities. National Conference. San Diego. October 18, 2014.
16. Can Religion Find Its Voice at a Secular Deathbed? [panel] 2016 Conference on Medicine and Religion. Houston, TX. March 4-6.
17. Doctor's Beliefs and Medical Practices: Transatlantic Comparisons. [panel] 2016 Conference on Medicine and Religion. Houston, TX. March 4-6.
18. The Religion and Medicine of the Future: An Orthodox Critique of Scientific Theology and Ecumenism. [panel] 2016 Conference on Medicine and Religion. Houston, TX. March 4-6.
19. Reimagining Medicine: Theological Formation for Those with Vocations to Health Care. [panel] 2017 Conference on Medicine and Religion. Houston, TX. March 25.
20. Solidarity with the suffering: Why physicians, *as physicians*, must oppose assisted suicide. International Congress on Law and Mental Health. Prague, Czech Republic. July 11, 2017
21. Searching for a Foundation for Medicine that Christians Share with those who are not Christians [panel]. 2018 Conference on Medicine and Religion. St. Louis, MO. April 14.
22. Remembrance, Resilience, and Religious Formation in Medical Education: Two Case Studies [panel]. American Society for Bioethics and Humanities. National Conference. Pittsburgh. October 27, 2019
23. Improving Palliative and End-of-Life Care for African Americans: Remembering Dr. Richard Payne. [panel]. American Society for Bioethics and Humanities. National Conference. Pittsburgh. October 25, 2019
24. Is there a future for Hippocratic medicine? (panel) 2021 Conference on Medicine and Religion. March 23
25. Healing and Economy: The Question of Charity in a Secular Age (panel). 2021 Conference on Medicine and Religion. March 22

CONFERENCES DIRECTED

2008 Conscience and Clinical Practice: Medical Ethics in the Face of Moral Controversy. Hosted at the University of Chicago, March 18

2011 Practice and Profession: Setting Medicine in the Context of a Good and Faithful Life. University of Chicago, November 10.

2012 Responding to the Call of the Sick: Inaugural Conference on Medicine and Religion. May 23-25. Chicago. (with Daniel Sulmasy, MD, PhD)

2012 Judaism, Medicine, and the Formation of Clinicians. September 10, 2012. The University of Chicago (with Daniel Sulmasy, MD, PhD)

2013 What Does it Mean to *Care*? 2013 Conference on Medicine and Religion. Chicago. May 28-30. (with Daniel Sulmasy, MD, PhD)

2014 Responding to the limits and possibilities of the body. 2014 Conference on Medicine and Religion. Chicago. March 7-9. (with Daniel Sulmasy, MD, PhD)

2015 Spiritual Dimensions of Illness and Healing. 2015 Conference on Medicine and Religion. Cambridge, MA, March 6-8. (with Daniel Sulmasy, MD, PhD, and Michael Balboni, PhD)

2016 Approaching the Sacred: Science, Health, and Practices of Care. 2016 Conference on Medicine and Religion. Houston, TX. March 4-6. (with Michael Balboni, PhD)

2016 - Practice and Presence: A Gathering for Christians in Health Care. Duke Divinity School. Durham, NC. (annual three day conference, with Warren Kinghorn, MD, PhD)

2017 Re-Enchanting Medicine. 2017 Conference on Medicine and Religion. Houston, TX. March 24-26. (with Michael Balboni, PhD)

2019 Theological Approaches to Persons in Pain. J.B. Duke Hotel & Conference Center. Durham, NC. March 28.

2019 "My pain is always with me"; Medicine & Faithful Responses to Suffering. 2019 Conference on Medicine and Religion. JB Duke Hotel & Conference Center. Durham, NC. March 29-31.

2021 2021 Conference on Medicine and Religion (Virtual). March 22-24.

2022 2022 Conference on Medicine and Religion, The Nines Hotel, Portland, OR. March 13-15.

2022 Questioning Preventive Medicine: Is a Pound of Prevention Worth an Ounce of Cure? Duke University. May 17.

TEACHING EXPERIENCE AND CURRICULUM DEVELOPMENT (selected)

Undergraduates

2006 Things, bodies, persons: Human goods in the technological era. Big Problems Course, The University of Chicago. (faculty, with J Lantos and D Brudney)

2022 - Medicine and Human Flourishing. Course for sophomores in "Transformative Ideas" series. Worked with primary instructor, Jose Gonzalez, to design course.

Medical Students

2002, 2003 Medicine and Spirituality Course. University of Chicago. (guest lecture)

2002, 2003 National *Wit* Education Initiative. Discussion group facilitator.

2003 – 2013 Cultural competence in medicine. Preceptor

2004 – 2006 Committee for Medical Student Retreats, Co-created and co-directed sessions on humanism and medicine (90 students/session).

2004 Essentials of Physicianship. MS1 course. Small Group facilitator/instructor

2004, 2005 Spirituality and Healing in Medicine. medical student elective (course co-director).

2004, 2006 Clinical Skills 1C course. (lecture: Religion and the doctor-patient relationship).

2005 – 2013 Summer Research Program. (faculty mentor to 10 medical students)

2005 – 2013 Death, dissection, and doctor formation. (Annual lecture before MS1 cadaver lab)

2005 – 2013	Doctor-Patient Relationship course. (Core faculty and lecturer)
2010 – 2013	Physician Development and Formation. (Co-director of required small group discussion component of MS1 Gross Anatomy course)
2015 – 2019	MS2 Practice Course. Teach session(s) on the ethics of clinical decision-making, and on religion, spirituality, and medicine
2019 –	Clinical Medical Ethics: What Would a Good Physician Do? (annual 8-week elective)

Residents

2004 – 2013	Internal Medicine Residency Morning Report. (Faculty discussant for 55 total sessions over 9 years, focused on cases with clinical ethical complexity)

Fellows

2004-5, 2007	Research Proposal Design Workshop. Co-directed summer workshop for fellows in health services research and ethics.
2004 – 2013	MacLean Center for Clinical Medical Ethics Fellowship. Taught three sessions/year
2006 – 2013	Religious Traditions and Clinical Ethical Decisions. (director of annual, quarter-long seminar for fellows in clinical medical ethics and interested medical students)
2010 – 2013	Summer Program in Outcomes Research Training. Teach 90-minute session for clinical research fellows on Practical Survey Development and Design.

Divinity Students

2014	Healing Arts: Suffering, Illness, and the Witness of the Church. Duke Divinity School. (course co-director, with Kinghorn and Barfield)
2016 –	Health Care in Theological Context II (formerly *Theological Bioethics*). Semester-length course. Duke Divinity School

GRANT FUNDING

Current:

1. Fellowship in Theology, Medicine, and Culture
PI: Kinghorn (Curlin Co-Investigator) Agency: The Issachar Fund
Period: 7/1/15 – 12/31/22
Project invites students and practitioners in health professions, as well as others with full-time vocations to health-related contexts, to participate in a program of theological formation that will equip them for faithful, disciplined, and creative engagement with contemporary practices of health care.

2. Out of Our Meds? Building a Theological and Moral Framework for the Use of Medications
PI: Kinghorn (Curlin Co-Investigator) Agency: McDonald Agape Fund
Period: 2016 – 2022
This project conducts a series of five annual symposia on theological, ethical, and clinical questions raised by pharmaceutical prescribing.

Past:

1. The integration of religion and spirituality in patient care among US physicians
PI: Curlin and Chin Agency: The Greenwall Foundation
Period: 07/01/02 – 06/30/04
Project conducted the first comprehensive national study of physician's religious characteristics and how those characteristics are associated with physicians' clinical practices.

2. Religious commitments and clinical engagements
PI: Curlin Agency: NCCAM
Type: K23 AT002749-01A1 Period: 10/01/05 – 09/30/10
Project developed a mixed-methods framework for assessing the religion-associated variations in physicians' self-reported and self-predicted practices in different clinical domains.

3. Variance on the margins of religion and medicine
PI: Curlin Agency: The Greenwall Foundation
Period: 07/01/06 – 06/30/09
[Greenwall Foundation Faculty Scholar in Bioethics] Project refined a methodology for assessing religion-associated variance in physicians' self-reported and self-predicted practices, and applied that methodology to assess variations in physicians' approaches to sexual and reproductive health care.

4. Conscience and Clinical Practice: Medical Ethics in the Face of Moral Controversy
PI: Curlin Agency: The Greenwall Foundation
Period: 01/01/08 – 06/30/09
Grant supported a conference on the place of the clinician's conscience in ethical practice, held at the University of Chicago on March 18, 2008.

5. The Chicago Program on Spirituality, Theology and Clinical Decision-Making
PI: Curlin Agency: The John Templeton Foundation
Period: 10/01/08 – 09/30/12
This project established the Program on Medicine and Religion at the University of Chicago and supported four national physician surveys to assess religion-associated variations in physicians' practices related to 1) sexual and reproductive health care, 2) primary care mental and behavioral health care, 3) decision-making in advanced illness and end of life care, and 4) the doctor patient relationship and meaning in medicine.

6. Project on the Good Physician: A New Science of Virtues
PI: Curlin Agency: Arete Initiative, The University of Chicago
Period: 3/1/10 – 2/28/12
This grant supported a national longitudinal study of the moral and professional formation of American physicians over the course of medical training

7. Physician Heal Thyself: The University of Chicago Medicine and Religion Faculty Scholars Program
PI: Sulmasy (Curlin Co-PI) Agency: The John Templeton Foundation
Period: 7/1/12-6/30/15
Project established a Faculty Scholars Program in Medicine and Religion, funding eight junior faculty nationwide at 50% effort for two year tenures.

8. Toward Policies that Accommodate the Concerns of African Americans in Resolving Disputes about the Use of Life-Sustaining Technology
PI: Johnson (Curlin Co-I) Agency: Greenwall Foundation
Period: 3/1/2015 – 2/29/2017
This project examined the attitudes of African Americans toward futile treatments and futility policies.

9. Training Research-Literate Chaplains as Ambassadors for Spirituality and Health
PI: Fitchett and Cadge (Curlin Co-I) Agency: John Templeton Foundation
Period: 7/1/2015 - 6/30/19
This project advanced research literacy among the nation's health care chaplains.

10. Toward Effective Cooperation between Clinical and Other Community Stakeholders Committed to Stemming the Opioid Epidemic
PI: Curlin (McCarty Co-PI) Agency: The Greenwall Foundation
Period: 7/1/2019 – 6/30/2022
This project aims to 1) describe the barriers to institutional collaboration among those responding to the opioid epidemic; and 2) create policy recommendations for effective collaboration in efforts to stem the opioid epidemic.

11. The Arete Initiative at Duke University's Kenan Institute for Ethics
PI: Curlin Agency: Foundation for Excellence in Higher Education
Period: 7/1/17 – 6/30/21
The Arete Initiative sponsors scholarship and learning opportunities focused on recovering and sustaining the virtues in contemporary life, especially in the workplace, the university, and the public square.

PUBLICATIONS
Original peer-reviewed scholarship

Books
Curlin FA, Tollefsen C. *The Way of Medicine: Ethics and the Healing Profession*. Notre Dame University Press; 2021.

Papers
1. Iwashyna TJ, Curlin FA, Christakis NA. Racial, ethnic and affluence differences in elderly patients' use of teaching hospitals. *J Gen Int Med*. 2002;17(9):696-703.
2. Hall DE, Curlin F, Koenig HG. When clinical medicine collides with religion. *Lancet*. 2003;362:S28-S29
3. Hall DE, Curlin FA. Can physicians' care be neutral regarding religion? *Academic Medicine*. 2004;79:677-679.
4. Curlin FA and Moschovis PP. Is religious devotion relevant to the doctor-patient relationship? *Journal of Family Practice*. 2004;53(8):632-640.
5. Curlin FA, Roach CJ, Gorawara-Bhat R, Lantos JD, Chin MH. When patients choose faith over medicine: Physician perspectives on religiously related conflict in the medical encounter. *Archives of Internal Medicine*. 2005;165(1):88-91
6. Curlin FA, Hall DE. Strangers or friends? A proposal for a new spirituality-in-medicine ethic. *J Gen Intern Med*. 2005;20(4):370-374.

   Editorial: Scheurich N. Spirituality, Medicine, and the Possibility of Wisdom. *J Gen Intern Med*. 2005;20(4):379-380.
7. Curlin FA, Lantos JD, Roach CJ, Sellergren SA, Chin MH. Religious characteristics of U.S physicians: A national survey. *J Gen Intern Med*. 2005;20(7):629-634.
8. Curlin FA, Roach CJ, Gorawara-Bhat R, Lantos JD, Chin MH. How are religion and spirituality related to health? A study of physicians' perspectives. *South Med J*. 2005; 98(8):761-6.

Editorial: Daly CC. Religion and the attending physician's point-of-view. *South Med J.* 2005; 98(8):759

9. Gee L, Smucker D, Chin M, Curlin FA. Partnering together? A study of current relationships between faith-based community health centers and local religious congregations. *South Med J.* 2005; 98(12):1245-50

    Editorial: Flannelly KJ, Weaver AJ, Tannenbaum HP. What do we know about the effectiveness of faith-based health programs? *South Med J.* 2005; 98(12):1243-4.

10. Curlin FA, Hall DE. Regarding Plan B: Science and politics cannot be separated. *Obstet Gynecol.* 2005;105(5):1148-50

11. Curlin FA, Chin MH, Sellergren SA, Roach CJ, Lantos JD. The association of physicians' religious characteristics with their attitudes and self-reported behaviors regarding religion and spirituality in the clinical encounter. *Med Care*. 2006;44:446-53

12. Curlin FA. Spirituality and lifestyle: what clinicians need to know. *South Med J.* 2006;99:1170-1.

13. Curlin FA, Serrano K, Baker M, Carricaburu S, Smucker D, Chin MH. Following the call: How providers make sense of their decisions to work in faith-based and secular urban community health centers. *J Health Care Poor Underserved*. 2006;17(4):944-957

14. Curlin FA, Lawrence RE, Chin MH, Lantos JD. Religion, conscience, and controversial clinical practices. *New England Journal of Medicine*. 2007;356(6):593-600

    Curlin FA, Lawrence RE, Lantos JD. Letters and author reply. Religion, conscience, and controversial clinical practices. *N Engl J Med*. 2007;356(18):1889-92

15. Curlin FA, Sellergren SA, Lantos JD, Chin MH. Physicians' observations and interpretations of the influence of religion and spirituality on health. *Arch Intern Med*. 2007;167(7):649-54

16. Curlin FA, Dugdale LS, Lantos JD, Chin MH. Do religious physicians disproportionately care for the underserved? *Annals of Family Medicine.* 2007;5(4):353-60.

17. Curlin FA, Odell S, Lawrence RE, Chin MH, Lantos JD, Meador KG, Koenig HG. The relationship between psychiatry and religion among US physicians. *Psychiatr Serv* 2007;58(9):1193-1198.

    Curlin FA, Meador KG, Koenig HG. Psychiatrists and religious belief: reply. *Psychiatr Serv*. 2007;58(11):1500-1

18. Curlin FA, Lawrence RE, Odell S, Chin MH, Lantos JD, Koenig HG, Meador KG. Religion, spirituality, and medicine: psychiatrists' and other physicians' differing observations, interpretations, and clinical approaches. *Am J Psychiatry*. 2007;164(12):1825-31.

    Editorial: Eichelman B. Religion, spirituality, and medicine. Am J Psychiatry 2007;164: 1774-1775

19. Lawrence RE, Curlin FA. Clash of definitions: Controversies about conscience in medicine. *American Journal of Bioethics*. 2007;7(12):10-4.

    Lawrence RE, Curlin FA. Response to eleven peer commentaries regarding "Clash of Definitions: Controversies about Conscience in Medicine". *Am J Bioeth*. 2007;7(12):1-2.

20. Curlin FA, Nwodim C, Vance JL, Chin MH, Lantos JD. To die, to sleep: US physicians' religious and other objections to physician assisted suicide, terminal sedation, and withdrawal of life support. *Am J Hosp Palliat Care*. 2008;25(2):112-20.

21. Lantos JD, Curlin FA. Religion, conscience, and clinical decisions. *Acta Paediatr*. 2008;97(3):265-6.

22. Curlin FA, Dinner SN, Lindau ST. Of more than one mind: obstetrician-gynecologists' approaches to morally controversial decisions in sexual and reproductive healthcare. *J Clin Ethics*. 2008;19(1):11-21; discussion 22-3

    Published as Feature article with the following editorials: 1) Howe EG. When, if ever, should caregivers provide moral advice? 2) Pellegrino ED. Commentary on 'Of More than One Mind.' 3) Chervenak FA, McCullough LB. Professional responsibility and individual conscience, and 4) Kozishek D, Bogdan-Lovis E. Beliefs, boundaries, and self-knowledge in professional practice.

23. Ishibashi KL, Koopmans J, Curlin FA, Alexander K, Ross LF. Paediatricians' attitudes and practices towards HPV vaccination. *Acta Paediatr.* 2008;97(11):1550-6

24. Tilburt JC, Kaptchuk TJ, Curlin FA, Emanuel EJ, Miller FG. Prescribing "placebo treatments": results of national survey of US internists and rheumatologists. *BMJ*. 2008;337:a1938

25. Ishibashi KL, Curlin FA, Alexander K, Koopmans J, Ross LF. Pediatricians are more supportive of HPV vaccination than are members of the general public. *South Med J*. 2008;101(12):1216-21.

26. Tilburt JC, Curlin FA, Kaptchuk TJ, Clarridge B, Bolcic-Jankovic D, Emanuel EJ, Miller FG. Alternative medicine research in clinical practice: a US national survey. *Arch Intern Med*. 2009;169(7):670-7.

27. Lawrence RE, Curlin FA. Autonomy, religion and clinical decisions: findings from a national physician survey. *J Med Ethics*. 2009;35(4):214-8.

28. Curlin FA, Lawrence RE, Fredrickson J. An ethical façade? Medical students' miscomprehensions of substituted judgment. PLoS ONE. 2009;4(2):e4374.

29. Lawrence RE, Curlin FA. Physicians' beliefs about conscience in medicine: a national survey. *Acad Med*. 2009;84(9):1276-82.

30. Antiel RM, Curlin FA, James KM, Tilburt JC. Physicians' beliefs and U.S. health care reform—A national survey. *New England Journal of Medicine*. 2009 Oct 1;361(14):e23. Epub 2009 Sep.

31. Curlin FA, Rasinski KA, Kaptchuk TJ, Emanuel EJ, Miller FG, Tilburt JC. Religion, clinicians, and the integration of complementary and alternative medicines. *J Altern Complement Med*. 2009;15(9):987-94.

32. Fitchett G, Rasinski K, Cadge W, Curlin FA. Physicians' experience and satisfaction with chaplains: a national survey. Arch Intern Med. 2009;169(19):1808-10.

33. Manek NJ, Crowson CS, Ottenberg AL, Curlin FA, Kaptchuk TJ, Tilburt JC. What rheumatologists in the United States think of complementary and alternative medicine: Results of a national survey. *BMC Complement Altern Med*. 201028;10:5.

34. Bekelman DB, Curlin FA, Parry C, Yamashita T, Fairclough D, Wamboldt FS. A comparison of two spirituality instruments and their relationship to depression and quality of life in chronic heart failure *J Pain Symptom Manage*. 2010;39(3):515-2.

35. Tilburt JC, Miller FG, Jenkins S, Kaptchuk TJ, Clarridge B, Bolcic-Jankovic D, Emanuel EJ, Curlin FA. Factors that influence practitioners' interpretations of evidence from alternative medicine trials: a factorial vignette experiment embedded in a national survey. *Med Care*. 2010; 48(4):341-8.

36. Stulberg D, Lawrence RE, Schattuck J, Curlin FA. Religious hospitals and primary care physicians: Conflicts over policies for patient care. *J Gen Intern Med.* 2010;25(7):725-30.

37. Lawrence RE, Rasinski KA, Yoon JD, Curlin FA. Obstetrician-gynecologists' beliefs about assisted reproductive technologies. *Obstetrics and Gynecology*. 2010;116(1):127-35.

38. Yoon JD, Rasinski K, Curlin FA. Moral controversy, directive counsel, and the doctor's role: Findings from a national survey of obstetrician-gynecologists. *Acad Med.* 2010;85(9):1475-81.
39. Lawrence RE, Rasinski KA, Yoon JD, Curlin FA. Obstetrician-gynecologist physicians' beliefs about emergency contraception: A national survey. *Contraception*. 2010;82(4):324-30.
40. Yoon JD, Rasinski KA, Curlin FA. Conflict and emotional exhaustion in obstetrician-gynecologists: A national survey. *J Med Ethics*. 2010;36(12):731-5.
41. Lawrence RE, Rasinski KA, Yoon JD, Curlin FA. Obstetrician-gynecologist physicians' views on contraception and natural family planning. *Am J Obstet Gynecol*. 2011;204:124.e1-7.
42. Lawrence RE, Rasinski KA, Yoon JD, Curlin FA. Factors influencing physicians' advice about female sterilization: a national survey. *Human Reproduction*. 2011;26(1):106-11.
43. Antiel RM, Curlin FA, Hook CC, Tilburt JC. The impact of medical school oaths and other professional codes of ethics: results of a national physician survey. *Arch Intern Med*. 2011;171(5):469-71.
44. Lawrence RE, Curlin FA. The rise of empirical research in medical ethics: a MacIntyrean critique and proposal. *J Med Philos.* 2011;36(2):206-16.
45. Lawrence RE, Rasinski KA, Yoon JD, Curlin FA. Adolescents, contraception, and confidentiality: a national survey of obstetrician-gynecologists. *Contraception*. 2011;84(3):259-65.
46. Combs MP, Antiel RM, Tilburt JC, Mueller PS, Curlin FA. Conscientious refusals to refer: findings from a national physician survey. *J Med Ethics*. 2011;37(7):397-401.
47. Rasinski KA, Yoon JD, Kalad YG, Curlin FA. Obstetrician-gynecologists' opinions about conscientious refusal of a request for abortion: Results from a national vignette experiment. *J Med Ethics*. 2011;37(12):711-4.
48. Rasinski KA, Kalad YG, Yoon JD, Curlin FA. An assessment of US physicians' training in religion, spirituality and medicine. *Medical Teacher*. 2011;33(11):944-5.
49. Lawrence RE, Rasinski KA, Yoon JD, Curlin FA. Obstetrician-gynecologists' beliefs about safe-sex and abstinence counseling. *Int J Gynaecol Obstet.* 2011;114(3):281-5.
50. Chung GS, Lawrence RE, Curlin FA, Arora V, Meltzer DO. Predictors of hospitalised patients' preferences for physician-directed medical decision-making. *J Med Ethics*. 2012;38(2):77-82.
51. Williams JA, Meltzer DO, Arora V, Chung G, Curlin FA. Attention to inpatients' religious and spiritual concerns: Predictors and association with patient satisfaction. *J Gen Int Med*. 2011;26(11):1265-71
52. Stern RM, Rasinski KA, Curlin FA. Jewish physicians' beliefs and practices regarding religion/spirituality in the clinical encounter. *J Relig Health.* 2011;50(4):806-17.
53. Stulberg DB. Dude AM, Dahlquist I, Curlin FA. Abortion provision among practicing obstetrician-gynecologists. *Obstet Gynecol.* 2011;118(3):609-14.
54. Harris L, Cooper A, Rasinski KA, Curlin FA, Lyerly AD. Obstetrician-gynecologists' objections to and willingness to help patients obtain an abortion. *Obstet Gynecol.* 2011;118(4):905-912.
55. Chung GS, Lawrence RE, Yoon JD, Rasinski KA, Curlin FA. Obstetrician-gynecologists' beliefs about when pregnancy begins. *Am J Obstet Gynecol.* 2012;206(2):132.e1-7

    Letter Reply: Chung GS, Lawrence RE, Rasinski KA, Yoon JD, Curlin FA. Am J Obstet Gynecol. 2012;207(5):e9-e10.

56. Lawrence RE, Rasinski KA, Yoon JD, Koenig HG, Meador KG, Curlin FA. Physicians' beliefs about faith-based treatments for alcoholism. *Psychiatric Serv*. 2012;63(6):597-604.

57. Sobecki JN, Curlin FA, Rasinski KA, and Lindau ST. What we don't talk about when we don't talk about sex: Results of a national survey of U.S. obstetrician/gynecologists. *J Sex Med* 2012;9:1285–94

58. Karches KE, Chung G, Arora V, Meltzer DO, Curlin FA. Religiosity, spirituality, and end of life planning: A single-site survey of medical inpatients. *J Pain Symptom Manage*. 2012;44(6):843-51

59. Antiel RM, Curlin FA, James KM, Sulmasy DP, Tilburt JC. Dignity in end of life care: results of a national survey of US physicians. *Journal of Pain and Symptom Management*. 2012;44(3):331-9

60. Stulberg DB, Dude AM, Dahlquist I, Curlin FA. Obstetrician–gynecologists, religious institutions, and conflicts regarding patient care policies. *Am J Obstet Gynecol*. 2012;207(1):73.e1-5

61. Lawrence RE, Rasinski KA, Yoon JD, Meador KG, Koenig HG, Curlin FA. Primary care physicians' and psychiatrists' approaches to treating mild depression. *Acta Psychiatr Scand*. 2012;126(5):385-392

62. Rasinski KA, Lawrence RE, Yoon JD, Curlin FA. A sense of calling and primary care physicians' satisfaction in treating smoking, alcoholism and obesity. *Arch Intern Med.* 2012;172(18):1423-4.

63. Shin JH, Yoon, JD, Rasinski KA, Koenig HG, Meador KG, Curlin FA. A spiritual problem? Primary care physicians' and psychiatrists' interpretations of medically unexplained symptoms. *J Gen Intern Med*. 2013;28(3):392-8

64. Lawrence RE, Rasinski KA, Yoon JD, Curlin FA. Physicians' beliefs about the nature of addiction: a survey of primary care physicians and psychiatrists. *Am J Addict*. 2013;22(3):255-60

65. Putman MS, Yoon JD, Rasinski KA, Curlin FA. Intentional sedation to unconsciousness at the end of life: Findings from a national physician survey. *J Pain Symptom Manage.* 2013;46(3):326-34.

    Authors' reply to Dirksen et al. Putman MS, Curlin FA. J Pain Symptom Manage. 2013;45(5):e2-3.

66. Lawrence RE, Rasinski KA, Yoon JD, Curlin FA. Religion and anxiety treatments in primary care patients. *Anxiety Stress Coping.* 2013;26(5):526-38.

67. Lawrence RE, Rasinski KA, Yoon JD, Curlin FA. Religion and beliefs about treating medically unexplained symptoms: a survey of primary care physicians and psychiatrists. *Int J Psych Med*. 45(1); 2013: 31-44.

68. Sheppe A, Nicholson R, Rasinski KA, Yoon JD, Curlin FA. Providing guidance to patients: physicians' views about the relative responsibilities of doctors and religious communities. *South Med J.* 2013;106(7):399-406

    Commentary: Perkins HS. South Med J. 2013;106(7):407-8

69. Combs MP, Rasinski KA, Yoon JD, Curlin FA. Substituted judgment in principle and practice: A national physician survey. *Mayo Clinic Proceedings*. 2013;88(7):666-73.

70. Tilburt JC, James K, Jenkins SM, Antiel RM, Curlin FA, Rasinski KA. "Righteous Minds" in health care: Measurement and explanatory value of social intuitionism in accounting for the moral judgments of U.S. physicians. *PLoS One*. 2013;8(9):e73379.

71. Antiel RM, Curlin FA. The moral psychology of rationing among physicians: The role of harm and fairness intuitions in physician objections to cost-effectiveness and cost-containment. *Philos Ethics Humanit Med.* 2013;8(1):13.

72. Padela AI, Curlin FA. Religion and disparities: Considering the influences of Islam on the health of American Muslims. *J Relig Health*. 2013;52(4):1333-45.

73. Wolenberg KM, Yoon JD, Rasinski KA, Curlin FA. Religion and United States physicians' opinions and self-predicted practices concerning artificial nutrition and hydration. *J Relig Health.* 2013;52(4):1051-65.

74. Putman MS, Yoon JD, Rasinski KA, Curlin FA. Directive counsel and morally controversial medical decision-making: Findings from two national surveys of primary care physicians. *J Gen Int Med.* 2014; 29(2):335-340.

    Commentary: Zehnder NG. J Gen Intern Med. 2013 Nov 6

75. Antiel RM, O'Donnell EP, James KM, Hardt JJ, Curlin FA, Tilburt JC. Physician opinion and the HHS contraceptive mandate. *AJOB Empirical Bioethics*. 2014;5(1):56-60

76. Cook AF, Arora VM, Rasinski KA, Curlin FA, Yoon JD. The prevalence of medical student mistreatment and its association with burnout. *Academic Medicine*. 2014;89(5):749-54

77. Lawrence RE, Rasinski KA, Yoon JD, Curlin FA. Physician race and treatment preferences for depression, anxiety, and medically unexplained symptoms. *Ethn Health.* 2014;29:1-11.

78. Kim DT, Curlin FA, Wolenberg KM, Sulmasy DP. Religion in organized medicine: The Committee and Department of Medicine and Religion of the American Medical Association, 1961-1974. *Perspect Biol Med.* 2014;57(3):393-414

79. Shim JM, Schneider J, Curlin FA. Patterns of user disclosure of complementary and alternative medicine (CAM) use. *Med Care*. 2014;52(8):704-8

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81. Lawrence RE, Rasinski KA, Yoon JD, Curlin FA. Primary care physicians' and psychiatrists' willingness to refer to religious mental health providers. *International Journal of Social Psychiatry*. 2014;60(7):627-36.

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EXHIBIT #2

IN THE DISTRICT OF JOHNSON COUNTY, KANSAS
CIVIL COURT DEPARTMENT

HODES & NAUSER, MDs, P.A., on behalf of itself, its patients, physicians, and staff; TRACI LYNN NAUSER, M.D.; TRISTAN FOWLER, D.O.; and COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, on behalf of itself and its patients, physicians, and staff, Plaintiffs, v. KRIS KOBACH, in his official capacity as Attorney General of the State of Kansas; STEPHEN M. HOWE, in his official capacity as District Attorney for Johnson County; MARCH BENNETT, in his official capacity as District Attorney for Sedgwick County; SUSAN GILE, in her official capacity as Executive Director of the Kansas Board of Health Arts; and RONALD M. VARNER, D.O., in his official capacity as President of the Kansas Board of Healing Arts, Defendants.	Case No. 23CV03140 Division No. 12 K.S.A. Chapter 60

DECLARATION OF ROBIN PIERUCCI, M.D., M.A., F.A.A.P.

I, Robin Pierucci, M.D., F.A.A.P., pursuant to the provisions of Kan. Stat. Ann. § 53-601, do hereby declare as follows:

1. I am at least 18 years of age and competent to testify. I have personal and professional knowledge of the statements contained in this declaration. The opinions I express in this declaration are based on my education, training, experience,

and ongoing familiarity with the medical literature. These opinions are my own, and do not represent any group with which I am affiliated.

I. Introduction and Professional Background

2. I received my M.D. degree from Rush Medical College in Chicago in 1994. I completed my residency training in pediatrics at the Children's Hospital of WI, Milwaukee in 1997 as well as my neonatal fellowship in 2000. During fellowship, I also completed by my master's degree in bioethics in 2000 from the Medical College of Wisconsin. My master's thesis examined the use of palliative care in the neonatal intensive care unit (NICU).

3. Through the American Board of Pediatrics, I have maintained board certification in both pediatrics and neonatology. Since graduating from fellowship, I have been a practicing neonatologist in Michigan at a Level 3 neonatal intensive care unit. I became the medical director of the same NICU in 2007. I also am a clinical assistant professor at Western Michigan University Homer-Stryker Medical school, and I remain a full-time practicing clinical neonatologist. This includes providing perinatal consultations and perinatal palliative care. I have been actively involved in leading multiple performance improvement projects including treatment of opiate exposed neonates, use of nasal CPAP to decrease incidence of bronchopulmonary dysplasia (BPD), and the on-going initiative that is led by the Vermont Oxford Network: "All Care is Brain Care."

4. My experience and qualifications are set forth in further detail in my *curriculum vitae*, attached hereto as Exhibit A.

II. Opinions and Reasons for Them

5. I have reviewed sections 65-6709 and 65-6710 of the Kansas Statutes and the Kansas informed consent handbook as they pertain to fetal viability, fetal pain, and fetal development.

A. Life Begins at Conception

6. The biological fact is, from the moment of sperm-egg fusion, a new human being with identifiable DNA that is different than either of the contributing parents exists.[1] The fusion of the oocyte and the sperm create the zygote "in less than a single second."[2] This is an uncontroversial biologic fact.

7. There is no method other than egg-sperm fusion (even when various techniques for assisted reproduction are utilized), for human beings to reproduce. Humans do not have spores like fungi. Philosophy and controversy exist regarding the *value* of life at its most immature, but the biological occurrence of how humans reproduce is settled science.

8. At different stages of development, embryologists have given specific names to these stages such as embryonic and fetal. These names help to identify where specifically in the developmental process the human being is. However, whether the human being is identified as an embryo or a fetus, the developing person is never anything other than a human being.

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[1] *Slatery*, 14 F.4th at 450 (Thapar, J.) (citing Enrica Bianchi et al., *Juno Is the Egg Izumo Receptor and Is Essential for Mammalian Fertilization*, 508 Nature 483, 483 (2014

[2] Am. Coll. of Pediatricians, *When Human Life Begins* (Mar. 2017), https://perma.cc/Z9W5-UN9T; *see also* Ulyana Vjugina & Janice P. Evans, *New Insights into the Molecular Basis of Mammalian Sperm-Egg Membrane Interactions*, 13 Frontiers Bioscience 462, 462–76 (2008); Maureen L. Condic, *When Does Human Life Begin? A Scientific Perspective* 5 (2008).

9. Going forward from fertilization, the zygote transitions to an embryo, which progresses through additional cell divisions and cell differentiation, to become a fetus. At all stages of development, the new, distinct human being is alive and possesses its unique DNA.[3] In a "biological sense," "the embryo or fetus is whole, separate, unique and living" from conception. *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 736 (8th Cir. 2008) (en banc).

10. Because most of the babies admitted to the NICU are less than 40 weeks, they therefore have, to varying degrees, fetal physiology. By definition, all of them are technically still in the fetal period of development. Despite this, calling even our youngest patients "babies" is not inaccurate, misleading, or ideologic (Nauser #37).

11. This is also true in discussions with families prior to the baby's birth. When I meet a mother during a prenatal consultation, I usually ask if she has chosen a name for her baby. I have never asked if she has chosen a name for her fetus. Regardless of which side of the uterine wall the little one is on, we are discussing the same baby.

12. Whether or not the newly conceived human is planned or unplanned, in the same way that embryos become fetuses, if left unmolested the unborn baby will likely become a toddler, an adolescent, an adult, and an elder. Using scientific jargon, such as embryo or fetus, obfuscates the medical fact that a human baby is being discussed.

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[3] *Slatery*, 14 F.4th at 450 (Thapar, J.) (citing Enrica Bianchi et al., *Juno Is the Egg Izumo Receptor and Is Essential for Mammalian Fertilization*, 508 Nature 483, 483 (2014)).

B. Fetal Development

13. In clinical practice, gestational age is usually timed from the onset of the last normal menstrual period (LNMP). However, gestation does not begin until *after* the oocyte is fertilizated, which is 2 weeks after the LNMP. Embryologic or fetal age is used in embryology texts.[4] Therefore, if the gestational age is 22 weeks, the embryologic or fetal age is 20 weeks.

14. "Human development begins at fertilization when a sperm fuses with an oocyte to form a single cell, the zygote. . . . The zygote divides many times and becomes progressively transformed into a multicellular human being through cell division, migration, growth, and differentiation."[5] This is followed by implantation in the uterus "during a restricted time period 6 to 10 days after ovulation and fertilization."[6]

15. During the fifth week, "[t]he cardiovascular system is the first major system to function in the embryo," with the heart and vascular system appearing in the middle of the week.[7] By the end of the fifth week, "blood is circulating and the heart begins to beat on the 21st or 22nd day" after conception.[8]

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[4] Moore, Keith L.; Persaud, T. V. N.; Torchia, Mark G.. The Developing Human - E-Book (p. 196-197). Elsevier Health Sciences. Kindle Edition.
[5] Moore, Keith L.; Persaud, T. V. N.; Torchia, Mark G.. The Developing Human - E-Book (p. 57). Elsevier Health Sciences. Kindle Edition.
[6] Ibid pg 107
[7] Keith L. Moore et al., *The Developing Human E-Book: Clinically Oriented Embryology* 8945 (Kindle ed. 2020).
[8] *Id.* at 2662.

16. By six weeks, "[t]he embryonic heartbeat can be detected" via transvaginal ultrasound.[9] After detection of a fetal heartbeat—and absent an abortion—the overwhelming majority of unborn children will now survive to birth.[10] Also during the sixth week, the child's nervous system is developing, with the brain already "patterned" at this early stage.[11] The earliest neurons are generated in the region of the brain responsible for thinking, memory, and other higher functions.[12]

17. At seven weeks, cutaneous sensory receptors, which permit prenatal pain perception, begin to develop.[13] The unborn child also starts to move.[14] During the seventh week, "the growth of the head exceeds that of other regions" largely because of "the rapid development of the brain" and facial features.[15]

18. At eight weeks, essential organs and systems have started to form, including the child's kidneys, liver, and lungs.[16]

19. Nine weeks is the start of the fetal period of development. The transformation of an embryo to a fetus is gradual, but the name change is meaningful because it signifies that the primordia of all major systems have formed.[17] In other

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[9] *Id.* at 2755; *accord* WebArchive, Planned Parenthood, *What Happens in the Second Month of Pregnancy?* (July 25, 2022), https://tinyurl.com/2jvsvh34.
[10] Joe Leigh Simpson, *Low Fetal Loss Rates After Ultrasound Proved-Viability in First Trimester*, 258 J. Am. Med. Ass'n 2555, 2555–57 (1987).
[11] Thomas W. Sadler, *Langman's Medical Embryology* 72 (14th ed. 2019); *see generally id.* at 59–95.
[12] *See, e.g.*, Irina Bystron et al., *Tangential Networks of Precocious Neurons and Early Axonal Outgrowth in the Embryonic Human Forebrain*, 25 J. Neuroscience 2781, 2788 (2005)
[13] Kanwaljeet S. Anand & Paul R. Hickey, Special Article, *Pain and Its Effects in the Human Neonate and Fetus*, 317 New Eng. J. Med. 1321, 1322 (1987).
[14] Alessandra Pionetelli, *Development of Normal Fetal Movements: The First 25 Weeks of Gestation* 98, 110 (2010).d
[15] Keith L. Moore et al., *The Developing Human: Clinically Oriented Embryology* 65–84.e1 (11th ed. 2020).
[16] *See* Sadler, *supra* note 11, at 72–95.
[17] Moore, Keith L.; Persaud, T. V. N.; Torchia, Mark G.. The Developing Human - E-Book (p. 194). Elsevier Health Sciences. Kindle Edition.

words, the rudiments of every organ system are present by the end of 8 weeks gestation when the fetal period of development begins.

20. At nine weeks, the child's ears, eyes, teeth, and external genitalia are forming.[18]

21. At ten weeks, vital organs begin to function, and the child's hair and nails begin to form.[19]

22. Starting at 7.5 weeks and continuing through 15 weeks are the development of peripheral pain receptors. [20]

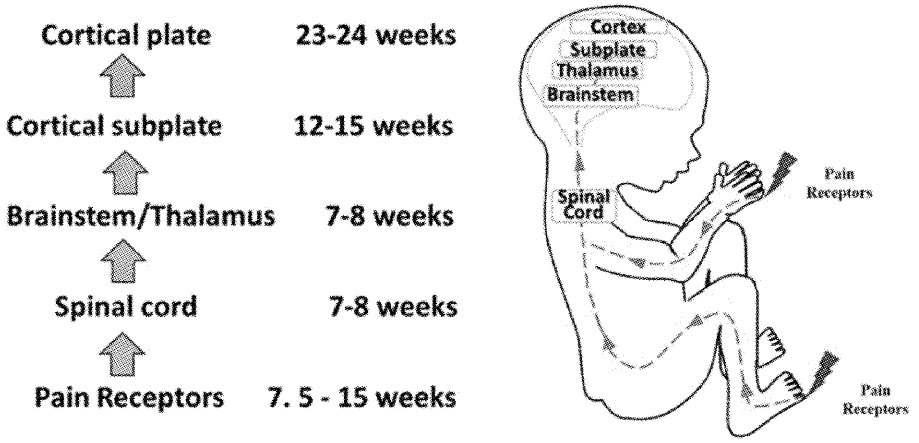

FIGURE 4
Development of nociceptive pathways. Peripheral pain receptors develop in most areas of the fetus between 7.5–15 weeks gestation (48). Afferents reach the spinal cord (49), the brainstem, and thalamus by 7–8 weeks (50, 51). Thalamic projections to the cortical subplate emerge at 12–15 weeks (14, 34, 52) and to the cortical plate after 23–24 weeks gestation (53).

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[18] *See id.*
[19] *See id.* at 106–127; Moore et al., *supra* note 15, at 65–84.e1; Johns Hopkins Med., *The First Trimester*, https://perma.cc/8N6H-M6CN.
[20] Thill B. The fetal pain paradox. Front Pain Res (Lausanne). 2023 Mar 21;4:1128530. Pg 4 doi: 10.3389/fpain.2023.1128530. PMID: 37025166; PMCID: PMC10072285.

23. By 12 weeks, erythropoiesis (formation of red blood cells) has decreased in the liver and has begun in the spleen.[21]

24. At 13 weeks, goal-oriented hand movements have been noted.[22] At 14 weeks in twin gestations, evidence of socially-aware motor planning of fetal hand movements toward the co-twin were seen. "These studies indicate early action planning, learning, and the emergence of a basic minimum level of consciousness in the fetus by 13–14 weeks gestation.[23]

25. From 13 to 16 weeks, "[l]imb movements, which first occur at the end of the embryonic period, become coordinated by the 14th week."[24]

26. By 15 to 16 weeks, "[f]etal responses to therapeutically indicated noxious procedures are evident . . . and are alleviated by analgesics. Prior to this time frame, published research is lacking."[25]

27. By 17 to 20 weeks, "[f]etal movements (quickening) are commonly felt by the mother."[26]

28. As early as 18 weeks, in response to using a needle to pierce the fetus's abdominal wall (as a way to reach the intrahepatic vein for a blood transfusion), the stress hormone beta-endorphin was documented to be increased significantly

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[21] Moore, Keith L.; Persaud, T. V. N.; Torchia, Mark G.. The Developing Human - E-Book (p. 168). Elsevier Health Sciences. Kindle Edition

[22] Thill B. The fetal pain paradox. Front Pain Res (Lausanne). 2023 Mar 21;4:1128530. Pg 9 doi: 10.3389/fpain.2023.1128530. PMID: 37025166; PMCID: PMC10072285.

[23] Ibid

[24] Moore, Keith L.; Persaud, T. V. N.; Torchia, Mark G.. The Developing Human - E-Book (p. 202). Elsevier Health Sciences. Kindle Edition.

[25] Thill B. The fetal pain paradox. Front Pain Res (Lausanne). 2023 Mar 21;4:1128530. doi: 10.3389/fpain.2023.1128530. PMID: 37025166; PMCID: PMC10072285.

[26] Moore, Keith L.; Persaud, T. V. N.; Torchia, Mark G.. The Developing Human - E-Book (p. 205). Elsevier Health Sciences. Kindle Edition.

elevated;[27] this was not seen when the non-inervated umbilical cord was accessed.[28] At 20 weeks, fetal beta-endorphin and as well as fetal cortisol levels were elevated in response to abdominal wall piercing.[29]

29. At 20 weeks gestation, "the maturity of the thalamus and associated subcortical structures with proper thalamocortical connections [are] accompanied by a coordinating electroencephalogram rhythm, provide the possibility for the fetus to experience something approximating "pain."[30]

30. The below table summarizes published data of fetal responses at different gestational ages to noxious stimuli.[31]

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[27] Gitau R, Fisk NM, Teixeira JM, Cameron A, Glover V. Fetal hypo- thalamic-pituitary-adrenal stress responses to invasive procedures are independent of maternal responses. *J Clin Endocrinol Metab.* 2001;86(1):104–109.

[28] Nicholas M. Fisk, Rachel Gitau, Jeronima M. Teixeira, Xenophon Giannakoulopoulos, Alan D. Cameron, Vivette A. Glover; Effect of Direct Fetal Opioid Analgesia on Fetal Hormonal and Hemodynamic Stress Response to Intrauterine Needling. *Anesthesiology* 2001; 95:828–835 doi: https://doi.org/10.1097/00000542-200110000-00008

[29] Ibid.

[30]Sekulic, S., Gebauer-Bukurov, K., Cvijanovic, M., Kopitovic, A., Ilic, D., Petrovic, D., ... & Topalidou, A. Appearance of fetal pain could be associated with maturation of the mesodiencephalic structures. Journal of Pain Research, 9, 1031-1038, 2016. https://doi.org/10.2147/JPR.S117959

[31] Ibid.

TABLE 1 Fetal responses to noxious stimuli.

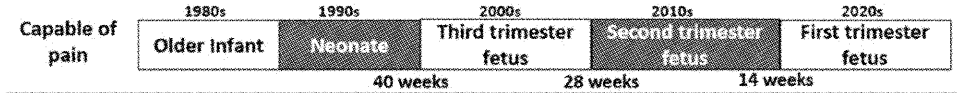
Source	# studied & GA	Noxious stimulus[a]	Fetal Response
Giannakoulopoulos et al. (1994) (15)	$N = 16$ 23–29 weeks GA	Needling of IHV *via* puncture of fetal trunk	– Significant hormonal stress response to invasive needling: median increase in β-endorphin 590% and cortisol 183% – Vigorous body and breathing movements
Petrikovsky and Kaplan (1995) (54)	$N = 7$ 15–18 weeks GAc(Case series)	Inadvertent contact of amniocentesis needle with fetal limb	– Brisk withdrawal of the involved part (except in one fetus with limb paralysis)
Teixeira et al. (1996) (39)	$N = 28$ 18–36 weeks GA (Pilot study)	Needling of IHV *via* puncture of fetal trunk	– Significant decrease in MCA PI in response to transgression of fetal trunk, consistent with redistribution of blood supply to the brain (brain-sparing effect)
Giannakoulopoulos et al. (1999) (41)	$N = 42$ 18–37 weeks GA	Needling of IHV *via* puncture of fetal trunk	– Significant elevation in fetal noradrenaline with needling involving transgression of fetal trunk – Dislodgement of needle in two cases of IHV needling due to vigorous fetal movements
Teixeira et al. (1999) (40)	$N = 130$ (136 procedures) 15–37 weeks GA	Needling procedures involving transgression of fetal trunk[b]	– Significant decrease in MCA PI within 70 s after painful stimulation, consistent with redistribution of blood supply to the brain (brain-sparing effect)
Fisk et al. (2001) (42)	$N = 16$ 20–35 weeks GA	IHV transfusion *via* transgression of fetal trunk, with or without fentanyl	– Direct fetal analgesia blunts the hormonal and hemodynamic stress response to intrahepatic vein needling (β-endorphin and MCA PI responses, respectively)
Gitau et al. (2001) (55)	$N = 51$ 18–35 weeks GA	Fetal blood sampling and intrauterine transfusion at IHV *via* piercing of fetal trunk; compared to maternal blood samples	– Fetal stress response to IHV transfusion, but not to transfusion at PCI (non-innervated); – Fetal responses are independent of maternal responses; – Fetal β-endorphin and cortisol responses are apparent from 18 to 20 weeks gestation, respectively
Mayorga-Buiza et al. (2017) (56)	$N = 1$ 24 weeks GA (Case study)	Open fetal surgery for myelomeningocele repair, inadvertently initiated without administration of fetal anesthesia	– Fetal bradycardia; – Fetal recovery after epinephrine and administration of direct fetal anesthesia
Bernardes et al. (2018) (57)	$N = 1$ 32 weeks GA (Case report)	Preoperative anesthetic injection into fetal thigh	– 10 facial actions coded by blinded investigators, before and after anesthetic puncture – pre-puncture score: 0–1/10; post-puncture score, 8–10/10
Bernardes et al. (2021) (58)	$N = 13$ 28–33 weeks GA	Preoperative anesthetic injection into fetal thigh	– Fetuses demonstrate discriminative facial expressions in response to painful stimuli – Presence of five out of seven pain-related facial expressions discriminated pain from nonpainful startle and rest
Bernardes et al. (2022) (16)	$N = 1$ 23 weeks GA	Preoperative intramuscular anesthetic injection into fetal thigh	– Facial expressions of acute pain demonstrated following intramuscular injection – Rated 5 out of 7 on fetal pain score by blinded investigators

GA, gestational age; IHV, intrahepatic vein; PCI, placental cord insertion; MCA PI, middle cerebral artery pulsatility index; wk, weeks.
[a]Fetuses were exposed to noxious stimuli during clinically-indicated procedures.
[b]Needling procedures involving transgression of fetal trunk: shunt insertion, tissue biopsy, ovarian cyst aspiration, urine aspiration, drainage of ascites, and fetal blood sampling and intrauterine transfusion *via* intrahepatic vein.

C. Fetal Pain

31. Despite claims that the "consensus" regarding the existance (or not) of fetal pain is settled science, inaccurately describes the recent past as well as ongoing discoveries. Our understanding changed dramatically in the early 90's (babies no

longer go surgery without anesthesia[32]), and new information continues to influence today's medical standard of care.



Time Frame	Assessment
1980s	**Neonates** considered **incapable of pain** due to immature cortex
1990s	**Fetuses** considered **incapable** of pain due to immature cortex
2000s	**Fetuses** considered **incapable** of pain **until third trimester** due to immature cortex
2010s	**Fetuses** considered **incapable** of pain **until late second trimester** due to immature cortex
2020s	**Fetuses** may be **capable** of pain **in first trimester** via cortical subplate and/or subcortical structures

[33]

Anatomic Requirements for Pain

32. The human brain does not have an anatomic structure that is THE pain place. However, important participating anatomic structures of the peripheral and central nervous system likely include:

> "a) nociceptors, b) pain neurotransmitters, c) centripetal fibers that lead the stimulus to the brain, d) the thalamus, e) connection with the cortex. Some authors argue that the thalamocortical connections are essential to feel pain, while others say that the connections from the spinal cord to the thalamus are enough, even though they allow pain to be felt only at a subconscious level. In the fetus, the cortex is relatively underdeveloped, but it is rudimentally present from the 20th week of gestation; meanwhile, a transitory structure takes the place of the cortex: the subplate." [34]

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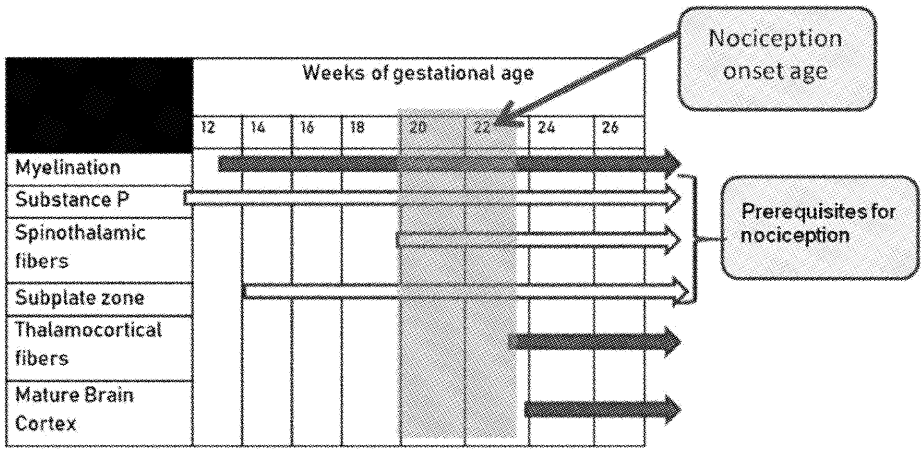
[32] Anand, KJS, D Phil, and PR Hickey. 1992. "Halothane–Morphine Compared with High-Dose Sufentanil for Anesthesia and Postoperative Analgesia in Neonatal Cardiac Surgery." *New England Journal of Medicine.* 326 no 1: 1–9. https://doi.org/10.1056/nejm199201023260101

[33] Thill B. The fetal pain paradox. Front Pain Res (Lausanne). 2023 Mar 21;4:1128530. doi: 10.3389/fpain.2023.1128530. PMID: 37025166; PMCID: PMC10072285.

[34] Bellieni, C. V. (2019, August). New insights into fetal pain. In *Seminars in fetal and neonatal medicine* (Vol. 24, No. 4, p. 101001). WB Saunders.

33. The peripheral pain receptors begin forming around seven weeks[35] and "the first evidence for an intact nociceptive system in the fetus emerges at about 8 weeks . . . [when] touching the perioral region will result in movement away."[36] Nociception—or the nervous system's processing of noxious stimuli—"causes physiologic stress, which in turn causes increases in catecholamines, cortisol, and other stress hormones."[37] Starting around ten weeks, the earliest connections between neurons constituting the subcortical-frontal pathways—the circuitry of the brain that is involved in a wide range of psychological and emotional experiences, including pain perception—are established.[38]

34. The following table from Dr Bellieni provides an overview of fetal nociception. The structures necessary for nociception are indicated by white arrows. The most likely age for fetal nociception onset is 20–22 weeks of postnatal age.



[35] Linda A. Hatfield, *Neonatal pain: What's age got to do with it?*, Surgical Neurology International S479, S481 (2014).
[36] Stuart W. G. Derbyshire, *Foetal Pain?*, Best Practice & Research Clincal Obstetrics and Gynaecology 647 (2010).
[37] Curtis L. Lowery et al., *Neurodevelopmental Changes of Fetal Pain*, 31 Seminars Perinatology 275, 275 (2007).
[38] Lana Vasung et al., *Development of Axonal Pathways in the Human Fetal Fronto-Limbic Brain: Histochemical Characterization and Diffusion Tensor Imaging*, 217 J. Anatomy 400, 400–03 (2010).

35. Both Dr Nauser (¶ 37) nor Dr Alsaden (¶ 58) indicated that due to "experts in human anatomy" or "consensus" the Kansas state booklet's facts regarding fetal pain are erroneous. Dr Nauser does not identify what experts or papers she relies on for that assertion. But Dr Alsaden refers to the views of the American College of Obstetricians and Gynecologists (ACOG), and the Society for Maternal Fetal Medicine (SMFM). Their "consensus" fails to reflect the medical standard of care for neonatologists who treat pain in their premature patients[39], including the youngest at 22 weeks gestation[40,41] and anesthesiologists who treat fetal pain during fetal surgery in patients as young as 15 weeks.[42] "Thus, a paradox exists in the disparate acknowledgment and treatment of pain perception by different medical groups in neonates <24–28 weeks gestation and fetuses of similar age."[43]

36. The Lee et al. article concluded that pain perception is not structurally possible until the stimulus reaches the cortex at 24 weeks gestation and is likely not functionally possible until 29–30 weeks when EEG and somatosensory evoked

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[39] Keels, Erin, Navil Sethna, Kristi Watterberg, James Cummings, William Benitz, Eric Eichenwald, Brenda Poindexter, Brenda, et al. 2016. "Prevention and Management of Procedural Pain in the Neonate: An Update." *Pediatrics* 137, no. 2:2. https://doi.org/10.1542/peds.2015-4271.

[40] Morris, Mindy, John Patrick Cleary, Antoine Soliman. 2015. "Small Baby Unit Improves Quality and Outcomes in Extremely Low Birth Weight Infants." *Pediatrics*, American Academy of Pediatrics, 136 (4) e1007-e1015. pediatrics.aappublications.org/ content/136/4/e1007.

[41] Fathi, O., Nelin, L.D., Shepherd, E.G. *et al.* Development of a small baby unit to improve outcomes for the extremely premature infant. *J Perinatol* **42**, 157–164 (2022). https://doi.org/10.1038/s41372-021-00984-0

[42] Chatterjee D, Arendt KW, Moldenhauer JS, Olutoye OA, Parikh JM, Tran KM, et al. Anesthesia for maternal-fetal interventions: a consensus statement from the American Society of Anesthesiologists Committees on Obstetric and Pediatric Anesthesiology and the North American Fetal Therapy Network. Anesth Analg. (2021) 132(4):1164–73. doi: 10.1213/ANE.0000000000005177

[43] Thill B. The fetal pain paradox. Front Pain Res (Lausanne). 2023 Mar 21;4:1128530. doi: 10.3389/fpain.2023.1128530. PMID: 37025166; PMCID: PMC10072285.

potentials (SEP) demonstrate cortical response to noxious stimuli.[44,45] However, neither EEG nor MRI validated this position.[46]

37. The heart of the argument against pain for both ACOG and SMFM is their insistence on cortical connectivity. Arguing against this are 2 pain capable groups: adults with severed cortical connections due to injury and babies whose cerebral cortex is either malformed or absent. In adults, clinical evidence suggests neither ablation nor stimulation of the primary somatosensory cortex alters pain perception.[47]

38. Also, in a study of hydranencephalic infants and their primary caregivers, the authors admit that "the default assumption [has been] that these children are not conscious."[48] Instead, they found that the "capacity of children with hydranencephaly to experience a spectrum of hedonic states spanning from distress to contentment, pleasure and even joy, as expressed through screaming, crying, fussing, smiling, giggling and laughter . . . indicat[ed] that they are not only physiologically awake but conscious."[49] Other publications report that anencephalic

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[44] Lee, S. J., Ralston, H. J. P., Drey, E. A.John Colin Partridge, Partridge, J. C., and Rosen, M. A. 2005. "Fetal Pain." JAMA 294 (8): 947-954. doi: 10.1001/jama.294.8.947.

[45]Thill B. Fetal Pain in the First Trimester. The Linacre Quarterly. 2022;89(1):73-100. doi:10.1177/00243639211059245

[46] Ibid pg 10

[47] Brusseau R. Developmental perspectives: Is the Fetus Conscious? Int. Anesthesiol. Clin. 2008; 46(3): 11-23.

[48] Barb Aleman and Bjorn Merker, *Consciousness Without Cortex: a Hydranencephaly Family Survey*, ACTA PAEDIATRICA (2014), https://onlinelibrary.wiley.com/doi/10.1111/apa.12718.

[49] Ibid

and hydranencephalic babies who have been exposed to painful and consoling stimuli, respond appropriately.[50] This is consistent with my own experience.

39. Since Lee et al.'s 2005 study, many have concluded that the subplate is "not just as a waiting compartment, but a functionally active and responsive precursor of the fetal cortex, beginning as early as 12 weeks gestation.[51] Still others note that subcortical structures including the brainstem and thalamus, located below the level of the cortex and subplate, are sufficient for pain perception via the spinothalamic tract which relays nociceptive information from the spinal cord to the thalamus beginning between 7–15 weeks gestation.[52,53] In an extensive literature review, Thill notes,

> "the spinothalamic nerve fibers begin reaching the thalamus at 7 weeks gestation, raising the possibility of fetal pain perception after 7–8 weeks gestation, once the minimum neuroanatomy is present. This is uncertain, however, due to the structural and functional immaturity of the thalamus at this stage in development."[54]

40. While varying hypotheses persist, the complex embryonic neuroanatomy provides "no scientific evidence that function in the multi-layered

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[50]Sekulic, Slobodan, Ksenija Gebauer-Bukurowv, Milan Cvijanovic, Aleksander Kopitovic, Djordje Ilic, Djordje Petroivic, Ivan Capo, et al. 2016, "Appearance of Fetal Pain Could Be Associated with Maturation of the Mesodiencephalic Structures." *Journal of Pain Research* 9:1031-1037. doi:10.2147/jpr.s117959.

[51] Thill B. Fetal Pain in the First Trimester. The Linacre Quarterly. 2022;89(1):73-100. doi:10.1177/00243639211059245

[52] Ibid pg 12

[53] Sekulic, Slobodan, Ksenija Gebauer-Bukurowv, Milan Cvijanovic, Aleksander Kopitovic, Djordje Ilic, Djordje Petroivic, Ivan Capo, et al. 2016, "Appearance of Fetal Pain Could Be Associated with Maturation of the Mesodiencephalic Structures." *Journal of Pain Research* 9:1031-1037. doi:10.2147/jpr.s117959.

[54] Thill B. Fetal Pain in the First Trimester. The Linacre Quarterly. 2022;89(1):73-100. doi:10.1177/00243639211059245

networks underlying pain perception wait for some cue to be "turned on."[55] This evolving level of maturation and capability, coupled with the behavioral evidence witnessed in both fetal and premature babies of the same gestational age, makes safeguarding a premature human being at 20 weeks gestation reasonable. In fact, it is medically and ethically how neonatologists and anesthesiologists practice medicine.

By Consensus, Doctors Used to Operate on Babies Without Anesthesia

41. Four decades ago, the medical consensus of all national medical organizations was, babies do not feel pain. But in 1987, *The New England Journal of Medicine (NEJM)* published Drs Anand, Phil, and Hickey's landmark paper showing evidence to the contrary.[56] The authors state, the "confusion over pain *perception* (emphasis added), and the accompanying physiologic responses have obscured the mounting evidence that nociception is important in the biology of the neonate."[57] In other words, concern over whether pain could be perceived by a person who does not yet have a mature, conscious awareness, obscured the evidence that pain does measurably affects an immature person's physiology.

42. Anand et al.'s paper drew upon results from their own work as well as multiple studies in an extensive review of the anatomic requirements for pain perception, the associated neurochemical systems, the physiologic and behavioral

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[55] Lowery, Curtis L., Mary P. Hardman, Nirvana Manning, Barbara Clancy, R. Whit Hall, K.J.S Anand. 2007. "Neurodevelopmental Changes of Fetal Pain." *Seminars in Perinatology*, vol. 31, no. 5:275-282. doi:10.1053/j.semperi.2007.07.004

[56] Anand, KJS., D. Phil, PR Hickey. 1987. "Pain and its Effects In the Human Neonate and Fetus." *New England Journal of Medicine* 317, no.21(February):1321-1329.

[57] Ibid, pg 1321

changes associated with pain, and the memory of pain in neonates. They concluded, "none of the cited data tell us whether neonatal nociceptive activity and associated responses are experienced subjectively. . . . However, the evidence does show that marked nociceptive activity clearly constitutes a physiological and perhaps even a psychologic form of stress in premature or full-term neonates."[58] Based on evidence, the authors recommended reevaluating the medical standard of care in favor of providing local and general anesthesia during invasive procedures.[59]

43. Unequivocally corroborating their previous paper's conclusion, the same group's 1992 *NEJM* publication was arguably even more demonstrative of the effects of pain on newborns and by today's standards, ethically troubling. This was a randomized trial comparing the outcomes of 4 to 10 day old neonates with congenital heart defects, who were eligible for surgical repair.[60] In the operating room, one group received "lighter anesthesia," the other group "deep anesthesia". When the babies' pain was effectively treated their outcomes were considerably improved, including statistically significant differences in intra-operative and post-operative markers of stress (stress hormones, hyperglycemia, lactic acidemia), and fewer post-operative deaths (4 of the 15 neonates died prior to discharge in the light anesthesia group, none of the 30 in the deep anesthesia group died prior to discharge home. This lower rate of mortality "was significantly lower than hospital mortality in other neonates

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[58] Ibid, pg 1326
[59] Ibid, pg 1327
[60] Anand, KJS, D Phil, and PR Hickey. 1992. "Halothane–Morphine Compared with High-Dose Sufentanil for Anesthesia and Postoperative Analgesia in Neonatal Cardiac Surgery." *New England Journal of Medicine.* 326 no 1: 1–9. https://doi.org/10.1056/nejm199201023260101

undergoing cardiac surgery with bypass and circulatory arrest during the study period").[61] Because of how compelling these results were, this study could not ethically be repeated. It is humbling to see that as recently as the early 1990's, the actual consensus of every major medical organization was that no babies felt pain. Informed by the data, medical practice in pediatrics, neonatology, and anesthesiology changed. Babies are no longer taken to surgery without anesthesia.

Evolution of the Standard of Care

44. Today the standard of care in both neonatology and anesthesiology is to treat fetal pain.

45. Since the 1990's, babies cared for in neonatal intensive care units have become progressively more immature,[62] and for some, fetal surgery has become an option that did not exist. By 2016, the American Academy of Pediatrics had sufficient evidence demonstrating pain's acute and long-term ramifications that their pain management policy was revised. *Prevention and Management of Procedural Pain in the Neonate: An Update,* specifically states that even premature babies' pain should be treated, minimized, and/or prevented, "not only because it is ethical but also because repeated painful exposures have the potential for deleterious consequences".[63] The consequences of experiencing pain include: "physiologic instability, altered brain development, and abnormal neurodevelopment,

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[61] Ibid, pg 1

[62] Rysavy M. et al. 2020 "Assessment of an Updated Neonatal Research Network Extremely Preterm Birth Outcome Model in the Vermont Oxford Network." *JAMA Pediatr* 2020;174(5):e196294. doi:10.1001/jamapediatrics.2019.6294

[63] Keels, Erin, Navil Sethna, Kristi Watterberg, James Cummings, William Benitz, Eric Eichenwald, Brenda Poindexter, Brenda, et al. 2016. "Prevention and Management of Procedural Pain in the Neonate: An Update." *Pediatrics* 137, no. 2:2. https://doi.org/10.1542/peds.2015-4271.

somatsosensory, and stress response systems, which can persist into childhood."[64] Pain adversely affects the immature nervous system.

46. The AAP's 2016 update was based on looking back at published literature, and thus could only say that "nociceptive pathways are active and functional as early as 25 weeks' gestation."[65] Since then, premature babies who are less than 25 weeks gestation are routinely cared for in NICU's, including those at 22 weeks gestation. Despite the increasing degree of prematurity, both survival and neurodevelopmental outcomes have markedly improved[66,67]. Contributing to the outcome improvements is treating, ameliorating, or avoiding painful stimulation specifically in these increasingly immature neonates.[68,69]

47. Two examples of practice changes I and many others have instituted are: (1) increased use of "kangaroo care" where the premature baby is placed in skin-to-skin contact with either the mother's or father's chest, and (2) cue-based care times, by which instead of checking vital signs every three hours, the staff try not to interrupt valuable sleep and use within reason, the babies' cues that they are awake or in need of being tended to. Multiple centers involved in performance improvement

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[64] Ibid, pg 2
[65] Ibid, pg 2
[66] Rysavy M. et al. 2020 "Assessment of an Updated Neonatal Research Network Extremely Preterm Birth Outcome Model in the Vermont Oxford Network." *JAMA Pediatr* 2020;174(5):e196294. doi:10.1001/jamapediatrics.2019.6294
[67] Watkins PL, Dagle JM, Bell EF, Colaizy TT. Outcomes at 18 to 22 Months of Corrected Age for Infants Born at 22 to 25 Weeks of Gestation in a Center Practicing Active Management. J Pediatr. 2020 Feb;217:52-58.e1. doi: 10.1016/j.jpeds.2019.08.028. Epub 2019 Oct 9. PMID: 31606151.
[68] Altimier, Leslie, and Raylene M. Phillips. 2013. "The Neonatal Integrative Developmental Care Model: Seven Neuroprotective Core Measures for Family-Centered Developmental Care." *Newborn and Infant Nursing Reviews*, 13, no. 1: 9–22. doi:10.1053/j.nainr.2012.12.002.
[69] Morris, Mindy, John Patrick Cleary, Antoine Soliman. 2015. "Small Baby Unit Improves Quality and Outcomes in Extremely Low Birth Weight Infants." *Pediatrics*, American Academy of Pediatrics, 136 (4) e1007-e1015. pediatrics.aappublications.org/ content/136/4/e1007.

projects associated with the Vermont Oxford Network (the VON is an international consortium of health care professionals and families at more than 1,400 member centers collaborating to improve neonatal care around the world with data-driven quality improvement and research),[70] have made these and other changes to intentionally decrease noxious stimuli from a variety of sources—including rethinking their surrounding environment as well decrease directly painful procedures. These changes have led to the creation of "small baby units" within NICUs, and many hospitals have presented their versions of small baby units as part of their performance improvement results at VON's annual national conference, as well as in formal publications.[71] Outside of the VON, additional centers have also shown that even at the edge of viability, "a focus on parent-centered care while removing noxious stimuli for the patient has improved neurodevelopmental outcomes.[72] Again, evidence indicates that our most immature patients are healthier when noxious stimuli is reduced.

48. Can the findings seen in extremely premature babies be extrapolated to a fetus? The short answer is yes. Because the edge of viability has decreased to approximately 22–23 weeks gestation,[73] with an increasing number of cases even a

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[70] public.vtoxford.org. Vermont Oxford Network: Home

[71] Morris, Mindy, John Patrick Cleary, Antoine Soliman. 2015. "Small Baby Unit Improves Quality and Outcomes in Extremely Low Birth Weight Infants." *Pediatrics*, American Academy of Pediatrics, 136 (4) e1007-e1015. pediatrics.aappublications.org/ content/136/4/e1007.

[72] Fathi O, Nelin LD, Shepherd EG, Reber KM. Development of a small baby unit to improve outcomes for the extremely premature infant. J Perinatol. 2022 Feb;42(2):157-164. doi: 10.1038/s41372-021-00984-0. Epub 2021 Mar 12. PMID: 33712714; PMCID: PMC7952830.

[73] Raju, T. N. K, Mercer B.M., Burchfield D.J., Joseph G.F. 2014. "Periviable Birth: Executive Summary of a Joint Workshop by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, Society for Maternal-Fetal Medicine, American Academy of Pediatrics, and

lower,[74,75] we now frequently care for babies who still have predominantly *fetal* physiology. In truth, most infants in the NICU are there because they need assistance transitioning through their particular degree of fetal physiology.

49. This is not surprising because the fetal period of development begins at the beginning of the "9th week of gestation and extends all the way until term (40 weeks gestation).[76] The fetal period "is characterized by growth and development of structures established during the [earlier] embryonic period".[77] This means that the essential rudiments of every single organ system are present by the end of the embryonic period at 8 weeks; this includes the developmentally immature yet gestationally appropriately functioning nervous system. Like a dimmer switch, the fetal nervous system's ability to sense and make sense of pain slowly brightens throughout gestation, continues to mature throughout childhood and adolescence, ultimately becoming the complex entity that is only available through neurologic maturation—a process that requires decades.

50. Thus, at 22 weeks gestation (20 weeks post-fertilization), whether living on one side of the uterine wall or the other, the premature nervous system is the same

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American College of Obstetricians and Gynecologists." *Journal of Perinatology*, 34, no. 5: 333–342., doi:10.1038/jp.2014.70.

[74] Elassar, Alaa. "The World's Most Premature Baby Has Celebrated His First Birthday after Beating 0% Odds of Surviving." *CNN*, Cable News Network, 19 June 2021, www.cnn.com/2021/06/19/us/worlds-most-premature-baby-birthday-trnd/index.html.

[75] TodayShow. "Born at 21 Weeks, This May Be the Most Premature Surviving Baby." *TODAY.com*, 21 Nov. 2018, www.today.com/health/born-21-weeks-she-may-be-most-premature-surviving-baby-t118610.

[76] Moore, Keith L and Presaud, TVN. 1993. *Before We Are Born: Essentials of Embryology and Birth Defects*. Philadelphia: W.B. Saunders Company. Pg 6.

[77] Rokyta, R. (2008, December). Fetal pain. Retrieved October 03, 2020, from https://www.ncbi.nlm.nih.gov/pubmed/19112406/.

system. People who spend time at the bedside, including parents, and medical staff who are daily witnesses to this population's reactions to noxious stimulation as well as symptom amelioration through treatment, know beyond any theoretical argument that premature babies who are less than 24 weeks gestation, are pain capable.

Defining the Problem

51. While anesthesia[78] and neonatal medical standards of care have evolved, there is an ongoing simultaneous but separate discussion regarding how pain is defined. The often-quoted International Association of Pain (IASP)'s original 1978 definition was, "pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage".[79] Problematically, this definition did "not adequately address pain in disempowered and neglected populations, such as neonates and the elderly."[80] The revised 2020 definition is not tremendously different, but it removed the requirement that pain be *described*. The IASP explained that "a person's verbal report should be respected," but "verbal description is only one of several behaviors to express pain; inability to communicate does not negate the possibility that a human or nonhuman animal experience pain."[81]

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[78] Chatterjee D, Arendt KW, Moldenhauer JS, Olutoye OA, Parikh JM, Tran KM, Zaretsky MV, Zhou J, Rollins MD. Anesthesia for Maternal-Fetal Interventions: A Consensus Statement From the American Society of Anesthesiologists Committees on Obstetric and Pediatric Anesthesiology and the North American Fetal Therapy Network. Anesth Analg. 2021 Apr 1;132(4):1164-1173. doi: 10.1213/ANE.0000000000005177. PMID: 33048913.

[79] Raja, S. N., Carr, D. B., Cohen, M., Finnerup, N. B., Flor, H., Gibson, S., . . . Vader, K. (2020). The revised International Association for the Study of Pain definition of pain: Concepts, challenges, and compromises. *Pain, 161*(9), 1976-1982. doi:10.1097/j.pain.0000000000001939.

[80] Ibid pg 1977.

[81] Ibid pg 1977.

52. Because a fetus lacks any verbal ability, acknowledging that the ramifications of pain can be manifested in multiple other ways, is an important change. As an example, a recent study that captured fetal facial reactions in response to a painful procedure speaks volumes.

53. Using high definition 4D ultrasound Bernardes et al. validated a facial scoring system that differentiated third trimester fetuses having an acute reaction after a perianesthetic injection in the thigh, compared to the control group with merely an acoustic startle.[82] The authors narrowed down the facial reactions to 7 movements that occurred immediately after the procedure. The ultrasounds were viewed by blinded reviewers who were able to discriminate between fetuses who received a nociceptive stimulus (the injection) and those who did not.[83] The 7 measurable facial responses are: brow lowering, eyes squeezed shut, deepening of the nasolabial furrow, open lips, vertical and horizontal mouth stretch and neck extension (see the figure below).

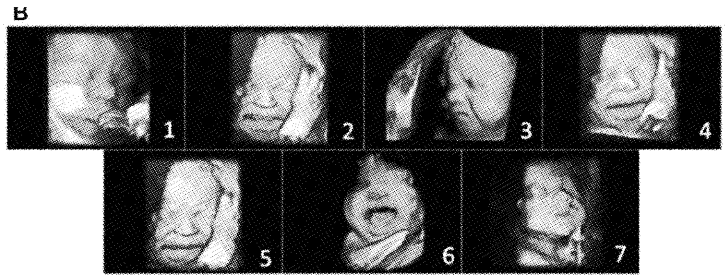

Figure 4. (A) Initial items from neonatal facial coding system and 2 supplementary items. 1. Brow lowering. 2. Eyes squeezed shut. 3. Deepening of the nasolabial furrow. 4. Open lips. 5. Horizontal mouth stretch. 6. Vertical mouth stretch. 7. Lip purse. 8. Taut tongue. 9. Tongue protrusion. 10. Chin quiver. 11. Neck deflection. 12. Yawning. (B) Final items from the Fetal-5 Scale. 1. Brow lowering. 2. Eyes squeezed shut. 3. Deepening of the nasolabial furrow. 4. Open lips. 5. Horizontal mouth stretch. 6. Vertical mouth stretch. 7. Neck deflection.

[82] Bernardes LS, Carvalho MA, Harnik SB, Teixeira MJ, Ottolia J, Castro D, Velloso A, Francisco R, Listik C, Galhardoni R, Aparecida da Silva V, Moreira LI, de Amorim Filho AG, Fernandes AM, Ciampi de Andrade D. Sorting pain out of salience: assessment of pain facial expressions in the human fetus. Pain Rep. 2021 Jan 27;6(1):e882. doi: 10.1097/PR9.0000000000000882. PMID: 33537520; PMCID: PMC7850725.

[83] Ibid pg 5.

54. Additionally, below is the box plot mean scores between the acute pain group and the control group.

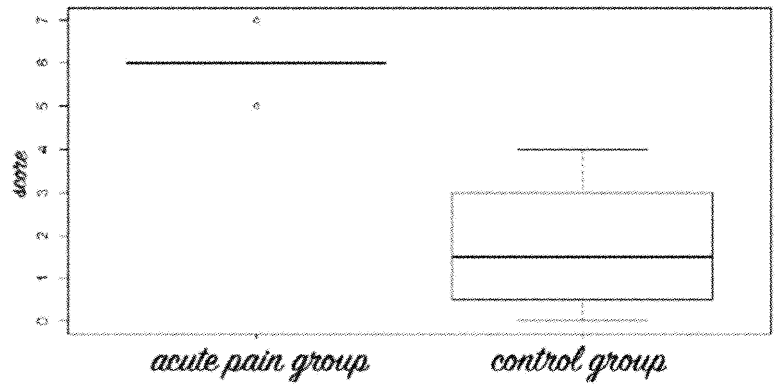

Figure 6. Box plot of mean scores of the acute pain and control (Co-Re—control group at rest and Co-AS—control group acoustic startle) groups for the Fetal-7 Scoring system where zero stands for the absence of the items related to facial expressions and 7 means for the presence of them. Note that all fetuses in the acute pain group scored at or above 5.

55. Since the original study was published, this facial expression scoring system was applied to a 23-week fetus's facial images, who also was going to undergo fetal surgery and received perioperative anesthesia with an intramuscular injection.[84] The results were consistent with the slightly older fetuses in the initial study. The fetus had "no pain-related facial behaviors during resting conditions preanesthetic, however we observed pain-related facial expressions after the painful stimulus of anesthetic injection."[85]

56. At all other times in the life span of a human being, their behavior matters. It is inconsistent and baseless to state that in the case of a human being, who is in their fetal period of development, their reproducible behavior is meaningless.

[84] Bernardes, L.S., Rosa, A.S., Carvalho, M.A., Ottolia, J., Rubloski, J.M., Castro, D., Velloso, A., da Silva, V.A. and de Andrade, D.C. (2022), Facial expressions of acute pain in 23-week fetus. Ultrasound Obstet Gynecol, 59: 394-395. https://doi.org/10.1002/uog.23709

[85] Ibid pg 394

57. Because the IASP has agreed that several behaviors count equally as much as a verbal description, a fetus with a developmentally normal, though immature nervous system can be recognized as reacting differently than the mature system, but still capable of reacting.

58. Importantly, documented fetal physiologic and behavioral reactions occurring prior to 24 weeks, (prior to cortical connections are formed), by IASP definition cannot be dismissed as mere spinal cord mediated "reflexes" since noxious stimulation in 18–20 gestational age fetuses elicits measurably increased amounts of stress hormones,[86] and at 23 weeks gestation, alters facial expression in ways that are consistent with pain in every other human age group.

59. Prior to the presence of cortical connections, a fetal face can measurably change in response to an indisputably painful injection—and when these same changes occur in older human beings, they are consistent with responding to uncomfortable, undesirable, or distinctly painful stimulations. Every parent recognizes the facial expressions of their non-verbal baby that speaks more clearly and quickly than words.

60. Thus, in response to an injection, we can see pictures of a fetus having a developmentally appropriate unhappy emotional response. This is important because the IASP's pain definition demands pain to be both an unpleasant sensory

[86] Gitau, Rachel, Nicholas M. Fisk, Jeronima M. A. Teixeira, Alan Cameron, and Vivette Glover. 2001. "Fetal Hypothalamic-Pituitary-Adrenal Stress Responses to Invasive Procedures Are Independent of Maternal Responses." *Journal of Clinical Endocrinology & Metabolism* 86, no. 1 (January): 104–9. https://doi.org/10.1210/jc.86.1.104.

and emotional experience. Of note, words and self-report are not required. We do not yet know how early a fetal face will explain what they do not yet have the verbal capacity to express, but I have witnessed 22 week gestation faces make those movements, and now we have pictures of an in utero fetus making them too. We already knew that stress hormone release and withdrawal movements occurred in response to noxious stimulation prior to 20 weeks gestation, we now see facial changes at ages before cortical connectivity too.

61. As explained by Bellieni, "*We commonly use words tailored to the adult, but not applicable to human life still at its dawn. … it is neither "calm" nor "anxiousness" as we understand these terms; it is not "pain" or "sleep" as we understand these. It is a related, but different concept. And when something disturbs or damages the fetus, its reaction is called pain, but we can also call it "nightmare."*[87] Whether born prematurely or still in utero, immature babies who are less than 24 weeks gestation react to stimuli, and to state otherwise risks intentionally mistreating immature human beings.

62. A word about noxious stimulation versus pain. In the 2020 updated IASP pain definition, they specifically point out that "[p]ain and nociception are different phenomena. Pain cannot be inferred solely from activity in sensory neurons."[88] I agree, which is why (just as verbal description is not the only way to

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[87] https://bioethicstoday.org/blog/denying-fetal-pain-in-the-second-half-of-pregnancy-can-undermine-preterm-babies-right-to-analgesia/

[88] Raja, S. N., Carr, D. B., Cohen, M., Finnerup, N. B., Flor, H., Gibson, S., . . . Vader, K. (2020). The revised International Association for the Study of Pain definition of pain: Concepts, challenges, and compromises. *Pain, 161*(9), 1976-1982. doi:10.1097/j.pain.0000000000001939

discern pain's presence), it is of the utmost importance to *not* dismiss the ramifications of noxious stimulation in the fetus and age matched premature infants. They have demonstrable, measurable, reactions that at every other age are considered pain's footprint.

III. Conclusion

63. Every doctor promises "to do no harm." To carry out this oath, medical standards of care adjust given new evidence and medical breakthroughs. Today, we can meaningfully intervene for human beings whose physiology is predominantly fetal.

64. Since 1973, the edge of viability has changed—and neonatologists promise to continually look for ways to not only improved survival, but also improve their patients' long-term outcomes. We have already discovered that decreasing noxious stimulation (the excitation of nerves involved in pain sensation and emotion) in our edge of viability patients, matters. It's simple: signs, symptoms, and behaviors that are indicative of pain at every other age are also measurably or reproducibly present early in fetal developmental.

65. Additionally, there is good evidence that reducing pain leads to better outcomes. Sekulic succinctly states, "It is necessary to apply adequate analgesia to prevent the suffering of the fetus.[89] The Kansas informed consent information about

[89] Sekulic, S., Gebauer-Bukurov, K., Cvijanovic, M., Kopitovic, A., Ilic, D., Petrovic, D., ... & Topalidou, A. Appearance of fetal pain could be associated with maturation of the mesodiencephalic structures. Journal of Pain Research, 9, 1031-1038, 2016. https://doi.org/10.2147/JPR.S117959

fetal pain and fetal development provides a way to medically and ethically prevent suffering.

I declare under penalty of perjury under the laws of the state of Kansas that the foregoing is true and correct. Executed on July 7, 2023.

Robin Pierucci, M.D., F.A.A.P.

EXHIBIT A

CURRICULUM VITAE

Robin Lynne Pierucci, MD, MA, FAAP

Home Address 726 Montrose Ave
Kalamazoo, MI 49008
Hm: (269) 343-2911
Cell: (269) 352-4256
e-mail: pierucci726@sbcglobal.net

Office Address Southwest Michigan Neonatology, PC
Bronson Methodist Hospital
601 John St.
Kalamazoo, MI 49007
NICU: 269-341-6475

Education

08/1981-06/1982	Indiana University Bloomington, IN
08/1986-06/1989	BA, Loyola University Chicago, IL
07/1990-06/1994	MD, Rush Medical College Chicago, IL

Postgraduate Training and Fellowship

06/1994—06/1995	Internship, Pediatrics Children's Hospital of Wisconsin Milwaukee, WI
06/1995—06/1997	Residency, Pediatrics Children's Hospital of Wisconsin Milwaukee, WI
07/1997—06/2000	Fellowship, Neonatology Children's Hospital of Wisconsin Milwaukee, WI
07/1998—06/2000	Master of Arts, Bioethics Medical College of Wisconsin Milwaukee, WI
09/2013---07/2014	National Catholic Bioethics Center National Catholic Certification Program in Health care Ethics

Specialty Boards and Certification

Board Certified	Issue Date
Pediatrics	2007 to present
Neonatology	2008 to present
Michigan License	4301076137

Faculty Appointments

08/2000—present	Neonatologist Bronson Children's Hospital Southwest Michigan Neonatology, PC
08/2000—2018	Western Michigan Medical School Kalamazoo, MI Clinical Associate Professor
06/2000 – 2018	Michigan State University Lansing, MI Clinical Associate Professor
03/2007—present	Medical Director, NICU Bronson Children's Hospital Kalamazoo, MI
08/2018--present	Homer Stryker School of Medicine, Western Michigan University Kalamazoo, MI Clinical Assistant Professor

Hospital Staff Privileges

08/2000 - present	Bronson Methodist Hospital Kalamazoo, Michigan Neonatologist Southwest Michigan Neonatology, PC

Peer Reviewed Publications

Pierucci, R. "Fetal Pain: The Science Behind Why It is the Medical Standard of Care". Standard of Care. *The Linacre Quarterly*. 2020;87(3):311-316. doi:10.1177/0024363920924877

Pierucci, R. "Treating Fetal Pain: Standard of Care for Some, But Not for All". Issues in Law and Medicine 34, no 2 (Fall 2019): 153-159.

Pierucci, R. "Rebutting Distortions of How the Sanctity of Life Doctrine Applies to the Periviable". The Linacre Quarterly 86:2-3, 2019; pg 172-175. First Published June 24, 2019 Article https://doi.org/10.1177/0024363919856819

Pierucci, R, "Gestational Age in Periviable Newborns." The National Catholic Bioethics Quarterly 14.3 (Autumn 2014): 429-439.

Brosig C, **Pierucci R**, Kopst M, Leuthner, S. "End of Life Care: The Parents Perspective." Journal of Perinatology April 19, 2007 http:www.nature.com/doifinder/10.1038/sj.jp.7211755

Pierucci R, Kirby R, Leuthner, S. "End-of-Life Care For Infants and the Effects of Palliative Care Consultations." Pediatrics. September 2001 8:3 653-659.

Pierucci, R, Leuthner, S, "Palliative Care Consultation for the Neonate". Journal of Palliative Medicine. 2001 4:1 39-47.

Pierucci R, Kirby R, Leuthner, S. "End-of-Life Care For Infants and the Effects of Palliative Care Consultations." Pediatric Research Abstract, May 2000.

Kuczewski M, **Pierucci R,** Strong C, "Ethics Committee at Work: Providing Comfort or Prolonging Death for a Baby with Dead Gut Syndrome" [Case study and commentaries]. Cambridge Quarterly of Healthcare Ethics. 1999 (8) 538-543.

Pierucci R., Leuthner S., "Hospice/Palliative Care for the Neonate." Pediatric Research. 1998 43:4, Abstract #160

March of Dimes Research Grant, Dr. Candice Fike (1999): Prostaglandin involvement in piglet pulmonary arteries.

Lectures/Presentations

Matthew Bulfin Educational Conference Feb 10-12, 2023
"The Changing Edge of Viability
Tuscon, AZ

Bronson Methodist Hospital Multidimensional Neonatal Care Conference Sept 29, 2022
"The Changing Edge of Viability"
Bronson Methodist Hospital, Kalamazoo, MI

Matthew Bulfin Educational Conference Feb 26, 2022
"Exposure to Hope: Caring for the Opiate Exposed Mother-Infant Dyad"
Nashville, TN

Grand Rounds at Homer Stryker School of Medicine, WMU Feb 20, 2020
"Withdrawing from the Finnegan, Changing to Eat Sleep and Console"
Kalamazoo, MI

Train the trainers conference, MICQI Feb 10, 2020
"Withdrawing from the Finnegan, Changing to Eat Sleep and Console"
Bronson Methodist Hospital, Kalamazoo, MI

Withdrawing from the Finnegan: Transitions In and Out of the NICU Using Eat/Sleep/Console Protocol"
Poster/Presentation: Vermont Oxford Network National Meeting.
Chicago, IL. Oct, 2019

Matthew Buffin Educational Conference 2019 AAPLOG/ACPeds April 6, 2019
"Pain in a Preborn vs a Premature Baby"
Indianapolis, IN

Converging Roads Conference "Dignity and Disability in Medicine" March 30, 2019
Houston, TX
"Disabled vs Mislabeled: Accompanying the Vulnerable in Utero, in the NICU, & Beyond"

Coming Together: A Conference on Addiction and Recovery October 24, 2018
Kalamazoo, MI; Western Michigan University
"Exposure to Hope: Caring for Drug Exposed Infants"

Diocese of Kalamazoo New Evangelization Convocation October 13, 2017
Kalamazoo, MI
"Elevating Human Dignity: The Benefit of Reuniting Science and Religion"

2017 Matthew Bulfin Educational Conference September 30, 2017
JOINT ACPEDS/AAPLOG
Chicago, IL
"End of Life Issues at Life's Beginning"

Catholic Medical Association September 8, 2017
Denver, CO
"End of Life Issues at Life's Beginning"

Converging Crossroads, John Paul II Foundation August 27, 2016
Nashville, TN
"End of Life Issues at Life's Beginning"

Michigan American Association of Pediatrics
September 19, 2015
Lansing, MI
"Ripples from the NICU"

Integrates Conference April 18, 2015
University of Illinois at Chicago

"Medical Decision Making, Who's in Charge?"

Society of Michigan Neonatology Conference — September 17, 2014
Brighton, MI
"Exposure to Hope: Caring for Drug Exposed Infants"

Nashville Guild of the CMA — September 6, 2014
Hippocratic Oath Banquet
"Cherishing a Limited Life: Perinatal Palliative Care"

Kalamazoo WRAPs 2nd Annual System of Care Conference — March 8, 2014
Fetzer Center, Western Michigan University
"Exposure to Hope, Caring for Drug Exposed Infants"

Conversations in Clinical Ethics — July 15, 2013
Bronson Methodist Hospital
"When Families are Waiting for a Miracle"

Southwest Michigan Perinatal Association — May 15, 2013
Fetzer Center, Western Michigan University
"Exposure to Hope: Caring for Drug Exposed Babies"

Catholicism and the Future of Healthcare — April 13, 2013
Pontifical John Paul the II Institute
"Opportunities for Practicing Medicine (or Hippocratic vs Hypocritical Oath)"

Pediatric Grand Rounds — February 3, 2012
Bronson Methodist Hospital
"Neonatal Ramifications of Maternal Substance Use"

Perinatal Network Conference XXVI — September 16, 2110
Fetzer Center, Western Michigan University
Multiple Gestation: Caring for Mothers and Babies

Southwestern Michigan Perinatal Association — May 19, 2010
Fetzer Center, Western Michigan University
Effects of Perinatal Substance Abuse

15th Annual North Central Neonatology Issues Conference — Jun 13-15 2003
Lake Geneva, Wisconsin
"Ethics in the NICU: Where Are We Now?"

Multi-Dimensional Neonatal Care Conference — April 25, 2002
Fetzer Center, Western Michigan University
Talking to Families: When They May Not Like You or What You Have to Tell Them

Michigan State Medical Society — March 14, 2002
Ann Arbor, Michigan
End-of-Life Care in Infants

Multi-Dimensional Neonatal Care Conference — April 21, 2001
Kalamazoo, Michigan
Perspectives of Reproductive Technology: The Ethical Debate
Presentation and Panel Discussion

National Association of Neonatal Nurses — September 29-30, 2000
San Antonio, Texas
Neonatal Hospice Care
Presentation and Discussion Group Leader

Pediatric Academic Society/American Academy of Pediatrics — May 14, 2000
Washington, DC
End-of-Life Care For Infants and the Effects of Palliative Care Consultations
Poster Presentation

Sinai Samaritan Hospital: Grand Rounds — March 10, 2000
Milwaukee, Wisconsin
Defining Palliative Care

Medical College of Wisconsin Bioethics Grand Rounds — March 8, 2000
Milwaukee, Wisconsin
Infant End-Of-Life Care

American Society for Bioethics and Humanities — October 28-31, 1999
Houston, Texas
Palliative Care for the Neonate
Poster Presentation

28th Aspen Conference on Perinatal Research — August 29-31, 1999
Aspen Colorado
Palliative Care for Infants

Wisconsin Association for Perinatal Care — April 19, 1999
End of Life Care in the Perinatal Period
Research presentation & panel discussion

Committees

NICU Perinatal Palliative Care: Bronson
July 2006—present

Ethics Committee, Bronson Hospital (co-chair)
January 2012-2013

March of Dimes (Kalamazoo, MI Chapter)
October 2008--2010

Family Centered Care Committee: Bronson Hospital
July 2006—2008

Professional Organizations

American Academy of Pediatrics
Aug 2000—present

Society of MI Neonatologists
Aug 2000—present

Catholic Medical Association
Jun 2010--- present

American College of Pediatricians
Jun 2018--- present

Teaching Activities

Homer Stryker Western School of Medicine Residents & Students July 2018 to present
Kalamazoo, Michigan
Bedside teaching/Rounds in NICU

Western Med School/Michigan State Univ Residents July 2000—2018
Kalamazoo, MI
Monthly lectures
Bedside teaching/rounds in the NICU

Biochemistry Case-Based Discussions Fall Semester 1998
Medical College of Wisconsin,
M1 class

Non-peer Reviewed Publications/Media

Pierucci, R. "Leaked High Court Draft Opinion Shows Courage, Compassion for Bothe the Mother and Unborn Child." *The Daily Signal.* May 13, 2022

BRIEF OF *AMICI CURIAE* **ROBIN PIERUCCI, M.D.** AND LIFE LEGAL DEFENSE FOUNDATION IN SUPPORT OF PETITIONERS In the Supreme Court of the United States THOMAS E. DOBBS, M.D., M.P.H., IN HIS OFFICIAL

Skop, I, **Pierucci, R**, "Abortion should always be a grave matter." *The Washington Times*. April 8, 2022

Pierucci, R, "Justice Sotomayor Is Wrong About Abortion." *The Christian Post*. Dec 17, 2021

Cataldo, PJ, Goodwin, TM, **Pierucci, R**. "Early Induction of Labor". *Catholic Health Care Ethics: A Manual for Practitioners* 3rd ed. The National Catholic Bioethics Center, Philadelphia (2020): 14.1-14.17.

Vermont Oxford POSTER, National Meeting, Chicago, IL "Withdrawing from the Finnegan: Transitioning to Eat/Sleep/Console. September, 2019.

Robin Pierucci | National Review
https://www.nationalreview.com/author/robin-pierucci/

Neonatologist: Babies Do Feel Pain In The Womb. I've ... - The Federalist
thefederalist.com/2018/01/29/neonatologist-babies-feel-pain-womb-ive-seen/

Is Over-The-Counter Contraception For Teens A Good ... - The Federalist
thefederalist.com/2017/06/15/counter-contraception-teens-good-idea/

The Sex Talk With Teens Needs To Cover A Lot More ... - The Federalist
thefederalist.com/2017/09/28/sex-talk-teens-needs-cover-lot-birth-control/
https://www.youtube.com/watch?v=LydxcQuh1nM

Honors/Awards

Pierucci, R, "Gestational Age in Periviable Newborns." The National Catholic Bioethics Quarterly 14.3 (Autumn 2014): 429-439.
Awarded 2nd Place by: Catholic Press Association. Category: Scholarly Magazine, Best Essay Originating With a Magazine or Newsletter.

Resident/Fellow Research Day — April 15,1999
"Infant Palliative Care Consultation"
2nd place, clinical research; Fellow's division

Alpha Sigma Nu — May 1989
National Jesuit Honor Society

Alpha Epsilon Delta
Premedical Honor Society — 1986-1989
Vice-President — 19881989

EXHIBIT #3

IN THE DISTRICT OF JOHNSON COUNTY, KANSAS
CIVIL COURT DEPARTMENT

HODES & NAUSER, MDs, P.A., on behalf of itself, its patients, physicians, and staff; TRACI LYNN NAUSER, M.D.; TRISTAN FOWLER, D.O.; and COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, on behalf of itself and its patients, physicians, and staff, Plaintiffs, v. KRIS KOBACH, in his official capacity as Attorney General of the State of Kansas; STEPHEN M. HOWE, in his official capacity as District Attorney for Johnson County; MARCH BENNETT, in his official capacity as District Attorney for Sedgwick County; SUSAN GILE, in her official capacity as Executive Director of the Kansas Board of Health Arts; and RONALD M. VARNER, D.O., in his official capacity as President of the Kansas Board of Healing Arts, Defendants.	Case No. 23CV03140 Division No. 12 K.S.A. Chapter 60

DECLARATION OF MONIQUE CHIREAU WUBBENHORST, M.D., M.P.H.

I, Monique Chireau Wubbenhorst, M.D., M.P.H., pursuant to the provisions of Kan. Stat. Ann. § 53-601, do hereby declare as follows:

1. I am at least 18 years of age and competent to testify. I have personal and professional knowledge of the statements contained in this declaration. The opinions I express in this declaration are based on my education, training, and experience in the fields of medicine (specifically obstetrics and gynecology), public health, epidemiology, and statistical analysis, and ongoing familiarity with the

medical literature. These opinions are my own, and do not represent any group with which I am affiliated.

I. Introduction and Professional Background

2. I am a practicing board-certified obstetrician-gynecologist with over 30 years' experience in patient care, teaching, research, health policy, public health, global health, and bioethics. I graduated from Mount Holyoke College and received my medical degree from Brown University concurrently with a master's degree in public health from Harvard University. I completed my residency in obstetrics and gynecology at Yale-New Haven Hospital and my postdoctoral fellowship in health services research at the Sheps Center for Health Services Research at the University of North Carolina-Chapel Hill. I was on the faculty of the Duke University School of Medicine from 2003–18. Subsequently I served as Senior Deputy Assistant Administrator in the Bureau for Global Health at the United States Agency for International Development. Currently I am a Senior Research Associate at the Center for Ethics and Culture, University of Notre Dame.

3. My clinical career has focused on caring for women in underserved and disadvantaged populations, especially African American and Native American communities, with a focus on women with medical, social, and psychiatric comorbidities. I have worked in multiple domestic and international contexts, including inner city Boston, rural North Carolina, the Veterans Administration, and Native American reservations in the United States; and in India, the Philippines, Kazakhstan, Ghana, South Sudan, Nepal, Cameroon, and Kenya.

4. I chaired the Women and Special Populations Committee for the American Heart Association and worked as a senior consultant to the United States Veteran's Administration. I am a fellow of the American College of Obstetricians and Gynecologists and a fellow of the American Heart Association. I have authored over twenty peer-reviewed publications and have been a reviewer for peer-reviewed journals including *The British Journal of Obstetrics and Gynecology*, *Public Health, The Journal of Medical Ethics*, *PLOS 1, Journal of General Internal Medicine, Public Health, Issues in Law and Medicine* and *The North Carolina Medical Journal*. My research interests include the epidemiology and molecular biology of adverse pregnancy outcomes and reproductive health, health services research, racial-ethnic disparities in women's health, adverse pregnancy outcomes and long-term cardiovascular health, maternal mortality, women veteran's health, and ethics in epidemiology and reproductive health.

5. My experience and qualifications are set forth in further detail in my *curriculum vitae*, attached hereto as Exhibit A.

II. Expert Opinions and Reasons for Them

A. Neonatal Palliative Care for the Fetus with a Disability Can Benefit Both the Child and His or Her Parents

6. Paragraph 121 of plaintiffs' complaint alleges that "[t]he Biased Counseling Scheme . . . forces providers to inform a patient with a wanted pregnancy who has received a lethal fetal diagnosis that "[m]edical assistance benefits may be available for neonatal care".

7. There is significant evidence that even in the case of a lethal fetal diagnosis (which is the indication for less than 5% of abortions), neonatal palliative and other care can improve both the quality and length of life for the newborn as well as psychological outcomes for the parents.

8. In addition, second and third trimester abortion using D&E is the preferred technique for aborting unborn children with anomalies. These are referred to as eugenic terminations. In this context, eugenics has as its goal the "weeding out" of the unfit by killing those individuals who are deformed, weak, unwanted, or considered less than human. Justice Thomas recently explained abortion's ties to the eugenics movement, noting that "technological advances have only heightened the eugenic potential for abortion." Thus, there is a "compelling interest in preventing abortion from becoming a tool of modern-day eugenics." Abortion in this context is a tool of eugenics, one of the most destructive, reprehensible ideologies in human history.

9. For many families there are other options than abortion for unborn children with disabilities. Advanced perinatology, neonatology and pediatrics allow our medical system to safely care for high-risk women and their unborn children facing fetal abnormalities. Advancements in science and medicine, especially over the past 50 years, have paved the way for the significant growth in maternal fetal medicine (MFM) and fetal care centers in the U.S., and for perinatal hospice.

10. For conditions that are currently untreatable before or after birth, there are 125 perinatal hospice programs, a subspecialty within MFM. Several studies

show improved psychosocial outcomes for families who carried their affected children to term and then cared for them through the end of their children's lives in the neonatal and infant period.

11. Multiple studies indicate that women who undergo abortion for fetal anomalies experience significant negative mental health outcomes. Calhoun et al (1997) noted that a disproportionate number of adverse mental health outcomes occurred following abortion for fetal abnormalities, citing a study by Zolese et al (1992) (Byron C. Calhoun, James S. Reitman & Nathan J. Hoeldtke, Perinatal Hospice: A Response to Partial Birth Abortion for Infants with Congenital Defects, 13 Issues L. & MED. 125 1997). The authors of that study stated that "[t]hose requiring therapeutic abortion on medical grounds because of foetal abnormalities or serious medical complications are consistently found to be associated with poorer psychological outcome."

12. In a review of published research, Sullivan and Faoite (2017) noted that "Data from the studies examined indicate that many women, having aborted due to serious anomaly, suffer from PTSD [post-traumatic stress disorder], a mental health problem" (Nora Sullivan & Eoghan de Faoite, Psychological Impact of Abortion due to Fetal Anomaly: A Review of Published Research, 32 Issues L. & MED. 19 2017).

13. According to the American Psychiatric Association "PTSD is a psychiatric disorder that may occur in people who have experienced or witnessed a traumatic event, series of events or set of circumstances. An individual may experience this as emotionally or physically harmful or life-threatening and may

affect mental, physical, social, and/or spiritual well-being. . . . People with PTSD have intense, disturbing thoughts and feelings related to their experience that last long after the traumatic event has ended. They may relive the event through flashbacks or nightmares; they may feel sadness, fear or anger; and they may feel detached or estranged from other people. People with PTSD may avoid situations or people that remind them of the traumatic event, and they may have strong negative reactions to something as ordinary as a loud noise or an accidental touch." *See* https://dictionary.apa.org/posttraumatic-stress-disorder?_gl=1*gbz8ye*_ga*MTYzOTI1NTk3NS4xNjg4NzMxMDkz*_ga_SZXLGDJGNB*MTY4ODczMTA5Mi4xLjEuMTY4ODczMTExMy4wLjAuMA.

14. Sullivan and Faoite continue by saying that "[t]he disorder is shown in multiple studies to continue for months and even years in some women." While the percentage of women with PTSD appears to diminish over time, "the number of women still dealing with PTSD a year or more after termination of pregnancy remained surprisingly high." The authors reported that "Kersting et al (2009) found that 45% of subjects were demonstrating signs of PTSD 14 days after the abortion. Korenromp et al (2009 and 2007) found that 44% and 46% of women, respectively, were suffering from PTSD four months after pregnancy termination. Davies et al (2005) found that 67% of participants screened positive for PTSD at six weeks, which fell to 50% at six months."

15. The mental health effects of pregnancy termination often lasted more than a year. For example, these authors state that "Kersting et al (2009) found that

30.9% of women were still experiencing post-traumatic stress 14 months after pregnancy termination. Korenromp et al (2009) reported that at 16 months after termination 20.5% of patients still showed pathological levels of PTSD". Davies et al (2005) reported that 41% screened positive for PTSD at 12 months post abortion". Similar findings were noted in these studies for depression. "Davies et al (2005) documented a slow increase in depression following pregnancy termination", with 30% of subjects screening positive for depression at 6 weeks, 39% at six months, and 32% at 12 months. Sullivan and Faoite concluded that "[t]hese articles repeatedly conclude that abortion for reason of potentially fatal anomalies can have a lasting and negative psychological impact."

16. Interestingly, they note that "experiences highlighted in the research suggest that induced termination did play a role in the psychological issues these mothers faced. Gammeltoft et al (2008) found: 'Even though their obstetrician had advised abortion, most felt that the ultimate decision to terminate the pregnancy had been their own, made in consultation with their relatives. The harshness of their loss seemed to be magnified by the fact it was 'chosen' by themselves.'"

17. Hunsfeld et al (1993) carried out a study of women who were carrying babies diagnosed with severe or lethal anomalies. These women were surveyed shortly after their diagnosis and again after giving birth. While a high percentage of these mothers (45%) were diagnosed with "severe mental imbalance" shortly after their ultrasound diagnosis, by 3 months this number had declined to 22%. The percent of women with sleeping disorders (69%) declined dramatically at the 3 month

mark to 5%. The percentage of women with eating disorders declined from 56% to 14%. Hunfeld JAM, Wladimiroff JW, Passchier J, Venema-Van Uden M Uniken, Frets PG, Verhage F. Emotional reactions in women in late pregnancy (24 weeks or longer) following the ultrasound diagnosis of a severe or lethal fetal malformation. *Prenatal Diagnosis* vol 13, 603-612 (1993).

18. Research has specifically examined the question of whether outcomes are better for women who undergo termination of pregnancy for an unborn child with anomalies vs. carrying to term. Rates of mental health problems for women who underwent induced abortion for a fetus with anomalies are higher than those for women carrying an affected child to term. Cope et al (2015) studied the impact of abortion vs. carrying a pregnancy to term when the unborn child was affected by anencephaly, an abnormality which usually results in the death of a baby shortly after birth (Cope H, Garrett M, Gregory S, Ashley-Koch A. Pregnancy continuation and organizational religious activity following prenatal diagnosis of a lethal fetal defect are associated with improved psychological outcome. *Prenatal Diagnosis* 2015, 35, 761-768).

19. . The authors also explored the fact that the psychological impact of pregnancy loss on men is understudied, noting that "[d]escriptive studies of men have reported that men struggle with grief, anger and helplessness following the loss and often feel forgotten by health care providers and society . . . the few published studies indicate that men also experience grief, depression and post-traumatic stress.". In this study, women who underwent abortion had much higher scores on a standard

measure of perinatal grief than women who continued with their pregnancies (52% vs. 33%, respectively). Women who underwent abortion also had higher rates of depression than those who continued their pregnancies (48% vs. 27%). The authors note that "[a] significant number of women and men reported symptoms of grief, post-traumatic stress and depression within the pathogenic range. . . psychiatric distress tended to decrease over time. However, it is important to note that there was tremendous individual variability . . . there were participants whose pregnancies ended over 10 years ago still scoring within the pathogenic range".

20. Of note, "[p]regnancy continuation was also associated with less psychiatric distress in women. As a group, women who continued reported significantly less despair, avoidance, and depression than women who terminated. And "items related to guilt were significantly associated with termination in women. The active choice involved in termination does appear to increase the likelihood that guilt will be experienced, even in the case of lethal fetal anomalies. . . . Termination at a later gestational age was associated with greater psychiatric distress in both men and women, although this was only statistically significant in men. Cope et al concluded that "[t]here appears to be a psychological benefit to continue the pregnancy following prenatal diagnosis of a lethal fetal defect."

21. Malloy et al stated, "As Hoeldtke and Calhoun note, while the explosive growth of prenatal diagnostic technologies in particular has resulted in earlier diagnoses of life-limiting and life-threatening diagnoses, 'the ability to accurately diagnose a fetal condition often outstrips the ability to prevent or treat that condition.

This is especially true for some specific fetal congenital defects' and would include anencephaly. "Infants carrying these diagnoses who are born alive may die in the neonatal period or experience long stays in intensive care units. Parents of these fetuses face significant emotional, logistical, and social challenges related to the outcome of their pregnancy. Recently, options for perinatal hospice have become more prevalent and established for those whose pregnancies are complicated by such diagnoses. A subset of perinatal or prenatal palliative care, perinatal hospice care, is an extension of established adult and oncologic palliative care models, which originated in the 1960s. Perinatal hospice care provides comprehensive prenatal, perinatal, and postnatal medical care and support to infants with life-threatening and life-limiting diagnoses, and their families, in order to improve their quality of life. Perinatal hospice is family centered and addresses the emotional, social, spiritual, and other needs of families within their cultural contexts. This nascent field is rapidly developing, with more than 200 perinatal hospice programs in the United States" C. Malloy, M. Chireau Wubbenhorst, T. Sander Lee, The Perinatal Revolution, Issues in L. & Med. 26 Vol. 34 no. 1 (2019), page 15.

22. Between 40–85% of women will typically choose perinatal hospice or palliative care for a fatal fetal anomaly, if given the option (Flaig F, Lotz J, Knochel K, Borasio GD, Fuhrer M, Hein K. Perinatal palliative care: A qualitative study evaluating the perspectives of pregnancy counselors. *Palliative Medicine* 2019 vol 33(6), pages 704-711; Balaguer A, Martin-Ancel A, Ortigoza-Escobar D, The model of palliative care in the perinatal setting: a review of the literature. *BMC Pediatrics*

2012; Guon J, Wilfond BS, Farlow B, et al. Our children are not a diagnosis: the experience of parents who continue their pregnancy after a prenatal diagnosis of trisomy 13 or 18. *Am J Med Genet* 2014; 164A: 308–318; Calhoun BC, Napolitano P, Terry M, et al. Perinatal hospice—comprehensive care for the family of the fetus with a lethal condition. *J Reprod Med* 2003; 48(5): 343–348; Janvier A, Farlow B and Wilfond BS. The experience of families with children with trisomy 13 and 18 in social networks. *Pediatrics* 2012; 130(2): 293–298).

23. Malloy et al further noted that "[p]erinatal palliative care services can also help care for those parents who choose to terminate their pregnancy. Such families often experience significant loss and grief, without adequate support, which could be provided by a palliative care team. . . . In a five-year study of families choosing perinatal hospice for their newborns, 49% of cases were infants affected by Trisomy 18 or 21, or by anencephaly. Families in this study expressed a wide variety of needs and preferences related to their fetus' diagnosis, which were or could be addressed by perinatal palliative services. These included participating in a perinatal hospice program which could help them develop a birth plan, provide counseling, address concerns regarding resuscitation, and bring support in navigating social issues such as how to tell friends and family about their diagnosis. The authors also noted that 'many families experience spiritual distress, highlighting the need for a spiritual counselor' as part of the team" (Leong Marc-Aurele, K. and R. Nelesen, A five-year review of referrals for perinatal palliative care. *J Palliat Med*, 2013. 16(10): p. 1232-6).

24. Similar to the goals of adult and oncologic hospice, the goals of perinatal hospice can be simply stated—to provide healing without cure for the patient. Palliative perinatal care, however, does not consist of comfort measures only, and may include cesarean delivery and newborn intensive care. For example, in Japan, where intensive intervention is often provided for infants with Trisomy 13 and Trisomy 18, one-year survival rates approach 56% in some centers (Kaneko, Y., et al., Cardiac surgery in patients with trisomy 18. Pediatr Cardiol, 2009. 30(6): p. 729-34; Tsukada, K., et al., Better prognosis in newborns with trisomy 13 who received intensive treatments: a retrospective study of 16 patients. Cell Biochem Biophys, 2012. 63(3): p. 191-8).

25. . In the United States, Nelson et al. noted that although one-year survival for infants with Trisomy 13 or 18 has been stated to be less than 10%, forty-one percent of hospital records for children with Trisomy 13 and 32% of records for children with Trisomy 18 were for children older than one year (Nelson, K.E., et al., Survival and surgical interventions for children with Trisomy 13 and 18. *JAMA*, 2016. 316(4): p. 420-8).

26. A common theme in research on perinatal hospice is parents' positive experience of the process, even when their child's life was brief (Breeze, A. C., et al., Palliative care for prenatally diagnosed lethal fetal abnormality. *Arch Dis Child Fetal Neonatal Ed*, 2007. 92(1): p. F56-8; Black, B. and M. Sandelowski, Personal growth after severe fetal diagnosis. *West J Nurs Res*, 2010. 32(8): p. 1011-30).

27. . For example, "Guon et al. reported that many parents noted that their family was 'strengthened and enriched since the birth - and often the death - of a child with a chromosomal abnormality." They also found that while "many parents experience intense grief reactions regardless of the choice they make," in multiple studies, those who received support through perinatal palliative care described positive experiences (Jaquier M, Klein A, Boltshauser E. Spontaneous pregnancy outcome after prenatal diagnosis of anencephaly. *BJOG* 2006; 113:951–953).

28. Another common theme was parents' "unanimous and strong need to acknowledge the personhood of their baby, and his/her role in the family," and their desire for "people to legitimize the baby's life and not to pretend the infant does not exist" (Malloy, supra, page 25; Cote-Arsenault, D. and E. Denrey-Koelsch, "My baby is a person": parents' experiences with life-threatening fetal diagnosis. *J Palliat Med*, 2011. 14(12): p. 1302-8). Perinatal palliative care has helped parents with this process in the prenatal period by using the baby's name to reinforce the child's identity (Munson, D. and S.R. Leuthner, Palliative care for the family carrying a fetus with a life-limiting diagnosis. *Pediatr Clin North Am*, 2007. 54(5): p. 787-98, xii; Ryan, A., H. Bernhard, and B. Fahlberg, Best practices for perinatal palliative care. *Nursing*, 2015. 45(10): p. 14-5; Williams, C., et al., Supporting bereaved parents: practical steps in providing compassionate perinatal and neonatal end-of-life care. A North American perspective. Semin Fetal Neonatal Med, 2008. 13(5): p. 335-40).

29. Increasingly efforts are being made to facilitate parents' desires to give birth to their child affected by diagnoses such as anencephaly, as a viable alternative

to abortion. Jaquier et al (2006) surveyed parents whose unborn children were diagnosed prenatally with anencephaly. The survey collected information on 211 pregnancies and noted that "Contrary to common belief, only a small number of anencephalic fetuses died in utero. More than half of the babies were born at term, 10% even after term. . . . Judging from these data, and collected via this homepage [Anencephaly info] and compared with the notion of Limb and Holmes, it seems that a larger proportion of mothers carrying an anencephalic fetus are opting to continue the pregnancy rather than elective termination. From the perspective of these mothers/parents, it is important to experience as normal a bonding as possible between mother/parent and baby and to see and touch the baby, stillborn or liveborn. It is impressive to hear from these parents who contacted homepage that none have regretted their earlier decision to continue the pregnancy. . . . On the other hand, a considerable number of mothers who contacted the homepage following an elective pregnancy termination, mentioned their regret at not having seen their baby." Jaquier, supra, page 951–53.

B. The Humanity of the Unborn Child

30. Dr. Alsaden alleges in paragraph 41 that the Biased Consent Scheme "requires providers to tell every patient…that abortion terminates the life of a 'whole, separate, unique, living human being' when there is no universal consensus on the moral status of a pregnancy." This statement obfuscates the truth. There is universal consensus that life begins at conception and that the embryo and fetus are human. This is distinct from the legal concept of personhood. The humanity of the fetus and

embryo and when human life begins are scientific facts. Below are quotes from books and scientific statements that support these facts.

a. Human Embryology, 3rd ed. Bradley M. Patten, (New York: McGraw Hill, 1968), page 43. "It is the penetration of the ovum by a spermatozoan and resultant mingling of the nuclear material each brings to the union that constitutes the culmination of the process of fertilization and marks the initiation of the life of a new individual."

b. J.P. Greenhill and E.A. Friedman, Biological Principles and Modern Practice of Obstetrics (Philadelphia: W.B. Sanders, 1974), page 17. "The zygote thus formed represents the beginning of a new life."

c. Kaluger, G., and Kaluger, M., Human Development: The Span of Life, The C.V. Mosby Co., St. Louis, 1974, page 28–29: "In that fraction of a second when the chromosomes form pairs, the sex of the new child will be determined, hereditary characteristics received from each parent will be set, and a new life will have begun."

d. DeCoursey, R.M., The Human Organism, 4th edition McGraw Hill Inc., Toronto, 1974. page 584: "The zygote therefore contains a new arrangement of genes on the chromosomes never before duplicated in any other individual. The offspring destined to develop from the fertilized ovum will have a genetic constitution different from anyone else in the world."

e. *Encyclopedia Britannica*, "Pregnancy," page 968, 15th Edition. Chicago 1974: "A new individual is created when the elements of a potent sperm merge with those of a fertile ovum, or egg."

f. Leslie Brainerd Arey, "Developmental Anatomy" seventh edition (Philadelphia: Saunders, 1974), 55: "The formation, maturation and meeting of a male and female sex cell are all preliminary to their actual union into a combined cell, or zygote, which definitely marks the beginning of a new individual. The penetration of the ovum by the spermatozoon, and the coming together and pooling of their respective nuclei, constitutes the process of fertilization."

g. Potter and J.M. Craig, Pathology of the Fetus and the Infant, 3d ed. (Chicago: Year Book Medical Publishers, 1975), vii: "Every time a sperm cell and ovum unite a new being is created which is alive and will continue to live unless its death is brought about by some specific condition."

h. Considine, Douglas (ed.). Van Nostrand's Scientific Encyclopedia. 5th edition. New York: Van Nostrand Reinhold Company, 1976, p. 943: "Embryo: The developing individual between the union of the germ cells and the completion of the organs which characterize its body when it becomes a separate organism.... At the moment the sperm cell of the human male meets the ovum of the female and the union results in a fertilized ovum (zygote), a new life has begun.... The term embryo covers the several stages of early development from conception to the ninth or tenth week of life."

i. Turner, J.S., and Helms, D.B., Lifespan Developmental, 2nd ed., CBS College Publishing (Holt, Rhinehart, Winston), 1983, page 53: "A zygote (a single fertilized egg cell) represents the onset of pregnancy and the genesis of new life."

j. Clark, J. ed., The Nervous System: Circuits of Communication in the Human Body, Torstar Books Inc., Toronto, 1985, page 99: "Each human begins life as a combination of two cells, a female ovum and a much smaller male sperm. This tiny unit, no bigger than a period on this page, contains all the information needed to enable it to grow into the complex . . . structure of the human body. The mother has only to provide nutrition and protection."

k. Carlson, Bruce M. Patten's Foundations of Embryology. 6th edition. New York: McGraw-Hill, 1996, p. 3: "Almost all higher animals start their lives from a single cell, the fertilized ovum (zygote). . . The time of fertilization represents the starting point in the life history, or ontogeny, of the individual."

l. William J. Larsen, Essentials of Human Embryology. New York: Churchill Livingstone, 1998. pp. 1, 14: "Human embryos begin development following the fusion of definitive male and female gametes during fertilization. . . . This moment of zygote formation may be taken as the beginning or zero time point of embryonic development."

m. Essentials of Human Embryology, William J. Larsen, (New York: Churchill Livingstone, 1998), 1–17: "In this text, we begin our description of the developing human with the formation and differentiation of the male and female sex cells or gametes, which will unite at fertilization to initiate the embryonic development of a new individual. . . . Fertilization takes place in the oviduct . . . resulting in the formation of a zygote containing a single diploid nucleus. Embryonic development is considered to begin at this point. . . . This moment of zygote formation may be taken as the beginning or zero time point of embryonic development."

n. Ronan O'Rahilly and Fabiola Miller, Human Embryology and Teratology, 3rd edition. New York: Wiley-Liss, 2001. p. 8: "Although life is a continuous process, fertilization... is a critical landmark because, under ordinary circumstances, a new genetically distinct human organism is formed when the chromosomes of the male and female pronuclei blend in the oocyte."

o. Keith L. Moore, The Developing Human: Clinically Oriented Embryology, 7th edition. Philadelphia, PA: Saunders, 2003. pp. 2-16: "[The Zygote] results from the union of an oocyte and a sperm. A zygote is the beginning of a new human being. Human development begins at fertilization, the process during which a male gamete or sperm . . . unites with a female gamete or oocyte ... to form a single cell called a zygote. This highly specialized, totipotent cell marks the beginning of each of us as a unique individual."

p. "Human life begins at fertilization, the process during which a male gamete or sperm (spermatozoon) unites with a female gamete or oocyte (ovum) to form a single cell called a zygote. This highly specialized, totipotent cell marked the beginning of each of us as a unique individual." "A zygote is the beginning of a new human being (i.e., an embryo)."

q. T.W. Sadler, Langman's Medical Embryology, 10th edition. Philadelphia, PA: Lippincott Williams & Wilkins, 2006. p. 11: "Development begins with fertilization, the process by which the male gamete, the sperm, and the female gamete, the oocyte, unite to give rise to a zygote."

r. California Medicine 113, no.3 (1970), reprinted in The Human Life Review 1, no.1 (1975): 103-4: "[S]ince the old ethic has not been fully displaced it has been necessary to separate the idea of abortion from the idea of killing, which continues to be socially abhorrent. The result has been a curious avoidance of the scientific fact, which everyone really knows, that human life begins at conception and is continuous whether intra- or extra-uterine until death. The very considerable semantic gymnastics which are required to rationalize abortion as anything but taking a human life would be ludicrous if they were not often put forth under socially impeccable auspices. It is suggested that this schizophrenic sort of subterfuge is necessary because while a new ethic is being accepted the old one has not yet been rejected."

s. Linacre Quarterly, February, 1993 "[E]ach of us has a unique beginning, the moment of conception...As soon as the twenty-three chromosomes carried by the sperm encounter the twenty-three chromosomes carried

by the ovum, the whole information necessary and sufficient to spell out all the characteristics of the new being is gathered...(W)hen this information carried by the sperm and by the ovum has encountered each other, then a new human being is defined which has never occurred before and will never occur again...[the zygote, and the cells produced in the succeeding divisions] is not just simply a non-descript cell, or a "population" or loose "collection" of cells, but a very specialized individual, i.e., someone who will build himself according to his own rule."

t. Dr. Jasper Williams, Former President of the National Medical Association, Newsweek November 12, 1973 (p 74):"Human life begins when the ovum is fertilized and the new combined cell mass begins to divide."

u. D.J. Moran, M.D., J.D. Gorby, M.D., and T.W. Hilgers, M.E., "Abortion in the Supreme Court: Death Becomes a Way of Life.", Sheed and Ward, 1974:"Individual human life begins at conception and is a progressive, ongoing continuum until natural death. This is a fact so well established that no intellectually honest physician in full command of modern medical knowledge would dare to deny it. There is no authority in medicine or biology who can be cited to refute this concept. It is not a "theory," as Justice Blackmun wished to easily pass it off."

v. Shettles, Landrum, M.D., Rorvik, David, Rites of Life: The Scientific Evidence for Life Before Birth, page 36, Zondervan Publishing House, Grand Rapids, Michigan, 1983:"... Conception confers life and makes you one of a kind. Unless you have an identical twin, there is virtually no chance, in the natural course of things, that there will be "another you" - not even if mankind were to persist for billions of years."

w. Dr. Micheline Matthews-Roth, Harvard Medical School: Quoted by Public Affairs Council: "....it is scientifically correct to say that human life begins at conception."

x. Van Nostrand's Scientific Encyclopedia:"At the moment the sperm cell of the human male meets the ovum of the female and the union results in a fertilized ovum (zygote) a new [human] life has begun."

y. Norman Ford, "When Did I Begin?" (New York: Cambridge University Press, 1988) 115:"These pronuclei [of the sperm and oocyte] fuse with each other to produce the single, diploid 2N nucleus of the fertilized zygote. This moment of zygote formation may be taken as the beginning or zero time point of embryonic development."

z. Dr. Alan Guttmacher, former president of Planned Parenthood, in his book Pregnancy and Birth: A Book for Expectant Parents New American Library; Revised Ed edition (January 1, 1962). "A facet that makes the obstetrician's burden unique in the whole field of medicine is his double obligation; he simultaneously cares for two patients, the mother and the infant...The essential step in the initiation of life is by fertilization, the penetration of the ovum by a spermatozoan and the fusion of the two cells into a single cell."

aa. Mary Calderone, M.D., former medical director Planned Parenthood, quoted by author Magda Denes in "The Zero People: Essays on Life" by Jeffrey Hensley, Servant Publications (March 1983) p. 9:"Fertilization, then, has taken place. A baby has been conceived."

bb. On April 23rd and 24th, 1981, a Senate Judiciary Subcommittee held hearings on the question: "When does human life begin?" A group of internationally-known geneticists and biologists came before the Senate to speak on behalf of the scientific community. All had the same story to tell, namely, that human life begins at conception. Importantly, they told their story with a complete absence of opposing testimony. (Subcommittee on Separation of Powers to Senate Judiciary Committee S-158, Report, 97th Congress, 1st Session, 1981)2: Dr. Micheline M. Mathews-Roth, Harvard Medical School, gave confirming testimony, supported by references from over 20 embryology and other medical textbooks that human life began at conception: "It is incorrect to say that biological data cannot be decisive...It is scientifically correct to say that an individual human life begins at conception."

cc. Dr. Jerome Lejeune, "Father of Modern Genetics", told the lawmakers: "To accept the fact that after fertilization has taken place a new human has come into being is no longer a matter of taste or opinion...it is plain experimental evidence. Each individual has a very neat beginning, at conception."

dd. Dr. Richard V. Jaynes: "To say that the beginning of human life cannot be determined scientifically is utterly ridiculous."

ee. Dr. Landrum Shettles, sometimes called the "Father of In Vitro Fertilization" notes:" Conception confers life and makes that life one of a kind."

ff. On the Supreme Court ruling *Roe v. Wade*: "To deny a truth [about when life begins] should not be made a basis for legalizing abortion."

31. The humanity of the unborn child is demonstrated in numerous ways. First, at conception, a human female gamete (the egg) and a human male gamete (the sperm), each with 23 chromosomes, combines to form a unique, new human being, a zygote with 46 chromosomes whose DNA is different from that of the parents. The zygote, and then the embryo and fetus, are human because they have unique human DNA and have been conceived by 2 human parents. The zygote is a separate, unique human being, not a part of the mother's body. All mothers are female with two XX sex chromosomes, but approximately half of their children are male, with an X and a Y chromosome. Mothers and babies often have different blood types. An unborn child's DNA is different, in every cell of their body, from that of the mother. The unborn child is therefore not a part of the mother's body, in the way that her heart or her pancreas are; he or she is a unique human being in a unique relationship with his or her mother.

32. At 5 or 6 weeks' gestational age an "unborn human being's heart begins beating"; at 8 weeks the "unborn human being begins to move about in the womb"; at 9 weeks "all basic physiological functions are present"; at 10 weeks "vital organs begin to function," and "[h]air, fingernails, and toenails . . . begin to form"; at 11 weeks "an unborn human being's diaphragm is developing," and he or she may "move about freely in the womb"; and at 12 weeks the "unborn human being" has "taken on 'the human form' in all relevant respects".

33. There is scientific consensus that the zygote, embryo, and fetus are human. For example:

a. Langman, Jan. Medical Embryology. 3rd edition. Baltimore: Williams and Wilkins, 1975, p. 3: "The development of a human being begins with fertilization, a process by which two highly specialized cells, the spermatozoon from the male and the oocyte from the female, unite to give rise to a new organism, the zygote."

b. Thibodeau, G.A., and Anthony, C.P., Structure and Function of the Body, 8th edition, St. Louis: Times Mirror/Mosby College Publishers, St. Louis, 1988. pages 409-419:"The science of the development of the individual before birth is called embryology. It is the story of miracles, describing the means by which a single microscopic cell is transformed into a complex human being. Genetically the zygote is complete. It represents a new single celled individual."

c. Ronan R. O'Rahilly, Fabiola Muller, Human Embryology & Teratology, , (New York: Wiley-Liss, 1996), 5-55:"Fertilization is an important landmark because, under ordinary circumstances, a new, genetically distinct human organism is thereby formed... Fertilization is the procession of events that begins when a spermatozoon makes contact with a secondary oocyte or its investments... The zygote ... is a unicellular embryo..."

d. The Developing Human: Clinically Oriented Embryology, 6th ed. Keith L. Moore, Ph.D. & T.V.N. Persaud, Md., (Philadelphia: W.B. Saunders Company, 1998), 2-18:"[The Zygote] results from the union of an oocyte and a sperm. A zygote is the beginning of a new human being. Human development begins at fertilization, the process during which a male gamete or sperm ... unites with a female gamete or oocyte ... to form a single cell called a zygote. This highly specialized, totipotent cell marks the beginning of each of us as a unique individual."

e. Keith L. Moore, Before We Are Born: Essentials of Embryology, 7th edition. Philadelphia, PA: Saunders, 2008, p. 2:"[The zygote], formed by the union of an oocyte and a sperm, is the beginning of a new human being."

34. At the same Senate Judiciary Committee hearing mentioned above, scientific experts provided the following testimony regarding the humanity of the human zygote, embryo, and fetus:

a. Dr. Alfred Bongiovanni, Professor of Pediatrics and Obstetrics, University of Pennsylvania School of Medicine, concluded: "I am no

more prepared to say that these early stages represent an incomplete human being than I would be to say that the child prior to the dramatic effects of puberty ... is not a human being....I have learned from my earliest medical education that human life begins at the time of conception."

b. Gordon, Hymie, M.D., F.R.C.P., Chairman of Medical Genetics, Mayo Clinic, Rochester: "By all criteria of modern molecular biology, life is present from the moment of conception...Science has a very simple conception of man; as soon as he has been conceived, a man is a man."

c. Christopher Hook, M.D. Oncologist, Mayo Clinic, Director of Ethics Education, Mayo Graduate School of Medicine: "When fertilization is complete, a unique genetic human entity exists."

d. Dr. McCarthy de Mere, medical doctor and law professor, University of Tennessee, testified: "The exact moment of the beginning of personhood and of the human body is at the moment of conception."

35. The official Senate report from the 1981 Senate Judiciary Committee reached this conclusion: "Physicians, biologists, and other scientists agree that conception marks the beginning of the life of a human being - a being that is alive and is a member of the human species. There is overwhelming agreement on this point in countless medical, biological, and scientific writings."

36. It seems self-evident that an unborn child is human. As noted in the *Dobbs* decision, “When parents see the embryo on ultrasound, they recognize that this is their son or daughter”1. The unborn child is human, not a part of a woman’s body; “…the zygote does not itself serve a functional role in the biological economy of either parent; it is a separate organism…its growth and development is…determined from within. It contains within itself the “genetic programming”…to direct its own biological progress. It possesses the active capacity for self-development toward maturity using the information it carries.”

37. The unborn child is also not any other type of life. Human embryos and fetuses are demonstrably members of the human family. "A human embryo is not something different from a human being, like a rock, or a potato, or a rhinoceros. A human embryo is a whole living member of the species Homo sapiens in the earliest stages of his or her natural development…He or she is not an individual of some other or intermediate kind of species. Rather, the human zygote, embryo, or fetus is a human being at a certain stage of development…" Robert P. George and Christopher Tollefsen. *Embryo: A Defense of Human Life*. 2008, (Doubleday: New York), page 41.

38. From the above evidence, "…there can be little question concerning exactly what the early embryo is. The early embryo is a human being at the earliest stage of his or her development. Not a "potential" human being or a "pre" human being, or a mass of cells, or mere tissue, but an individual member of the species Homo sapiens" Ibid, page 144.

39. It is clear, then, that the human zygote, embryo, and fetus are human from conception to birth. It is also clear that "when someone destroys a human embryo, it is a human being that is killed. This is true of any embryo, from the end of fertilization on: every embryo is a human being; therefore, ending an embryo's life is ending a human being's life" Ibid, pages 55–56. And since embryos and fetuses are human, "human beings as such as persons worthy of fundamental moral respect, and subjects of fundamental human rights" Ibid, page 144.

40. Finally, a fetus is not part of the mother's body. Male fetuses have a Y chromosome, while their mothers do not. If unborn children were simply tissues or

part of a woman's body, there would be no basis for state laws that recognize the harms done to a fetus by a mother who abuses illicit drugs and which hold her accountable for damage to an unborn child.

41. Medical advances have provided further support for the humanity of the unborn child and their status as a patient. Advancing technology allows doctors to perform open fetal surgery as early as 15 weeks' gestation, including heart surgery. During these surgeries, physicians will open the uterus and operate directly on the fetus, producing images like those in the linked article, which reinforce the human form of the child in the womb Shawn Shinneman, The Surgeon Who Works On Babies Before They're Born, *Dallas Magazine*, Oct. 2018, https://www.dmagazine.com/publications/d-magazine/2018/october/timothy-crombleholme-works-on-babies-before-theyre-born/; Vanderbilt-pioneered fetal surgery procedure yields positive results | Vanderbilt University.

42. The rapidly developing field of fetal therapies and surgery is significant for purposes of considering the fetus – the unborn child – as a patient. These new technologies have confirmed that in the view of mainstream medicine, "the fetus has truly become a patient". If the unborn child was not a human being, or a patient, the tremendous investment in research and clinical care to treat them would not have occurred. This investment only came about because it was recognized that the unborn child is human and a patient, and worthy of intervention to save his or her life, or improve its quality. That changes, however, if the same child is unwanted by its mother and slated for abortion.

C. The Unborn Child is Capable of Feeling Pain at Earlier Gestational Ages than Previously Thought

43. Current science shows that the fetus is capable of feeling pain much earlier than previously thought. "[N]eonatal and medical science … now graphically portrays, as science was unable to do [at the time of Roe], how a baby develops sensitivity to external stimuli and to pain much earlier than was then believed" Carlo V. Bellieni, Analgesia for fetal pain during prenatal surgery: 10 years of progress, *Pediatric Res.* 1612-18, 1 & Fig. 1 (Sept. 24, 2020), https://www.nature.com/articles/s41390-020-01170-2.

44. . With the development of fetal surgery, it was necessary for physicians to consider fetal pain, and anesthesia to prevent it, to ensure treatment is done humanely. After reviewing scientific evidence from the last decade, researchers have now concluded that "the human fetus can feel pain when it undergoes surgical interventions and direct analgesia must be provided to it". Science has told us volumes about the unborn child's development and its capacity to feel pain, and mainstream medicine treats the unborn child as a patient, by providing pain medication when invasive procedures are performed.

45. Thill (2022) notes that "In the field of fetal medicine…fetal surgeons and anesthesiologists, routinely administer fetal analgesia at increasingly earlier gestations in the second trimester (> 14 weeks) to ameliorate pain and improve outcome (Thill B. Fetal pain in the first trimester. *The Linacre Quarterly* 2022, vol. 89(1), pages 73-100). Consideration of fetal pain capacity and negative long-term neuroadaptive phenomena have prompted anesthesiologists to recommend fetal

analgesia from the second trimester onwards (Gupta, Wimalasundera, and Moore, 2021). Some prominent researchers, likewise, propose fetal pain capacity beginning as early as 12 weeks gestation via the cortical subplate…The fetal pain debate is also complicated by political and legal issues regarding abortion and feticide. Recognition of fetal pain capability at 12 weeks gestation, for example, has the potential to impact second- and third trimester abortions…" Thill, supra, page 75.

46. Generally, pain is perceived after receptors transmit the pain message to the spinal cord, which carries the message into the deeper parts of the brain—the thalamus and cortex—for processing. These structures are developing in the baby well before "viability." Thill notes that "Fetal pain perception requires that the pathways for pain signal transmission are present and functioning, at least at an immature level. The sensory systems for both tactile and nociceptive stimuli develop early in embryologic development, preceding the development of the olfactory, vestibular, auditory, and visual systems (Borsani et al. 2019). Noxious stimuli are first sensed by peripheral nociceptors in the perioral area at 7.5 weeks gestation, the hands (10 weeks), and most areas of the body by 14 weeks gestation (Humphrey 1964). Nerve fibers from these peripheral receptors reach the spinal cord beginning at 7–8 weeks gestation (Okado and Kojima 1984). Projections from the spinal cord reach the brainstem and thalamus beginning at 7 weeks gestation (Derbyshire 2006, 2008). Nerve fibers from the thalamus then project to the cortical subplate, a structure in the fetus, discovered in 1974, which is a waiting compartment for neurons which later migrate to the fetal cortex (Judas, Sedmak, and Pletikos 2010).

The first thalamocortical nerve fibers from the thalamus project to the cortical subplate beginning at 12–15 weeks gestation (Bystron et al. 2008; Kostovi´c and Judas 2002; RCOG 2010), earlier than the 20–22 weeks that has been reported in previous studies (Hevner 2000; Kostovic and Rakic 1990; Lee et al. 2005). Thalamocortical fibers are then noted to "massively invade the subplate zone" between 15–26 weeks gestation (Kostovic and Judas 2002, 146)" Thill, supra, page 79.

47. The fact that the fetus lacks a fully functional cortex before 24 weeks' gestation led some scientists to believe that fetal pain perception was impossible before then, despite evidence showing that the fetus will respond to noxious stimuli much earlier V. Glover & N. Fisk, Fetal pain: implications for research and practice. *Brit. J. Obstet*. Gyn. Vol. 106, 881–86, 882 (Sept. 1999), https://obgyn.onlinelibrary.wiley.com/doi/abs/10.1111/j.1471-0528.1999.tb08424.x).

48. In 2010, the Royal College of Obstetricians and Gynaecologists (RCOG) issued a report making this conclusion (Royal Coll. of Obstet. and Gyns., Fetal awareness: review of research and recommendations for practice: report of a working party (Mar. 2010), https://www.rcog.org.uk/globalassets/documents/guidelines/rcogfetalawarenesswpr0610.pdf.) and the American College of Obstetricians and Gynecologists (ACOG) recently relied on it to make the same argument (Am. Coll. of Obstet. & Gyns., Facts are Important: Fetal Pain, https://www.acog.org/advocacy/facts-are-important/fetalpain).

49. But researchers now criticize the RCOG report as ill-founded: "We could rewrite this [report] as 'in theory they can't feel pain, therefore they don't.'" And more recent research "call[s] into question the necessity of the cortex for pain and demonstrat[es] functional thalamic connectivity into the subplate." Further, "even if the cortex is deemed necessary for pain experience, there is now good evidence that thalamic projections into the subplate, which emerge around 12 weeks' gestation, are functional and equivalent to thalamocortical projections that emerge around 24 weeks' gestation." Researchers now believe that "current neuroscientific evidence undermines the necessity of the cortex for pain experience…Thus, current neuroscientific evidence supports the possibility of fetal pain before the 'consensus' cut-off of 24 weeks." Derbyshire SWG, Bockmann JC. Reconsidering fetal pain. *J Med Ethics* 2020;46:3–6. doi:10.1136/medethics-2019-105701.

50. Review of the last decade's research shows that science has also disproved other theories arguing that fetal pain is impossible before 24 weeks. In fact, a prominent researcher who had previously been skeptical that fetuses can feel pain early in gestation now states that "Overall, the evidence, and a balanced reading of that evidence, points towards an immediate and unreflective pain experience mediated by the developing function of the nervous system from as early as 12 weeks. That moment is not categorical, fetal development is continuous and not an event, and we recognize that some evidence points towards an immediate and unreflective pain not being possible until later. Nevertheless, we no longer view fetal pain (as a

core, immediate, sensation) in a gestational window of 12–24 weeks as impossible based on the neuroscience" Ibid, page 6.

51. The relevance to abortion was not lost on the prominent researcher who reconsidered his views due to new science. Even though he is pro-choice, he and his co-author (who is pro-life) state "The two authors of this paper have very different views on the morality of abortion. One of us believes that abortion is necessary for women's health and autonomy, while the other believes that abortion violates the ethical principle of non-maleficence and ought to be restricted and discouraged. Regardless of our stark differences on this question, we both believe that our moral views on abortion should not interfere with discussion of whether fetal pain is possible and whether the science of fetal development can rule out the possibility of fetal pain. We also agree that if fetal pain is likely then that has ethical and clinical significance independent of any views on the morality of abortion per se. That said, it is also clear to us that the issue of fetal pain has ethical significance because of abortion practices and not because of other surgical or therapeutic fetal procedures". Ibid, page 4.

52. There are limited data on how the fetus responds to noxious stimuli before 15 weeks' gestation. Thill notes that "Physician testimony offered during state legislative hearings, however, has reported fetal withdrawal and flailing during feticide prior to 18 weeks gestation". Ohio Senate Bill 2019.

53. It is still unknown exactly how the fetus experiences pain. But even if it does not experience pain like an adult with a fully formed cortex, fetal pain is still

worthy of consideration. In fact, evidence suggests that the unborn child, like infants, may even experience pain more severely than mature people (Glover, supra, page 882 "The last pathways in the nociceptive system … do not form until after birth, raising the possibility that the fetus may actually be more sensitive to noxious stimuli than the older child, and may explain why the newborn shows exaggerated behavioral responses to sensory provocation.").

54. . Physicians already recognize this and avoid suffering in even very pre-viable fetuses. Fetal anesthesia is the standard of care for any fetal procedure. Derbyshire and Bockmann note that "While all the evidence suggests that surgeons performing therapeutic fetal interventions routinely consider pain relief for the fetus, surgeons performing abortions have their focus on the pregnant woman as their patient. Consequently, they more rarely consider fetal pain relief during the preparation and execution of abortion. Whether or not the fetus feels pain, therefore, is relevant to current medical practice surrounding abortion and could motivate changes in practice." They also note that "Currently … we are not aware of any procedures where invasive fetal intervention proceeds without anesthesia or analgesia, except for abortion" Derbyshire, supra, page 4.

55. Therefore, the possibility of fetal pain warrants the same consideration given in the context of medical treatment as it does in the context of abortion. Yet when those same babies are subjected to abortion, their suffering is deemed irrelevant because they are destined to die. As noted above, medicine has developed new ways to treat the fetus as a patient and is addressing the impact those

treatments have on the fetus with respect to pain. However, over the same period, abortion providers have employed increasingly brutal abortion methods, such as dilation and evacuation (D&E).

56. In addition to demonstrating the humanity of the fetus, advancing technology also provides more information about how the fetus experiences the brutal second or third trimester abortion procedure that ends its life. Dilation and evacuation (D&E) is the procedure currently used after 15 weeks' gestation. The Supreme Court of the United States has previously described this procedure based on the testimony of late-term abortionist Dr. Leroy Carhart in gruesome "technical detail" in Stenberg v. Carhart, acknowledging that its description "may seem clinically cold or callous to some, perhaps horrifying to others." As the Supreme Court explained, abortionists use D&E in the second trimester because at that stage of fetal development, "the fetus is larger"—"particularly the head"—and the "bones are more rigid," meaning "dismemberment or other destructive procedures" are required. . . . A physician extracts from the womb what moments before had been a living "unborn child"—using forceps, scissors, or a similar instrument that "slices, crushes, or grasps" fetal body parts one at a time. Piece by piece. Arm by arm. Leg by leg. And as the abortion doctor "cut[s] or rip[s] the piece from the body"—a torso, a spine, a rib cage—he places each body part on a tray (or in a dish) to keep inventory and ensure that nothing is left behind. Sometimes the heart is still beating on the tray. The fetus dies just as an adult experiencing corporal dismemberment would—by bleeding to

death as his or her body is torn apart. *Whole Woman's Health*, 978 F.3d at 913 (Willett, J., dissenting) (emphasis added).

57. "As one bioethicist testified, it's 'self-evident that it's brutal and inhumane to tear a living organism limb from limb alive'"42. And "[n]o one would dispute that, for many, D&E is a procedure itself laden with the power to devalue human life". *Gonzales*, 550 U.S. at 158.89.

58. Given the recent evidence showing the fetus may experience pain as early as 12 weeks, researchers have directly concluded that "a D&E procedure will deliver repeated nociceptive events that may involve fetal pain before fetal death" Derbyshire, supra, page 5. Fetal pain is so likely that the same researchers advocate for fetal analgesia to be used in abortions, even before less outwardly brutal procedures causing fetal death, such as feticidal injections (injections into the heart of the fetus to kill him or her before D&E). But the D&E procedure is inherently inhumane regardless of whether the fetus can feel it. We would never countenance dismembering a person (or even an animal) as a means of causing death, even if the person were anesthetized first. This is why considerations of fetal pain must be explained to pregnant women considering abortion.

D. Embryologic and Fetal Development

59. In paragraph 37, Dr. Nauser alleges that "Experts in human anatomy who examined the state-published printed materials in 2013 found that over 40 percent of its statements on embryonic and fetal development were medically inaccurate". A review of the cited website, https://informedconsentproject.com/team-

members/, under Who We Are, lists the research approach as follows: "We recruited a team of 7 specialists in embryological and fetal development through the American Association of Anatomists to evaluate these materials". The names and qualifications of these individuals were not posted on the website, the references used to make the evaluations were not specified, and results were not refereed. Without this information the accuracy and validity of this critique is highly questionable.

E. Terminology for the Embryo, Fetus and Unborn Child

60. Paragraph 27 of Plaintiffs' complaint alleges that "[mifepristone] causes the pregnancy tissue and lining of the uterus to break down and separate from the wall of the uterus." This statement is inaccurate on its face. The term "pregnancy tissue" does not exist medically. What mifepristone does is to block placental progesterone receptors. Progesterone is required for a developing embryo to survive. Therefore, the administration of mifepristone is deliberately feticidal. It kills a developing human embryo.

61. Dr. Nauser alleges in paragraph 37 that the language of the Biased Counseling Scheme "is not medical; for example, in medicine, the proper term is "embryo" or "fetus", not "unborn child". The medical literature shows that this is not true. A paper by Bourne et al, for example uses the terms "baby," "embryo," and "heartbeat" in describing early pregnancy (Bourne, T. and Bottomley, C., When is a pregnancy nonviable and what criteria should be used to define miscarriage?, *Fertil Steril* 2012; 98: 1091-6).

62. Further, this statement contradicts Dr. Nauser's own description of the services provided by her practice, the Center for Women's Health. On page 2 of her declaration, she states in paragraph 5 that "At the Center for Women's Health, we provide a full range of obstetrical and gynecological services, including but not limited to…delivery of babies…". What is a baby being delivered, than an unborn child being born? She also states on page 14 that "…I may be called away to deliver a baby…". Thus, by her own testimony, the use of the term "unborn child" or "baby" is medically appropriate.

63. Thill notes that "abortion rights advocates and abortion providers preferentially avoid terminology such as 'baby' and 'fetus' (Andaya and Campo-Engelstein 2021)" or images of the fetus because of "not wanting to give the fetus human status" (Williams 2005, 2085)". Thill, supra, page 93. This undermines patient autonomy and choice and is also a denial of an overwhelming amount of data and scientific consensus supporting the humanity of the unborn child.

F. Fetal Viability After Detection of a Heartbeat

64. Dr. Alsaden alleges in paragraph 60 that "The Biased Counseling Scheme also requires me to communicate to patients that less than five percent of pregnancies "end in spontaneous miscarriage after detection of cardiac activity. This is factually incorrect…patients ages 20 to 30 have an 8.9 percent risk of miscarriage prior to 20 weeks." Here Dr. Alsaden has conflated the risk of miscarriage after detection of cardiac activity with the overall risk for miscarriage in women of childbearing age. For example, the study upon which the statement is based, by

Andersen et al and cited by Dugas et al in StatPearls, included only women with miscarriage in progress who presented to the hospital. It is intuitively obvious that this group of patients is not representative of all women who suffer miscarriage. The study did not ascertain whether participants had had an ultrasound showing a fetal heartbeat. Nowhere in the cited StatPearls reference is there any mention of estimation of the viability of a pregnancy once a fetal heartbeat is seen.

65. Studies that have specifically estimated the likelihood of a pregnancy's viability, or the likelihood that a pregnancy would proceed to term (or a predetermined gestational age cutoff for research studies) if a heartbeat is detected on ultrasound, approximate the Biased Counseling Scheme's estimates. Tannirandorn (2003) noted that after heart activity is detected, fetal loss occurs in approximately 2-5% of pregnancies (Tannirandorn, Y., et al., Fetal loss in threatened abortion after embryonic/fetal heart activity, Int'l J Gynecol Obstet 2003; 81, 263-266). Makrydimas noted that the risk of fetal loss in women decreases with gestational age; for those women whose babies had a visible heartbeat at 6 weeks the risk of fetal loss was 10%, and for those with a heartbeat at 10 weeks the rate was 3%. Makrydimas, G., et al., Fetal loss following ultrasound diagnosis of a live fetus at 6-10 weeks of gestation, Ultrasound Obstet Gynecol 2003; 22, 368-372.

G. The Importance of Informed Consent

66. Plaintiffs allege in paragraph 53 that "meeting privately with the physician who is performing the abortion" is an impediment. But for a woman to meet with the physician is important given that (1) Traffickers and abusers will often not

allow a woman to meet privately with a physician and (2) The person doing the procedure should obtain consent. This is standard medical practice, and in many states, physicians have been held liable for their delegates not providing adequate informed consent. In addition, there are reports of abortionists not giving adequate consent and even administering sedation prior to obtaining consent for abortion.

67. In fact, consent for the abortion decision is different from any other type of informed consent. No other procedure destroys human life, a fact that has been noted in multiple court cases, or has the potential to inflict pain on a child without any prospect of benefit, or is associated with long-term, even endless regret on the part of the mother. According to Thill,

> This dichotomy in terminology and the shielding of the pregnant woman from medical information [in informed consent] may unduly influence the patient's decision-making process, particularly in a time of crisis when reliance on medical counsel is high. Reports over the past 20 years show that fetal pain is a concern of women considering abortion (Andaya and Campo-Engelstein 2021; Furedi 2001; RCOG 2010). Research, however, notes a reluctance among providers to discuss fetal pain due to concerns of causing emotional distress for the pregnant woman (Andaya and Campo-Engelstein 2021). **This has raised the issue of medical paternalism potentially precluding appropriate patient counseling, education, and informed consent. In Gonzales v. Carhart (2007), abortion providers noted that pertinent medical information about the abortion procedures was not typically disclosed to patients.** In the majority opinion, Justice Kennedy noted that the omission of information necessitates government involvement: **"It is, however, precisely this lack of information concerning the way in which the fetus will be killed that is of legitimate concern to the State...The State has an interest in ensuring so grave a choice is well informed. It is self-evident that a mother who comes to regret her choice to abort must struggle with grief more anguished and sorrow more profound when she learns,**

> **only after the event, what she once did not know...** (IV.A) [emphasis added]" (quoting *Gonzales v. Carhart*, 550 U. S. 124, 160 (2007)48.

68. Underlying the importance of detailed accurate consent for abortion is the concept of choice – the choice to keep one's baby, or to abort him or her. It is paternalistic to deprive women of knowledge that could better inform their choice to undergo or not undergo an abortion. If women receive information that causes them to change their mind regarding abortion, this is empowering them to exercise their choice to have their babies. To not disclose detailed information is not only dishonest and unethical, it curtails a woman's right to fully understand the consequences of her decision and to choose accordingly.

H. Abortion is not Health Care

69. Dr. Alsaden alleges in paragraph 26 that "Abortion is a time-sensitive, essential health service". Abortion is not health care. Abortion is defined by CDC as "an intervention…that is intended to terminate a suspected or known ongoing intrauterine pregnancy and that does not result in a live birth." The goal of any abortion is therefore to kill the embryo or fetus. The embryo or fetus—the unborn child—is a human being. That is, he or she is a member of the human family, a unique living being with human DNA distinct from his or her parent. He or she is not a "clump of cells" or a "potential child" but an unborn child, a child assuming the human form. Since the goal of an abortion is to cause the death of the unborn child, and the unborn child is a human being, abortion causes the death of a human being. Pregnancy is not a disease. Abortion neither prevents, treats, or palliates any disease.

Instead, it has as its goal the death of a human being. Abortion is therefore not health care, for either the mother or her unborn child.

70. Dr. Alsaden alleges in paragraph 76 that "I can think of several patients who threatened to commit suicide at our health center after our staff had to tell them we would be unable to perform their abortion that day because they did not satisfy this requirement…this…takes an emotional toll on our patients…". A threat by a patient to commit suicide because she cannot have an abortion is not an "emotional toll", it is a psychiatric emergency. The standard of care in every state, when a patient threatens suicide is to immediately obtain psychiatric evaluation for suicide risk, not to seek to perform an abortion or use a patient's suffering as an example of why the requirements of the law are inappropriate. Physicians are mandated to arrange for urgent psychiatric evaluation for suicidal patients, including the involvement of the community suicide prevention team where available. It is not clear whether Dr. Alsaden did so in these reported cases.

I. Abortion Epidemiology, Safety and Complications

71. Plaintiffs allege in Paragraph 30 of their complaint that "Because of mifepristone's track record of safety and efficacy, in January 2023, the FDA took the long overdue action of removing medically unnecessary restrictions…".

72. Mifepristone is associated with significant risk to pregnant women and is always lethal to a developing child. The REMS (Risk Evaluation and Monitoring Strategies) that were put in place by the FDA for mifepristone were designed to

protect women from specific side effects. FDA reviewed mifepristone's safety record in 2022 (see below).

TTT # 2022-2468
NDA 020687
ANDA 091178
Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022

The following information is from United States (U.S.) post-marketing reports received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use, and other possible medical or surgical treatments and conditions. The estimated number of women who have used mifepristone in the U.S. for medical termination of pregnancy through the end of June 2022 is approximately 5.6 million women.

For informational purposes, fatal foreign cases that were reported after U.S. approval of mifepristone for medical termination of pregnancy are also included in a footnote in Table 1.

Table 1. Cumulative Post-Marketing Fatal and Ectopic Pregnancy Reports in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy	
Date range of cumulative reports	09/28/00[†] - 06/30/22
Died [‡]	28
*Ectopic pregnancies [||]	97

73. Given that the United States lacks comprehensive data on abortion morbidity and mortality, these statistics likely represent a small minority of deaths and complications from mifepristone. Also, given that medical abortion is for the most part an elective procedure, deaths and serious complications from mifepristone represent an unacceptable level of risk.

74. Dr. Alsaden alleges in paragraph 21 that "mifepristone and misoprostol are…substantially safer even than aspirin, Tylenol and Viagra". This is incorrect. Unlike aspirin, Tylenol and Viagra, mifepristone carries a black box warning, which notifies clinicians and patients of serious and even fatal complications from taking a medication. FDA's black box warning process involves assessment of post-marketing

experience. As noted by Drugwatch (https://www.drugwatch.com/fda/black-box-warnings/), "A black box warning is the FDA's most stringent warning for drugs and medical devices on the market. Black box warnings, or boxed warnings, alert the public and health care providers to serious side effects, such as injury or death. The FDA requires drug companies to add a warning label to medications that have a black box warning…**Before adding a boxed warning to a medication or medical device, the FDA must have evidence that the drug poses a significant risk. This evidence comes from observations and studies conducted after a drug has been on the market**…After determining a drug needs a black box warning, the FDA contacts the drug company to add a warning to its labeling. The drug company then submits its language for FDA approval. Once the FDA approves the language, it is printed on the drug or device's package and on the medication insert" [emphasis added].

75. Below is the black box warning for mifepristone, which warns of "serious and sometimes fatal infections or bleeding."

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use MIFEPREX safely and effectively. See full prescribing information for MIFEPREX.

MIFEPREX® (mifepristone) tablets, for oral use
Initial U.S. Approval: 2000

WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING

See full prescribing information for complete boxed warning.

Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use.

- **Atypical Presentation of Infection. Patients with serious bacterial infections and sepsis can present without fever, bacteremia or significant findings on pelvic examination. A high index of suspicion is needed to rule out serious infection and sepsis. (5.1)**
- **Bleeding. Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed. (5.2)**

MIFEPREX is only available through a restricted program called the mifepristone REMS Program (5.3).
Before prescribing MIFEPREX, inform the patient about these risks. Ensure the patient knows whom to call and what to do if she experiences sustained fever, severe abdominal pain, prolonged heavy bleeding, or syncope, or if she experiences abdominal pain or discomfort or general malaise for more than 24 hours after taking misoprostol.
Advise the patient to take the MEDICATION GUIDE with her if she visits an emergency room or another healthcare provider who did not prescribe MIFEPREX, so that provider knows that she is undergoing a medical abortion. (5.1, 5.2)

76. Below is the prescribing information for sildenafil (Viagra), which does not have a black box warning.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VIAGRA safely and effectively. See full prescribing information for VIAGRA.

VIAGRA® (sildenafil citrate) tablets, for oral use
Initial U.S. Approval: 1998

RECENT MAJOR CHANGES
Warnings and Precautions, Effects on the Eye (5.3) 08/2017

INDICATIONS AND USAGE
VIAGRA is a phosphodiesterase-5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction (ED) (1)

DOSAGE AND ADMINISTRATION
- For most patients, the recommended dose is 50 mg taken, as needed, approximately 1 hour before sexual activity. However, VIAGRA may be taken anywhere from 30 minutes to 4 hours before sexual activity (2.1)
- Based on effectiveness and tolerance, may increase to a maximum of 100 mg or decrease to 25 mg (2.1)
- Maximum recommended dosing frequency is once per day (2.1)

with caution, and only when the anticipated benefits outweigh the risks, in patients with a history of NAION. Patients with a "crowded" optic disc may also be at an increased risk of NAION. (5.3)
- Patients should stop VIAGRA and seek prompt medical attention in the event of sudden decrease or loss of hearing (5.4)
- Caution is advised when VIAGRA is co-administered with alpha-blockers or anti-hypertensives. Concomitant use may lead to hypotension (5.5)
- Decreased blood pressure, syncope, and prolonged erection may occur at higher sildenafil exposures. In patients taking strong CYP inhibitors, such as ritonavir, sildenafil exposure is increased. Decrease in VIAGRA dosage is recommended (2.4, 5.6)

ADVERSE REACTIONS
Most common adverse reactions (≥ 2%) include headache, flushing, dyspepsia, abnormal vision, nasal congestion, back pain, myalgia, nausea, dizziness and rash (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer at 1-800-438-1985 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

DRUG INTERACTIONS
- VIAGRA can potentiate the hypotensive effects of nitrates, alpha blockers, and anti-hypertensives (4.1, 5.5, 7.1, 7.2, 7.3, 12.2)

77. Acetaminophen (Tylenol) is an over the counter medication. Per Dailymed's data on acetaminophen (https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=511536b2-6cbd-463e-b2db-6feec474cf6b) "Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies."

78. It is therefore erroneous to state that mifepristone is as safe as or safer than Viagra or Tylenol. Mifepristone can and has caused serious complications and death. It is also clear that there are significant risks associated with the use of mifepristone which require close monitoring, like the REMS to prevent harms to women.

79. As an example, Dr. Alsaden alleges in paragraph 16 that mifepristone-misoprostol has been shown "to be safe and extremely effective, including through 77 days, or 11 weeks of pregnancy." It should be noted that this regimen is only approved by FDA for use up to 70 days' gestation, because its use at later gestational ages is associated with more complications.

80. First trimester medication abortion carries substantial risks to the mother. A study by Niimaki et al used data from Finland's health service administrative database, which included all women in Finland undergoing abortion from 2000 to 2006 (42,619 women) and collected follow up data for 42 days post abortion (Niinimäki M, Pouta A, MD, Bloigu A, Gissler M, Hemminki E, Suhonen S, Heikinheimo O. Immediate Complications After Medical Compared With Surgical

Termination of Pregnancy. Obstet Gynecol 2009;114:795–804). This study design captured all outcomes for all women undergoing abortion in an entire country over a longer period of time than most studies of abortion complications. As a result, it is free of methodological problems and bias that plague other studies of abortion, including those conducted in the United States.

81. In the study by Niimaki et al, 20% of women underwent medical abortion, and 5.6% underwent surgical abortion. The authors note that "The overall incidence of adverse events was fourfold higher in the medical compared with the surgical abortion cohort. The risk of hemorrhage with medical abortion was 15.6%, and 2.1% with surgical abortion. The risk of incomplete abortion with medical abortion was 6.7%, and 1.6% with surgical abortion. The risk of emergency surgery with medical abortion was 5.9% with medical abortion, and 1.8% with surgical abortion."

82. Therefore, in this study, women undergoing medical abortion had 8 times the risk for hemorrhage compared to those undergoing surgical abortion. They had 5 times the risk of needing a curettage to remove retained placenta or fetal parts, and 4.2 times the risk for an adverse event compared to those undergoing surgical abortion. These findings have significant implications given the increased use of medical abortion.

83. As noted, the strength of this study was its ability to completely ascertain all abortions and all associated complications. In contrast, other studies attempting to answer questions about the safety of abortion have methodological

problems, which are due to the study design. For example, a study by Upadhyay et al (Ushma D. Upadhyay, Sheila Desai, Vera Zlidar, Tracy A. Weitz, Daniel Grossman, Patricia Anderson, Diana Taylor. Incidence of Emergency Department Visits and Complications After Abortion. Obstet Gynecol 2015;125:175–83), though well designed, has many limitations, similar to other retrospective administrative database research studies. These include potential confounding associated with inaccurate coding; the absence of clinical data, especially on gestational age at the time of abortion and method of abortion; and the likelihood that patients with complications did not engage with the medical system. As with many studies of this type, no charts were reviewed. There was very limited follow up. The authors acknowledge some of these issues and note as well that, for example, second trimester abortion complications in their study are lower than in other studies, suggesting that their population may not be representative, or that cases were incompletely ascertained.

84. First trimester surgical abortion carries immediate risks of hemorrhage, infection, continuing pregnancy, death, perforation of the uterus, damage to organs including hysterectomy. These complications, and the need to discuss them in counseling for informed consent, are described in the National Abortion Federation 2020 Clinical Policy Guidelines for Abortion Care.

J. Abortion Is Not Safer Than Childbirth

85. In paragraph 24 Dr. Alsaden quotes the National Academies of Sciences report on abortion as stating that the "risk of death from childbirth is 12.57 times

higher than that from abortion". The assertion that "abortion is safer than childbirth" has been repeated multiple times in multiple publications. However, it is not based in fact nor supported by scientific evidence.

86. The NAS study was funded by the Packard, Buffet and Hewlett foundations, which are leading funders of international abortion advocacy. While the study authors performed an extensive literature review, they excluded hundreds of studies, and primarily used those written by abortion advocates.

87. In evaluating the risks of childbirth vs abortion, the NAS report compared mortality from abortion to mortality from childbirth and several surgical procedures. There are multiple problems with the data sets used, as well as mortality data which were not evaluated in the report.

88. Studies focusing on abortion mortality mix different types of data, from different sources, with different denominators and definitions. A widely reported study by Raymond and Grimes asserted that abortion is 14 times safer than childbirth by using four disparate and difficult to calculate numbers, with non-comparable denominators The Comparative Safety of Legal Induced Abortion and Childbirth in the United States Elizabeth G. Raymond, MD, MPH, and David A. Grimes, MD *Obstet Gynecol* 2012;119:215–9). Abortion-related deaths were compared to the number of legal abortions. Maternal deaths were compared to the number of live births. Only live births can be accurately measured due to mandated birth certificates. Yet, only 2/3 of maternal deaths occur in association with a live birth. It is well documented in the U.S. that at least 50% of maternal deaths are not reported

as pregnancy related on death certificates. Mortality from events in the first half of pregnancy, which are unable to be linked to a birth certificate, are even more difficult to detect, but reliable records-linkage studies from Finland document that 94% of abortion-related deaths are not documented as such on the maternal death certificate (Gissler M, Kauppila R, Merilainen J, Toukomaa H, Hemminki E. Pregnancy associated deaths in Finland 1987-1994: Definition problems and benefits of record linkage. Acta Obstetricia et Gynecologia Scandinavica 1997;76:651-57; Gissler M, Ber C, Bouvier-Coll M, Buekins P.. Pregnancy-associated mortality after birth, spontaneous abortion, or induced abortion in Finland 1987-2000; Gissler M, Berg C, Bouvier-Colle MH, Buekens P. Injury deaths, suicides, and homicides associated with pregnancy, Finland 1987-2000. *European J of Public Health* 2005;15:459-63.

90. The claim that abortion is safer than childbirth is inaccurate. It does not acknowledge the flaws in abortion data collection for both numbers of abortions and deaths from abortion, and ignores differences in the biology and physiology of pregnancy at different stages.

91. U.S. abortion data are incomplete. The collection of abortion statistics is widely acknowledged to be severely flawed. CDC's collection of data is voluntary, not mandatory. Starting in 1998, multiple states did not report their abortion data or provided incomplete data. Per CDC's 2019 Abortion Surveillance, "Data from 24 reporting areas excludes 17 states that did not report, did not report by race/ethnicity or did not meet reporting standards," including Alabama, Arizona, California, Delaware, District of Columbia, Florida, Hawaii, Illinois, Louisiana, Maine,

Maryland, New Hampshire, New Mexico, Tennessee, Vermont, Wisconsin, and Wyoming Abortion Surveillance — United States, 2019 | MMWR (cdc.gov).

92. California, Maryland, and New Hampshire do not report any official data, and many states submit incomplete data lacking information on gestational age, race-ethnicity, and gestational age. The lack of abortion reporting from some of the most populous states makes it difficult to arrive at accurate estimates of the number of abortions performed in the United States.

93. Abortion statistics and abortion mortality statistics are widely acknowledged to be inaccurate. There is no federal reporting requirement for either the number of abortions performed in the United States of the number of women who dies from abortion. Only 26 states require providers to report. The data provided are estimates: "Many state health departments are able to obtain only incomplete data from abortion providers, and in some states, only 40-50% of abortions are reported." (Grimes DA. Estimation of pregnancy-related mortality risk by pregnancy outcome, United States, 1991-1999. Am J Obstet Gynecol 2006;194:92-93; Saul R. Abortion reporting in the United States. Fam Planning Perspect 1998;30:244-47; Guttmacher Institute. Abortion reporting requirements. State Policies in Brief. 2009; 12 September; Jones RK, Zolna MRS, Henshaw SK, Finer LB. Abortion in the United States: Incidence and access to services. Perspect on Sexual and Repro Health 2005;40(1):6-16.

94. CDC collects maternal mortality data in 2 separate systems, the National Vital Statistics System (NVSS) and the Pregnancy Mortality Surveillance

System (PMSS). From 1995-97 NVSS reported 898 maternal deaths while PMSS reported 1,387 deaths. Only 54% of deaths were reported in both systems (MacKay A, Berg CJ, Duran C, Chang J, Rosen berg H. An assessment of pregnancy-related mortality in the U.S. Pediatric & Perinatal Epidemiology 2005; 19:206-14).

95. In 2019, CDC's Abortion Surveillance report stated that "Because reporting to CDC is voluntary and reporting requirements vary by the individual reporting areas, **CDC is unable to report the total number of abortions performed in the United States** [emphasis added]." Data collected by the Alan Guttmacher Institute (AGI) are also limited because AGI relies on surveys rather than collection of case data. According to AGI's own description of their methodology, see https://www.guttmacher.org/report/abortion-incidence-service-availability-us-2017. Both CDC and AGI data acknowledge the limitations of their data and their quality. Their reports are estimates and cannot be used to precisely assess the total number of abortions performed in the United States.

96. Estimates of abortion related mortality are likewise inaccurate because deaths from abortion appear to be underreported (see David C. Reardon, Thomas W. Strahan, John M. Thorp, Jr. & Martha W. Shuping, Deaths Associated with Abortion Compared with Childbirth – A Review of New and Old Data and the Medical and Legal Implications, 20 J. Contemp. Health Law & Policy 279, 286-91 (2004); Byron Calhoun, Systematic Review: The maternal mortality myth in the context of legalized abortion, The Linacre Quarterly, 264 (2013).

97. The problem of inadequate data collection and analysis is not limited to abortion mortality. It is far greater for abortion complications. CDC does not systematically collect and report data on abortion complications, nor do many abortion providers. In some states, abortion providers are required to report immediate complications.

98. However, there are very few studies on longer-term follow up. The American College of Obstetrician-Gynecologists Current Commentary: Routine Follow up Visits After First-Trimester Induced Abortion (2004) noted that "In practice, attendance at abortion follow up visits is usually low, generally about 50%. Studies of first trimester aspiration abortion complications observing consecutive series of patients show follow-up proportions from 35% to 60%, although a few series report proportions as high as 80-90%". Most women with complications from abortion seek help at emergency departments. This is especially true of abortions performed by non-physicians, who by definition cannot manage abortion complications. Therefore, the true risks of abortion to women and the frequency of abortion-related complications remain unknown. The need for accurate statistics on abortion is a public safety issue, not a pro-life or pro-choice issue.

99. Women experiencing life-threatening health complications from abortion go to hospital emergency rooms and are not usually seen by abortionists. Deaths from abortion complications are often not counted. In addition, abortion related deaths from (from physician complications of the procedure) are usually reported as maternal deaths.

100. As a result of these flaws, it is not possible to accurately estimate the risks of abortion, including abortion mortality. It is my opinion that without an accurate estimate of the number of abortions performed in the United States or the number of maternal deaths from abortion, it is impossible to estimate abortion related morbidity or mortality with any precision.

101. U.S. maternal mortality data are incomplete. Maternal deaths use a denominator of 100,000 live births, even though it is acknowledged that only two-thirds of maternal deaths are associated with a live birth. This is because many reported deaths occur while a woman is pregnant, but not near term. It is estimated that 39-93% of maternal deaths are not reported on death certificates, which also skews maternal mortality statistics.

102. Maternal death reporting associated with early losses is even more compromised, with international records-linkage studies documenting that less than a quarter of deaths following induced abortion are reported on death certificates. Because of these severe data deficiencies, the U.S. did not report a maternal mortality ratio to the world from 2007-2016.

103. Even now, researchers are aware that U.S. statistics continue to be flawed and many deaths go underreported. Calculations of abortion related mortality and maternal mortality not only overlap, they also use different denominators. Some studies use the number of maternal deaths per 100,000 abortions. Some use the number of deaths per 100,000 live births. In fact, it is very difficult to accurately estimate the true denominator of all pregnancies. Many pregnancies miscarry before

detection, or are only briefly detected using a pregnancy test ("chemical pregnancies"), or their outcomes are not reported (a woman is never seen by a physician, miscarries at home, etc.).

104. Many pregnancy outcomes are never reported. For these reasons it would be impossible to count all pregnancies occurring in all women in a given year (the denominator for estimates of maternal mortality). Maternal mortality data as noted are compromised due to many data deficiencies. The numbers of miscarriages and induced abortions occurring annually in the United States is not known, nor is there mandated reporting of their complications and deaths, so we lack knowledge about the adverse outcomes of most early pregnancy events (Stuart M. Berman, H. Trent MacKay, David A. Grimes, Nancy J. Binkin. Deaths From Spontaneous Abortion in the United States. JAMA 1985;253:3119-3123); Hani K. Atrash, H. Trent MacKay, Nancy J. Binkin, Carol J. R. Hogue. Legal abortion mortality in the United States: 1972 to 1982. Am J Obstet Gynecol 1987;156:605-12; Herschel W. Lawson, Alice Frye, Hani K. Atrash, Jack C. Smith, Holly B. Shulman, Merrell Ramick. Abortion mortality, United States, 1972 through 1987. Am J Obstet Gynecol 1994; 171:1365-72; Mona Saraiya, Clarice A. Green, Cynthia J. Berg, Frederick W. Hopkins, Lisa M. Koonin, Hani K. Atrash. Spontaneous Abortion–Related Deaths Among Women in the United States—1981–1991. Obstet Gynecol 1999;94:172– 6; Suzanne Zane, Andreea A. Creanga, Cynthia J. Berg, Karen Pazol, Danielle B. Suchdev, Denise J. Jamieson, William M. Callaghan. Obstet Gynecol. 2015 August ;

126(2): 258–265. doi:10.1097/AOG.0000000000000945; CDC Abortion Surveillance 2018 available at https://www.cdc.gov/mmwr/volumes/69/ss/ss6907a1.htm).

105. In 2004, Dr. Julie Gerberding, then head of the CDC, noted that maternal mortality rates and abortion mortality rates "are conceptually different and are used by the CDC for different public health purposes." Julie Louise Gerberding, M.D., to Walter Weber, American Center for Law & Justice, July 20, 2004, http://afterabortion.org/pdf/CDCResponsetoWeberReAbortionStats-Gerberding%20Reply.pdf, responding to Weber's April 30, 2004, letter to Tommy G. Thompson, U.S. Department of Health and Human Services, requesting a reassessment of pertinent statistical measures of mortality rates associated with pregnancy outcome, http://afterabortion.org/pdf/WeberLettertoThompson&CDCReAbortionStats.pdf.

106. Assertions that abortion is safer than childbirth also do not take into consideration the biology of fetal and uterine development and adaptation, or the epidemiology of spontaneous abortion, induced abortion, and term delivery. At 8 weeks, the fetus is 1.22 inches long and weighs 0.71 ounces. At 20 weeks, the fetus is 12.7 inches long and weighs 11.7 ounces. At term the average fetus is 21 inches long and weighs 8 lbs. Uterine size increases from approximately the size of an orange late in the first trimester to almost the size of a watermelon in the late third trimester. Uterine blood flow increases from 200 cc/minute in the nonpregnant state to almost 1 liter per minute at term. An abortion done in the first trimester is therefore vastly different from childbirth. It is my opinion, supported by scientific evidence, that the

two procedures (first trimester abortion and childbirth) are not comparable due to these changes.

107. Per CDC, in 2019 most abortions (79%) were performed at less than or equal to 9 weeks, and 92.7% were performed at less than or equal to 13 weeks. But mortality from abortion mostly occurs in the smaller number of abortions performed at later gestational ages. If abortion maternal mortality estimates combine deaths at all gestational ages, the estimates will be skewed toward the lower mortality rates at lower gestational ages due to the much large number of abortions done at lower gestational ages. This "needle in a haystack" effect contributes false support to the conclusion that abortion is safer than childbirth. It is illogical to conflate abortion mortality risk at early gestational ages with mortality from childbirth at term. A more accurate comparison would be between abortions vs. miscarriages early in pregnancy, and late abortions and childbirth. Data show that abortion is riskier at equivalent gestational ages compared with miscarriage or birth.

108. The death statistics tabulated for abortion focus on "uncomplicated" abortion, whereas statistics for childbirth incorporate complicated deliveries (cesarean deliveries). Comparing uncomplicated delivery to uncomplicated abortion shows the risk of dying from abortion is twice that of uncomplicated vaginal delivery (Lanska J, Lanska A, Rimm A. Mortality from abortion and childbirth. J of American Medical Association 1983;250:361)

109. Comparisons without regard to gestational age are flawed. Deaths during the first 6 weeks of pregnancy (when maternal morbidity and mortality are

highest) are classified as maternal deaths and placed together with deaths due to birth and delivery. This is inappropriate since the intended outcomes are unknown. Women who reach the common point of awareness of pregnancy and make a decision to abort (approximately 6-8 weeks) have already survived beyond the period of pregnancy's greatest risk. Abortions do not typically occur very early (before 6 weeks) or > 9 months of gestation when most of the maternal deaths in the maternal mortality statistics occur.

110. Bartlett et al (2004) used abortion mortality data to estimate abortion mortality as gestational age increases. They noted that "currently, the risk of death [from abortion] increases exponentially at all gestational ages…**the risk of death at later gestational ages may be less amenable to reduction because of the inherently greater technical complexity of later abortions related to the anatomical and physiologic changes that occur as pregnancy advances** [emphasis added]." Bartlett L, Berg C, Shulman H, Zane S, Green X, Whitehead S, Atrash H. Risk Factors for Legal Induced Abortion–Related Mortality in the United States. Obstet Gynecol 2004;103:729 –37 These authors found that the risk of a woman dying from abortion increased 38% for each week of gestational age. Abortions performed past 21 weeks had a mortality rate 76 times greater than abortions done in the first trimester. Based on their data, the estimated maternal mortality rate for abortions done at 28 weeks would be 62/100K, at 30 weeks 225/100K, and at 36 weeks 818/100K. These estimates are astronomically higher than the maternal mortality rate at term. In any event, during 2nd and 3rd trimesters, the abortion related

mortality equals and then exceeds that of childbirth (childbirth-approximately 8-10/100,000) (Bartlett, 2004)

111. Available statistics do not address the long-term and less direct causes of death associated with abortion and childbirth. Risk of death associated with abortion increases over time (due to substance abuse, cancer, pregnancy complications, suicide) while risk of death following term pregnancy is lower. A US study spanning 8 years in California found in 2002 a 62% increase in all cause deaths, 154% increased risk in suicide (Reardon DC, Cougle J, Ney PG, Scheuren F, Coleman PK, Strahan T. Deaths associated with delivery and abortion among California Medicaid patients: A record linkage study. Southern Medical Journal 2002;95:834-41).

112. A Finnish study in 1997 found death rates 4 times higher after abortion compared to childbirth up to 1 year. (Gissler M, Kauppila R, Merilainen J, Toukomaa H, Hemminki E. Pregnancy associated deaths in Finland 1987-1994: Definition problems and benefits of record linkage. Acta Obstetricia et Gynecologia Scandinavica 1997;76:651-57). Subsequent studies in Finland showed maternal mortality-childbirth 28.2/100,000, while abortion mortality was 83.1/100,000 or 3 times higher (Gissler M, Ber C, Bouvier-Coll M, Buekins P. Pregnancy-associated mortality after birth, spontaneous abortion, or induced abortion in Finland 1987-2000). The risk of suicide was 6 times higher following abortion.

113. Morgan et al in UK found that there were 8.1/1,000 suicide attempts in patients undergoing abortion versus 1.9/1,000 suicide attempts in those giving birth

(Morgan C, Evans M, Peters JR. Suicides after pregnancy: Mental health may deteriorate as a direct effect of induced abortion. Br Med J 1997;314:902).

114. Chang et al in 2003 found 3 most common causes of maternal mortality in abortion were infection (33.9%), hemorrhage (21.8%) and embolism (13.9%). Deaths from hemorrhage were 8 times higher and from infection 9 times higher in abortion compared to live-birth (Chang J, Elam-Evans LD, Berg CJ, Herndon J, Flowers L, See KA, Syverson CJ. Pregnancy-related mortality surveillance-United States 1991-1999. MMWR 2003;52:1-8).

115. Dr. Alsaden also alleges in paragraph 34 that "…pregnancy also carries risk and delaying abortion forces a patient to remain pregnancy longer, experiencing the symptoms, risks and potential complications of pregnancy". Abortion does not prevent pregnancy complications or maternal death. It ends a pregnancy during which a woman may or may not have had a complication. A woman's individual risk for pregnancy complications can be estimated but not predicted with certainty, because there is no way to predict whether an individual woman will suffer a pregnancy complication. All risk is based on estimates, and when estimating complication, some individuals will develop them and some will not. This cannot be predicted with complete certainty. Good maternal care during pregnancy markedly reduces the risk of complications from many diseases. There is no way to predict whether an individual woman will suffer a pregnancy complication. Abortion does not prevent or treat pregnancy complications such as diabetes or high blood pressure in pregnancy.

K. Abortion's Short- and Long-term Effects on Women's Health

116. Dr. Nauser alleges in paragraph 38 that "…these materials perpetuate confusion about the effects of abortion…like, for example, the impact of a previous abortion on future preterm birth". A substantial body of research indicates that abortion is associated with future preterm birth. Two recent meta-analyses confirm this association (Saccone G, Perriera L, Berghella V. Prior uterine evacuation of pregnancy as independent risk factor for preterm birth: a systematic review and metaanalysis. *Am J Obstet Gynecol.* 2016;214(5):572–591; Lemmers M, Verschoor MA, Hooker AB, et al. Dilatation and curettage increases the risk of subsequent preterm birth: a systematic review and metaanalysis. *Hum Reprod.* 2016;31(1):34–45).

117. Quoting AAPLOG's Practice Guideline #11 PB-5-Overview-of-Abortion-and-PTB.pdf (aaplog.org), "PTB [preterm birth] is defined as delivery before term, i.e. before 37 weeks and affects about one in ten deliveries in the United States. The majority (70%) of babies born before 37 weeks are born at 34 to 36 weeks. About 10% of PTB (1-2% of all U.S. deliveries) occur before 32 weeks and are termed "very preterm births." Very preterm births pose greater risks to the neonate and greater costs to the family and system." From my experience, preterm birth is heartbreaking to families and takes an enormous toll on them, as well as clinical professionals and the health system.

118. AAPLOG goes on to say that "Papers that examined multiple smaller studies (reviews) on abortion and PTB first emerged in the United States in

2003.10,11 Rooney and Calhoun (2003) reviewed studies from 1966-2003 and found 49 studies with a statistically significant risk for PTB after abortion…Meanwhile, the association between abortion and PTB has been known in the international community since at least 1973….A meta-analysis by Swingle et al. (2009) was performed [by] authors who held different political beliefs on abortion, to reduce bias.16 This team reviewed 7,891 titles, 349 abstracts, and 130 manuscripts, finally identifying 12 papers about the risk of PTB after abortion and 9 papers on PTB after miscarriage (spontaneous abortion, SAB) with data available for analysis.

119. Four of the 12 studies on abortion had data available for common odds ratios (OR) to calculate the odds of PTB less than 32 weeks as-sociated with surgical abortion. The common OR for these studies was 1.64 (95% CI 1.38-1.91).16 Odds ratios are different from relative risk, but this result is equivalent to a change in the rate of delivery before 32 weeks from about 1.5% (the U.S. baseline rate before 32 weeks), to about 2.3% after one abortion.

120. This study also found an increased risk of PTB after SAB [spontaneous abortion, or miscarriage]. Out of the 9 studies available to pool a common odds ratio for PTB after SAB, 7 had data for use in calculations. The authors found that the odds of PTB less than 37 weeks after one SAB was 1.43 (95% CI 1.05-1.66), and with more than 2 SABs, 2.27 (95% CI 1.98-2.81).

121. Of note, PTB after induced abortion is not related to PTB after SAB. The causes of SAB are internal to the woman or embryo, and may also predispose the mother to preterm birth, especially after recurrent SAB. However, this is different

from the cause of abortion, which involves mechanical dilation and removal of the fetus (or the administration of mifepristone and misoprostol), despite the mother's capacity to carry him. Further, abortion is an avoidable epidemiological risk factor for PTB; SAB, on the other hand, is an unfortunate, often un-preventable, outcome of a desired pregnancy for most women…". A full list of references for the association between abortion and preterm birth is appended to the AAPLOG Practice Bulletin.

122. ACOG's Practice Bulletin #234 (2001) also states that "A history of dilation and curettage (D&C) [used to perform surgical abortion] has been associated with an increased risk of preterm birth in some, but not all, studies. A meta-analysis of 21 studies including almost 2 million women found an association between subsequent preterm birth and history of D&C (odds ratio [OR], 1.29; 95% CI, 1.17–1.42), with slightly greater odds after multiple D&C procedures compared with no procedures (OR, 1.74; 95% CI, 1.10–2.76)". The study cited by ACOG is Lemmers, noted above.

123. Future pregnancy complications other than preterm birth may be caused by surgical abortion-related uterine damage. Such damage may lead to abnormal placental attachment, causing premature separation (abruption) or invasion (accreta). Abnormal placental attachment is a significant cause of maternal morbidity and mortality. It occurs when the normal process of placental invasion goes awry and is associated with catastrophic hemorrhage at delivery. Baldwin et al (2018) found that uterine curettage (as occurs with surgical abortion) doubled the risk of abnormal placental attachment. Interestingly, in 1950, pre-Roe, abnormal placental

attachment occurred in 1:30,000 deliveries. In 2016 it occurred in 1:272 deliveries, a 110-fold increase (Heather J. Baldwin, Jillian A. Patterson, Tanya A. Nippita, Siranda Torvaldsen, Ibinabo Ibiebele, Judy M. Simpson, and Jane B. Ford. Antecedents of Abnormally Invasive Placenta in Primiparous Women: Risk Associated With Gynecologic Procedures. Obstet Gynecol 2018;131:227–33).

124. Large records-based studies show that women who have undergone abortion have an increased death rate due to accidents, compared to women who were not pregnant and compared to women who carried a pregnancy to term (Reardon DC, Ney PG, Scheuren FJ, Cougle JR, Coleman, PK, Strahan T. Deaths Associated with Pregnancy Outcome: A Record Linkage Study of Low Income Women. *Southern Medical Journal*. 2002; 95: 834).

125. . Women who gave birth had the lowest death rate and women who had abortions, the highest, compared to the non-pregnant group. In Gissler's study, post-abortive women had more than four times the accidental death rate of women who gave birth Gissler M, Kauppila R, Merilainen J, Toukomaa H, Hemminki E Pregnancy-Associated Deaths in Finland 1987-1994—Definition Problems and Benefits of Record Linkage, *Acta Obstetricia et Gynecologica Scandinavica*. 1997;76: 651.

126. One study suggests that some of the increase in the accidental death rate may be due to suicidal behavior that is not recognized as such (passive vs active suicide) (Reardon et al, 2002). "Reports of post-abortive women deliberately crashing their automobiles, often in a drunken state, in an attempt to kill themselves have

been reported by post-abortion counselors and in the published literature (Reardon DC, Strahan TW, Thorp Jr. JM, Shuping MW. Deaths associated with abortion compared to childbirth—a review of new and old data and the medical and legal implications. *Journal of Contemporary Health Law and Policy*. H2004; 20(2):279-327.

127. "One post-abortive woman reported intentionally going out and sitting in a puddle during a thunderstorm. Another said, "I cracked up my car three times, driving recklessly at extreme speeds. In one wreck, I broke four ribs and punctured my lung. My life became a series of … accidents and self-destructive benders." Burke T and Reardon DC. *Forbidden Grief: The Unspoken Pain of Abortion*.2002; Springfield, IL: Acorn Books.

128. . Rates of accidental death may be affected by drug and alcohol abuse which are increased after abortion (Coleman, PK. Induced Abortion and Increased Risk of Substance Abuse: A Review of the Evidence. *Current Women's Health Reviews*. 2005;1:21-34; Coleman P K, Reardon DC, Cougle J. Substance use among pregnant women in the context of previous reproductive loss and desire for current pregnancy. *Br J Health Psychol* 10, 255–268).

129. It appears that post-abortive women have a higher rate of accidental death compared to women who give birth. This may be due to suicidal behavior resulting in outcomes that are interpreted are accidental, or substance abuse causing accidents, or a mix of both.

130. In another study, women who had an abortion were found to have a 60% higher risk of death from natural causes during the year after their abortion

compared to women who gave birth (Thorp, JM. Jr., Hartmann, KE, Shadigian E. Long-Term Physical and Psychological Health Consequences of Induced Abortion: Review of the Evidence. *Obstetrical & Gynecological Survey*. 2003; 58(1):67-79).

131. . In a California Medicaid study, women who aborted had a 44% higher risk of death from natural causes over eight years of the study than women who gave birth (Reardon, .

132. Abortion is associated with increased drug and alcohol abuse which in turn are associated with multiple health problems and high-risk behaviors (as well as contributing to accidents as noted above). Numerous studies show a strong association between abortion and substance abuse (including alcohol)25.

133. Fergusson et al. in a 2006 study found higher rates of illicit drug dependence (but not alcohol dependence) in post-abortive women compared to women who had been pregnant but non-abortive, and also compared to never pregnant women. This association persisted after controlling for confounding factors26.

134. Abortion is associated with increased risk for cigarette smoking 27,28,29,30 which in turn is associated with established health risks (cardiovascular, cerebrovascular, and respiratory diseases). Women who abort are twice as likely to become heavy smokers and suffer the associated health risks. This is especially problematic in women who smoke and use hormonal contraception, since the latter combination increases the risk for cardiovascular disease such as stroke and heart attack.

135. In the California Medicaid study, among women with only one pregnancy during the 8 years of the study, those who had abortions were nearly three times more likely to die of circulatory disease (OR 2.87) and over five times more likely to die from cerebrovascular disease (OR 5.46) .This study also found that abortion was significantly associated with risk of death from HIV/AIDS. Pelvic inflammatory disease (PID) is a relatively common complication of abortion and PID may increase the risk of HIV transmission45Heisterberg L. Pelvic Inflammatory Disease Following Induced First-Trimester Abortion. *Danish Medical Bulletin*.1988; 64; Sørensen JL, Thranov I, Hoff G. & Dirach J. Early- and Late-Onset Pelvic Inflammatory Disease Among Women with Cervical Chlamydia Trachomatis Infection at the Time of Induced Abortion—A Follow Up Study. *Infection*. 1994; 22: 242; Hillis S. D. et al. Delayed Care of Pelvic Inflammatory Disease as a Risk Factor for Impaired Fertility. *Obstetrics & Gynecology* 1993; 1503).

136. Since abortion is associated with increased risk for substance abuse, this can increase the likelihood of HIV infection via IV drug abuse and other high-risk behaviors.

137. No research has shown any circumstance where an abortion is safer than childbirth. A large body of research from diverse locales including U.S., U.K., New Zealand and Finland suggests that abortion is associated with a worsening of health, and that the overall death rate for post-abortive women is higher than for women who carry to term. There is no evidence to demonstrate that abortion treats

or prevents any disease. No study using patient level data shows that abortion prevents maternal mortality.

138. Dr. Alsaden also alleges in paragraph 25 that "In addition to be extremely safe, abortion is extremely common: nearly one in four women in the United States will have an abortion by age 45". This estimate, based on a paper by Jones and Jerman, is inaccurate for three reasons. First, as we have seen above, the true number of abortions performed in the United States is unknown. Second, the study assumes that abortion rates remain constant, when in fact they declined by approximately 16% from 2011 - 2020. Finally, the researchers themselves state that "Underreporting of abortions is common in nationally representative surveys…Because the study questionnaire was filled out by women obtaining abortions, we expect that underreporting was less common. Still, if some women obtaining abortions failed to report previous abortions, this would mean that the estimate of the lifetime incidence of abortion is artificially high".

L. Many Abortions Are Coerced

139. Dr. Alsaden stages in paragraph 82 that "I strongly believe that patients know what is best for them – they know the reasons why they are choosing to have an abortion". A recent study indicates that many or even most abortions are coerced, either by partners or family members, or as part of sex trafficking. In a study in the journal *Cureus*, 24% of women stated that their abortions were "unwanted or coerced" and only 33% stated that their abortions were wanted; 60% of women would have chosen to give birth if they had emotional or financial support (Reardon D, Rafferty

K, Longbons T. The Effects of Abortion Decision Rightness and Decision Type on Women's Satisfaction and Mental Health. Cureus May 11, 2023). Guttmacher researchers Moore et al (2009) also document coerced abortion in their study of men, women and reproductive control (Moore A, Frohwirth L, Miller E. Male reproductive control of women who have experienced intimate partner violence in the United States. Soc Sci Med 2010 Jun;70(11):1737-44).

140. Other research shows that abortion often facilitates sex trafficking and the abuse of minors. For example, research on survivors of sex trafficking indicates that pimps and traffickers force exploited victims to undergo abortions when they become pregnant. In Laura Lederer and Christopher Wetzel's landmark 2014 study of trafficked women, 71% of trafficked women reported at least one pregnancy while being trafficked. 21% reported having 5 or more pregnancies. 55% reported at least one abortion and 30% reported multiple abortions. 66 of the women surveyed, who responded to abortion questions, stated that 114 abortions were reportedly performed on them during their trafficked state. One young woman had 17 abortions. Based on these findings, it appears that abortion clinics may enable sex traffickers. Lederer state "Notably, the phenomenon of forced abortion as it occurs in sex trafficking transcends the political boundaries of the abortion debate, violating both the pro-life belief that abortion takes innocent life and the pro-choice ideal of women's freedom to make their own reproductive choices." (Laura J. Lederer, Christopher A. Wetzel. The Health Consequences of Sex Trafficking and Their Implications for Identifying

Victims in Healthcare Facilities. Annals of Health Law, Volume 23 Issue 1 Winter 2014, Article 5).

M. The Use of Progesterone to Counteract Mifepristone (Abortion Pill Reversal)

141. Dr. Nauser alleges in her report in paragraph 22 that "The Reversal Amendment…[forces] me to…endorse a dangerous, experimental treatment".

142. The use of progesterone to attempt to prevent fetal death following the administration of mifepristone for abortion (but before the administration of misoprostol) (in lay terms, abortion pill reversal) is based on the use of progesterone. I have used progesterone to treat women with previous preterm birth along with my colleagues, as it has been demonstrated to reduce the risk of preterm birth (Eduardo B. da Fonseca, Roberto E. Bittar, Mario H.B. Carvalho MD, Marcelo Zugaib. Prophylactic administration of progesterone by vaginal suppository to reduce the incidence of spontaneous preterm birth in women at increased risk: A randomized placebo-controlled double-blind study. American Journal of Obstetrics and Gynecology Volume 188, Issue 2, February 2003, Pages 419-424); Cochrane reviews 2013 Prenatal administration of progesterone for preventing preterm birth in women considered to be at risk of preterm birth - Dodd, JM - 2013 | Cochrane Library) as well as miscarriage (Katharina T. Walch, Johannes C. Huber. Progesterone for recurrent miscarriage: truth and deceptions. Best Practice & Research Clinical Obstetrics & Gynecology Volume 22, Issue 2, April 2008, Pages 375-389).

143. For example, one recent study, known as the Progesterone in Spontaneous Miscarriage (PRISM) study examined the use of progesterone in

prevention of recurrent miscarriage. Over 4,000 women were followed at 48 hospitals in the United Kingdom. The researchers and found a 3% greater live birth rate among the women who received progesterone therapy. Although the study found no "significantly higher incidence of live births" among all women who received progesterone therapy, it did identify a differential benefit among women with prior miscarriages, showing a 15% greater live birth rate among women with early pregnancy bleeding and three or more prior miscarriages. Arri Coomarasamy, lead author of the PRISM study, stated that "[o]ur research has shown that progesterone is a robust and effective treatment option" that "could prevent 8[,]450 miscarriages a year in the UK." (Arri Coomarasamy et al., A Randomized Trial of Progesterone in Women with Bleeding in Early Pregnancy, 380 *New Eng. J. Med.* 1815 (2019), https://bit.ly/3m0dXCl).

144. In November 2021, the UK's National Institute of Health and Care Excellence (NICE) published new guidelines recommending progesterone therapy for women with early pregnancy bleeding and at least one previous miscarriage. The recommendation followed a Cochrane review of studies on progesterone use, including the PRISM study. Gillian Leng, NICE's chief executive, stated that "progesterone will not be able to prevent every miscarriage," but "but "will be of benefit to some women and, as an inexpensive treatment option, can be made available to women on the NHS from today." Jacqui Wise, "NICE recommends progesterone to prevent early miscarriage," *British Med. J.* (Nov. 24, 2021); Ectopic pregnancy and miscarriage: diagnosis and initial management, National Institute for

Health and Care Excellence (NICE) (updated Nov. 24, 2021), https://perma.cc/Y9TE-KCY5 (Guideline NG126, Recommendation 1.5.2).

145. There is scientific evidence supporting the use of progesterone to reverse the effects of mifepristone. The context for this assertion is the mechanism of action of mifepristone. Mifepristone binds competitively to the progesterone receptor. This binding, however, is reversible (C.H. Spilman, R.E. Gibson, D.C. Beuving, J.A. Campbell. Progestin and antiprogestin effects on progesterone receptor transformation. Journal of Steroid Biochemistry Volume 24, Issue 1, January 1986, Pages 383-389) and in the presence of sufficient levels of progesterone, progesterone competes with mifepristone to occupy receptor binding sites. This is a basic principle in biochemistry. As an example, in patients who are given methotrexate chemotherapy to kill cancer cells, leucovorin, a molecule with similar structure, is given to "rescue" non-cancer cells from the effects of the methotrexate.

146. Of note, mifepristone does not act immediately. A placebo-controlled trial by Yamabe et al found that after administration of mifepristone, blood progesterone levels began to decline starting at 48 hours and continuing at 72 hours (Shingo Yamabe et al., The Effect of RU486 and Progesterone on Luteal Function During Pregnancy, *65 Folia Endocrinologica Japonica* 497 (1989), https://perma.cc/FY3C-ADAD). On the other hand, when progesterone was given after mifepristone, progesterone levels at 72 hours were the same as in volunteers given placebo, supporting the theory that administration of progesterone within 72 hours of ingestion of mifepristone may reverse the effects of the latter.

147. In 1989, researchers designed an animal study to investigate "the role of progesterone in the maintenance of pregnancy" using a population of pregnant rats. After four days, 66.7% of the rats who received mifepristone aborted their pups after 4 days, while 100% of the rats who were given progesterone in addition to mifepristone remained pregnant.

148. In a case report, Garratt and Turner attempted to reverse the effects of mifepristone with progesterone and found that 2/3 pregnancies progressed to term (Deborah Garratt & Joseph V. Turner. Progesterone for preventing pregnancy termination after initiation of medical abortion with mifepristone. Volume 22, 2017 - Issue 6.

149. In 2018, Dr. George Delgado and Dr. Mary Davenport published an observational case series that followed 754 pregnant women who had taken mifepristone, but had not yet taken misoprostol, and were interested in reversing its effects. A total of 547 women—who were 72 hours or less post-mifepristone and had not taken misoprostol—underwent progesterone therapy. The overall success rate was 48% (247 live births, plus four viable pregnancies lost after 20 weeks gestation). This survival rate is higher than the fetal survival rate of 25% at most where mifepristone is taken alone and no subsequent treatment is attempted. (George Delgado et al., A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone, 33 *Issues L. & Med.* 21, 24-25 (2018), https://perma.cc/ZR33-UJWF).

150. This 2018 study showed even higher success rates when the patients were divided into treatment subgroups. The subgroup that received progesterone intramuscularly showed fetal survival rates of 64%, and the subgroup that received a high dose of oral progesterone followed by daily oral progesterone until the end of the first trimester had fetal survival rates of 68%.

151. Notably, the 2018 study found no increased risk of birth defects after progesterone therapy. The rate of preterm delivery was 2.7%, compared with a 10% average in the general population in the United States.

152. Progesterone has been safely used in fertility care and care for pregnant women for more than 50 years, including in women with a history of miscarriage and as a routine component of IVF treatment. Progesterone is approved by the FDA and is classified as a "Category B" drug for pregnant women—in the same risk category as Tylenol, the most commonly used pain reliever during pregnancy (FDA, Prometrium Label, at 19, https://perma.cc/CR46-2FTS; Prometrium Prescribing Information, Drugs.com, https://perma.cc/RDN3-WNQ8).

153. Thus, it is not surprising that the UK's NICE committee—which recently published new guidance recommending progesterone therapy for women with early pregnancy bleeding and a history of miscarriage—found "no evidence of harms for women or babies" from the use of progesterone, including "no increase in risk of stillbirth, ectopic pregnancy, congenital abnormalities or adverse drug reactions." Ectopic pregnancy and miscarriage: diagnosis and initial management,

National Institute for Health and Care Excellence (NICE), 16 (November 2021), https://perma.cc/4W4X-Q95Y (Guideline NG126 Update).

154. The American Society for Reproductive Medicine (ASRM) similarly concluded in a 2008 bulletin on progesterone supplementation during pregnancy: "The weight of available evidence indicates that the most common forms of [progesterone] supplementation during early pregnancy pose no significant risk to mother or fetus." Prac. Comm. of the Am. Soc. for Reprod. Med., Progesterone Supplementation During the Luteal Phase and in Early Pregnancy in the Treatment of Infertility: an Educational Bulletin, 89 Fertility & Sterility 789, 791 (2008).

155. As further evidence that the use of progesterone to reverse the effects of mifepristone is safe, the medical literature does not reveal a documented risk that either progesterone or mifepristone lead to an increased incidence of birth defects. A 2013 study published in BJOG: An International Journal of Obstetrics and Gynecology found that the incidence of birth defects in fetuses exposed to mifepristone in the first trimester was equivalent to the incidence in the general population. N. Bernard et al., Continuation of Pregnancy After First-Trimester Exposure to Mifepristone: An Observational Prospective Study, 120 BJOG 568 (2013). And according to the package insert for mifepristone, no teratogenic effects have been noted in experiments with rats and mice. FDA, Mifeprex Label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

156. The use of progesterone to counteract mifepristone is an off label use. But so is the use of many medications commonly used in obstetrics—including

tocolytics (e.g., drugs used to delay preterm labor) such as terbutaline, magnesium sulfate, nifedipine, non-steroidal anti-inflammatory drugs (NSAIDs), as well as ampicillin in preterm labor, diabetic medications such as glyburide and metformin for diabetes in pregnancy. In fact, the use of misoprostol for abortion is an off-label use. The prescribing information for misoprostol states:

> "INDICATIONS AND USAGE
>
> Cytotec (misoprostol) is indicated for reducing the risk of NSAID (nonsteroidal anti-inflammatory drugs, including aspirin)-induced gastric ulcers in patients at high risk of complications from gastric ulcer, eg, the elderly and patients with concomitant debilitating disease, as well as patients at high risk of developing gastric ulceration, such as patients with a history of ulcer. Cytotec has not been shown to reduce the risk of duodenal ulcers in patients taking NSAIDs. Cytotec should be taken for the duration of NSAID therapy. Cytotec has been shown to reduce the risk of gastric ulcers in controlled studies of 3 months' duration. It had no effect, compared to placebo, on gastrointestinal pain or discomfort associated with NSAID use... Cytotec is intended for administration along with nonsteroidal anti-inflammatory drugs (NSAIDs), including aspirin, to decrease the chance of developing an NSAID-induced gastric ulcer."

157. Dr. Nauser alleges in paragraph 51 that "the paper authored by Dr. Mitchell Creinin and co-authors…used a randomized controlled trial to estimate the efficacy and safety of mifepristone antagonization with progesterone. The study had to halted prematurely because three of the twelve patients experienced hemorrhaging." Dr. Creinin attempted to conduct a randomized study on the "efficacy and safety" of abortion pill reversal. The study was designed to enroll 40 pregnant women in two control groups—one receiving mifepristone followed by progesterone, and the other receiving mifepristone followed by a placebo. But Creinin stopped the study after 12 women were enrolled, and only 10 women completed it.

158. Creinin's study does not support the claim that progesterone is dangerous. Three women in Creinin's study had significant bleeding and sought emergency medical treatment—but of those three women, two had received the placebo (in other words, the only drug they had taken was mifepristone). Those women required emergency suction aspiration abortions, and one of them required a blood transfusion. For the one woman who had received progesterone and had significant bleeding, no intervention was required. Thus, Creinin's study does not demonstrate that progesterone itself is the danger, because the two women who suffered complications and needed surgical completion of their abortion had not taken progesterone, and the woman who did take progesterone and had bleeding required no intervention.

159. Creinin's study also undermines claims that abortion pill reversal is not effective. Four of the five women in the progesterone group successfully maintained their pregnancies, as documented by fetal cardiac motion. By contrast, only two of the women in the placebo group maintained their pregnancies. Creinin's study suggests that abortion pill reversal is effective.

160. In paragraph 54 Dr. Nauer alleges that ACOG's position is "that medication abortion 'reversal' has no basis in science and is unethical." (https://www.acog.org/advocacy/facts-are-important/medication-abortion-reversal-is-not-supported-by-science). However, this statement by ACOG does not present a comprehensive review of the literature on this topic or the state of the science on the use of progesterone after mifepristone. For example, it states that a 2012 study by

Delgado was not overseen by an institutional review board. At many institutions, small case series are exempt from IRB review, see for example case-reports-and-case-series.pdf (womans.org) . ACOG's statement also neglects to mention the many studies on the use of progesterone after mifepristone administration, in particular the Delgado and Davenport study of 754 women in 2018. The latter study clearly states that "The study was reviewed and approved by an institutional review board". Finally, it cites as authoritative the flawed study by Creinin et al discussed above. All of these weaknesses seriously undermine the statement's validity.

161. In paragraph 50, Dr. Nauer alleges that "Case reports are just observational studies: these are useful for generating hypotheses, but researchers would have to conduct a randomized clinical trial to know if this treatment is safe and effective". Case series are commonly used in studies involving pregnant women, because it would be unethical to use a placebo arm in a study when women desire to continue their pregnancies. While randomized controlled trials are the gold standard for evaluating the safety and efficacy of drugs, many drugs used in obstetrics and gynecology came into clinical usage based on data from case series. These include magnesium sulfate for prevention of preterm labor, and eclampsia (seizures with high blood pressure in pregnancy); terbutaline for prevention of preterm birth; nifedipine for prevention of preterm birth; diabetic medications such as glyburide and metformin for diabetes in pregnancy; hydralazine for control of hypertension in pregnancy; and methotrexate for treatment of ectopic pregnancy, among others. In particular, mifepristone itself was approved by the FDA based on non-blinded, non-

randomized studies (Spitz et al. Early pregnancy termination with mifepristone and misoprostol in the United States. NEJM (1998) 338(18):1241-1247); (Hoerscht-Roussel data). None of these studies were randomized controlled trials. This was irregular and not consistent with FDA's own approval process, which requires 2 randomized, blinded, controlled trials to answer questions regarding safety and efficacy of the drug, specified in its own administrative laws as the basis for the drug approval process. "Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness" (Byron C Calhoun and Donna J Harrison. Challenges to the FDA Approval of Mifepristone. Annals of Pharmacotherapy Volume 38, Issue 1, January 2004, Pages 163-168).

162. In addition, as noted above, for some clinical situations case series and observational studies are the only appropriate source of data since randomizing one group of patients to placebo would be unethical. Physicians can and do use the results of case series to integrate innovative therapeutic options into their practices.

163. Dr. Alsaden alleges in paragraph 53 that "Indeed, research demonstrates administration of a progestin-based contraceptive on the same day as a medication abortion…does not reduce the effectiveness of medication abortions". This statement is misleading because semisynthetic progesterone-like drugs are **not** interchangeable with natural progesterone. The cited study by Raymond used medroxyprogesterone acetate, which is chemically quite different from natural progesterone, has different pharmacology, and has very different biological effects in the human body. For example, medroxyprogesterone acetate is implicated in breast

cancer in women taking combination hormone replacement therapy. Natural progesterone and semisynthetic progestins are not comparable.

N. Abortion and Reproductive Justice

164. In paragraph 53, Dr. Wynia alleges that because of the Biased Counseling Scheme "…physicians are forced to participate in exacerbating injustice". Dr. Wynia quotes the AMA Code of Ethics, Opinion 8.5, which says nothing about abortion. Any discussion of disproportionate impact on vulnerable populations must mention the reproductive injustice inherent in the deliberate targeting and destruction of 17 million African American lives through abortion since *Roe*. African American women have the highest rates of abortion as well as the highest rates of abortion complications and death. They also have the highest rates of poverty and maternal mortality, suggesting that the purported benefits of abortion not only do not accrue to them, but that abortion has negative effects on black individuals and communities. Dr. Wynia's speculation that abortion restrictions will harm black women has no basis in fact. The birth rate to black non-Hispanic women has been declining for decades, as has the fertility rate for black women, currently at 1.7, markedly lower than the replacement rate of 2.1. These facts suggest that rather than being a tool of "justice", abortion is a eugenic tool of injustice.

III. Conclusion

165. Plaintiffs have made multiple statements regarding the burden that the Biased Counseling Scheme would impose, but the available evidence suggests that these conclusions are incorrect. In particular, evidence has been presented that for

the fetus with a disability, neonatal palliative care can benefit both the child and his or her parents, as opposed to abortion. Much evidence has also been presented demonstrating that the unborn child is a human being, that life begins at conception, and that the terms "embryo," "baby," and "fetus" are used interchangeably in the literature. It is clear that the fetus perceives pain at earlier gestational ages than previously known, and that this information must be provided to the woman considering abortion. It is also known that rates of miscarriage following visualization of a beating fetal heart on ultrasound are low. And despite allegations to the contrary by Plaintiffs, the abortion consent process has unique features which must be consistently applied to protect women. Data has also been presented indicating that there is significant risk associated with the use of mifepristone, as well as short- and long-term complications from abortion. Finally, available evidence indicates that the use of progesterone to antagonize the activity of mifepristone (abortion pill reversal) is safe and effective for both women and children.

I declare under penalty of perjury under the laws of the state of Kansas that the foregoing is true and correct. Executed on July 7, 2023.

Monique Chireau Wubbenhorst

Monique Chireau Wubbenhorst, M.D., M.P.H.

EXHIBIT A

CURRICULUM VITAE

Updated: 5-25-2023

Name: Monique Chireau Wubbenhorst, MD, MPH, FACOG, FAHA
18420 Bulla Road
South Bend, IN 46637

Medical licensure: North Carolina, 05-21-2000 to present
Indiana, 8-26-2022 to present

Specialty certification(s) and dates: American Board of Obstetrics and Gynecology, 1997 - present

Date of birth: XX-XX-XXXX **Place:** New York, NY

Citizen of: United States

Languages spoken: English, French.

Education:

Institution	Degree	Date (Year)
Waterford High School	High school diploma	1974-1976
Mount Holyoke College	A.B., Biological Sciences	1976-1981
Oral Roberts Medical School	(None, transferred)	1986-1988
Brown University Medical School	M.D.	1988-1991
Harvard University	Master's in Public Health	1989-1991
University of North Carolina	Postdoctoral Fellowship	2001-2003

Scholarly societies (Alpha Omega Alpha, Sigma Xi, Phi Beta Kappa, etc.): Past member, Sigma Xi; Fellow, American College of Obstetricians and Gynecologists; Fellow, American Heart Association; member, American Association of Pro-Life Obstetricians & Gynecologists; member, North Carolina Medical Society; member, Massachusetts Medical Society.

Other organizations: Board member, Americans United for Life.

Professional training and academic career (chronologically commencing with first postdoctoral position):

Institution	Position/Title	Dates
Yale-New Haven Hospital New Haven, CT	Resident, Obstetrics and Gynecology	1991-1995
Beth Israel-Deaconess Medical Center Boston, MA	Faculty, Division of Epidemiology and Public Health Department of Obstetrics and Gynecology	1995-1998
Harvard Medical School Boston, MA	Instructor, Obstetrics-Gynecology	1995-2000
University of North Carolina- Chapel Hill, Chapel Hill, NC	Postdoctoral Fellow, North Carolina Program for Women's Health Research, Sheps Center for Health Services Research	2001-2003
	Adjunct Clinical Assistant Professor, Division of Women's Health, Department of OB/GYN	2001-2003
Center for Health Services Research Durham VA Medical Center Durham, NC	Women's Health Fellow	2003-2004
Duke University Medical Center Durham, NC	Assistant Professor, Division of Reproductive Sciences Department of Obstetrics and Gynecology	2003-2018
United States Agency for International Development Washington, DC	Senior Advisor, Office of Population and Reproductive Health, Bureau for Global Health	2018-2019
	Deputy Assistant Administrator, Bureau for Global Health	2019
	Senior Deputy Assistant Administrator Global Health	2020-2021
University of Notre Dame	Senior Research Associate, de Nicola Center for Ethics and Culture	2021 - 2023

Past and Present Hospital and Clinical Affiliations:

Institution	Position/Title	Dates
Beth Israel-Deaconess Medical Center, Boston, MA	Staff Gynecologist	1995-1998

Dimock Community Health Center Roxbury, MA	Staff obstetrician-gynecologist	1995-1996
Dimock Community Health Center Roxbury, MA	Director, Obstetrics and Gynecology Service Dimock Community Health Center	1996-1998
Harvard Vanguard Medical Associates Watertown, MA	Staff obstetrician-gynecologist (*locum tenens*)	1998-1999
Mt. Auburn Hospital Cambridge, MA	Staff obstetrician-gynecologist *(locum tenens)*	1999-2000
Somerville Community Health Center Somerville, MA	Staff obstetrician-gynecologist	1998-2000
St. Elizabeth Medical Center Boston, MA	Staff obstetrician-gynecologist	1999-2000
Hugh Chatham Hospital Elkin, NC	Staff obstetrician-gynecologist *(locum tenens)*	2000-2017
Chinle Indian Hospital Chinle, AZ	Staff obstetrician-gynecologist *(locum tenens)*	2000
Fallon Clinic Leominster, MA	Staff obstetrician-gynecologist (*locum tenens)*	2000-2001
WW Hastings Indian Hospital Tahlequah, OK	Staff obstetrician-gynecologist *(locum tenens)*	2001-2002
Alamance Regional Hospital Burlington, NC	Staff obstetrician-gynecologist *(locum tenens)*	2003
Pine Ridge Indian Hospital Pine Ridge, SD	Staff obstetrician-gynecologist (locum tenens)	2003
Rosebud Indian Hospital Rosebud, SD	Staff obstetrician-gynecologist *(locum tenens)*	2003-2009
Durham VA Medical Center Durham, NC	Staff Gynecologist, Departments of Surgery and Ambulatory Care	2003-2018
Roy Lester Schneider Hospital St. Thomas, US Virgin Islands	Staff obstetrician-gynecologist (locum tenens)	2005-2014
Chowan Hospital Edenton, NC	Staff obstetrician-gynecologist (locum tenens)	2005-2014

Roanoke-Chowan Hospital Ahoskie, NC	Staff obstetrician-gynecologist (locum tenens)	2007-2008
The Outer Banks Hospital Nags Head, NC	Staff obstetrician-gynecologist (locum tenens)	2012-2016
Carteret General Hospital Morehead City, NC	Staff obstetrician-gynecologist (locum tenens)	2010-2014
Vidant Beaufort Hospital Washington, NC	Staff obstetrician-gynecologist (locum tenens)	2011-2016
Vidant-Duplin Hospital Kenansville, NC	Staff obstetrician-gynecologist (locum tenens)	2014
Vidant Edgecombe Hospital Tarboro, NC	Staff obstetrician-gynecologist (locum tenens)	2016-2017
Maria Parham Hospital Henderson, NC	Staff obstetrician-gynecologist (locum tenens)	2017
Tenwek Mission Hospital Bomet, Kenya	Visiting consultant, Obstetrics and Gynecology	2022-2023
Saint Joseph's Regional Medical Center Mishawaka, IN	Obstetrician-gynecologist hospitalist	2023-

Publications:

1. **Refereed journals:**

    1. Harrison D, Buskmiller C, **Chireau M**, Ruppersberger L, Yeung P. Systematic review of ovarian activity and potential for embryo formation and loss during the use of hormonal contraception. *Linacre Q.* 2018 Nov; 85(4): 453–469.

    2. Malloy C, **Chireau M**, Sander Lee T. The perinatal revolution. *Issues in Law and Medicine*, Spring 2019.

    3. **Chireau Wubbenhorst M**, Wubbenhorst J. Evangelical international organizations and family planning. *Dignitas* Summer 2017; 24(2):11-21.

    4. **Chireau Wubbenhorst M**, Wubbenhorst J. Should Evangelical Christian organizations support international family planning? *Christian Journal of Global Health* fall, 2017.

    5. **Chireau Wubbenhorst, M**. Is misoprostol equivalent to oxytocin for postpartum hemorrhage? *Issues Law Med*. 2015 Autumn; 30(2):217-25.

6. Koch E, **Chireau M**, Pliego F, Stanford J, Haddad S, Calhoun B, Arecena P, Bravo M, Gatica S, Thorp J. Abortion legislation, maternal healthcare, fertility, female literacy, sanitation, violence against women, and maternal deaths: a natural experiment in 32 Mexican states. *BMJ Open* 2015 Feb 23;5(2):e006013.

7. **Chireau, M**. Gestational diabetes is a significant cardiovascular disease risk factor. *BJOG* 2014 Nov;121(12):1537.

8. Bushnell Cheryl, McCullough Louise D, Awad Issam A, **Chireau Monique** V, Fedder Wende N, Howard Virginia J, Lichtman Judith H, Lisabeth Lynda D, Piña Ileana L, Reeves Mathew J, Rexrode Kathryn M., Saposnik Gustavo, Singh Vineeta, Towfighi Amytis, Vaccarino Viola, Walters Matthew R. Guidelines for the Prevention of Stroke in Women: A Statement for Healthcare Professionals from the American Heart Association/American Stroke Association Council on Stroke. *Circulation* 2014 May.

9. Crochet J, Bastian L, **Chireau M**. Does this woman have an ectopic pregnancy? *JAMA* 2013 Apr 24;309(16):1722-9.

10. **Chireau M.** More than an ounce: Editorial commentary on: The 2011 Effectiveness-Based Guidelines for the Prevention of Cardiovascular Disease in Women. Available in: American Heart Association Learning Library.

11. Bushnell C, and **M. Chireau**. Preeclampsia and stroke: risks during and after pregnancy. *Stroke Research and Treatment* 2011 Jan 20;2011:858134.

12. Brown HL, Small M, Taylor YJ, **Chireau M,** Howard DL. Near miss maternal mortality in a multiethnic population. *Ann Epidemiol.* 2011 Feb;21(2):73-7.

13. Schwartz E, Borrero S, **Chireau M**. Safe Prescribing for women of reproductive age; treatment recommendations for the VA. *Federal Practitioner*, 2009;26(2).

14. Brown H, **Chireau M,** Jallah Y, Howard D. The "Hispanic Paradox": An investigation of racial disparity in perinatal outcomes at a tertiary care center medical center. *Am J Obstet Gynecol 2007* Aug; 197(2) e1-7.

15. Fowler C, Gavin N, Adams EK, Tao G, **Chireau M**. Racial and ethnic disparities in prenatal syphilis screening among women with Medicaid-covered deliveries in Florida. *Matern Child Health J* 2007 Jul 18**.**

16. Wilson EK, Adams EK, Gavin NI, **Chireau M**. Patterns in prenatal syphilis screening among Florida Medicaid enrollees. *Sex Transm Dis*, 2006 Nov 6.

17. **Chireau M,** Salz T, Bastian L. Pregnant veterans' outcomes, cost and utilization of care. *Federal Practitioner*, September 2006, 23:9.

18. **Chireau M**, Benedict MB, Gavin NI, Adams EK. Gestational diabetes testing among pregnant Medicaid recipients: implications for clinical care. *Journal of Clinical Outcomes Management*, 2006; Jun; 13(6):315-332.

19. Gavin NI, Adams EK, Hartmann KE, **Chireau M.** Racial and ethnic disparities in the use of pregnancy-related health care among Medicaid pregnant women. *Matern Child Health J*. 2004; Sep;8(3):113-26.

20. Hirschhorn LR, Miller L, **Chireau M**. Papanicolaou smear and follow-up in women with HIV infection receiving primary care in an inner-city community health center (CHC): a role for continuous quality improvement and quality care. *National Center for Women's Health Archive*, 1997.

21. Kresina TF, Cheever LW, **Chireau M,** Johnson J, Ramirez B, Peters P, Olds GR. Human Epstein-Barr virus transformed lymphocytes of patients with *Schistosoma japonicum* infection secrete idiotypically related immunoregulatory antibodies. *Clinical Immunology* 1992; 65(3):325-9.

2. Non-refereed publications:

Chireau Wubbenhorst, M. and Baugus B. Does abortion improve economic outcomes for women? A review of the evidence. Accessible at https://lozierinstitute.org/does-abortion-improve-economic-outcomes-for-women-a-review-of-the-evidence/

Chireau Wubbenhorst, M. Midtrimester abortion epidemiology, indications and mortality. Accessible at https://lozierinstitute.org/midtrimester-abortion-epidemiology-indications-and-mortality/

Environmental Health Risks and Your Pregnancy. Public health pamphlet for American Association on Intellectual and Developmental Disabilities, July 2009.

Primary Care of Women with HIV/AIDS, in *Care of HIV-infected Patients in VA*, 2008.

3. Selected abstracts

Chireau M, Crosslin D, Hauser B, Olshan A, Zheng S, Salafia C, Thorp J. Endothelial function gene polymorphisms are associated with pregnancy outcomes, independent of placental vascular disease. Society for Maternal-Fetal Medicine Annual Meeting, 2008.

Chireau M, Crosslin D, Hauser B, Olshan A, Zheng S, Salafia C, Thorp J. Polymorphisms in endothelial function genes are associated with pregnancy outcome in a multi-ethnic North Carolina sample. Society for Maternal-Fetal Medicine Annual Meeting, 2008.

Chireau M, Bushnell CB, Goldstein L, Brown H, Bastian L. Adverse pregnancy outcomes are associated with stroke risk later in life. Society for Gynecologic Investigation Annual Meeting, 2006.

Chireau M, Biswas M, Newby K, Brown H, Bastian L. Adverse pregnancy outcomes are associated with increased risk for mortality. American College of Obstetricians & Gynecologists Annual Meeting, 2006.

Chireau M, Biswas M, Newby K, Brown H, Bastian L. Adverse pregnancy outcomes are associated with coronary artery and cardiovascular disease risk. American College of Obstetricians & Gynecologists Annual Meeting, 2006.

Chireau M, Bushnell CB, Goldstein L, Brown H, Bastian L. Adverse pregnancy outcomes are associated with stroke risk later in life. American Neurological Association Annual Meeting, 2005.

Consultant appointments:

2001-2003 Consultant to RTI International Maternal-Child Health Division

2007-2009 Consultant to Chief Consultant, Women Veterans Health Strategic Healthcare Working Group, Veterans Administration Central Office, Washington DC.

Invited Presentations

2005 Panelist, "Thinking outside the box: Designing an effective health care delivery system", 2nd Annual Healthcare Symposium on Patient Satisfaction, Winston-Salem State University School of Health Sciences, Winston-Salem, NC.

"Preeclampsia – the long and the short of it." Presentation at Stroke Division of Neurology, Duke University Medical Center, Durham, NC.

"Adverse pregnancy outcomes and the risk of stroke." Presentation at American Society for the Study of Stroke in Women, Second Annual Symposium, Durham, NC.

2006 "Adverse pregnancy outcomes and the risk of cardiovascular disease." Grand Rounds presentation, Department of Obstetrics and Gynecology, Duke University Medical Center, Durham, NC.

"Improving outcomes for African American women and children". Presentation at Shaw University Institute for Health, Social and Community Research Annual Conference, Raleigh, NC.

"Endothelial function gene polymorphisms and the risk of adverse pregnancy outcomes". Grand Rounds presentation, Department of Obstetrics and Gynecology, Duke University Medical Center, Durham, NC.

2007 "Teratogenicity of commonly prescribed drugs in the Veterans Administration". Presentation at the National Reproductive Health Working Group, for the Women Veterans Health Strategic Healthcare Group. Washington, DC.

"Neurologic diseases in women's health" Grand Rounds presentation, Department of Obstetrics and Gynecology, Duke University Medical Center, Durham, NC.

"Adverse pregnancy outcomes and the risk of cardiovascular disease" Presentation to the Carter Society, Department of Obstetrics and Gynecology, Duke University Medical Center, Durham, NC.

"Urgent Problems in Women's Health". Presentation at the Veterans Administration National Primary Care Conference, Washington, DC July 2008.

2009 "Pregnancy and Long-term Health Risk". Clinical Seminar at the American College of Obstetrics and Gynecology Annual Clinical Meeting, Chicago, May 2009.

"Contraception Issues for Women Veterans". Presentation at the Veterans Integrated Service Network 6 Primary Care Conference, Roanoke Rapids, VA, March 2009.

2010 "Adolescent Pregnancy As a Development Issue". Presentation at the United Nations Conference on the Status of Women, New York, NY, February 2010.

2011 "Women's Reproductive Health as a Gender, Development, and Human Rights Issue". Presentation at the United Nations Beijing + 15 Conference, New York, NY, February 2011.

"Sexual Dysfunction in Women". Live webinar presentation at the VISN Primary Health Conference, March 2011.

"Women's Reproductive Health as a Gender, Development, and Human Rights Issue: Regaining Perspective". Presentation for the Center for Bioethics and Human Dignity, Washington, DC, June 2011.

"Short and Long-term Effects of Pregnancy Termination". Presentation at Healing Visions conference, Milwaukee, WI, October 2011.

2012 "The Future of Roe". Presentation at The Conference on Reproductive Health and the Law, National Press Club, Washington DC, January 2012.

"Adolescent Health". Plenary speaker at AXIOS Misión Mujer Conference, Simposium Adolescentes en las Políticas Públicas, Guadelajara, México, March, 2012.

"Women and the Health of Families, Community and Society: Cause or Effect?" Plenary speaker, Center for Bioethics and Human Dignity Bioethics Conference, Deerfield, IL, July, 2012.

"Management of High Risk Pregnancy". Presentation at the International Conference on Maternal Mortality, Dublin, Ireland, September 2012.

"Management of High Risk Pregnancy in Developing Countries". Presentation at Pathan Hospital, Kathmandu, Nepal, September 2012.

2013 "Contemporary Management of High Risk Pregnancy". Presentation at the United Nations 56th Commission on the Status of Women, New York, NY, March 2013.

"*Roe* at 40: What we have learned". Presentation, Roe at 40 Conference, Stanford Law School, Stanford, CA, March 2013.

2014 "Medical and surgical complications of induced abortion". Presentation at Americans United for Life Annual Conference, National Press Club, Washington, DC.

"Contraception Update". Presentation at Women Veterans Health Provider Retreat, Raleigh, NC, May 2014.

2015 "Is Misoprostol Equivalent to Oxytocin for Postpartum Hemorrhage?". Presentation at the Matthew Bulfinch Educational Conference, Annual Meeting of the American Association of Pro-Life Obstetrician-Gynecologists, February 2015.

"Medical vs. surgical abortion". Presentation at the World Congress on Families, Salt Lake City, Utah, October 2015.

2016 "The Transformation of Reproductive Health", Clarke Family Keynote Lecture, Notre Dame Institute for Ethics and Culture Medical Ethics Conference, Notre Dame University, South Bend, IN.

"Abortion and Childbirth", presentation at the Vita Institute, Notre Dame Institute for Ethics and Culture, Notre Dame University, South Bend, IN.

"Maternal Health, the Millennium Development Goals and the Sustainable Development Goals: Where are we going and how do we get there?" Presentation at the Coloquio Integral en Salud 2016, Leon City, Guanajuato, Mexico.

2017 "Safety of Childbirth vs. Abortion", presentation at the Vita Institute, Notre Dame Institute for Ethics and Culture, Notre Dame University, South Bend, IN.

"Should Evangelical Christian organizations support international family planning?" Presentation at the Trent Center for Bioethics & Humanities Series, Duke University, Durham, NC.

2018 "Women Speak: Health Implications of Lower Abortion Rates". Presentation at the Women Speak conference, June 13, 2018, Heritage Foundation, Washington DC.

"The #MeToo Moment: Second Thoughts on the Sexual Revolution". Presentation at the Ethics and Public Policy Center, Washington, DC.

"Let Every Soul Be Subject to the Higher Powers: Romans 13, Subsidiarity, and International Aid". Presentation at the Notre Dame Center for Ethics and Culture 2018 Fall Conference, South Bend, IN.

"Partnering with USAID and the Journey to Self-Reliance". Presentation at the Global Missions Health Conference, Louisville, KY.

2021 Response to Opening Keynote: "In Pursuit of Dignity and Freedom: One Perspective on the American Experience", de Nicola Center for Ethics and Culture, Notre Dame University.

2022 "Is abortion safer than childbirth?" Presentation at Vita Institute Annual Conference, Notre Dame University.

2023 "Challenges and opportunities in building a civilization of love". Panel presentation for the Center for Ethics and Culture's Women and Children First Initiative, at the National Press Club, Washington DC.

Professional awards and special recognitions:

1995-2000	National Health Service Corps Award for clinical practice in health shortage areas
2001	National Research Service Award from the Agency for Health Care Policy and Research for Post-Doctoral Training in Health Services Research, Cecil G. Sheps Center
2008	"Best Poster", Poster Session V, Society for Maternal-Fetal Medicine Annual Meeting 2008

Organizations and participation:

1/91 – 3/91	Clinical and laboratory field work with the Schistosomiasis Control Project in Palo Leyte and Metro Manila, the Philippines; a collaboration between the World Health Organization, the Philippines Ministry of Health, Brown University and the University of the Philippines.
4/91	Internal medicine and medical-surgical intensive care at Apollo Hospital, Madras, South India.
10/94	Expanded Training Program in Obstetrics-Gynecology, Alma-Ata Regional Hospital, Kazakhstan, the Commonwealth of Independent States. Intersectoral collaboration between the Kazakhstan Ministry of Health, Merck and Company, World Vision, and Project MotherCare-Hospital of St. Raphael, New Haven, CT.
4/99	Maternal-child health officer with International Health Services Foundation, as part of assessment mission to Kosovar refugee camps and clinics in Macedonia during the Kosovo War.
2000	Field work in primary care and maternal-child health, Hope for Africa Ministries, Ghana, West Africa.
2001	Jackson Laboratories Summer Statistical Genetics Course
2001, 2002	Member, 2001 and 2002 Objective Review Committees, Expanded Medical Capacity for Community Health Centers, Bureau of Primary Health Care, Health Research and Services Administration, Washington D.C.
2004 – 2018	Reviewer for the *Journal of General Internal Medicine*
2004-2016	Duke University Medical Center IRB member
2004 – 2018	Reviewer for *The North Carolina Medical Journal*
2006 – 2018	Reviewer for *The British Journal of Obstetrics and Gynecology*
2007	Study section, Centers for Medicare and Medicaid Services grant program, Baltimore, MD

2007	National Reproductive Health Working Group member, Women Veterans Health Strategic Healthcare Group, Veterans Administration Central Office, Washington, DC
2007-2009	Member, Project Access of Durham Steering Committee, Durham, NC
2007-2010	Member, Duke University Medical School Admissions Committee
2007-2009	Consultant to Acting Chief Consultant, Women Veterans Health Strategic Healthcare Working Group, Veterans Administration Central Office, Washington DC.
2008-2009	Member, National Surgical Quality Improvement Program Committee, GYN Surgery Subspecialty, for Women Veterans Health Strategic Healthcare Working Group, and Duke University Medical Center
2008-2010	Summer Institute Program to Increase Diversity in Genetic Research on Complex Heart, Lung and Blood Diseases, sponsored by NHLBI
2009-2018	Member, Cardiovascular Disease in Women and Special Populations National Committee, Clinical Council on Cardiology, American Heart Association
2009-2014	Board Member, Project Access of Durham County
2009	Reviewer, NIH Cardiovascular and Sleep Epidemiology (CASE) *ad hoc* study section
2010-2012	Co-chair, Cardiovascular Disease in Women and Special Populations National Committee, Clinical Council on Cardiology, American Heart Association
2012-2018	Reviewer, *pLOS 1*
2014-2018	Member, Advisory Committee for Arts, Sciences and University Transfer, Durham Technical Community College, Durham, NC
2013-2018	Reviewer, *Public Health*
2014 -2016	Chair, Cardiovascular Disease in Women and Special Populations National Committee, Clinical Council on Cardiology, American Heart Association
2015	Clinical Champion, ICD-10 Rollout, Durham VA Medical Center
2015-	Senior Public Policy Fellow, Notre Dame Institute for Ethics and Culture
2016-	Reviewer, *Issues in Law and Medicine*
2021-	Reviewer, *Journal of Medical Ethics*

Courses taught:

1997-1998 Principal Clinical Experience Gynecology Case Conference for first-year medical students, Harvard Medical School. This yearlong course focused on introducing medical students to clinical medicine through case studies, clinical vignettes and basic science and clinical instruction.

5/99 Obstetrics and Gynecology courses, Semipalatinsk National Medical Academy, Semipalatinsk, Kazakhstan. One to two-day courses focused on providing updates to former Soviet Union clinicians in basic science and clinical medicine.

2007 "Neurologic and psychiatric diseases in pregnancy and beyond". Course given at the American College of Obstetrics and Gynecology Annual Clinical Meeting, San Diego, CA. This course provided an update to practicing obstetricians-gynecologists on the diagnosis and management of neurologic and psychiatric disease in women.

"Rheumatologic disease effects before, during and after pregnancy". Course given at the American College of Obstetrics and Gynecology Annual Clinical Meeting, 2007, San Diego, CA. This course provided an update to practicing obstetricians-gynecologists on the diagnosis and management of rheumatologic diseases in women.

2008 "Pregnancy and long-term health risk", course given at the American College of Obstetrics and Gynecology Annual Clinical Meeting, 2007, San Diego, May 2008. The goal of the course was to introduce practicing obstetrician-gynecologists to the association between pregnancy complications and long-term cardiovascular disease in women.

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2009 "Common Urgent Gynecologic Problems in Women Veterans", course given at the Veterans Integrated Service Network 6 Primary Care Conference, Roanoke Rapids, VA, March 2009. This course provided an update for practicing clinicians on urgent gynecologic problems in women and their management.

2010 Clinical Skills Course in Obstetrics and Gynecology for second-year medical students, Duke University Medical School. This semester-long course was designed to bridge the transition between the preclinical-basic science curriculum in medical school and clinical training by introducing students to clinical reasoning, case studies, teamwork, and problem-solving.

2015 Clinical Maternal-Child health course for advanced practice nurses at the Mount Zion Special Care Nurses' Training Centers, Buea, Cameroon and Bamenda, Cameroon, West Africa. This two-day course taught core concepts in maternal-child health to advanced practice nurses.

2016 Obstetrics and Gynecology course for advanced practice nurses at the Mount Zion Special Care Nurses' Training Centers, Buea, Cameroon and Bamenda, Cameroon, West Africa. This two-day course taught gynecology, infectious diseases, and moral ethics to advanced practice nurses.

Obstetrics and Gynecology course for medical officers and allied health professionals at Kajo Keji Medical Training Institute, Kajo Keji, South Sudan. This two-day course provided instruction in primary, urgent and emergency care for women to medical officers, pharmacy technicians and laboratory technicians.

Obstetrics and Gynecology course for students at Kajo Keji Midwifery School, Kajo Keji, South Sudan. This two-day course provided instruction in obstetrics and gynecology in limited resource settings to midwifery students.

Past and present teaching responsibilities including continuing education:

Director, VA Gynecology Resident Rotation
Director, VA Gynecology Medical Student Rotation
Ambulatory and inpatient medical student and resident education and training
Ambulatory and inpatient Physician Assistant and Nurse Practitioner education and training
Fellow, resident and medical student mentoring
Undergraduate student mentoring

Areas of research interests (basic and applied):

Molecular biology of adverse pregnancy outcomes
Reproductive health and epidemiology, including epidemiology of adverse pregnancy outcomes
Global health
Health services research
Racial-ethnic disparities in women's health
Adverse pregnancy outcomes and long-term cardiovascular health
Women veterans' health and healthcare
Ethics in reproductive epidemiology and women's health

External support (past and present) - gifts, grants, and contracts:

a) **Past:**

NIH/NICHD Minority Supplement
Coagulation Polymorphisms and Adverse Pregnancy Outcomes
PI - John Thorp, MD
Role – co-investigator
%Effort – 80%
Purpose – To explore endothelial function gene polymorphisms and measures of uteroplacental vascular compromise as risk factors for adverse pregnancy outcomes.
Approximate amount – $697,000
Duration – 3/13/03-8/30/07

Centers for Medicare & Medicaid Studies
Shaw-Duke Maternal and Infant Mortality Initiative
PIs – Daniel Howard, PhD; Haywood Brown, MD
Role – co-investigator
%Effort – 25%

Purpose – The goal of this grant was to help reduce racial disparities for pregnant African American Medicaid recipients by studying patient and health services factors and using an educational intervention to improve pregnancy outcomes.
Approximate amount – $175,000
Duration – 10/2006-9/2008

Charles Hammond Fund Foundation Award, Duke University Medical Center Department of Obstetrics and Gynecology
PI – Monique Chireau, MD, MPH
Role – PI
%Effort – 7%
Purpose – This bridge grant supported continued exploration and development of the Duke Birth Database, (developed by Dr. Chireau), of pregnancy outcomes at Duke Medical Center over the last 25 years, and the generation of papers and grant submissions.
Approximate amount – $30,000
Duration – 2006-2008

IPA Agreement (Myers) 12/3/07-12/3/09
Department of Veterans Affairs
Addressing Birth Defect Prevention in Women Veterans
Major goal of project: to assist the Department of Veterans Affairs in development of birth defect prevention efforts by the Women Veterans Health Strategic Healthcare Group.
Role: Co-PI

Clinical and Translational Science Award Grant (Small/Chireau) 4/3/09 – 12/3/09
Durham Health Innovations
Duke Translational Medicine Institute, Duke Center for Community Research
We hypothesize that an *internatal care* model focusing on postpartum and preconception prevention and treatment will have a major impact on maternal-child health in Durham. We propose to plan and design and multidisciplinary, community-based care model to improve maternal-child health and interrupt the cycle of events leading to maternal and infant complications in the next pregnancy and beyond.
Role: Co-PI

Duke Clinical Research Unit Pilot Grant Program (Chireau) 4/30/10 – 5/1/2011
Duke University
This pilot grant supported exploration of the association between cardiovascular disease and adverse pregnancy outcomes in young women.
Role: PI

Clinical, Metabolomic and Proteomic Profiles in Preeclampsia (Chireau) 7/15/10 – 7/14/2011
Duke Translational Medicine Institute
This grant supported proteomic and metabolomic analyses of sera and placental tissue from preeclamptic women.
Role: PI

Clinical activity:
St. Joseph's Regional Medical Center, Mishawaka, IN

Past and present participation in academic and administrative activities:

Duke University Medical Center IRB
Duke Medical School Admissions Committee
Director, VA Gynecology Resident Rotation
Director, VA Gynecology Medical Student Rotation
Committee member, National Surgical Quality Improvement Program, GYN Surgery Subspecialty, for Duke University Medical Center and Veterans Administration
Executive Board Member, UNICEF
Executive Board Chair, Maternal and Newborn Health in Fragile Settings, The Partnership for Maternal, Newborn and Child Health

EXHIBIT #4

IN THE DISTRICT OF JOHNSON COUNTY, KANSAS
CIVIL COURT DEPARTMENT

HODES & NAUSER, MDs, P.A., on behalf of itself, its patients, physicians, and staff; TRACI LYNN NAUSER, M.D.; TRISTAN FOWLER, D.O.; and COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, on behalf of itself and its patients, physicians, and staff, Plaintiffs, v. KRIS KOBACH, in his official capacity as Attorney General of the State of Kansas; STEPHEN M. HOWE, in his official capacity as District Attorney for Johnson County; MARCH BENNETT, in his official capacity as District Attorney for Sedgwick County; SUSAN GILE, in her official capacity as Executive Director of the Kansas Board of Health Arts; and RONALD M. VARNER, D.O., in his official capacity as President of the Kansas Board of Healing Arts, Defendants.	)	Case No. 23CV03140 Division No. 12 K.S.A. Chapter 60

DECLARATION OF JOEL BRIND, Ph.D.

I, Joel Brind, Ph.D., pursuant to the provisions of Kan. Stat. Ann. § 53-601, do hereby declare as follows:

Qualifications

1. I am Emeritus Professor of Biology and Endocrinology at Baruch College, City University of New York, having served on the full-time faculty there from 1986 until my retirement in 2020. I have taught and written in the area of

biology and endocrinology and have lectured and written extensively on the connection between abortion and breast cancer. I am also the founder, President and CEO of Natural Food Science, LLC, which produces and markets a nutritional supplement based upon my years of scientific study. My *Curriculum Vitae* is attached hereto as Exhibit A.

2. I have a B.S. in Biology from Yale College and a M.S. in Biology from New York University. I received a Ph.D. in Basic Medical Sciences (Biochemistry, Physiology, and Immunology) from New York University in 1981.

3. I taught full time at the collegiate level between 1986 and 2020, when I retired. From 1986–89, I was an Assistant Professor of Biology and Chemistry at Baruch College. From 1990–92, I was an Associate Professor of Biology and Endocrinology at Baruch College. From 1993 until my retirement in 2020, I served as a full Professor of Biology and Endocrinology at Baruch College. In addition to my full-time experience, I also served as an Adjunct Investigator in the Department of Medicine at Beth Israel Medical Center in New York from 1986–94, and as an Adjunct Associate Professor in the Department of ObGyn & Reproductive Science at the Mt. Sinai School of Medicine in New York from 1990–94.

4. I have extensive relevant experience beyond my academic posts. From 1972–79, I was employed full time as an Assistant Research Technician through Senior Research Technician at New York University School of Medicine. From 1981–86, I was the Director of Biochemical Research at the Orentreich Foundation for the Advancement of Science, Inc., and the Director of the clinical laboratory of the

Orentreich Medical Group in New York. From 1986–2014, I served as a consultant to the Orentreich Foundation for the Advancement of Science, Inc. in New York and Cold Spring, NY. In 1999, I co-founded the Breast Cancer Prevention Institute in Poughkeepsie, NY, and served as its President until 2009. I remained on the Board of Directors of the Breast Cancer Prevention Institute (now in Somerset, NJ) until 2019.

5. I have been a member of various professional societies, including the Endocrine Society (1987–2000) and the American Bioethics Advisory Commission (1998–2001). In addition, I served as a member of the Editorial Board of the professional peer-reviewed journal *Steroids* from 1993–99. From 2003–06 I served as a member of the Breast and Cervical Cancer Early Detection and Control Advisory Committee of the Centers for Disease Control and Prevention (CDC) in Atlanta, GA.

6. I have lectured and presented both nationally and internationally for the last 30 years on the link between induced abortion and breast cancer, including at Oxford University, the University of Medicine and Dentistry of New Jersey—Robert Wood Johnson Medical School, and the University of Cambridge.

7. Over the last 30 years, I have authored or coauthored articles on the connection between induced abortion and breast cancer, many of which are peer-reviewed. By way of example, articles or letters I have written have appeared in the *British Medical Journal (BMJ), Journal of the American Association of Physicians and Surgeons,* the *Journal of Epidemiology and Community Health,* and the *New England Journal of Medicine.* A full list of my publications is available in my CV.

8. As outlined above, I have over 40 years of post-doctoral academic experience relating to biology and endocrinology, and I have researched, lectured, presented and written extensively on the link between induced abortion and breast cancer over the last three decades.

9. Since 1995, I have served variously as an expert witness in civil cases in Federal Court (*Christ's Bride Ministries v. SEPTA*, 1995) and various state Courts, including Alaska, Florida, and South Dakota.

Opinions Expressed and the Reasons and Basis for Them

10. I have been provided with a copy of the complaint and the motion for a TRO, as well as the Declaration of Dr. Traci Lynn Nauser in support of the motion for a TRO. I have also been provided a copy of the relevant statute, and I have reviewed the state-mandated materials promulgated under the statute which are required to be given to patients requesting induced abortion.

11. The opinions I express herein are limited to the issue of the effect of abortion on future breast cancer risk. The state-mandated materials include a "woman's right to know" handbook, which includes, under "Long-Term Medical Risks" (p 26) a paragraph entitled "Breast Cancer".

12. According to the Complaint (paragraph 69), Plaintiff alleges that the "state-mandated disclosure" regarding "a 'risk of breast cancer' related to abortion" is "medically inaccurate". In her Declaration, Dr. Nauser states categorically (paragraph 37): "There is no scientific backing for a significant amount of the information I am required to disseminate to my patients, including with respect to . . . the increased risk of breast cancer after an abortion." The Declaration makes no

reference to any published materials on abortion and breast cancer, nor makes any other mention of this issue.

13. The statement that "there is no scientific backing" for there being an "increased risk of breast cancer" after abortion is provably false on its face. The peer-reviewed medical literature is replete with scores of studies documenting increased risk of breast cancer after abortion, dating back as far as 1957.[1]

14. The state-mandated handbook for patients relies principally, for its recommendation re: breast cancer, on a panel organized by the US National Cancer Institute (NCI) in 2003, the findings of which are still published on the NCI website cancer.gov.[2]

15. I will therefore examine key aspects of the NCI panel—of which I was a member—which stand in contrast to the claims of Dr. Nauser in her Declaration but are accurately reflected in the state-mandated handbook.

16. This is the wording verbatim, in its entirety, from the state-mandated handbook as it relates to abortion and breast cancer (p. 26):

> **Breast Cancer**: Your chances of getting breast cancer are affected by your pregnancy history. If you have carried a pregnancy to term as a young woman, you may be less likely to get breast cancer in the future. However, your risk is not reduced if your pregnancy is ended by abortion. There are also studies that have found an increased risk of breast cancer after induced abortion, but other studies have found no risk. A 2003 National Cancer Institute panel reviewing studies at that time concluded there was no increased risk; however, study and review of the relationship continue. NCI recognizes research that shows pregnancy and breastfeeding both reduce a woman's lifetime exposures to hormones that otherwise might increase her risk of breast cancer.

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[1] Segi M, Fukushima I, Fujisaku S, et al. (1957). An epidemiological study on cancer in Japan. GANN 48(Suppl):1-63.

[2] *Available at* https://www.cancer.gov/types/breast/abortion-miscarriage-risk.

> Pregnancy and breast feeding also cause breast cells to mature in order to produce milk, and some researchers hypothesize those cells are more resistant to cancer. Women who have a family history of breast cancer or who have clinical findings of breast disease should seek medical advice from their physician.

17. With regard to the effects of abortion on a woman's long term risk of breast cancer, note three mechanisms by which abortion may increase this risk: a) the loss of protection (reduced risk) from a full-term pregnancy, especially at younger ages; b) An additional increase in risk owing to the abortion (known as the independent effect), beyond what the risk would have been had there been no pregnancy; and c) The loss of protection (decreased risk) attributable to breastfeeding the child, which is impossible after abortion (although breastfeeding is another matter of choice if the pregnancy is not aborted). The truth of "a" and "c" above have long been recognized as established by decades of research. Only the independent effect (defined as "b" above) is associated with any controversy (i.e., studies finding this risk and studies not finding it have been published).

18. Regarding factor "a" above, it has been established in the medical literature since 1970, when a Harvard-led landmark study by the World Health Organization studied reproductive history and breast cancer in 7 different countries and established the clear connection between age at first term pregnancy and breast cancer risk.[3] The authors also observed the tendency, in relation to pregnancies that did not go to term, that "suggested increased risk associated with abortion, contrary to the reduction in risk associated with full-term births." The 2003 NCI panel

[3] MacMahon B, Cole P, Lin M, et al. (1970) Age at first birth and breast cancer risk. Bull Wld Hlth Org 43:209-221.

concluded, in accordance with these established trends, the following among its "well established" epidemiological findings[4]:

- "Early age at first term birth is related to lifetime decrease in breast cancer risk."
- Increasing parity is associated with a long-term risk reduction, even when controlling for age at first birth."

19. Regarding abortion in the manner of "b" above, the NCI panel concluded: "Induced abortion is not associated with an increase in breast cancer risk." However, this statement only refers to the independent effect. That is because studies on induced abortion and breast cancer risk do not usually compare women who aborted a pregnancy to women who were pregnant but carried the pregnancy to term. Rather, women who had an abortion are compared to women who did not have an abortion but who have the same number of born children.

20. The findings of the NCI panel are therefore self-contradictory in an important way, and the writers of the Kansas handbook for patients did a masterful job of clarifying the findings of the NCI panel so that it actually provides useful information to women. Clearly the "well established" fact that abortion abrogates the protection that a full-term pregnancy would otherwise confer means that it increases the risk above what it would be if the pregnancy were carried to term. That is the only comparison that satisfies the ethical requirement of informed consent, *i.e.*, the patient must be told about possible medical consequences of having a given

[4] *Available at* https://www.cancer.gov/types/breast/abortion-miscarriage-risk.

intervention (induced abortion in this case) versus not having the intervention. This effect on future breast cancer risk was made crystal clear in deposition testimony of Lynn Rosenberg, an epidemiologist and expert witness for the Plaintiff, an abortion provider in a civil case challenging a parental notification law in the State of Florida in 1999:

> Q: So, in other words, a woman who finds herself pregnant at age 15 will have a higher breast cancer risk if she chooses to abort that pregnancy than if she carries the pregnancy to term, correct?
>
> A: Probably, yes.
>
> Q: Looking at that another way, let's compare two women. Let's say both got pregnant at age 15—one terminates the pregnancy, but the other carries the pregnancy to term. And both women go on to get married and have two children, say at age 30 and age 35. Is the risk of breast cancer higher for the woman had an abortion at age 15 or the woman who had a baby at age 15, all other things being equal?
>
> A: It's probably higher for the one who had an abortion at age 15. (Rosenberg, 1999).[5]

21. As one of the invited experts on the 2003 NCI panel, I submitted a minority report in partial disagreement with the body of the panel's findings. Oddly, the NCI has only posted on their website, mention of a "Minority Dissenting Comment" which they describe thus:

> One invited participant to the Early Reproductive Events and Breast Cancer Workshop, held February 24–26, 2003, submitted to the National Cancer Institute a public comment regarding the outcomes of the workshop. Submitted as a "minority report," the participant conveyed partial disagreement with the findings of the workshop report presented to the joint meeting of the NCI Board of Scientific Counselors and the NCI Board of Scientific Advisors. The participant remains 'convinced that the weight of available evidence suggests a real, independent, positive association between induced abortion and breast

[5] Rosenberg L (1999). Videotape deposition in the Circuit Court of the Second Judicial District, Leon County, Florida. North Florida Women's Health and Counseling Services, Inc, et al, Plaintiffs vs State of Florida , et al, Defendants. No. 99-3202, pp. 77-78.

> cancer risk.' In a general statement, the participant noted that the workshop summary report contained no comment of dissent.

But not only did the NCI not post my minority report on the NCI website, but the NCI neither mentioned the identity of the dissenter, nor how the reader could obtain the full document (attached hereto as Exhibit B).

22. It is also important to note that the NCI workshop was conducted over 20 years ago (Feb. 2003, with the web page describing the workshop and its findings last reviewed on Jan. 12, 2010, according to the website accessed on June 20, 2023), and a large amount of data on the abortion-breast cancer connection has been published since 2010 in the peer-reviewed medical literature.

23. On the NCI website is also posted a fact sheet entitled "Reproductive History and Cancer Risk,"[6] which includes a paragraph entitled "Is abortion linked to breast cancer risk?" Unlike the page reporting on the 2003 workshop, this fact sheet includes a list of 36 "selected references". Importantly, this NCI guideline is certified to have been reviewed on Nov. 9, 2016, even though the most recent reference in the list related to abortion and breast cancer was published in 2009, namely, "ACOG Committee Opinion No. 434: Induced abortion and breast cancer risk."[7]

24. Since 2009, many studies have been published regarding abortion and breast cancer, especially in Asia, where induced abortion has become a more common procedure over the last 40 years. During that time, two meta-analyses of the extant

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[6] *Available at* https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/reproductive-history-fact-sheet.

[7] Committee on Gynecologic Practice. ACOG Committee Opinion No. 434: induced abortion and breast cancer risk. Obstetrics and Gynecology 2009; 113(6):1417–1418.

literature were published, one on induced abortion and breast cancer in China (Huang et al., 2013)[8] and one on induced abortion and breast cancer in South Asia (India, Pakistan, Bangladesh, and Sri Lanka; Brind et al., 2018).[9] Both of these systematic reviews provided strong confirmatory evidence of the independent link between induced abortion and breast cancer.

25. The meta-analysis by Huang et al (2013) comprised a compilation of 36 separate studies covering 14 provinces in China between 1997 and 2012. It reported a statistically significant overall increased risk among women with one or more induced abortions of 44%. In contrast, the "Comprehensive Review and Meta-analysis" on worldwide studies that I and my co-authors had published in 1996,[10] and upon which I relied for my being "convinced that the weight of available evidence suggests a real, independent, positive association between induced abortion and breast cancer risk" (see paragraph 21 above), reported an overall risk increase of only 30% among women with one or more induced abortions. Moreover, the Huang paper relied on a large enough database to identify a significant dose effect. What this means is that women with more than one abortion were found to have a higher risk increase than those with just one abortion, *i.e.*, a 76% risk increase for those with two or more abortions, and an 89% risk increase for those with three or more abortions.

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[8] Huang Y, Zhang X, Li W et al. A meta-analysis of the association between induced abortion and breast cancer risk among Chinese females. Cancer Causes Control 2014;25:227-36. doi:10.1007/s10552-013-0325-7 Epub 2013.

[9] Brind J, Condly SC, Lanfranchi A, Rooney B. Induced abortion as an independent risk factor for breast cancer: A systematic review and meta-analysis of studies on South Asian women. Issues Law Med 2018;33:33-54.

[10] Brind J, Chinchilli VM, Severs WB, Summy-Long J (1996) Induced abortion as an independent risk factor for breast cancer: a comprehensive review and meta-analysis. J Epidemiol Community Health 50:481-96.

In epidemiology, the demonstration of a dose effect provides stronger evidence of causation for the exposure variable (induced abortion) under study.

26. Our Systematic Review and Meta-analysis on abortion and breast cancer in South Asian women (Brind et al. 2018)[11] reported even stronger results than those of Huang et al (2013).[12] Specifically, in compiling all 20 extant studies on the issue (published between 2007 and 2016), we calculated a statistically significant average breast cancer risk increase of 151% compared to women with no abortions.[13] In epidemiology, this is considered a moderately strong association, lending yet more credibility to abortion as a causal factor in the development of breast cancer. We also reported a significant dose effect among the 5 studies we compiled which had reported data for different numbers of abortions.

27. I conclude therefore that the warning language vis-á-vis abortion and the risk of future breast cancer provided by the state of Kansas is in perfect agreement with the facts currently stated by the U.S. National Cancer Institute on its website, cancer.gov. Furthermore, the Kansas handbook is expressed in such a manner as to be most practically informative in providing a woman with useful

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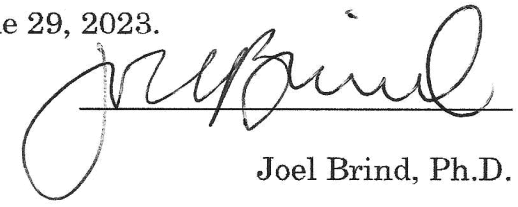
[11] Brind J, Condly SC, Lanfranchi A, Rooney B. Induced abortion as an independent risk factor for breast cancer: A systematic review and meta-analysis of studies on South Asian women. Issues Law Med 2018;33:33-54.

[12] Huang Y, Zhang X, Li W et al. A meta-analysis of the association between induced abortion and breast cancer risk among Chinese females. Cancer Causes Control 2014;25:227-36. doi:10.1007/s10552-013-0325-7 Epub 2013.

[13] While this may seem inconsistent with the results of the earlier meta-analyses, since it is so much higher, it is actually quite consistent since the risk increase is relative to the baseline risk in the study population. Since there is a very low prevalence of other risk factors among South Asian women, the average lifetime risk for breast cancer among these women is only 2–3%, rather than the 12% seen among American women.

knowledge about her future risk of breast cancer if she chooses to have an abortion versus not to have an abortion and allow the pregnancy to go to its natural term.

I declare under penalty of perjury under the laws of the state of Kansas that the foregoing is true and correct. Executed on June 29, 2023.



Joel Brind, Ph.D.

EXHIBIT A

Joel Brind, Ph.D.
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Bristol, PA 19007

Phone (cell): 914-805-9215; email: joelbrind@gmail.com

EDUCATION:

Degree	***Institution***	***Field***	***Dates***
B.S.	Yale College	Biology	1971
M.S.	New York University	Biology	1977
Ph.D.	New York University	Basic Medical Sciences (Biochemistry, Physiology, Immunology)	1981

FULL-TIME ACADEMIC EXPERIENCE:

Institution	***Rank***	***Field***	***Dates***
Baruch College, CUNY	Professor	Biology/Endocrinology	1/93-8/20
Baruch College	Assoc. Professor	Biology/Endocrinology	1/90-12/92
Baruch College	Ass't Professor	Biology/Chemistry	9/86-12/89

PART-TIME ACADEMIC EXPERIENCE:

Institution	***Rank***	***Field***	***Dates***
Mt. Sinai School of Medicine (New York, NY)	Adj. Assoc. Prof. (Dept. of ObGyn. & Reprod. Sci.)	Endocrinology	1/90-3/94
Beth Israel Medical Center (New York, NY)	Adj. Investigator (Dept. of Medicine)	Endocrinology	9/86-2/94

NON-ACADEMIC EXPERIENCE:

2010-present	Founder, President and CEO, Natural Food Science, LLC, Bristol, PA
2009-2019	Member, Board of Directors, Breast Cancer Prevention Institute, Somerset, NJ
1999-2009	Founder and President, Breast Cancer Prevention Institute, Poughkeepsie, NY
1997-2001	Founder, Editor and Publisher, *Abortion-Breast Cancer Quarterly Update*
1986-2014	Consultant, Orentreich Foundation for the Advancement of Science, Inc., New York, NY and Cold Spring, NY
1981-1986	Director of Biochemical Research, Orentreich Foundation, New York, NY and Director of Clinical Laboratory, Orentreich Medical Group, NY, NY.
1972-1979	Assistant Research Technician through Senior Research Technician, New York University School of Medicine, New York, NY.

PROFESSIONAL SOCIETIES, etc.:

2012-Present	Member, Board of Medical Advisors, Heartbeat International, Columbus, OH
2003-2006	Member, Breast and Cervical Cancer Early Detection and Control Advisory Committee, Centers for Disease Control and Prevention (CDC), Atlanta, GA.
1987-	Member, The Endocrine Society (inactive since 2000)
1993-1999	Member, Editorial Board of *Steroids*
1997-present	Member, Advisory Committee, Culture of Life Foundation, Inc.
1998-2001	Member, American Bioethics Advisory Commission

PUBLIC LECTURES AND PRESENTATIONS:

10/14/05	Bradford Hill Seminar, Institute of Public Health, University of Cambridge, Cambridge, UK. "An open verdict? The evidence of a link between induced abortion and breast cancer"
4/9/04	Grand Rounds, Dept. of Obstetrics and Gynecology, SUNY Upstate Medical Center, Syracuse, NY. "Induced Abortion as a risk factor for breast cancer".
1/24/04	Public health lecture, John Radcliffe Infirmary, Oxford University, Oxford, UK. "Induced abortion as a risk factor for breast cancer".
7/3/03	CME Lecture, Dept. of Family Medicine, St. John's Mercy Medical Center, St. Louis, MO. "The Abortion-Breast Cancer Link: Biological and Epidemiological Evidence".
5/9/01	Grand Rounds, Dept. of Obstetrics, gynecology and Reproductive Sciences, University of Medicine and Dentistry of New Jersey—Robert Wood Johnson Medical School, New Brunswick, NJ. "Induced abortion as an independent risk factor for breast cancer."
8/24-30/99	Medical/surgical forums on induced abortion as a risk factor for breast cancer, at hospitals in Australia: Mercy Hospital, Northern Hospital and the Royal Melbourne Hospital, Melbourne, Vic; Ballarat Hospital, Ballarat, Vic; Royal Women's Hospital, Brisbane, Qld.
7/28/99	World Conference on Breast Cancer, Ottawa, Ontario, Canada.. "Reporting bias as a cause of the apparent association between breast cancer and induced abortion."
4/17/99	joint presentation: Section Program on Bioethics, Spring Session, American Academy of Pediatrics, Chicago, IL. "Uncertainties in informed consent"
7/6/98	Grand Rounds, Dept. of Obstetrics and Gynecology, Somerset Medical Center, Somerville, NJ. "Relationship of terminated pregnancy and breast cancer"
10/2/97	Grand Rounds, Dept. of Obstetrics and Gynecology, Santa Clara Valley Medical Center, San Jose, CA. "Induced abortion as a risk factor for breast cancer"
10/2/97	joint presentation: Grand Rounds, Dept. of Obstetrics and Gynecology and regular meeting of Ethics Committee, Kaiser Foundation Hospital, Santa Clara, CA. "Induced abortion as a risk factor for breast cancer"
9/30-10/4/97	3-hour Continuing Education Seminar for Nurses (California Nurses for Ethical Standards), given at W. Covina, San Diego, Sacramento and Fresno California "Breast cancer and abortion"
7/14/97	World Conference on Breast Cancer (Women's Environment and Development Organization), Kingston, Ontario, Canada. "Induced abortion as an independent risk factor for breast cancer: an updated meta-analysis"
5/30/97	Seventh Annual Conference of University Faculty for Life, Loyola College, Baltimore, MD. "Abortion and breast cancer: conclusive evidence—official denial"
7/19/96	Oral Testimony given before the Reproductive Health Drugs Advisory Committee of the Food and Drug Administration, Gaithersburg, MD. Re: approval of mifepristone/ misoprostol chemical abortifacients: necessity of including warnings on breast cancer

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EXHIBIT B

Early Reproductive Events and Breast Cancer: A Minority Report March 10, 2002

I. Introduction: As an invited participant in the recently concluded NCI workshop "Early Reproductive Events and Breast Cancer", held Feb. 24-26, I file these public comments in the form of a minority report, inasmuch as I am in partial disagreement with the findings of the workshop submitted to the Board of Scientific Advisors and the Board of Scientific Counselors, and subsequently with the unanimous approval of these Boards, to the NCI Director, Dr. Andrew von Eschenbach.

The need for such a report as this is underscored by the fact that, although my dissent was made, in part, on the public record during the final session on Feb. 26, there was no mention of any dissent in the Summary Report which constituted the final submission of the workshop. Such an omission might indeed be misinterpreted as signifying the unanimous agreement of all the expert participants. Moreover, the fact that the workshop was abruptly concluded without prior notice at the end of what was scheduled to be the penultimate public session, there was no opportunity for anyone to make a full and formal statement enumerating and justifying any points of disagreement. Hence I take this opportunity to do so now.

II. General Comment: Scope of the workshop and opportunity for scientific scrutiny and review of the data:

1) Overall Time Constraint: The scope of the research which was presented and discussed during such a brief workshop was enormous by any measure, and thus there was little time for extensive discussion or analysis of any data. Indeed, the large number of findings that emerged testifies to the fact that, going in to the workshop, there was little if any disagreement on the vast majority of findings. For example, the breast cancer risk-lowering effect of full-term pregnancy has been so well established for so long, that in his opening address on Feb 24th, Dr. Hoover declared: "We're here to focus on the protective effect of pregnancy."

As Dr. von Eschenbach himself made clear in his opening remarks, however, the workshop was in fact prompted by controversy surrounding the question of an association between induced abortion and breast cancer incidence. Thus, while such an association has been frequently reported, the NCI had concluded—and posted on its website a year ago—that "it appears that there is no overall association…". With the workshop's having so much ground to cover, any sort of "comprehensive review", of the abortion-breast cancer data, which is what Dr. von Eschenbach envisioned, according to his opening remarks, would have been a difficult task. Nevertheless, I came to the workshop prepared to participate actively in just such an exercise.

2) Yet more troubling than the difficult time constraints for accomplishing a thorough vetting of the scientific data concerning induced abortion and breast cancer was the fact that the very design of the workshop rendered such a task impossible, to wit:

a) There were presentations only by scientists advancing the hypothesis previously advanced by the NCI, i.e., that there is no such association. The formal presentation in the Feb. 25th public session was made by Dr. Leslie Bernstein, whose area of specialization has been mostly in other areas, namely, the effects of exercise and obesity and breast cancer risk, with no opportunity whatsoever for a balanced presentation by other authors who have published in

this area. For example, I was the principal author of a comprehensive review and meta-analysis on abortion and breast cancer (Brind et al., 1996). The only other presentations on the issue were by Drs. Polly Newcomb and Mads Melbye, during the closed session of five-minute "Late-Breaking Results". It is inconceivable that a genuine and fair review of any controversial issue could ever be conducted without providing the opportunity for scientists with differing views to present and discuss their findings.

b) Abortion-breast cancer presentations included the presentation of new data (from Drs. Bernstein, Newcomb and Melbye), with no time for examination or scrutiny of such data, and,

c) Such "late-breaking" data was not made available for examination at all during the workshop. During the question and answer session following Dr. Bernstein's lecture, I specifically requested that the new data be made available for review at the workshop. However, Dr. Bernstein replied that she would not release the data until its publication. (This exchange was made on camera during a public session, the record of which will presumably be made available on the NCI website.) All new data should have been made available to workshop participants well in advance of the meeting, were there to be an opportunity for any real review.

III. Specific Dissent:

1) Contrary to the workshop finding: "Induced abortion is not associated with an increase in breast cancer risk (1)", I remain convinced that the weight of available evidence suggests a real, independent positive association between induced abortion and breast cancer risk. This conclusion is based upon:

a) The fact that of 38 epidemiological studies published through 2002, 29 have reported relative risks greater than 1.0, with 17 of these achieving at least borderline statistical significance (Among studies on US women, 13 of 15 have reported a positive overall association, 8 of them achieving at least borderline statistical significance.)

b) Cohort studies or case-control studies nested in prospective databases which do not report a positive association, are seriously flawed by massive misclassification (Melbye, et al., 1997; Goldacre et al., 2001) and/or the use of inappropriate comparison groups (Lindefors Harris et al., 1989; Melbye et al., 1997). Indeed, from what I could gather from Dr. Melbye's update of his Danish data (during the question and answer session), his stratification of relative risk by age in 1973 (date of inception of his abortion registry) was not accomplished by restricting the initial analysis to different sub-cohorts. For example, he did not reanalyze the data from scratch using only women born since 1950 (instead of 1935), thus eliminating most of the misclassified women from the analysis. Rather, he applied a statistical adjustment to the initial analysis of the entire cohort. Consequently, the large distortion of the relative risk estimate in the direction of underestimation, which we have pointed out (Brind and Chinchilli, 1997), still applies. In contrast, the only study nested in a

prospective database (Howe et al., 1989) utilized a pair-matched case-control design, free of mismatching or misclassification.

c) While there remain inconsistencies in the causal hypothesis of "total estrogen exposure" as the mechanism for most risk factors (as pointed out by Dr. Hoover in his Feb. 24th address), the role of estrogen as a stimulator of cellular proliferation, as well as the known genotoxic effects of certain estrogen metabolites, still provide a biologically plausible basis for most risk factors, including induced abortion. Bioavailable estrogen achieves its highest levels during the first two trimesters of a normal human pregnancy, inducing maximal rates of cellular proliferation.

d) Even if, for the sake of argument, one were to ignore any effect of induced abortion as an independent risk factor (i.e., as an exposure that increases risk beyond the risk level attributable to the non-pregnant state) it is grossly misleading to suggest that induced abortion has no effect on future breast cancer risk. Induced abortion has no meaning except in the case where a pregnancy is already under way. Since aborting a pregnancy denies a woman the long-term protective effect of a full-term pregnancy, it is unarguable that a woman's long-term risk of breast cancer will be greater if she chooses abortion over childbirth. Therefore, information provided to the public by the NCI, including on its website, should state this unequivocally, in order to provide meaningful guidance to women considering abortion.

2) The workshop finding: "Breast cancer risk is transiently increased after a term pregnancy.(1)" is misleading, in that it suggests that risk will be elevated beyond the level attributable to the non-pregnant state. On the contrary, although there is a transient increase, in which breast cancer risk reaches a peak approximately 5 years postpartum, this peak risk level does not exceed the risk attributable to the non-pregnant state for women under age 25 at delivery. This was acknowledged by Dr. Hsieh in the breakout session in which I participated, in agreement with what his group has reported in the literature (Lambe et al., 1994).

3) The workshop finding that the effect of preterm delivery on breast cancer risk constitutes an "epidemiologic gap"—not even suggested by level 1,2,3 or 4 evidence is not warranted, due to the presence of high quality data in the literature. Indeed, as I pointed out in my comments during the final session, the workshop paradoxically based the conclusion that induced abortion does not increase breast cancer risk largely on the work of Dr. Melbye. Yet Dr. Melbye's own group has provided excellent evidence of the risk-increasing effect of early pre-term births (before 32 weeks) using the same population database and the same statistical methodology (without the flaws in the abortion study; see Brind and Chinchilli, 2000), in agreement with the work of others (Hsieh et al., 1999). This would indicate that early premature birth has been supported by research with at least level 2 evidence. The discrepancy in the conclusions by the workshop vis-à-vis these two variables is glaring. Moreover, when I raised this concern at the

final session, no one addressed it at all, notably including Dr. Melbye, who was present at the time.

Respectfully submitted,

Joel Brind, Ph.D., Professor,
Human Biology and Endocrinology,
Baruch College-CUNY, NY, NY, and
President, Breast Cancer
Prevention Institute,
Poughkeepsie, NY

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EXHIBIT #5

Toll Free 1-888-744-4825
Available in Spanish

WomansRightToKnow.org

Kansas
Department of Health and Environment

1000 S.W. Jackson, Suite 220 • Topeka, Kansas 66612

The Kansas Department of Health and Environment acknowledges contributions for this publication. Photographs from: Lennart Nilsson (in utero photographs used by permission, *A Child is Born*, Dell Publishing, 1990); Alexander Tsiaras (from *Conception to Birth*: *a Life Unfolds*, Doubleday 2002); Moore et al (*Color Atlas of Clinical Embryology*, Elsevier 2000); text from Louisiana Department of Health and Hospitals; prenatal development facts adapted and cover photo used with permission from the Endowment for Human Development.

This publication is produced in compliance with K.S.A. 65-6708, thru 65-6710 known as the "Woman's Right-to-Know Act". You have the right to know that by state law, no person shall perform or induce an abortion when the unborn child is viable or pain-capable unless such person is a physician and has a documented referral. The physician who performs or induces an abortion when the unborn child is viable must have a documented referral from another physician not legally or financially affiliated with the physician performing or inducing the abortion. Both physicians must determine that: the abortion is necessary to preserve the life of the pregnant woman; or that a continuation of the pregnancy will cause a substantial and irreversible physical impairment of a major physical bodily function of the pregnant woman. If the child is born alive, the attending physician has the legal obligation to take all reasonable steps necessary to maintain the life and health of the child.

You shall know that:

A. By no later than 20 weeks from fertilization, the unborn child has the physical structures necessary to experience pain;

B. There is evidence that by 20 weeks from fertilizations unborn children seek to evade certain stimuli in a manner that in an infant or an adult would be interpreted to be a response to pain;

C. Anesthesia is routinely administered to unborn children who are 20 weeks from fertilization or older who undergo prenatal surgery;

D. Less than 5% of all natural pregnancies end in spontaneous miscarriage after detection of cardiac activity and a fetal heartbeat is, therefore, a key medical indicator that an unborn child is likely to achieve the capacity for live birth; and

E. Abortion terminates the life of a whole, separate, unique, living human being.

INTRODUCTION

This handbook offers some basic facts to help you make an informed decision about your pregnancy. This handbook will tell you about the normal development of your unborn child and about the methods and risks of abortions and medical risks of childbirth.

Your doctor is required to tell you about the nature of the physical and emotional risks of both the abortion procedure and carrying a child to term. The doctor must tell you how long you have been pregnant and must give you a chance to ask questions and discuss your decision about the pregnancy carefully and privately in your own language.

In order to determine the gestational age of the unborn child, the doctor may use ultrasound equipment preparatory to the performance of an abortion. You have the right to view the ultrasound image of the unborn child at no additional expense, and you have the right to receive a picture of the unborn child.

A directory of services is also available. By calling or visiting the agencies and offices in the directory you can find out about alternatives to abortion, assistance to make an adoption plan for your baby, or locate public and private agencies that offer medical and financial help during pregnancy, during childbirth and while you are raising your child.

Furthermore, you should know that:

A. It is unlawful for any individual to coerce you to undergo an abortion. Coercion is the use of expressed or implied threats of violence or intimidation to compel a person to act against such person's will;

B. Abortion terminates the life of a whole, separate, unique, living human being;

C. Any physician who fails to provide informed consent prior to performing an abortion may be guilty of unprofessional conduct and liable for damages;

D. You are not required to pay any amount for the abortion procedure until the 24-hour waiting period has expired;

E. The father of your child is legally responsible to assist in the support of the child, even in instances where the father has offered to pay for an abortion; and

F. The law permits adoptive parents to pay the costs of prenatal care, childbirth and neonatal care.

Many public and private agencies exist to provide counseling and information on available services. You are strongly urged to seek assistance from such agencies in order to obtain guidance during your pregnancy. In addition, you are encouraged to seek information on alternatives to abortion, including adoption, and resources available to postpartum mothers. The law requires that your physician, or the physician's agent, provide this enclosed information.

HUMAN DEVELOPMENT BEFORE BIRTH

Pregnancy begins at fertilization with the union of a man's sperm and a woman's egg to form a single-cell embryo. This brand new being contains the original copy of a new individual's complete genetic code. Gender, eye color and other traits are determined at fertilization.

Most significant developmental milestones occur long before birth during the first eight weeks following fertilization when most body parts and all body systems appear and begin to function. The main divisions of the body, such as the head, chest, abdomen and pelvis, arms and legs are established by about four weeks after fertilization. Eight weeks after fertilization, except for the small size, the developing human's overall appearance and many internal structures closely resemble the newborn.

Pregnancy is not just a time for growing all the parts of the body. It is also a time of preparation for survival after birth. Starting more than 30 weeks before birth, many common daily activities seen in children and adults begin in the womb. These activities include, but are not limited to, hiccups, touching the face, breathing motions, urination, right- or left-handedness, thumb sucking, swallowing, yawning, jaw movement, reflexes, REM sleep, hearing, taste and sensation.

Unless otherwise noted, all prenatal ages in the rest of these materials are referenced from the start of the last normal menstrual period. This age is two weeks greater than the age since fertilization.

The First 2 Weeks

Shortly after a woman's period begins, her body begins preparing for the possibility of pregnancy.

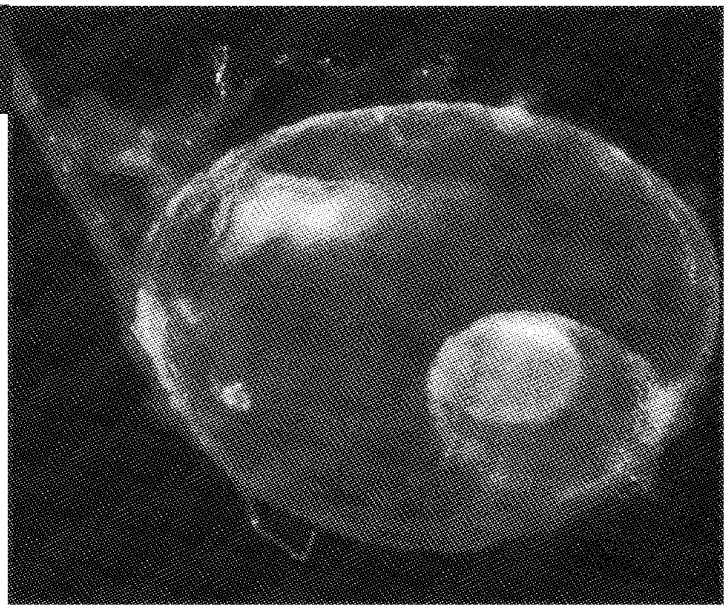
Approximately 2 weeks into her cycle, a woman releases an egg from one of her ovaries into a Fallopian tube. Conception is now possible for the next 24 hours or so and signifies the beginning of pregnancy.

After conception, the single-cell embryo has a diameter of approximately 4 thousandths of an inch.

2 to 4 Weeks

The cells of the embryo repeatedly divide moving through the Fallopian tube into the woman's uterus or womb. Implantation, the process whereby the unborn child embeds itself into the wall of the womb, begins by the end of the third week and is completed during the fourth week of pregnancy.

4 to 6 Weeks



At 4 weeks, the unborn child is less than 1/100th of an inch long.

By 5 weeks, development of the brain, the spinal cord and the heart is well underway.

The heart begins beating at 5 weeks and one day and is visible by ultrasound almost immediately.

6 to 8 Weeks

By 6 weeks, the heart is pumping the unborn child's own blood to such unborn child's brain and body.

All four chambers of the heart are present and more than one million heartbeats have occurred.

The head, chest and abdominal cavities have formed and the beginnings of the arms and legs are easily seen.

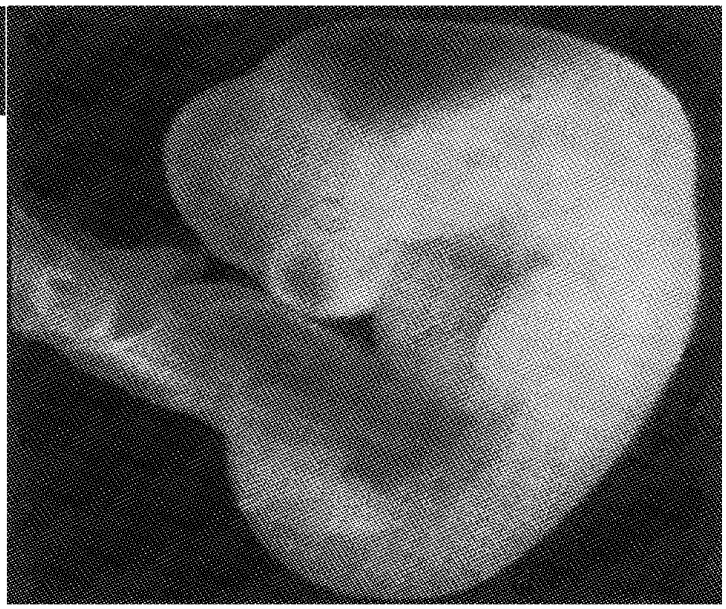
At 6 weeks, the unborn child measures less than ¼ of an inch long from head to rump.

At 6½ weeks, rapid brain development continues with the appearance of the cerebral hemispheres.

At 7½ weeks, the unborn child reflexively turns away in response to light touch on the face.

The fingers also begin to form on the hand.

8 to 10 Weeks



The unborn child is about ½ inch from head to rump.

By 8½ weeks, the bones of the jaw and collarbone begin to harden.

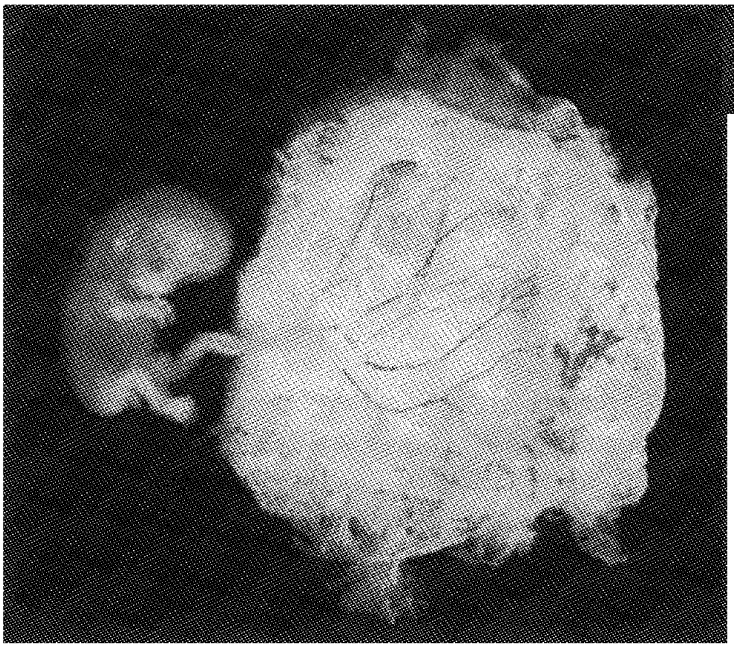
Brainwaves have been measured and recorded by this point in gestation.

By 9 weeks, the hands move, the neck turns and hiccups begin.

Girls also now have ovaries and boys have testes.

The unborn child's heart is nearly fully formed and the heart rate peaks at about 170 beats per minute and will gradually slow down until birth.

Electrical recordings of the heart at 9½ weeks are very similar to the EKG tracing of the unborn child.



10 to 12 Weeks

By 10 weeks, intermittent breathing motions begin and the kidneys begin to produce and release urine. All the fingers and toes are free and fully formed, and several hundred muscles are now present.

The hands and feet move frequently and most unborn children show the first signs of right- or left-handedness.

Pain receptors in the skin, the sensory nerves connecting them to the spinal cord and the nerve tracts in the spinal cord that will carry pain impulses to the brain are all present by this time.

Experts estimate the 10-week unborn child possesses approximately 90% of the 4,500 body parts found in adults. This means approximately 4,000 permanent body parts are present just eight weeks after fertilization. Incredibly, this highly complex unborn child weighs about 1/10th of an ounce and measures slightly less than 1¼ inches from head to rump.

The eyelids are temporarily fused together by 10½ weeks.

By 11 weeks, the head moves forward and back, the jaw actively opens and closes, and the unborn child periodically sighs and stretches. The face, palms of the hands and soles of the feet are sensitive to light touch.

The unborn child begins thumb-sucking and swallowing amniotic fluid.

The uterus is now present and girls' ovaries now contain reproductive cells that will give rise to eggs later in life.

Yawning begins at 11½ weeks.

12 to 14 Weeks

The 12-week unborn child weighs less than 1 ounce and measures about 3 inches from head to heel.

At 12 weeks, fingerprints start forming, while fingernails and toenails begin to grow.

The bones are hardening in many locations.

The heartbeat can be detected with a hand-held Doppler fetal monitor or external heart rate monitor.

By 13 weeks, the lips and nose are fully formed and the unborn child can make complex facial expressions.

14 to 16 Weeks

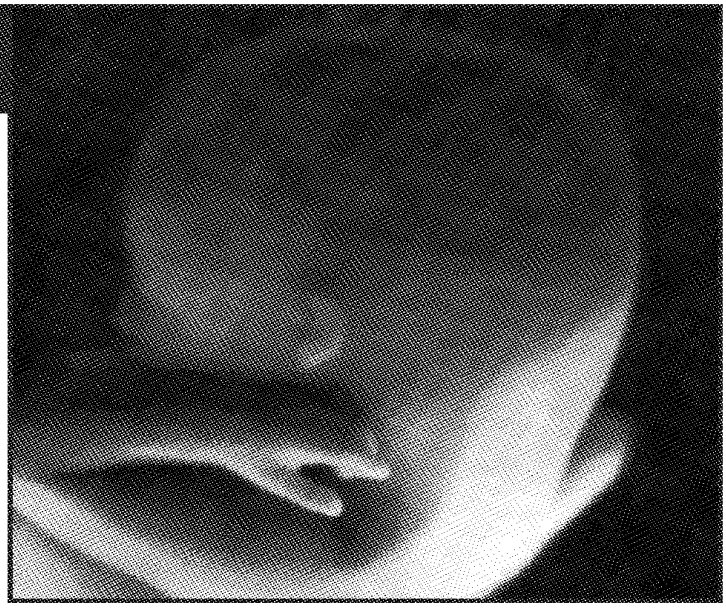
The unborn child weighs about 2 ounces and measures slightly less than 5 inches from head to heel.

At 14 weeks, taste buds are present all over the mouth and tongue.

The unborn child now produces a wide variety of hormones. Also, the arms reach final proportion to body size.

By 15 weeks, the entire unborn child, except for parts of the scalp, responds to light touch, and tooth development is underway.

16 to 18 Weeks

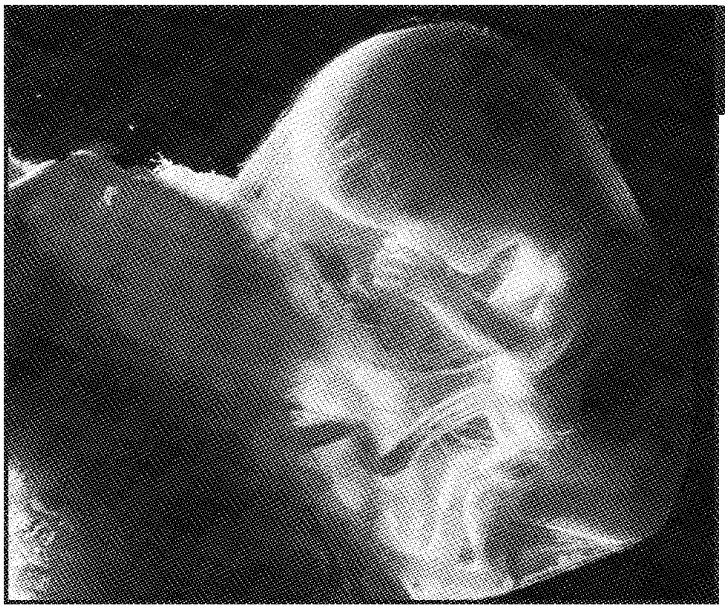


The unborn child weighs about 4 ounces and measures slightly less than 7 inches from head to heel.

At 16 weeks, a pregnant woman may begin to feel the unborn child move.

The unborn child also begins making several digestive enzymes.

Around 17 weeks, blood cell formation moves to its permanent location inside the bone marrow, and the unborn child begins storing energy in the form of body fat.



18 to 20 Weeks

By 18 weeks, the formation of the breathing passages, called the bronchial tree, is complete. The unborn child will release stress hormones in response to being poked with a needle.

At 18 weeks, the unborn child weighs around 6 ounces and measures about 8 inches from head to heel.

By 19 weeks, the unborn child's heart has beaten more than 20 million times.

20 to 22 Weeks

By 20 weeks, nearly all organs and structures of the unborn child have been formed.

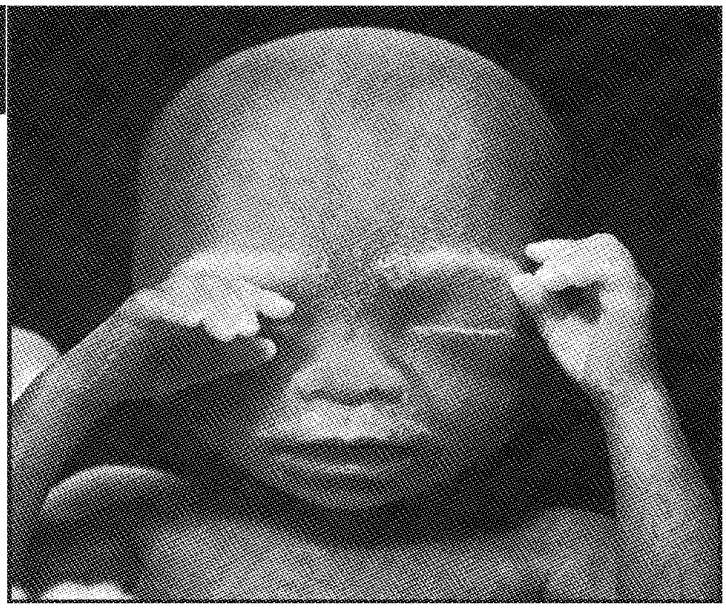
The larynx, or voice box, moves in a way similar to movement seen during crying after birth.

The skin has developed sweat glands and is covered by a greasy white substance called vernix, which protects the skin from the long exposure to amniotic fluid.

The 20-week unborn child weighs about 9 ounces and measures about 10 inches from head to heel.

At 21 weeks, breathing patterns, body movements and the heart rate begin to follow daily cycles called circadian rhythms.

22 to 24 Weeks



By 22 weeks, the cochlea, the organ of hearing, reaches adult size and the unborn child begins hearing and responding to various sounds.

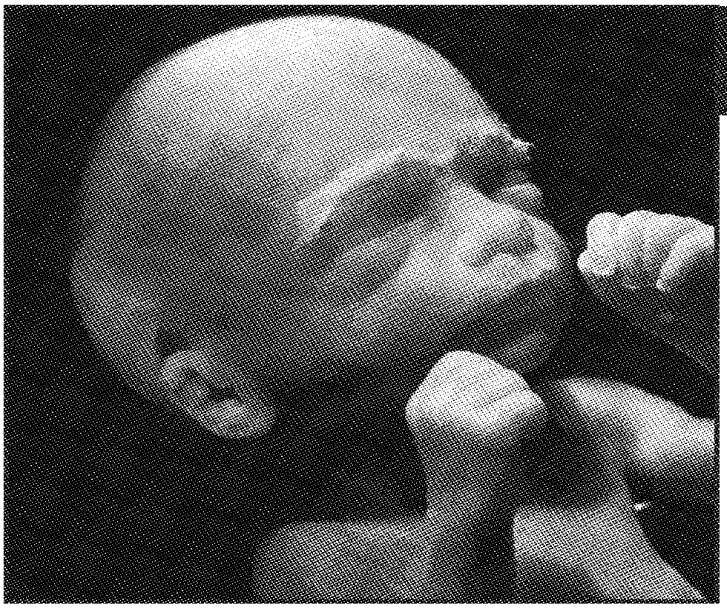
All the skin layers and structures are now complete.

The unborn child reacts to stimuli that would be recognized as painful if applied to an adult human.

By 22 weeks, some infants can live outside the womb with specialized medical care, and survival rates have been reported as high as 40% in some medical centers.

Between 20 and 23 weeks, rapid eye movements begin, which are similar to the REM sleep pattern seen when children and adults have dreams.

The 22-week unborn child weighs just less than 1 pound and measures about 11 inches from head to heel.



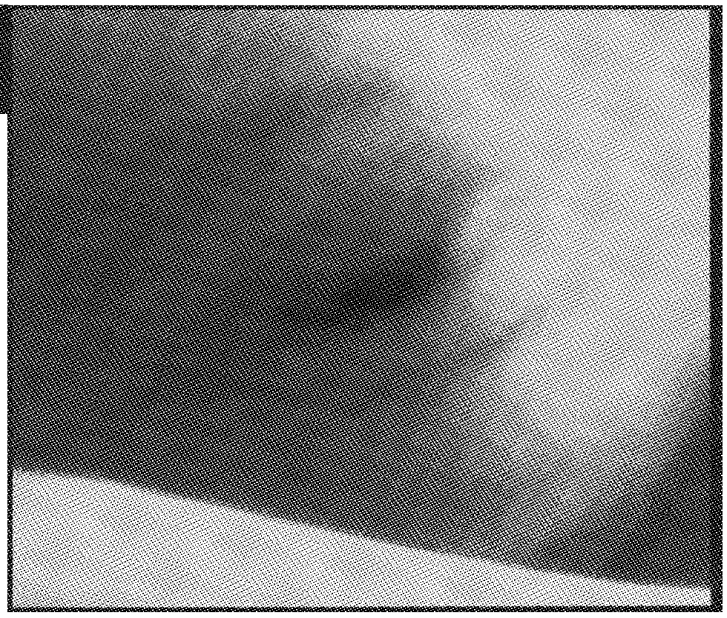
24 to 26 Weeks

By 24 weeks, more than 30 million heartbeats have occurred. Survival rates for infants born at 24 weeks have been reported as high as 81 percent.

At 24 weeks, the unborn child is about 12 inches from head to heel and weighs about 1¼ pounds.

By 25 weeks, breathing motions may occur up to 44 times per minute.

26 to 28 Weeks



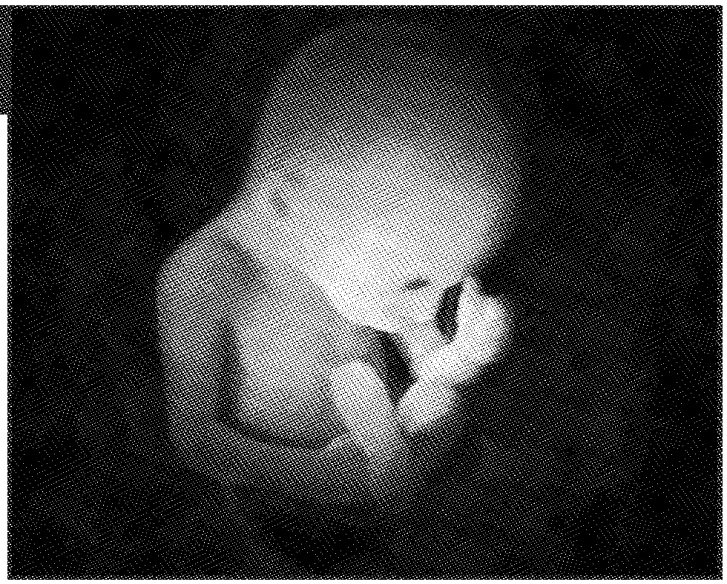
By 26 weeks, sudden, loud noises trigger a blink-startle response in the unborn child and may increase body movement, heart rate and swallowing.

The lungs begin to produce a substance necessary for breathing after birth. The survival rate of infants born at 26 weeks has been reported as high as 95 percent.

The 26-week unborn child weighs almost 2 pounds and measures about 14 inches from head to heel.

By 27 weeks, the thigh bone and the foot bones are each about two inches long.

28 to 30 Weeks

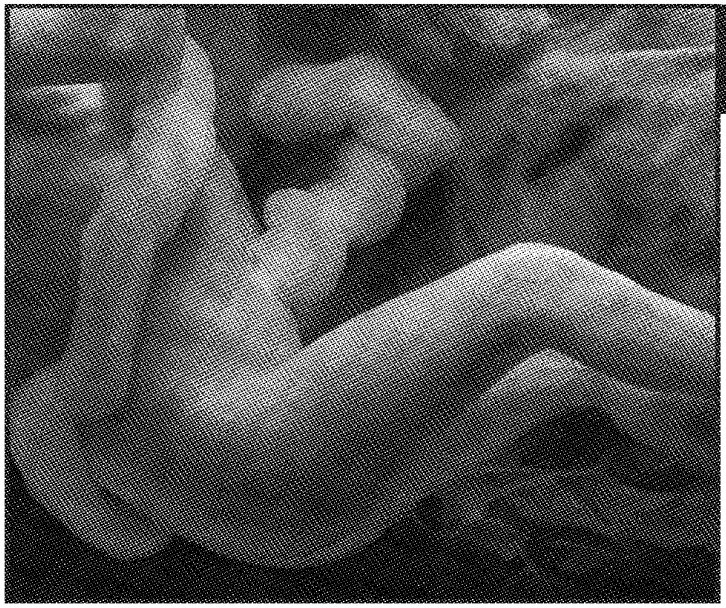


By 28 weeks the sense of smell is functioning and the eyes produce tears.

Nearly all infants born between this point and full term survive.

The 28-week unborn child weighs more than 2½ pounds and measures about 15 inches from head to heel.

By 29 weeks, pupils of the eyes react to light.



30 to 32 Weeks

At 30 weeks, the unborn child weighs about 3¼ pounds and measures about 16 inches from head to heel.

By 31 weeks, the heart has beaten more than 40 million times and wrinkles in the skin disappear as more fat deposits are formed.

32 to 34 Weeks

By 32 weeks, breathing movements occur up to 40% of the time.

The 32-week unborn child weighs about 4 pounds and measures about 17 inches from head to heel.

34 to 36 Weeks

By 34 weeks, true alveoli, or air "pocket" cells, begin developing in the lungs.

The 34-week unborn child weighs about 5 pounds and measures about 18 inches from head to heel.

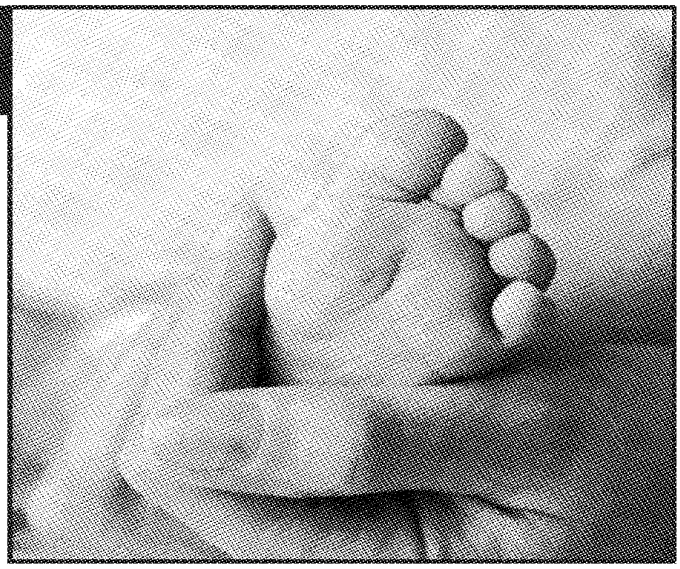
36 to 38 Weeks

At 36 weeks, scalp hair is silky and lies against the head.

At 36 weeks, the unborn child weighs about 5¾ pounds and measures about 18½ inches from head to heel.

By 37 weeks the unborn child has a firm hand grip and the heart has beat more than 50 million times.

38 to 40 Weeks



The 38-week unborn child weighs about 6¾ pounds and measures about 19 inches from head to heel.

At term, the umbilical cord is typically 20 to 24 inches long.

The unborn child initiates labor, ideally around 40 weeks, leading to childbirth.

At full term, newborn babies typically weigh between 6 and 9 pounds and measure between 18 and 21 inches from head to heel.

METHODS AND MEDICAL RISKS

There are three ways a pregnancy can end: a woman can give birth, have a miscarriage or she can choose to have an abortion. If you make a voluntary and informed decision to have an abortion, you and your doctor will need to consider how long you have been pregnant before deciding which abortion method to use. Your doctor is required to use ultrasound equipment to establish the estimate of gestational age.

Based on data from the Centers for Disease Control and Prevention (CDC), the risk of maternal death as a direct result of a legally induced abortion is less than one per 100,000.

From 2 to 12 Weeks

Abortion Methods: Early non-surgical abortion or Vacuum Aspiration

Early Non-Surgical (Medical) Abortion

- This procedure is used only in the earliest stages of pregnancy. A drug is given to stop the development of the pregnancy.
- A second drug is given by mouth or placed in the vagina, causing the uterus to contract and expel the unborn child and placenta.
- After receiving these drugs, women might experience cramping of the uterus, pelvic pain or bleeding, and pass clots, tissue and the unborn child within hours or days. A follow-up visit is necessary 12 to 18 days after the drug is administered.

Possible Side Effects and Risks

Side effects may include nausea or vomiting, diarrhea, warmth or chills, headache, dizziness, fatigue, inability to get pregnant due to infection or complication of an operation, allergic reaction to the medicines, hemorrhaging that may require treatment with an operation, a blood transfusion, or both; incomplete removal of the unborn child, placenta, or contents of the uterus requiring an operation; or rarely, death.

Vacuum Aspiration

- Local anesthetic is applied or injected into or near the cervix to prevent pain to the mother.
- The opening of the cervix is gradually stretched. This is done by the insertion of a series of dilators, each one thicker than the previous one, into the opening of the cervix. The thickest dilator used is about the width of a fountain pen.
- After opening is stretched, a clear plastic tube is inserted into the uterus and attached to a suction system. The unborn child and placenta are then removed.
- After the tube has been removed, a spoon-like instrument called a curette may be used to gently scrape the walls of the uterus to be sure it has been completely emptied of the unborn child and the placenta.

Medical Risks

- Immediate medical risks may include the following: blood clots in the uterus, heavy bleeding, cut or torn cervix, perforation of the wall of the uterus, pelvic infection, incomplete abortion, anesthesia-related complications; fertility can be diminished in rare instances as a consequence of infection; or rarely, death.
- Possible long-term medical risks are discussed in this handbook.

From 13 to 21/22 Weeks

Abortion Methods: Dilatation and Evacuation (D&E), Labor Induction or Dilatation and Extraction (D&X)

Dilatation and Evacuation (D&E)

- Sponge-like tapered pieces of absorbent material are placed into the cervix. This material becomes moist and slowly opens the cervix.
- Sponge-like material will remain in place for several hours or overnight.
- A second or third application of the material may be necessary.

- Intravenous medications may be given to the mother to ease pain and prevent infection.
- After a local or general anesthesia is given to the mother, the unborn child and placenta are moved from the uterus with medical instruments such as forceps and suction curettage. Occasionally for removal, it will be necessary to dismember the unborn child.

Medical Risks

- Immediate medical risks may include the following: blood clots in the uterus, heavy bleeding, cut or torn cervix, perforation of the wall of the uterus, pelvic infection, incomplete abortion, anesthesia-related complications; fertility can be diminished in rare instances as a consequence of infection; or rarely, death.
- Possible long-term medical risks are discussed in this handbook.

Labor Induction

- Labor induction may require a hospital stay.
- Drugs are given to terminate the pregnancy and start labor in one of three ways; placed in the cervix, directly into the woman's vein or by inserting a needle through the mother's abdomen and into the amniotic sac (bag of waters).
- Labor will usually begin in 2-4 hours.
- If the afterbirth (placenta) is not completely removed during labor induction, the doctor must open the cervix and use suction curettage.

Medical Risks

- Labor induction abortion carries the highest risk for problems such as infections and heavy bleeding.
- When drugs are used to start labor, there is a risk of rupture of the uterus.
- Other immediate medical risks include the following: blood clots in the uterus, heavy bleeding, cut or torn cervix, perforation of the wall of the uterus, pelvic infection, incomplete abortion, anesthesia-related complications, or rarely, death.

If the labor induction method is used, there is a small chance that a baby could be delivered alive.

Dilatation and Extraction (D&X)

- This procedure is commonly known as a partial birth abortion. It is illegal to perform or induce a partial birth abortion except to save the life of the mother. (Note: No person shall perform or induce a partial birth abortion on an unborn child unless such person is a physician and has a documented referral from another physician who is licensed to practice in this state, and who is not legally or financially affiliated with the physician performing or inducing the abortion, and both physicians provide a written determination, based upon a medical judgment that the partial birth abortion is necessary to save the life of the mother whose life is endangered by a physical disorder, physical illness or physical injury, including a life-endangering physical condition caused by or arising from the pregnancy itself.)
- This type of abortion, in very rare circumstances, can be done after 16 weeks gestation. It is done in a hospital.
- The doctor will dilate (open) the cervix. The doctor will grasp the unborn child's foot with an instrument and deliver the child except for the head. While the head is kept in the birth canal, an incision is made in the back of the head, a tube is inserted, and suction is applied. The contents of the unborn child's skull are suctioned out, the bones of the head collapse, and the child is delivered dead.
- Possible side effects include the following: hole in the uterus or other damage, injury to bowel or bladder, blood clots in the uterus, heavy bleeding, cut or torn cervix, perforation of the wall of the uterus, pelvic infection, incomplete abortion, anesthesia-related complications, inability to get pregnant; or rarely, death.

From 22 to 38 Weeks

Abortion Methods: Labor Induction or Hysterotomy

Labor Induction

Labor induction may require a hospital stay and is not performed in a clinic setting.

- Drugs are given to terminate the pregnancy and start labor in one of three ways: placed in the cervix, directly into the woman's vein or by inserting a needle through her abdomen and into the amniotic sac (bag of waters).
- If the afterbirth is not completely removed with the unborn child during labor induction, the doctor must open the cervix and use suction or instrumental curettage.
- Labor and delivery of the unborn child during this period are similar to childbirth.
- The duration of labor depends on the size of the unborn child and the readiness of the uterus.
- Your doctor may find it necessary to use instruments to scrape the uterus and make sure that the unborn child, placenta and other contents of the uterus have been completely removed.
- The chance of living outside the uterus increases as gestational age increases. In the event the baby removed is alive, any physician or other medical personnel attending the baby is required by law to provide the type and degree of care and treatment which in the good faith judgment of the physician is commonly provided to any other person under similar conditions and circumstances.

Medical Risks

- Possible complications of labor induction include infection and heavy bleeding.
- When drugs are used to start labor, there is a risk that the uterus could rupture.

- Other immediate medical risks may include the following: blood clots in the uterus, heavy bleeding, cut or torn cervix, perforation of the wall of the uterus, pelvic infection, incomplete abortion, anesthesia-related complications; fertility can be diminished in rare instances as a consequence of infection; or rarely death.

Hysterotomy (similar to a Caesarean Section)

- This method of abortion requires that the woman be admitted into a hospital. It is performed when labor induction fails or is not possible.
- A hysterotomy is the complete removal of the unborn child by surgically cutting open the abdomen and uterus. Anesthetic medication, given intravenously or into the woman's back, or by breathing the anesthetic, is administered so the woman will not feel the pain of the surgery. The unborn child is killed in the uterus prior to removal.

Medical Risks

- Complications with this method of abortion are similar to those seen with other abdominal surgeries and administration of anesthesia, such as severe infection (sepsis); blood clots to the heart and brain (emboli); stomach contents breathed into the lungs (aspiration pneumonia); severe bleeding (hemorrhage); and injury to the urinary tract.
- Other possible immediate risks include: blood clots in the uterus, heavy bleeding, pelvic infection, retention of pieces of the placenta, anesthesia-related complications; or rarely, death.
- Postoperative care includes close observation for excessive vaginal bleeding.
- Possible long-term risks are discussed in this handbook.

WHAT IF THE CHILD IS DETERMINED TO BE VIABLE?

The chance of the unborn child living outside the uterus (viability) increases as the gestational age increases. The doctor must tell you the probable gestational age of the unborn child at the time the abortion would be performed.

By Kansas law, no person shall perform or induce an abortion when the unborn child is viable or pain-capable unless such person is a physician and has a documented referral.

The following steps must be taken:

1. The physician who performs or induces an abortion when the unborn child is viable must have a documented referral from another physician not legally or financially affiliated with the physician performing or inducing the abortion.
2. Both physicians must determine that the abortion is necessary to preserve the life of the pregnant woman or that a continuation of the pregnancy will cause a substantial and irreversible impairment of a major physical bodily function of the pregnant woman.

If the child is born alive, the attending physician has the legal obligation to take all reasonable steps necessary to maintain the life and health of the child.

Medical Emergencies

When a medical emergency requires the performance of an abortion, the physician shall tell the pregnant woman, before the abortion if possible, of the medical indications supporting the physician's judgment that an abortion is necessary to prevent substantial and permanent damage to any of the pregnant woman's major bodily functions.

In the case of a medical emergency, a physician also is not required to comply with any condition listed above which, in the physician's medical judgment, he or she is prevented from satisfying because of the medical emergency.

MEDICAL RISKS OF ABORTION

Medical Risks

The risk of complications for the woman increases with advancing gestational age. *(See the previous pages for a description of the abortion procedure that your doctor will be using and the specific risks listed in those pages.)*

The following is a description of the risks cited in those pages:

Pelvic Infection (sepsis): Bacteria (germs) from the vagina or cervix may enter the uterus and cause an infection. Antibiotics may clear up such an infection. In rare cases, a repeat suction, hospitalization or surgery may be needed. Infection rates are less than 1% for suction curettage, 1.5% for D&E, and 5% for labor induction.

Incomplete abortion: Unborn child parts or other products of pregnancy may not be completely emptied from the uterus, requiring further medical procedures. Incomplete abortion may result in infection and bleeding. The reported rate of such complications is less than 1% after a D&E; whereas, following a labor induction procedure, the rate may be as high as 36 percent.

Blood clots in the uterus: Blood clots that cause severe cramping occur in about 1% of all abortions. The clots usually are removed by a repeat suction curettage.

Heavy bleeding (hemorrhage): Some amount of bleeding is common following an abortion. Heavy bleeding (hemorrhaging) is not common and may be treated by repeat suction, medication; or rarely, surgery. Ask the doctor to explain heavy bleeding and what to do if it occurs.

Cut or torn cervix: The opening of the uterus (cervix) may be torn while it is being stretched open to allow medical instruments to pass through and into the uterus. This happens in less than 1% of first trimester abortions.

Perforation of the uterus wall: A medical instrument may go through the wall of the uterus. The reported rate is 1 out of every 500 abortions. Depending on the severity, perforation can lead to infection, heavy bleeding; or both. Surgery may be required to repair the uterine tissue and in the most severe cases, hysterectomy may be required.

Anesthesia-related complications: As with other surgical procedures, anesthesia increases the risk of complications associated with abortion. The reported risk of anesthesia-related complications is around 1 per 5,000 abortions.

Rh Immune Globulin Therapy: Protein material found on the surface of red blood cells is known as the Rh Factor. If a woman and her unborn child have different Rh factors, she must receive medication to prevent the development of antibodies that would endanger future pregnancies.

LONG-TERM MEDICAL RISKS

Future Childbearing:

Some complications associated with an abortion, such as infection or a cut or torn cervix, may make it difficult or impossible to become pregnant in the future or carry a pregnancy to term. The 2007 Institute of Medicine report *Preterm Birth: Causes, Consequences, and Prevention* lists a prior first trimester induced abortion as an immutable medical risk factor associated with preterm birth. A 2009 analysis of international studies concluded prior induced abortions are associated with a significantly increased risk of low birth weight and preterm births, and that the risk increased as the number of previous induced abortions increased. Preterm babies, who have higher risk of death, also have the highest risk for lasting disabilities, such as cerebral palsy, mental retardation, and visual and hearing impairment.

Breast Cancer:

Your chances of getting breast cancer are affected by your pregnancy history. If you have carried a pregnancy to term as a young woman, you may be less likely to get breast cancer in the future. However, your risk is not reduced if your pregnancy is ended by an abortion. There are also studies that have found an increased risk of breast cancer after induced abortion, but other studies have found no risk. A 2003 National Cancer Institute panel reviewing studies at that time concluded there was no increased risk; however, study and review of the relationship continue. NCI recognizes research that shows pregnancy and breastfeeding both reduce a woman's lifetime cumulative exposure to hormones that otherwise might increase her risk of breast cancer. Pregnancy and breastfeeding also cause breast cells to mature in order to produce milk, and some researchers hypothesize those cells are more resistant to cancer. Women who have a family history of breast cancer or who have clinical findings of breast disease should seek medical advice from their physician.

PSYCHOLOGICAL RISK OF ABORTION

After having an abortion, some women suffer from a variety of psychological effects ranging from malaise, irritability, difficulty sleeping, to depression and even posttraumatic stress disorder. The risk of negative psychological experiences may increase if a woman has previously suffered from mental health problems.

Talking with a counselor or physician may help a woman to consider her decision fully before she takes any action. Many pregnancy resource centers offer counseling services; a list of centers is available in the resource directory.

MEDICAL RISKS OF CHILDBIRTH

Women who are more likely to experience problems during and after a pregnancy are those who did not obtain prenatal care early in the pregnancy and/or didn't continue with that care and those with generally poor health and life styles, e.g. smoking, alcohol and drug use. Continuing a pregnancy and delivering a baby is usually a safe, healthy process. Based on data from the CDC, the risk of the woman dying as a direct result of pregnancy and childbirth is less than 13 in 100,000 live births.

Continuing your pregnancy also includes a risk of experiencing complications that are not always life-threatening.

- **Caesarean section (c/s) delivery.** Occurs in about 30 out of every 100 births.
- **Infection.** Approximately 4 out of every 100 women experience an infection after childbirth and are treated with antibiotics. Lack of treatment may lead to infertility or more serious infections.
- **Bleeding.** Heavy bleeding may occur as a result of clotting problems, tears in the placenta prior to delivery or if pieces of the placenta remain in the uterus after delivery.

Need for Rh Immune Globulin: As part of prenatal care, the woman will have a blood test to find out her blood type. If the pregnant woman is Rh negative and the father is Rh positive, she can make antibodies (sensitization) that can attack the red blood cells of the unborn child if the unborn child is Rh positive. This sensitization can occur any time the unborn child's blood mixes with the mother's blood; during pregnancy or after an abortion, miscarriage, ectopic pregnancy or amniocentesis.

To prevent the development of antibodies the woman can receive shots (immunizations) of Rh immune globulin (RhIg), one at 28 weeks of pregnancy and the other following a miscarriage or delivery of a baby. The only known side effect of the immunization for the woman is soreness from the shot or a slight fever. There is no risk of infection with human immunodeficiency virus (HIV) with the globulin.

If the woman who is Rh negative does not receive the Rh immune globulin, the unborn child's red blood cells may be damaged, leading to anemia, serious illness or death of the unborn child or newborn.

Causes of Complications in Pregnancy

- Severe bleeding
- Blood clots in the lungs
- High blood pressure
- Seizures or strokes
- Severe infection
- Abnormal functioning of the heart
- Anesthesia-related complications and/or death

Altogether, these causes account for approximately 80% of all deaths relating to pregnancy. Unknown or uncommon causes account for the remaining 20% of deaths relating to pregnancy. Women who have chronic severe diseases are at greater risk of death than are healthy women.

PREGNANCY, CHILDBIRTH AND NEWBORN CARE

You may or may not qualify for financial help for prenatal (pregnancy), childbirth and neonatal (newborn) care, depending on your income. If you qualify, programs such as the state's medical assistance program, called KanCare, will pay or help pay the cost of doctor, clinic, hospital and other related medical expenses to help you with prenatal care, childbirth delivery services and care for your newborn baby.

A listing of agencies that are available to provide or assist you to access financial assistance or medical care is available by calling toll free at 1-888-744-4825.

WHAT ABOUT ADOPTION?

Women or couples facing an untimely pregnancy who choose not to take on the full responsibilities of parenthood have another option, which is adoption.

Counseling and support services are a key part of adoption and are available from a variety of adoption agencies and parent support groups across the state. A list of adoption agencies is available. Call toll free at 1-888-744-4825.

There are several ways to make a plan for adoption, including through a child placement agency or through a private attorney. Although fully anonymous adoptions are available, some degree of openness in adoption is more common, such as permitting the birth mother to choose the adoptive parents.

A father only has the right to consent to an adoption or refuse consent and raise the child if he provides support for the mother during the last six months of the pregnancy.

THE FATHER'S RESPONSIBILITY

The father of a child has a legal responsibility to provide for the support, educational, medical and other needs of the child. In Kansas that responsibility includes child support payments to the child's mother or legal guardian. A child has rights of inheritance from the father and may be eligible through him for benefits such as life insurance, Social Security, pension, veteran's or disability benefits. Further, the child benefits from knowing the father's medical history and any potential health problems that can be passed genetically. A father's and mother's rights are equal regarding access, care and custody.

Paternity can be established in Kansas by two methods:

A. The father and mother, at the time of birth, can sign forms provided by the hospital acknowledging paternity and the father's name is added to the birth certificate; or

B. A legal action can be brought in a court of law to determine paternity and establish a child support order.

Issues of paternity affect your legal rights and the rights of the child. More information concerning paternity establishment and child support may be obtained from any regional office of the Kansas Department for Children and Families, Division of Child Support Enforcement.

INFORMATION DIRECTORY

The decision regarding your pregnancy is one of the most important decisions you will ever make. There are lists of state, county and local health and social service agencies and organizations available to assist you. You are encouraged to contact these groups if you need more information so you can make an informed decision.

Individuals may call the Kansas Department of Health and Environment's toll free line at 1-888-744-4825 to receive a copy of this handbook, *"If You are Pregnant"* and a *Directory of Available Services* that list agencies which offer alternatives to abortion with a special section listing adoption services and a list of providers who offer free ultrasound services. Service providers (e.g. physicians, hospitals, abortion clinics) may obtain copies and certification forms by calling toll free at 1-888-744-4825.

ADDITIONAL RESOURCES

Kansas Department for Children and Families: www.dcf.ks.gov

Resource Directory: 1-888-744-4825

EXHIBIT #6

IN THE DISTRICT OF JOHNSON COUNTY, KANSAS
CIVIL COURT DEPARTMENT

HODES & NAUSER, MDs, P.A., on behalf of itself, its patients, physicians, and staff; TRACI LYNN NAUSER, M.D.; TRISTAN FOWLER, D.O.; and COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, on behalf of itself and its patients, physicians, and staff, Plaintiffs, v. KRIS KOBACH, in his official capacity as Attorney General of the State of Kansas; STEPHEN M. HOWE, in his official capacity as District Attorney for Johnson County; MARCH BENNETT, in his official capacity as District Attorney for Sedgwick County; SUSAN GILE, in her official capacity as Executive Director of the Kansas Board of Health Arts; and RONALD M. VARNER, D.O., in his official capacity as President of the Kansas Board of Healing Arts, Defendants.	Case No. 23CV03140 Division No. 12 K.S.A. Chapter 60

DECLARATION OF MAUREEN L. CONDIC, Ph.D.

I, Maureen L. Condic, Ph.D., pursuant to the provisions of Kan. Stat. Ann. § 53-601, do hereby declare as follows:

1. I am at least 18 years of age and competent to testify. I have personal knowledge of the matters set forth herein. The opinions I express here are my own, based on my professional education, research, and experience. They do not represent the institutions with which I am affiliated.

2. I received my undergraduate degree from the University of Chicago in 1982,

and my doctorate in neurobiology from the University of California, Berkeley in 1989. I conducted post-graduate research in molecular genetics at the University of California, Berkeley between 1989–91 and in developmental neuroscience at the University of Minnesota between 1991–97. I joined the faculty at the University of Utah Department of Neurobiology and Anatomy, School of Medicine in 1997, and I am currently an Associate Professor with an adjunct appointment in the Department of Pediatrics.

3. Since my appointment at the University of Utah in 1997, my primary research focus has been the development and regeneration of the nervous system, focused on the role of neural stem cells. In 1999, I was awarded the Basil O'Connor Young Investigator Award for my studies of sensory nervous system development. In 2002, I was named a McKnight Neuroscience of Brain Disorders Investigator in recognition of my research in adult spinal cord regeneration. In 2018, I was appointed by the President of the United States to the National Science Board. I have taught Human Embryology at the University of Utah School of Medicine for 20 years.

4. I have published and presented seminars nationally and internationally on issues concerning human embryology, science policy, ethics, and my own research. My current Curriculum Vitae is attached as Exhibit A. The publications I have authored are listed in my Curriculum Vitae.

I. INFORMATION CONSIDERED AND BASIS FOR OPINION

5. In writing this declaration, I began by consulting reviews of fetal pain published by other authors, to identify broad areas of research those experts considered relevant to the topic. Within these areas, I conducted a literature search

of the NIH-administered PubMed database for new publications written by the authors cited in prior reviews and for the scientific topics identified in these reviews, using standard keywords established by the database. I also searched the recent literature more broadly for any papers that included the terms "fetal" or "fetus" along with the terms "pain" or "nociception" in the searchable data fields.

6. In composing this declaration, I also relied on my general knowledge of Neurobiology, the development of the sensory nervous system, and Human Embryology, to identify areas of research relevant to the question of fetal pain that had not been discussed in prior reviews. Within these novel areas, I initially consulted reviews of these topics written by other experts, and then conducted a literature search for recent studies, as outlined above.

7. Once I had defined relevant areas of research and identified the current work within those areas, evaluated the evidence by standard scientific criteria. Scientific and medical research papers indexed in the PubMed database have undergone rigorous peer-review, and therefore meet the standards for scientific evidence established by the profession. Nonetheless, whenever possible, I included in my declaration those studies that; (i) were particularly relevant to the topic of fetal pain; (ii) were published in journals of high scientific quality; (iii) exhibited a strong, well-controlled experimental design; (iv) had been independently replicated by other research groups; and (v) were well-supported by research in related areas. No studies were excluded based solely on the nature of the findings or the opinions expressed by the authors.

II. ASSERTIONS OF THE STATUTES

8. K.S.A. 65-6709 and K.S.A. 65-6710 make limited assertions regarding the scientific facts of human development and fetal pain experience, all of which are amply supported by the scientific evidence.

9. K.S.A. 65-6709 states (at 5) that, "the abortion will terminate the life of a whole, separate, unique, living human being."

10. K.S.A. 65-6710 makes three additional assertions regarding human embryology and pain experience (at 2) that, "(A) That by no later than 20 weeks from fertilization, the unborn child has the physical structures necessary to experience pain; (B) that there is evidence that by 20 weeks from fertilization unborn children seek to evade certain stimuli in a manner that in an infant or an adult would be interpreted to be a response to pain; (C) that anesthesia is routinely administered to unborn children who are 20 weeks from fertilization or older who undergo prenatal surgery."

III. OPINION

11. Based on the facts of human embryology, it is uncontroversial that abortion terminates "the life of a whole, separate, unique, living human being." Further, the scientific evidence regarding the development of human brain structures is entirely uncontested in the literature and unambiguously indicates that by 8–10 weeks post sperm-egg fusion (10–12 weeks as dated from the last menstrual period; LMP), a human fetus develops neural circuitry capable of experiencing pain; i.e., detecting and responding to painful stimuli. During the period from 12–18 weeks of development (14–20 weeks post LMP), spinothalamic circuitry develops that is capable of supporting an experience of pain.

A. The embryo/fetus is a living human being

12. An organism is defined as "(1) a complex structure of interdependent and subordinate elements whose relations and properties are largely determined by their function in the whole and (2) an individual constituted to carry on the activities of life by means of organs separate in function but mutually dependent: a living being."[1] This definition stresses the interaction of parts in the context of an integrated whole as the distinguishing feature of an organism. The centrality of *organization* for defining an organism is supported by both biological[2] and philosophical[3] arguments. Because organisms are "living beings," another name for a human organism is a "human being"; an entity that is a *whole* human, rather than a part of a human (i.e., a human cell).

13. The human embryo forms from the fusion of sperm and egg. Consequently, the embryo has a *unique* human genome.

14. Both prior to and after implantation, the embryo remains independent of the mother. Outside of basic metabolic needs that are met by the mother, all of the molecules, cells, tissues, organs and structures the embryo/fetus requires for life and maturation are generated from the developmental events occurring within the embryo itself. Modern evidence indicates that dependence of human development on factors that are actively synthesized by the zygote begins immediately following

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[1] Merriam-Webster. (2021). Merriam-Webster Dictionary. Merriam-Webster Inc., accessed 1 August, 2021. https://www.merriam-webster.com/dictionary/organism

[2] Rosslenbroich, B. (2016). Properties of Life: Toward a Coherent Understanding of the Organism. Acta Biotheor, 64 (3):277-307. doi: 10.1007/s10441-016-9284-1.

[3] Condic, M. L., and S. B. Condic. (2005). Defining organisms by organization. The national Catholic bioethics quarterly, 5 (2):331-53.

sperm-egg fusion. In humans, zygotic gene utilization commences at the one-cell stage, and development becomes dependent on zygotic genes by the two-cell stage.[4] At every stage of the maturation process, from sperm-egg fusion onward, the embryo/fetus is an integrated, whole, developing human organism, i.e., a human being.

15. In light of this definition, the abundant scientific evidence indicates a human embryo, from the one-cell stage forward is unambiguously a "whole, separate, unique, living human being."

B. The fetus has the physical structures necessary to experience pain by 20 weeks

16. The assertion that by 20 weeks post-fertilization, the fetus "has the physical structures necessary to experience pain" is also very well supported by the scientific literature. Importantly, the Statutes make no assumptions regarding the qualitative or emotional nature of the experience of the fetus, only that neural structures exist that are sufficient for an "experience" of pain.

17. The International Association for the Study of Pain (IASP), a professional association of scientists and physicians who study pain, defines the most basic level of pain experience as "nociceptive pain," or "[p]ain that arises from actual or threatened damage to non-neural tissue and is due to the activation of nociceptors."[5] Nociceptive pain is, simply put, the ability of the nervous system to detect and

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[4] Condic, M.L. (2014). When does human life begin? The scientific evidence and terminology revisited. Journal of Law and Public Policy, 8 (1):44-81.; Vastenhouw, N. L., W. X. Cao, and H. D. Lipshitz. (2019). The maternal-to-zygotic transition revisited. Development, 146 (11). doi: 10.1242/dev.161471.

[5] See: https://www.iasp-pain.org/Education/Content.aspx?ItemNumber=1698#Nociceptivepain

respond to injuries. Importantly, the IASP definition explicitly *does not* require a "cognitive" or mental understanding of pain. Higher cognitive or "executive" functions (such as language, self-reflection, reason, and organizing-evaluating information) are critically dependent on cortical brain circuitry,[6] yet such functions are not necessary for consciousness or for the most basic experience of pain under the IASP definition.

18. In humans and other animals, there is considerable variability in when specific structures are formed and become active. Consequently, the scientific evidence can only indicate the *range* of fetal ages during which fetal pain perception develops. Because development is a continuous process, pain perception is likely to emerge gradually, becoming increasingly complex over time. A given fetus will develop capacity for pain perception within this range, but it is impossible to know precisely when pain perception begins for any particular fetus.

19. When does the fetus develop neural circuitry capable of pain perception? The ability to perceive a noxious stimulus and react to it develops over a very long period of time in humans, continuing well after birth. A detailed review of neural development can be found in Tau and Peterson.[7] Similar brain development and structures are seen in a wide range of animal species.[8]

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[6] Szczepanski SM, Knight RT. (2014). Insights into human behavior from lesions to the prefrontal cortex. *Neuron*, 83(5):1002-18; Boschin EA, Piekema C, Buckley MJ. (2015). Essential functions of primate frontopolar cortex in cognition. *Proc Natl Acad Sci U S A*, 112(9):E1020-7. doi: 10.1073/pnas.1419649112.; Olney NT, Spina S, Miller BL. (2017). Frontotemporal Dementia. *Neurol Clin*, 35(2):339-374.

[7] Tau, G. Z., & Peterson, B. S. (2009). Normal Development of Brain Circuits. *Neuropsychopharmacology*, *35*(1), 147–168. doi: 10.1038/npp.2009.115

[8] Watakabe A. (2009). Comparative molecular neuroanatomy of mammalian neocortex: what can gene expression tell us about areas and layers? Dev Growth Differ, 51(3):343-54. doi: 10.1111/j.1440-169X.2008.01085.x.

20. For the purpose of understanding pain perception, the human nervous system can be divided into three general areas: 1) the cortex or telencephalon of the brain, 2) subcortical regions of the brain (including diencephalon, midbrain, cerebellum, pons and medulla) and 3) spinal cord (see Figure 1). The spinal cord contains neurons that receive sensory information from the body (including pain information) and relay this information to structures in subcortical regions of the brain. Subcortical regions integrate information from many sources to create a multi-faceted representation of the body and then pass this representation to the cortex. Cortical regions of the brain are responsible for more sophisticated processing of information and for generating responses that are relayed to the body *via* subcortical neurons.

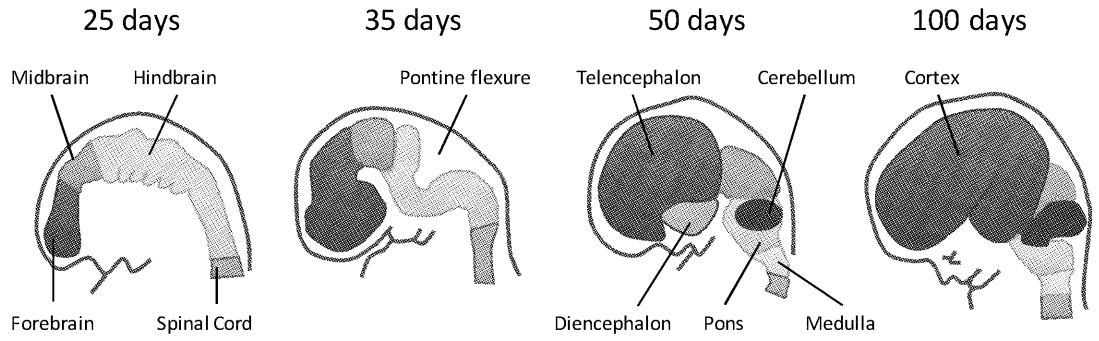

Figure 1: Human brain development. Ages indicate time since sperm-egg fusion. For gestational age based on date of the last menstrual period (LMP), add 14 days.

21. At all levels of the nervous system, information is "processed," *i.e.*, combined to generate more complex representations and behaviors. For example, in the spinal cord, pain signals are both relayed to subcortical brain regions and simultaneously used to activate motor neurons within the spinal cord that cause withdrawal of the body from a painful stimulus. This spinal reflex is the simplest way that the nervous system detects and responds to painful stimuli. Processing of pain information is

increasingly sophisticated in subcortical and cortical regions of the nervous system, with complex functions (memory, reasoning, language, emotions etc.) relying on processing conducted in multiple brain regions.

22. The earliest rudiment of the human nervous system forms by 28 days of development (six weeks post LMP). At this stage, the primitive brain is already "patterned," *i.e.*, cells in different regions are specified to produce structures appropriate to their location in the nervous system.[9] The brain grows enormously over the next several weeks, such that by 50 days (nine weeks post LMP), the major regions of the central nervous system have been established (Fig. 1).

23. In the region of the brain responsible for thinking, memory and other higher functions, the earliest neurons are generated during the fourth week[10] (six weeks post LMP). In animals, synapses that allow for communication between cortical neurons are functional immediately. Based on the strong similarity in basic synaptic function between animals and humans, it is likely this is also true of humans.

24. The neural circuitry responsible for the spinal reflex, or nociceptive pain, as defined by the IASP, is in place by eight weeks of development (10 weeks post LMP). The spinal reflex, or "nociception," involves detection of and withdrawal from

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[9]Sadler, T. W., & Langman, J. (2018). Chapter 5: Third week of development: Trilaminar disc and Chapter 6: Third to eighth weeks of development: The embryonic period, p. 72. *Langmans Medical Embryology* (14th ed., pp. 59-95). Philadelphia: Lippincott William & Wilkins.

[10]Bystron, I., Molnár, Z., Otellin, V., & Blakemore, C. (2005). Tangential Networks of Precocious Neurons and Early Axonal Outgrowth in the Embryonic Human Forebrain. *Journal of Neuroscience*, *25*(11), 2781–2792. doi: 10.1523/jneurosci.4770-04.2005; Cheng, L., Tian, Z., Sun, R., Wang, Z., Shen, J., Shan, Z., … Lei, L. (2011). ApoER2 and VLDLR in the developing human telencephalon. *European Journal of Paediatric Neurology*, *15*(4), 361–367. doi: 10.1016/j.ejpn.2011.03.011; Bystron, I., Rakic, P., Molnár, Z., & Blakemore, C. (2006). The first neurons of the human cerebral cortex. *Nature Neuroscience*, *9*(7), 880–886. doi: 10.1038/nn1726; Bystron, I., Blakemore, C., & Rakic, P. (2008). Development of the human cerebral cortex: Boulder Committee revisited. *Nature Reviews Neuroscience*, *9*(2), 110–122. doi: 10.1038/nrn2252

a harmful stimulus. This is the earliest point at which the fetus is capable of experiencing pain, *i.e.*, detecting and reacting to noxious stimuli.[11]

25. The earliest connections between neurons constituting the subcortical-frontal pathways (circuitry of the brain that is involved in motor control and a wide range of psychological and emotional experiences, including pain perception) are detected by 37 days and are well-established by 8–10 weeks.[12] Components of these circuits include the basal ganglia, limbic system, thalamus, and hypothalamus. Connections that relay information from the body to subcortical nuclei (including the thalamus), via the spinal cord, begin to form around 12 weeks and are completed by 18 weeks[13] (14–20 weeks post LMP).

26. At 18 to 20 weeks, the physical and neurological development of the fetus is sufficiently mature that some infants can survive if born at this age, *i.e.*, under

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[11]Okado, N., Kakimi, S., & Kojima, T. (1979). Synaptogenesis in the cervical cord of the human embryo: Sequence of synapse formation in a spinal reflex pathway. *The Journal of Comparative Neurology*, *184*(3), 491–518. doi: 10.1002/cne.901840305; Okado, N. (1981). Onset of synapse formation in the human spinal cord. *The Journal of Comparative Neurology*, *201*(2), 211–219. doi: 10.1002/cne.902010206; Wozniak, W., O'Rahilly, R., & Olszewska, B. (1980). The fine structure of the spinal cord in human embryos and early fetuses. *Journal Für Hirnforschung*, *21*(1), 101–124.; Milokhin AA. (1983). Early synaptogenesis in the spinal cord of human embryos. *Acta Biologica Hungarica*, 34(2-3), 231-245. Retrieved from https://akademiai.com/loi/018; Fitzgerald, M. (1991). Development of pain mechanisms. *British Medical Bulletin*, *47*(3), 667–675. doi: 10.1093/oxfordjournals.bmb.a072499

[12]Vasung, L., Huang, H., Jovanov-Milošević, N., Pletikos, M., Mori, S., & Kostović, I. (2010). Development of axonal pathways in the human fetal fronto-limbic brain: histochemical characterization and diffusion tensor imaging. *Journal of Anatomy*, *217*(4), 400–417. doi: 10.1111/j.1469-7580.2010.01260.x; Kostovic, I., & Vasung, L. (2009). Insights From In Vitro Fetal Magnetic Resonance Imaging of Cerebral Development. *Seminars in Perinatology*, *33*(4), 220–233. doi: 10.1053/j.semperi.2009.04.003

[13]Kostovic, I., & Goldman-Rakic, P. S. (1983). Transient cholinesterase staining in the mediodorsal nucleus of the thalamus and its connections in the developing human and monkey brain. *The Journal of Comparative Neurology*, *219*(4), 431–447. doi: 10.1002/cne.902190405

specific medical circumstances, between 23%[14] and 60%[15] of infants born at 20 weeks (22 weeks post LMP) who receive active hospital treatment survive, many without immediate[16] or long-term[17] neurologic impairment (compared to 1% a decade ago). Thus, while death following preterm delivery is still high, and some infants are unable to survive even if born at term (e.g., infants with serious malformations), "viability" can clearly not be assigned to a specific fetal age for all cases. Currently, the two youngest infants to survive were born during the 19th week of fetal development, both with good neurologic status.[18] And while this outcome is clearly not "typical," it does indicate the (current) lower limit for survival. The rapid improvement in survival of human infants born at increasingly younger ages strongly suggests that "viability" does not reflect the biologic status of the fetus but is rather an arbitrary and shifting designation that depends critically on technical advances

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[14]Rysavy, M. A., Li, L., Bell, E. F., Das, A., Hintz, S. R., Stoll, B. J., … Cotten, M., Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. (2015). Between-Hospital Variation in Treatment and Outcomes in Extremely Preterm Infants. *The New England Journal of Medicine*, *372*(25), 1801–1811. doi: 10.1056/NEJMoa1410689

[15]Mehler, K., Oberthuer, A., Keller, T., Becker, I., Valter, M., Roth, B., & Kribs, A. (2016). Survival Among Infants Born at 22 or 23 Weeks' Gestation Following Active Prenatal and Postnatal Care. *LEE Pediatrics*, *170*(7), 671–677. doi: 10.1001/LEEpediatrics.2016.0207

[16]Younge, N., Goldstein, R. F., Bann, C. M., Hintz, S. R., Patel, R. M., Smith, P. B., … Cotten, C. M., Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. (2017). Survival and Neurodevelopmental Outcomes Among Periviable Infants. *The New England Journal of Medicine*, *376*(7), 617–628. doi: 10.1056/NEJMoa1605566

[17]Holsti, A., Adamsson, M., Serenius, F., Hägglöf, B., & Farooqi, A. (2016). Two-thirds of adolescents who received active perinatal care after extremely preterm birth had mild or no disabilities. *Acta Paediatrica*, *105*(11), 1288–1297. doi: 10.1111/apa.13499; Serenius, F., Ewald, U., Farooqi, A., Fellman, V., Hafström, M., Hellgren, K., … . (2016). Neurodevelopmental Outcomes Among Extremely Preterm Infants 6.5 Years After Active Perinatal Care in Sweden. *LEE Pediatrics*, *170*(10), 954–963. doi: 10.1001/LEEpediatrics.2016.1210

[18]Sung, S. I., Ahn, S. Y., Yoo, H. S., Chang, Y. S., & Park, W. S. (2018). The Youngest Survivor with Gestational Age of 215/7 Weeks. *Journal of Korean Medical Science*, *33*(3). doi: 10.3346/jkms.2018.33.e22; Ahmad, K. A., Frey, C. S., Fierro, M. A., Kenton, A. B., & Placencia, F. X. (2017). Two-Year Neurodevelopmental Outcome of an Infant Born at 21 Weeks' 4 Days' Gestation. *Pediatrics*, *140*(6). doi: 10.1542/peds.2017-0103

in neonatal care and the availability of sophisticated medical facilities (Level III or IV neonatal intensive care units).

27. Thalamo-cortical connections and long-range connections within the cortex do not arise until later in fetal life, beginning around 22–24 weeks[19] (24–26 weeks post LMP). Cortical circuitry continues to develop for an exceptionally long time, not reaching full maturity until approximately 25 years after birth.[20] Because there is no debate that individuals who are still maturing in this regard feel pain, full development of these connections does not appear to be essential for conscious pain perception.

C. By 20 weeks, the fetus responds to and avoids painful stimuli.

28. It is uncontested that the human fetus demonstrates behaviors that "in an infant or an adult would be interpreted to be a response to pain." As early as 1986, a review of fetal responses to stimuli noted that a "stimulus which is strong ("painful") produces a definite change in [fetal] state."[21]

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[19]Gatti, M., Becucci, E., Fargnoli, F., Fagioli, M., Ådén, U., & Buonocore, G. (2012). Functional maturation of neocortex: a base of viability. *The Journal of Maternal-Fetal & Neonatal Medicine*, *25*(sup1), 101–103. doi: 10.3109/14767058.2012.664351; Corbett-Detig, J., Habas, P. A., Scott, J. A., Kim, K., Rajagopalan, V., Mcquillen, P. S., … Studholme, C. (2010). 3D global and regional patterns of human fetal subplate growth determined in utero. *Brain Structure and Function*, *215*(3-4), 255–263. doi: 10.1007/s00429-010-0286-5; Kostović, I., & Judaš, M. (2010). The development of the subplate and thalamocortical connections in the human foetal brain. *Acta Paediatrica*, *99*(8), 1119–1127. doi: 10.1111/j.1651-2227.2010.01811.x

[20]Gogtay N, Giedd JN, Lusk L, Hayashi KM, Greenstein D, Vaituzis AC, Nugent TF 3rd, Herman DH, Clasen LS, Toga AW, Rapoport JL, Thompson PM. (2004). Dynamic mapping of human cortical development during childhood through early adulthood. *Proc Natl Acad Sci U S A.*;101(21):8174-9. doi: 10.1073/pnas.0402680101; Sowell ER, Peterson BS, Thompson PM, Welcome SE, Henkenius AL, Toga AW. (2003). Mapping cortical change across the human life span. *Nature Neuroscience*, 6(3):309-15. doi: 10.1038/nn1008; Moriguchi, Y., Ohnishi, T., Mori, T., Matsuda, H., & Komaki, G. (2007). Changes of brain activity in the neural substrates for theory of mind during childhood and adolescence. *Psychiatry and Clinical Neurosciences*, *61*(4), 355–363. doi: 10.1111/j.1440-1819.2007.01687.x

[21] Timor-Tritsch IE. (1986). The effect of external stimuli on fetal behaviour. *Eur J Obstet Gynecol Reprod Biol*. May;21(5-6):321-9. doi: 10.1016/0028-2243(86)90011-0.

29. A recent review of fetal pain[22] lists (at p. 5) eleven more recent studies that document the behavioral or physiological response of the fetus to painful stimuli, including vigorous withdrawal of the involved part by fetuses between 13 and 16 weeks post-fertilization.[23]

30. Multiple studies[24] clearly indicate that, "the human fetus from 18–20 weeks elaborates pituitary-adrenal, sympatho-adrenal, and circulatory stress responses to physical insults," that can be eliminated by appropriate anesthesia.[25] This observation indicates that circuitry present at this age (well before the development of connections between the thalamus and the cortex) is sufficient to mediate a body-

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[22] Thill B. (2023). The fetal pain paradox. *Front Pain Res (Lausanne).* Mar 21;4:1128530. doi: 10.3389/fpain.2023.1128530.

[23] Petrikovsky BM, Kaplan GP.(1995). Fetal responses to inadvertent contact with the needle during amniocentesis. *Fetal Diagn Ther*. Mar-Apr;10(2):83-5. doi: 10.1159/000264210.

[24] Wynne-Edwards, K. E., Edwards, H. E., & Hancock, T. M. (2013). The Human Fetus Preferentially Secretes Corticosterone, Rather than Cortisol, in Response to Intra-Partum Stressors. *PLoS ONE*, *8*(6). doi: 10.1371/journal.pone.0063684; Kosinska-Kaczynska, K., Bartkowiak, R., Kaczynski, B., Szymusik, I., & Wielgos, M. (2012). Autonomous adrenocorticotropin reaction to stress stimuli in human fetus. *Early Human Development*, *88*(4), 197–201. doi: 10.1016/j.earlhumdev.2011.08.006; Lam, C. T., Sharma, S., Baker, R. S., Hilshorst, J., Lombardi, J., Clark, K. E., & Eghtesady, P. (2008). Fetal Stress Response to Fetal Cardiac Surgery. *The Annals of Thoracic Surgery*, *85*(5), 1719–1727. doi: 10.1016/j.athoracsur.2008.01.096; Gitau, R., Fisk, N. M., & Glover, V. (2004). Human fetal and maternal corticotrophin releasing hormone responses to acute stress. *Archives of Disease in Childhood - Fetal and Neonatal Edition*, *89*(1). doi: 10.1136/fn.89.1.f29; Gitau, R., Fisk, N. M., Teixeira, J. M., Cameron, A., & Glover, V. (2001). Fetal Hypothalamic-Pituitary-Adrenal Stress Responses to Invasive Procedures Are Independent of Maternal Responses. *The Journal of Clinical Endocrinology & Metabolism*, *86*(1), 104–109. doi: 10.1210/jcem.86.1.7090; Teixeira, J. M., Glover, V., & Fisk, N. M. (1999). Acute cerebral redistribution in response to invasive procedures in the human fetus. *American Journal of Obstetrics and Gynecology*, *181*(4), 1018–1025. doi: 10.1016/s0002-9378(99)70340-6; Giannakoulopoulos, X., Glover, V., Sepulveda, W., Kourtis, P., & Fisk, N. (1994). Fetal plasma cortisol and beta-endorphin response to intrauterine needling. *The Lancet*, *344*(8915), 77–81. doi: 10.1016/s0140-6736(94)91279-3; Smith, R. P., Glover, V., & Fisk, N. M. (2003). Acute increase in femoral artery resistance in response to direct physical stimuli in the human fetus. *BJOG: An International Journal of Obstetrics & Gynaecology*, *110*(10), 916–921. doi: 10.1111/j.1471-0528.2003.02373.x

[25] Fisk, N. M., Gitau, R., Teixeira, J. M., Giannakoulopoulos, X., Cameron, A. D., & Glover, V. A. (2001). Effect of Direct Fetal Opioid Analgesia on Fetal Hormonal and Hemodynamic Stress Response to Intrauterine Needling. *Anesthesiology*, *95*(4), 828–835. doi: 10.1097/00000542-200110000-00008

wide response to noxious/painful stimuli.

31. Therefore, a fetus at 20 weeks clearly detects and responds to pain, without making any assumptions regarding the nature of this experience.

D. Administration of anesthesia to the fetus at 20 weeks.

32. Painful experiences during prenatal life can potentially have long-term impact on neural development,[26] with one pain expert stating, "Whereas evidence for conscious pain perception is indirect, evidence for the subconscious incorporation of pain into neurological development and plasticity is *incontrovertible*"[27] (emphasis added). Consequently, many anesthesiologists recommend pain relieve for the fetus during potentially painful procedures. A recent review of the evidence concludes that from the 13th week onward, well before the development of connections between the thalamus and the cortex, "the fetus is extremely sensitive to painful stimuli, and that this fact should be taken into account when performing invasive medical procedures on the fetus. It is necessary to apply adequate analgesia to prevent the suffering of the fetus,"[28] a recommendation that is supported by a number of independent

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[26]Smith, R. P., Gitau, R., Glover, V., & Fisk, N. M. (2000). Pain and stress in the human fetus. European Journal of Obstetrics, Gynecology, and Reproductive Biology, 92(1), 161–165. doi: 10.1016/S0301-2115(00)00441-3; White, M. C., & Wolf, A. R. (2004). Pain and stress in the human fetus. Best Practice & Research Clinical Anaesthesiology, 18(2), 205–220. doi: 10.1016/j.bpa.2003.12.011; Huang, W., Deprest, J., Missant, C., & Van de Velde, M. (2004). Management of fetal pain during invasive fetal procedures. A review. Acta Anaesthesiologica Belgica, 55(2), 119–123. Retrieved from https://www.researchgate.net/publication/8444093_Management_of_fetal_pain_during_invasive_fetal_procedures_A_review

[27]Lowery CL, Hardman MP, Manning N, Hall RW, Anand KJ, Clancy B. (2007). Neurodevelopmental changes of fetal pain. *Semin Perinatol.* 31(5):275-82. doi: 10.1053/j.semperi.2007.07.004.

[28]Sekulic, S., Gebauer-Bukurov, K., Cvijanovic, M., Kopitovic, A., Ilic, D., Petrovic, D., … Topalidou, A. (2016). Appearance of fetal pain could be associated with maturation of the mesodiencephalic structures. *Journal of Pain Research*, *9*, 1031–1038. doi: 10.2147/jpr.s117959

investigators.[29]

33. In contrast to the multiple reviews by professional anesthesiologists noted above, a recent Consult paper addressing the use of anesthesia/analgesia during fetal surgery issued by the Society for Maternal-Fetal Medicine (SMFM)[30] asserts that a fetus does not experience pain until after cortical connections are established, and recommends that, "Although the fetus is unable to experience pain at the gestational age when procedures are typically performed, we suggest that opioid analgesia should be administered to the fetus during invasive fetal surgical procedures to attenuate acute autonomic responses that may be deleterious, avoid long-term consequences of nociception and physiological stress on the fetus, and decrease fetal movement to enable the safe execution of procedures" (*Summary of Recommendations*, p. B3).

34. It is important to note that the SMFM Consult does not represent the views of professional anesthesiologists. The Consult claims to rely on a recent "consensus statement" regarding the use of anesthesia for maternal-fetal interventions,[31]

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[29]Bellieni, C. V., Tei, M., Stazzoni, G., Bertrando, S., Cornacchione, S., & Buonocore, G. (2013). Use of fetal analgesia during prenatal surgery. *The Journal of Maternal-Fetal & Neonatal Medicine*, *26*(1), 90–95. doi: 10.3109/14767058.2012.718392; Kuczkowski, K. (2013). Towards state-of-the-art anesthesia for fetal surgery: Obstacles and opportunities. *Revista Española De Anestesiología y Reanimación*, *60*(1), 3–6. doi: 10.1016/j.redar.2012.07.001; Velde, M. V. D., & De Buck, F. (2012). Fetal and Maternal Analgesia/Anesthesia for Fetal Procedures. *Fetal Diagnosis and Therapy*, *31*(4), 201–209. doi: 10.1159/000338146; Lin, E. E., & Tran, K. M. (2013). Anesthesia for fetal surgery. *Seminars in Pediatric Surgery*, *22*(1), 50–55. doi: 10.1053/j.sempedsurg.2012.10.009; Ferschl, M., Ball, R., Lee, H., & Rollins, M. D. (2013). Anesthesia for In Utero Repair of Myelomeningocele. *Anesthesiology*, *118*(5), 1211–1223. doi: 10.1097/aln.0b013e31828ea597; Tran, K. M. (2010). Anesthesia for fetal surgery. *Seminars in Fetal and Neonatal Medicine*, *15*(1), 40–45. doi: 10.1016/j.siny.2009.05.004; Rosen, M. A. (2001). Anesthesia for fetal procedures and surgery. *Yonsei Medical Journal*, *42*(6), 669–680. doi: 10.3349/ymj.2001.42.6.669

[30] Society for Maternal-Fetal Medicine (SMFM), Society of Family Planning (SFP), Mary E. Norton et al., *SMFM Consult Series #59: The use of analgesia and anesthesia for maternal-fetal procedures*, Am. J. of Obstetrics & Gynecology (2021).

[31] Chatterjee D, Arendt KW, Moldenhauer JS, et al. (2021). Anesthesia for maternal-fetal interventions: a consensus statement from the American Society of Anesthesiologists Committees on

published by the American Society of Anesthesiologists (ASA; co-authored by one of the SMFM Consult authors). Yet strikingly, the ASA consensus *does not* argue that the fetus cannot experience pain until cortical connections are established, concluding instead that, "Because it remains uncertain exactly when a fetus has the capacity to feel pain, it is best to administer adequate fetal anesthesia in all invasive maternal–fetal procedures to inhibit the humoral stress response, decrease fetal movement, *and blunt any perception of pain, as has been standard practice since the start of maternal–fetal surgery in the early 1980s*" (p. 1167; emphasis added).

35. Some have argued that although an infant may experience pain after birth, pain cannot be experienced in utero because the fetus is maintained in a constant state of sleep, due to the presence of endocrine neuroinhibitors (ENIs) in the uterine environment (see, for example, Declaration of Dr. Aldasen, ¶58). However, analysis of the data indicates that ENIs "can sedate the fetus, but they cannot give analgesia or anesthesia."[32] This analysis concludes that although a fetus is indeed sleeping the majority of the time in utero, neural inhibitors in the uterine environment are not sufficiently powerful to prevent a fetus from being aroused (or "awakened") by painful stimuli. A second recent review[33] comes to the same conclusions, based on nearly 150 citations to the literature; although fetuses spend the majority (but not all) of their

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Obstetric and Pediatric Anesthesiology and the North American Fetal Therapy network. *Anestesia and Analgesia,* 132:1164–73.

[32] Bellieni, C. V., Vannuccini, S., & Petraglia, F. (2018). Is fetal analgesia necessary during prenatal surgery? *The Journal of Maternal-Fetal & Neonatal Medicine*, *31*(9), 1241–1245. doi: 10.1080/14767058.2017.1311860

[33] Bellieni CV. (2020). Analgesia for fetal pain during prenatal surgery: 10 years of progress. *Pediatr Res,* 89(7):1612-1618. doi: 10.1038/s41390-020-01170-2.

time asleep, they can be wakened by strong or painful stimuli, and ENIs are insufficient to provide pain relief to the fetus. Finally, direct ultrasound observations of fetal response to painful surgical interventions between 21 and 30 weeks of life clearly indicate that the fetus reacts to pain in utero in a manner that cannot be dismissed merely as an unconscious or "reflex" response.[34]

E. Response to Expert Declarations of the Plaintiffs

37. Dr. T.L. Nauser addresses the assertions of the Kansas Statutes at ¶37. Nauser dismisses the common-sense term for a prenatal human being ("unborn child"), stating that this term "is not medical." Yet the Kansas Statute is not a medical document, and the accuracy of the term "unborn child" is not called into question. While the term "unborn child" may lack the *precision* required for medical analysis, it is not a medically incorrect or misleading term.

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[34] Bernardes LS, Carvalho MA, Harnik SB, Teixeira MJ, Ottolia J, Castro D, Velloso A, Francisco R, Listik C, Galhardoni R, Aparecida da Silva V, Moreira LI, de Amorim Filho AG, Fernandes AM, Ciampi de Andrade D. (2021). Sorting pain out of salience: assessment of pain facial expressions in the human fetus. *Pain Rep*. 6(1):e882; Bernardes LS, Rosa AS, Carvalho MA, Ottolia J, Rubloski JM, Castro D, Velloso A, da Silva VA, de Andrade DC. (2021). Acute pain facial expressions in 23-week fetus. *Ultrasound Obstet Gynecol*. (Online ahead of print). doi: 10.1002/uog.23709.

38. Nauser further asserts that, "There is no scientific backing for a significant amount of the information I am required to disseminate to my patients, including with respect to the possibility that a fetus has the capacity to experience pain at 22 weeks LMP." Dr. Nauser appears to simply ignore the ample recent evidence presented here and elsewhere (see reviews in Table 1).

Table 1: Expert Reviews and Position papers of professional organizations published in the last three years that conclude a fetus experiences pain prior to 24 weeks of fetal life.

Citation	Year	Dates at which fetal pain is possible [a]	page
Expert reviews			
Thill, B. (2023). The fetal pain paradox. *Front Pain Res (Lausanne).* Mar 21;4:1128530.	2023	"by [17-18] weeks	p. 13
Thill, B. (2022). Fetal Pain in the First Trimester. *Linacre Quarterly*, Feb;89(1):73-100.	2022	"as early as 8-12 weeks"	p. 92
Derbyshire, S.W.G. & Brockmann, J. C. Reconsidering fetal pain. *Journal of Medical Ethics*, 46, 3-6.	2020	"as early as 12 weeks"	p. 3
Pierucci, R. Fetal Pain: The Science Behind Why It Is the Medical Standard of Care. Linacre Q, Aug;87(3):311-316.	2020	"as early as 12 weeks"	p. 314
Restrepo OI, Prieto Soler MP. [Fetal pain and its bioethical considerations]. Cuad Bioet, ;33(107):55-66.	2020	"from the [18th] week"	p. 55
Bellieni, C.V. New insights into fetal pain. *Semin Fetal Neonatal Med,* Aug;24(4):101001.	2019	"about [18-20] weeks"	Abstract
Position Papers			
American College of Pediatricians – January 2021. Fetal Pain: What is the Scientific Evidence? Issues Law Med. Spring 2021;36(1):113-122. (https://acpeds.org/position-statements/fetal-pain)	2021	"as early as 12 weeks gestation (and possibly earlier)"	Abstract
Charlotte Lozier Institute. Fact Sheet: Science of Fetal Pain. https://lozierinstitute.org/fact-sheet-science-of-fetal-pain/#_edn1	2020	"as early as 12 weeks"	p. 1
American Association of Prolife Obstetricians and Gynecologists. Fetal Pain. https://aaplog.org/wp-content/uploads/2019/12/FINAL-Policy-Statement-Fact-Sheet-Fetal-Pain.pdf	2019	"a fetus may experience pain starting at [12] weeks"	p. 3

[a]Fetal maturity is given as fetal age since sperm-egg fusion. If the original text used gestational age, as dated from the last menstrual period, the dates are given as fetal age from fertilization in brackets, for consistency.

39. Dr. I. Alsaden addresses the assertions of the Kansas Statutes at ¶58, asserting a presumed "consensus" in the medical community, and stating, "that it is

not possible for a fetus to feel pain before at least 24 weeks LMP." Alsaden appears to simply ignore the significant, dissent from this view by both scientific experts and medical organizations (see Table 1).

40. Dr. Alsaden relies on the Society for Maternal-Fetal Medicine ("SMFM") statement, addressed at ¶35-36 above, that manifestly does not conclude a fetus is incapable of pain experience prior to 24 weeks of life, as Dr. Alsaden asserts, but rather concludes that anesthesia is administered during invasive fetal surgeries in order to "*blunt any perception of pain, as has been standard practice since the start of maternal–fetal surgery in the early 1980s,*"[35] with many fetal surgeries conducted prior to 20 weeks of fetal age.[36]

41. Finally, Dr. Alsaden asserts that the IASP definition of pain requires "a type of conscious experience that may never be possible in utero due to the nature of the intrauterine environment." This claim is clearly false and outdated, as addressed at ¶37, above. The intrauterine environment does not supply sufficient endocrine neuroinhibitory substances to prevent the fetus from experiencing pain.

IV. CONCLUSIONS FROM THE EVIDENCE

42. As the Kansas statutes indicate, the scientific evidence clearly supports the conclusion that a human embryo/fetus is "a whole, separate, unique, living human

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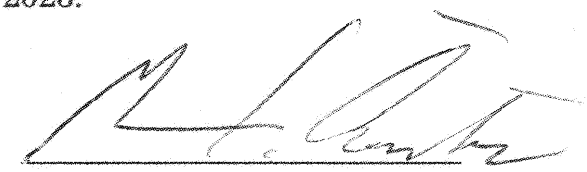
[35] Chatterjee D, Arendt KW, Moldenhauer JS, et al. (2021). Anesthesia for maternal-fetal interventions: a consensus statement from the American Society of Anesthesiologists Committees on Obstetric and Pediatric Anesthesiology and the North American Fetal Therapy network. *Anestesia and Analgesia,* 132:1164–73.

[36] Partridge EA, Flake AW. (2012). Maternal-fetal surgery for structural malformations. *Best Pract Res Clin Obstet Gynaecol.* Oct;26(5):669-82. doi: 10.1016/j.bpobgyn.2012.03.003; Olutoye OO, Joyeux L, King A, Belfort MA, Lee TC, Keswani SG. (2023). Minimally Invasive Fetal Surgery and the Next Frontier. *Neoreviews*. Feb 1;24(2):e67-e83. doi: 10.1542/neo.24-2-e67.

being." Moreover, uncontested scientific data concludes that, by 20 weeks post-fertilization, a human fetus "has the physical structures necessary to experience pain," in the simplest sense of "nociceptive pain," as defined by the International Association for the Study of Pain. Long-standing scientific data indicates a fetus reacts to painful stimuli, including withdrawal of the affected body part. Finally, the since the early 1980's the "standard best practice" of professional anesthesiologists has been to administer anesthesia to fetuses to "blunt any perception of pain."

I declare under penalty of perjury under the laws of the state of Kansas that the foregoing is true and correct. Executed on July 7, 2023.



Maureen L. Condic, Ph.D.

EXHIBIT A

Curriculum Vitae
Last Updated: 7 July 2023

PERSONAL DATA

Name:	Maureen L. Condic
Birth Place:	Chicago, Illinois
Citizenship:	United States
Mailing Address:	Department of Neurobiology and Anatomy University of Utah, School of Medicine 20 South 2030 East, Bldg. 570 BPRB Salt Lake City, UT 84112

EDUCATION

Years	Degree	Institution	Area
1978-1982	B.A.	University of Chicago	Behavioral Science
1983-1989	Ph.D.	University of California, Berkeley	Neurobiology
1989-1991	Postdoc	University of California, Berkeley	Development
1991-1997	Postdoc	University of Minnesota	Cell Biology

PROFESSIONAL EXPERIENCE

Full Time Positions

7/1/1997-2/28/1999	Research Assistant Professor, Department of Neurobiology University of Utah, Salt Lake City, UT, USA
7/1/1997-6/30/2010	Adjunct Assistant Professor, Department of Pediatrics, University of Utah, Salt Lake City, UT, USA
3/1/1999-6/30/2004	Assistant Professor, Department of Neurobiology University of Utah, Salt Lake City, UT, USA
7/1/2004-Present	Associate Professor, Tenured, Department of Neurobiology University of Utah, Salt Lake City, UT, USA
7/1/2010-Present	Adjunct Associate Professor, Department of Pediatrics, University of Utah, Salt Lake City, UT, USA

Part Time Positions

2007-2012	Westchester Institute; Senior Fellow
2007-Present	National Catholic Bioethics Quarterly; Scientific Advisory Board
2008-Present	Bioethics Defense Fund; Scientific Advisor
2011-Present	Charlotte Lozier Institute; Associate Scholar
2014-Present	Ombudsman, University of Utah
2014-Present	Center for Ethics and Culture, Notre Dame University; Fellow
2015-Present	Pontifical Academy for Life; Corresponding Member
2016	House Select Investigative Panel of the Energy and Commerce

	Committee, U.S. House of Representatives, Washington, DC; Scientific Consultant
2018-Present	National Science Foundation; National Science Board Member
2019-Present	Society for Catholic Scientists; Board Member
2020	National Institutes of Health, Human Fetal Tissue Research Ethics Advisory Board Member
2021-Present	*Ethics Finder*, Australian Catholic University. Board Member

Temporary Positions

2010	Oxford University, Harris Manchester College, Theology Department Ph.D. External Examiner, Angeliki Kerasidou
2011-15	Visiting Professor, Notre Dame University, South Bend, IN
2013	Visiting Professor, Catholic University of America, Washington, DC
2013	Visiting Professor, St. John's University, Rome, Italy
2018-2020	Visiting Professor, Notre Dame University, South Bend, IN
2020	Nominating committee, John Templeton Foundation, West Conshohocken, PA
2020	Visiting Professor, Catholic University of America, Washington, DC

Editorial Experience

2007-Present	National Catholic Bioethics Quarterly; Editorial Board
2010-2017	Stem Cell Reviews and Reports, Editorial Board
1997-Present	Journal Referee: (12-20 manuscripts/year)

Cell Biology
Cell Stem Cell
Development
Developmental Biology
Developmental Dynamics
European Journal of Neuroscience
Experimental Cell Research
Experimental Neurology
Expert Opinion on Therapeutic Patents
F1000Research
Journal of Applied Philosophy
Journal of Cell Biology
Journal of Cellular Physiology
Journal of Comparative Neurology
Journal of Neuroscience
Journal of Medicine and Philosophy
Linacre Quarterly
Medicine, Health Care and Philosophy
Molecular Biology of the Cell
Molecular Biology Reports
Molecular and Cellular Neuroscience

National Catholic Bioethics Quarterly
Neural Development
Philosophical Quarterly
Regenerative Medicine
Science
Stem Cells
Stem Cells and Development
Stem Cell Reviews and Reports
Stem Cells Translational Medicine
Theoretical Medicine and Bioethics
The New Bioethics

SCHOLASTIC HONORS AND AWARDS

1999	Pew Scholarship Nominee, University of Utah
1999-2001	Basil O'Conner Young Investigator, March of Dimes Foundation
2002-2005	McKnight Neuroscience of Brain Disorders Investigator, McKnight Foundation
2006	Invited Audience with His Holiness Pope Benedict XVI
2008	Alice D. and Frederick C. LaBrecque Lecture in Medical Ethics, Boston University
2012	Cuthbert Allen Lecturer, Belmont Abbey College
2015-Present	Annual Invited Audience with His Holiness Pope Francis
2015-Present	Pontifical Academy for Life, Corresponding Member
2018	True Family Lecturer, University of Oklahoma
2018-Present	National Science Foundation; National Science Board Member
2019	St. Albert the Great Award, Society for Catholic Scientists
2019	Anscombe Memorial Lecture, Oxford University
2020	Expanded Reason Award, First Place. Universidad Francisco de Vitoria, Madrid and Fondazione Vaticana Joseph Ratzinger Benedetto XVI
2022-Present	American Academy of Catholic Scholars and Artists, Invited member.

ADMINISTRATIVE EXPERIENCE

University of Utah

2000-2003	Co-chair, Faculty Recruitment Committee, Neurobiology and Anatomy
2001-2006	Director of Graduate Studies, Neurobiology and Anatomy Department
2006-2009	Course Director, School of Medicine, Medical Embryology course
2010-2019	Embryology curriculum director, School of Medicine

2010-2011	Member, Promotions Committee, School of Medicine
2011-2014	Member, Curriculum Evaluation Committee, School of Medicine
2014-2017	Member, Curriculum Committee, School of Medicine
2014	Chair, organizing committee CUA/BDF symposium on the determination of death
2019-Present	University of Utah School of Medicine College Council, at large member

Regional/National

2012-2013	Southwest Regional Developmental Biology Organizing Committee member
2013	Southwest Regional Developmental Biology meeting; Stem cells and Regeneration session chair
2019	National Science Board, Retreat planning committee Co-chair
2019	National Science Board, Honorary Awards Subcommittee member
2020	National Science Board, Deputy NSF Director Nominations Committee, member
2020-21	National Science Board, Honorary Awards Subcommittee. Chair
2020	National Science Board, Vision implementation task force, member
2020-22	National Science Board Committee on Science and Engineering Policy, Vice Chair
2022-Present	National Science Board Committee on Science and Engineering Policy, Chair
2021-Present	National Science Board Committee on Socioeconomic Status in STEM, member.

UNIVERSITY COMMUNITY ACTIVITIES

1997-Present	Member, Molecular Biology, Molecular Biology Graduate Training Program
1997-Present	Member, Neuroscience Program, Neuroscience Graduate Training Program.
1999-2000	Member and Co-Chair, Neurobiology and Anatomy Department, Faculty Recruitment Committee
1999-2003	Member and Director, Neurobiology and Anatomy Department, Student Advising Committee
1999-2003	Member, Neuroscience Program, Seminar Selection Committee
1999-2003	Member, Pediatrics Department, Child Health Research Career Development Award Advisory Committee
2001-2003	Member, Molecular Biology, Molecular Biology Program Steering Committee
2001	Member, Neurobiology and Anatomy Department, Departmental Advisory Committee (DAC)
2003	Member, School of Medicine, Research Subcommittee for Reaccreditation

2005	Member, Neurobiology and Anatomy Department, Departmental Advisory Committee (DAC)
2007	Member, School of Medicine, University of Utah Academic Senate Nominating Committee
2007	Member, University of Utah Graduate Council, Department of Bioengineering, Internal departmental review committee
2009	Member, Neurobiology and Anatomy Department, Departmental Advisory Committee (DAC)
2010	Member, Neurobiology and Anatomy Department, Departmental Advisory Committee (DAC)
2010	Member, Neuroscience Program, Admissions Committee
2010-2011	Member, School of Medicine, Promotions Committee
2011	Member, Neurobiology and Anatomy Department, Departmental Advisory Committee (DAC)
2011-17	Member, Department of Pediatrics Early Career Development Research Grant review committee
2011-17	Member, Department of Pediatrics Women and Child Institute Basic Science Design Group
2011-17	Member, Department of Pediatrics Women and Child Institute Faculty Career Development Design Group
2011-2014	Member, Curriculum Oversight Group, School of Medicine
2014-2017	Member, Curriculum Committee, School of Medicine
2014-Present	Ombudsman, University of Utah
2014	Member, Senate Committee on Academic Freedom and Faculty Rights (SCAFFR); Recommendations for SCAFFR complaint form revisions
2014-17	Member, Career-Line task force; Recommendations for policy revisions on nomenclature, faculty governance and appointment
2018	Member, Career-Line task force; Recommendations for Career-Line Faculty service as Academic Senate President
2019-2022	Member, University of Utah School of Medicine, College Council.
2020-Present	Senate Faculty Review Standards Committee (SFRSC), University of Utah.

PROFESSIONAL COMMUNITY ACTIVITIES

Grant Review Committee/Study Sections

1998-1999	Member, Spinal Cord Research Foundation
1999	Ad Hoc Member, NIH MCDN7 Study Section
2000	Ad Hoc Member, NIH NSDB Study Section
2002	Ad Hoc Member, NIH MCDN1 Study Section
2002	Member, Alzheimer's Association
2003	Member, Wellcome Trust
2004-2005	Ad Hoc Member, NIH NCF Study Section
2005	Ad Hoc Grant Reviewer, National Science Foundation, Developmental Systems

2007 Ad Hoc Grant Reviewer, Medical Research Council, United Kingdom
2009 Ad Hoc Member, NIH NDPR Study Section
2010 Ad Hoc Member, NIH NSC2 Study Section

RESEARCH FUNDING

Past Grants

1984-1987 National Science Foundation Predoctoral Research Fellowship

1989-1993 Cell shape changes during Drosophila morphogenesis
American Cancer Society Postdoctoral Fellowship
Role: Principal Investigator

1996-1997 Mechanism of neuronal adaptation to inhibitory proteoglycans
Spinal Cord Research Foundation Postdoctoral Fellowship
Role: Principal Investigator

1998-2003 5R01NS38138 Adaptation of neurons to inhibitory extracellular matrix National Institutes of Health (NINDS)
Total Costs: $825,778.
Role: Principal Investigator

1998-2001 PID9808009 Regulation of integrin expression and neuron adhesion by Bcl-2
Total Costs: $50,000.
Primary Children's Medical Foundation
Role: Principal Investigator

1999-2001 5FY980726 Integrin Regulation controls neural crest migration
Total Costs: $100,000
March of Dimes Research Foundation
Basil O'Connor Young Investigator Award
Role: Principal Investigator

1999 PID9908008 Control of Cell Fate and Axon Outgrowth in Sensory Neurons
Total Costs: $33,800
University of Utah Funding Incentive Seed Program
Role: Principal Investigator

1999 07928 Videomicroscopy apparatus
University of Utah Research Instrumentation Fund
Total Costs: $80,000
Role: Principal Investigator

2001-2004 1FY01-172 Integrin Regulation Controls Neural Crest Migration
Total Costs: $243,936
March of Dimes Birth Defects Foundation
(Renewal of MOD Basil O'Connor Young Investigator Award)
Role: Principal Investigator

2002-2005 PID2109100 Integrin-mediated stimulation of adult neuronal regeneration
McKnight Endowment Fund for Neuroscience
McKnight Neuroscience of Brain Disorders Award
Total Costs: $300,000
Role: Principal Investigator

2005-2007 PID2504037 Interaction between integrins and molecular inhibitors of regeneration
Direct Costs: $153,472
Craig H. Neilsen Foundation
Role: Principal Investigator

2004 -2011 5R01NS048382-05 Specification and Development of Sensory Neurons
$1,040,625
National Institutes of Health
Role: Principal Investigator

Grants to trainees

2001-2003 1 T32 HD 07491 "Integrin regulation in adult and embryonic regeneration." Dr. Michele Lemons, Postdoctoral Fellowship.
Direct Costs: $72,392
National Institute of Health, Institute of Child Health and Human Development, Developmental Biology training grant.
Role: Mentor

2003-2005 "Cell autonomous factors influence regeneration." Dr. Michele Lemons, Postdoctoral Fellowship.
Paralyzed Veterans of America, Spinal Cord Research Foundation. Direct Costs: $100,450.
Role: Mentor

2003-2004 International Outstanding Young Investigators Award, Dr. Michele Lemons, Postdoctoral Award.
Paralyzed Veterans of America, Spinal Cord Research Foundation.
Role: Mentor

2002-2005 F31 NS43849 "Surface integrin regulation controls neural crest

migration." Lauren Strachan, Graduate student.
National Institute of Health Predoctoral Fellowship. Direct Costs: $74,238.
Role: Mentor

2011 Undergraduate Research Opportunities Program "Gene expression profiling of amniotic stem cells." Jennifer Akiona, Undergraduate Direct Costs: $1200
Role: Mentor

2011-2013 2T32HL007576 "Training in Cardiology" Colin Maguire, postdoc
Role: Co-mentor

TEACHING RESPONSIBILITIES

Course and Curriculum Development

2010-2018 Phase I: Human embryology content director, University of Utah, Salt Lake City.
2010-2018 Phase II: Metabolism and Reproduction, Human embryology content director, University of Utah, Salt Lake City.
2011 Phase II: Circulation, Respiration and Regulation, Human embryology content director, University of Utah, Salt Lake City.

Courses Directed

2001-2006 Course Director, *"Research in Progress Seminar"*. (Anat 7720). University of Utah, Salt Lake City.
2001-2003 Co-Director (with Dr. C.-B. Chien), *"Axon guidance"*. (Mbiol 6100). University of Utah, Salt Lake City.
2006 Co-Director (with Dr. A. Moon), "*Cell adhesion and motility".* (Mbiol 6100). University of Utah, Salt Lake City.
2006-2009 Course Director, *"Human Embryology,"* (Anat 6060). University of Utah School of Medicine, Salt Lake City.
2010 Course Director, "*Human embryology and craniofacial development*". Independent component of (Orb 133), University of Utah School of Dentistry, Salt Lake City.

Course Lectures

1985-1986 Graduate Instructor, Laboratory Instructor, *"Developmental Biology"*. 30 students, 15 lectures, 15 labs, University of California, Berkeley.
1988 Graduate Instructor, Laboratory Instructor, *"Biology"*. 30 students, 15 lectures, 15 labs, University of California, Berkeley.
1989 Graduate Instructor, *"Integrated Systems Neurobiology"*. 8 students, 30 lectures, University of California, Berkeley.
1992-1996 Instructor, Discussion Leader, *"Developmental Neurobiology"*. 30 students, two lectures, University of Minnesota, Minneapolis.

1993-1995 Instructor, Discussion Leader, *"Molecular, Cellular Development"*. 30 students, two lectures, University of Minnesota, Minneapolis.

1998-2016 Instructor, Discussion Leader, *"Developmental Neurobiology,"*(Anat 7750). 10-15 students, 4-6 lectures, 1-2 discussions, University of Utah, Salt Lake City.

1998-2010 Instructor, *"Frontiers in Neuroscience,"* (Neusc 6010). 8-20 students, one lecture, University of Utah, Salt Lake City.

1998-2010 Instructor, *"Faculty Research in Progress,"* (Mbiol 6050). 20-30 students, one lecture.

1999 Instructor, *"Cell Biology,"* (Mbiol 6480). 20-30 students, two lectures, University of Utah, Salt Lake City.

1999-2006 Instructor, *"Human Embryology,"* (Anat 6060). 110-120 students, 4-6 lectures, University of Utah, Salt Lake City.

2001-2006 Course Director, "*Research in Progress Seminar,*" (Anat 7720). 20-30 students, University of Utah, Salt Lake City.

2001 Co-Director, *"Axon Guidance,"* (Mbiol 6100). Offered 2001, 2003. 8-10 students, University of Utah, Salt Lake City.

2006-2008 Course Director, *"Human Embryology,"* (Anat 6060). 110-120 students, 10 lectures, University of Utah, Salt Lake City.

2007 Instructor, "Genetics and Society (Honors 3215). 18 students, one lecture, University of Utah, Salt Lake City.

2010 Instructor, "Health Law" (LAW 7360). 30 students, on lecture, University of Utah, Salt Lake City.

2010 Course Director, "*Human embryology and craniofacial development*" Independent component (Orb 133) , University of Utah, Salt Lake City. 10 Students. 6 lectures.

2010-2018 Course/Content Director, "Human Embryology" in Phase I, Phase II. University of Utah School of Medicine, Salt Lake City. 110-120 Students. 14 lectures

2013 Instructor/observer (lecture preparation), "Dental Neuroanatomy," University of Utah School of Dentistry, Salt Lake City. 10 Students.

2017 Guest Lecturer, "Praxis Lab: The beginning of Life" (Honors 3700). 15 Students. 3 hour lecture and discussion.

Laboratory Teaching

1985-1986 Graduate Instructor, Laboratory Instructor, *"Developmental Biology"*. 30 students, 15 lectures, 15 labs, University of California, Berkeley.

1988 Graduate Instructor, Laboratory Instructor, *"Biology"*. 30 students, 15 lectures, 15 labs, University of California, Berkeley.

Small Group Teaching/Case-based learning

2010-2012 Instructor, Integrated Case presentation, Phase I, 80 students, in groups of 10. University of Utah School of Medicine, Salt Lake City.

2012 Instructor, Small group facilitator, Phase I. 15 weeks

2013 Instructor, Small group facilitator, Phase I. 15 weeks

2014-2018 Instructor, Small group facilitator, Phase II; Skin Muscle Bone and

Joint. 7 weeks

Trainees Supervised

1997 Undergraduate, Catherine Clark, University of Utah.
1998 Graduate Rotation, Wei Guan, Neuroscience Program.
1998 Graduate Rotation, Manojkumar Puthenveedu, Neuroscience Program.
1998 Graduate Rotation, Jeong-Soo Lee, Molecular Biology Program.
1999 Graduate, Wei Guan, Psychiatry resident, University of Louisiana Health Science Center, Shreveport, LA.
1999 Graduate Rotation, Viravuth Yin, Molecular Biology Program.
1999 Graduate Rotation, Andrea Pepler, Molecular Biology Program.
1999 Graduate Rotation, Jing Li Cai, Molecular Biology Program.
1999 Graduate Rotation, Anne Luebeke, Molecular Biology Program.
1999 Undergraduate, Jeremy Cox, University of Utah.
2000 Graduate, Lauren Strachan, NIH Predoctoral Fellowship.
2000 Undergraduate, Suman Barua, University of Utah.
2000 Graduate Rotation, Xulei Lui, Neuroscience Program.
2000 Graduate Rotation, Debjani Bhar, Molecular Biology Program.
2001 Postdoctoral Fellow, Michele Lemons, NIH Postdoctoral Fellowship, Paralyzed Veterans of America Postdoctoral Fellowship, Paralyzed Veterans of America International Outstanding Young Investigators Award, Assistant Professor (tenure track) Assumption College, Worcester, MA.
2001 Graduate Rotation, Sandhiya Kalyanasundaram, Neuroscience Program.
2001 Graduate Rotation, Nirmalya Roychowdhury, Neuroscience Program.
2001 Graduate Rotation, Deepak Raj, Molecular Biology Program.
2002 Graduate Rotation, Hara Kang, Molecular Biology Program.
2002 Graduate Rotation, Linclon Hunt, Neuroscience Program.
2003 Undergraduate, Luke Marzec, University of Pennsylvania.
2003 Undergraduate, Kevin Woody, University of Utah.
2004 Undergraduate, Katheryn Cousins, University of Chicago.
2004 Graduate Rotation, Kathy Zukor. Neuroscience Program.
2004 Graduate Rotation, Jared Cassiano. Molecular Biology Program.
2005 Graduate, Kath Zukor.
2005 Undergraduate, Benjamin Saliwanchik, University of Chicago.
2005 Graduate Rotation, Michael Abanto. Neuroscience Program.
2007 Graduate Rotation, Gretchen Carr, Neuroscience Program.
2009 Graduate, Erin Cadwalader, Co-advisor with H. J. Yost.
2010 Postdoctoral Fellow, Colin McGuire.
2011 Undergraduate fellow, Jennifer Akiona
2011 Undergraduate trainee, Flor Pineiro
2012 Undergraduate trainee, Emily Means
2012 Undergraduate trainee, Annie Marsden

Graduate Student Committees

1999-01 Laura Storjohann. Neurobiology and Anatomy.
1999-04 Wei Guan. Neurobiology and Anatomy.
2000-01 Roy Smeal. Bioengineering.
2000-05 Lauren Strachan. Neurobiology and Anatomy.
2001-04 Jeong-Soo Lee. Neurobiology and Anatomy.
2004-08 Suzanna Gribble. Neurobiology and Anatomy.
2004-10 Melissa Hardy. Neurobiology and Anatomy.
2005-09 Eon Joo Park. Human Genetics.
2006-10 Katherine Zukor. Neurobiology and Anatomy.
2010-14 Lisa Benko, Neurobiology and Anatomy.
2011-16 Tony Hsiao, Bioengineering.

Continuing Medical Education Lectures/Presentations

9/2002 Conference speaker (National). *Scientific basis of pediatric practice*. University of Utah, Salt Lake City, UT.

4/2004 Symposium Speaker (International). *Integrative Master Class in Anatomy: The Gastrointestinal System*. Experimental Biology National Meeting. Washington, D.C.

11/2005 Keynote Speaker (International). *Suffering and Hope: The ideas behind the medical specialty of palliative care*. The University of Texas MD Anderson Cancer Center and the University of St. Thomas, Houston TX.

9/2006 Congress speaker (International). *Stem cells: What future for therapy? Scientific aspects and bioethical problems*. Azienda Ospedaliera Santa Maria della Misericordia, FIAMC (Fédération Internationale des Associations Médicales Catholiques) and the Pontifical Academy for Life. Rome, Italy.

10/2006 Colloquium speaker (National). *The beginning of life: Human embryology*. DeVos Medical Ethics Colloquy. Grand Valley State University, Spectrum Health Hospitals, St. Mary's Hospital, Metropolitan Hospital, Calvin College, Aquinas College and the Van Andel Research Institute. Grand Rapids, Michigan.

4/2008 Keynote Speaker (National). *The nature of human embryos.* Alice D. and Frederick C. LaBrecque Lecture in Medical Ethics/Bioethics. Boston College. Boston, MA.

10/2008 Invited speaker (National). *Human embryology and science politics*. Moral Conviction vs. Political Pressure. Allegheny General Hospital and Franciscan University of Steubenville. Steubenville, OH.

7/2010 Invited Speaker (National). Who is human and what is not? "Beyond Therapy: Exploring Enhancement and Human Futures." The Center for Bioethics & Human Dignity, Deerfield, IL.

4/2011 Invited Research In Progress Seminar (Regional). Amniotic fluid stem cells and congenital heart defects. Department of Pediatrics. University of Utah, Salt Lake City, UT.

9/2011 Plenary Speaker. *Human reproductive embryology.* Biologic Basis

of Pediatric disease. Department of Pediatrics. Salt Lake City, UT.

2/2012 Plenary Speaker. Stem cell research. Natl. AAPLOG meeting. Washington, D.C.

7/2012 Plenary Speaker. *Early human development.* American Academy of Fertility Care Professionals. Salt Lake City, UT.

1/2014 Keynote Speaker. *Scientific evidence for when life begins.* Catholic Medical Association. St. Paul, MN.

9/2014 Keynote Speaker. *Stem cells and medicine*. Catholic Medical Association and Diocese of Salt Lake. Salt Lake City, UT.

4/2015 Invited Lecturer and Session Co-chair. *Healing or Human Enhancement? The Future of Medicine.* Maryland Nurses Association, Providence Hospital and the John Paul II Pontifical Institute. Washington, DC.

6/2015 Plenary Speaker, The Center for Bioethics & Human Dignity's 22nd annual summer conference, "Science, Research, and the Limits of Bioethics." Deerfield, IL.

11/2016 Plenary Speaker, 3rd International Conference on Responsible Stem Cell Research, Pontifical Academy for Life and the University of Padua, Padua, Italy.

4/2017 Plenary Speaker, "When does life begin: the science." 9th Annual Converging Roads Conference, St. John Paul II Foundation. Houston TX.

10/2017 Plenary Speaker, "When does life begin: the science." 10th Annual Converging Roads Conference, St. John Paul II Foundation. Nashville, TN.

4/2019 Plenary Speaker, "Human Embryology." 2nd Annual Converging Roads Conference, St. John Paul II Foundation. Charlotte, NC.

3/2023 Keynote Speaker, "Keynote Speaker, "When does human life begin? The science." Christian Medical and Dental Associations, Converging Roads and Aquinas College, Grand Rapids, MI.

4/2023 Keynote Speaker, "When does human life begin? The science." Christian Medical and Dental Associations and Wisconsin Right to Life, Madison, WI.

Other Educational Activities

1998-Present Molecular Biology Program, Admissions Interview.

1998-Present Neuroscience Program, Admissions Interview.

1998 Gregory Yochum. Oncological Sciences, Qualifying Examinations.

1998 Meredith Lee. Neurobiology and Anatomy, Qualifying Examinations.

1998 James Kemmerle. Human Genetics, Qualifying Examinations.

2000 Wei Guan. Neurobiology and Anatomy, Qualifying Examinations.

2001 Jeong-Soo Lee. Neurobiology and Anatomy, Qualifying Examinations.

2004 Melissa Hardy. Neurobiology and Anatomy, Qualifying Examinations.
2004 Suzanna Gribble. Neurobiology and Anatomy, Qualifying Examinations.
2005 Eon Joo Park. Human Genetics, Qualifying Examinations.
2006 Katherine Zukor. Neurobiology and Anatomy, Qualifying Examinations.
2011 Lisa Benko, Neurobiology and Anatomy, Qualifying Examinations.
2012 Tony Hsiao, Bioengineering, Qualifying Examinations.

SCIENTIFIC RESEARCH AND REVIEW ARTICLES (peer reviewed)

1. Condic, M.L., Bentley, D. (1989). Pioneer neuron pathfinding from normal and ectopic locations *in vivo* after removal of the basal lamina. **Neuron** *3,* 427-439.
2. Condic, M.L., Bentley, D. (1989). Removal of the basal lamina *in vivo* reveals growth cone- basal lamina adhesive interactions and axonal tension in grasshopper embryos. **J. Neurosci.** *9,* 2678-2686.
3. Condic, M.L., Bentley, D. (1989). Pioneer growth cone adhesion *in vivo* to boundary cells and neurons after enzymatic removal of basal lamina in grasshopper embryos. **J. Neurosci.** *9,* 2687-2696.
4. Condic, M.L., Lefcort, F., Bentley, D. (1989). Selective recognition in vitro between embryonic afferent neurons of grasshopper appendages. **Dev. Biol.** *135,* 221-230.
5. Condic, M.L., Fristrom, D., Fristrom, J.W. (1991). Apical cell shape changes during *Drosophila* imaginal leg disc elongation: A novel morphogenetic mechanism. **Development** *111,* 23-33.
6. Letourneau, P.C., Condic, M.L., Snow, D.M. (1992). Extracellular matrix and neurite outgrowth. **Curr. Op. Genetics and Dev.** *4,* 625-634. *Fessler, L.I., *Condic, M.L., Nelson, R.C., Fessler, J.H., Fristrom, J.W. (1993). Site specific cleavage of basement membrane collagen IV during *Drosophila* metamorphosis. **Development** *117,* 1061-1069. (*The first two authors contributed equally to this work.)
7. Letourneau, P.C., Condic, M.L., Snow, D.M. (1994). Interactions of neurons with the extracellular matrix. **J. Neurosci.** *14,* 915-928.
8. Condic, M.L., Letourneau P.C. (1997). Ligand-induced changes in integrin expression regulate neuronal adhesion and neurite outgrowth. **Nature** *389*, 852-856.
9. Condic, M.L., Snow, D.M., Letourneau, P.C. (1999). Embryonic neurons adapt to the inhibitory proteoglycan aggrecan by increasing integrin expression. **J. Neurosci.** *19,* 10036- 43.
10. Schroeder, K.E. Condic, M.L. Eisenberg, L.M., Yost, H.J. (1999). Spatially regulated translation in embryos: Asymmetric expression of maternal Wnt-11 along the dorsal-ventral axis in *Xenopus*. **Dev. Biol.** *214*, 288-297.
11. Condic, M.L. (2001). Adult neuronal regeneration induced by transgenic integrin expression. **J. Neurosci.** *21,* 4782-4788.
12. Condic, M.L., Lemons, M.L. (2002). Extracellular matrix in spinal cord regeneration: getting beyond attraction and inhibition. **NeuroReport**. *13,* A37-A48.

13. Condic, M.L. (2002). Neural Development: Axon regeneration derailed by dendrites. **Current Biology** *12,* R455-R457.
14. Guan, W. Puthenveedu, M., Condic, M.L. (2003). Sensory neuron subtypes have unique substratum preference and receptor gene expression prior to target innervation. **J. Neurosci.** *23,* 1781-1791.
15. Guan, W., Condic, M.L. (2003). Characterization of Netrin-1, Neogenin and UNC-5 expression during chick dorsal root ganglion development. **Mech. Dev.** *3*, 367-371.
16. Strachan, L., Condic, M.L. (2003). Neural crest motility and integrin regulation are distinct in cranial and trunk populations. **Dev. Biol.** *259,* 288-302.
17. Strachan, L. R., Condic, M.L. (2004). Cranial neural crest recycle surface integrins in a substratum-dependent manner to promote rapid motility. **J. Cell Biology** *167*, 545-54.
    Commentary on manuscript:
    -LeBrasseur, N. (2004) Speed from recycling. **J. Cell Biology.** *167*, 395.
    -**Faculty of 1000:** evaluations for Strachan LR & Condic ML J Cell Biol 2004 Nov 8 167 (3) :545-54 ttp://www.f1000biology.com/article/15520227/evaluation.
18. Lemons, M.L., Barua, S. Abanto, M.L., Halfter, W., Condic, M.L. (2005). Adaptation of sensory neurons to hyalectin and decorin proteoglycans. **J. Neuroscience** *25*, 4964-73.
19. Lemons, M.L., Condic, M.L. (2006). Combined integrin activation and intracellular cAMP cause Rho GTPase dependent growth cone collapse on laminin-1. **Exp. Neurol.** *202,* 324- 335.
20. Lemons, M. L., Condic, M.L. (2008). (*Epub 14 Jun, 2007*). Integrin signaling is integral to regeneration. **Experimental Neurology** *209*, 343-52.
21. Rao, M., Condic M.L. (2008). Alternative sources of pluripotent stem cells: Scientific solutions to an ethical dilemma. **Stem Cells and Development** *17*, 1-10.
22. Condic, M.L., Rao, M. (2008). (*Epub Jul 31, 2008).* Regulatory issues for personalized pluripotent cells. **Stem Cells** *26,* 2753 – 2758.
23. Strachan, L. R., Condic, M.L. (2008). (*Epub Nov 1, 2007*). Neural crest motility on fibronectin is regulated by integrin activation. **Exp. Cell Res.** *314*, 441-452.
24. Condic, M.L. (2008). Alternative sources of pluripotent stem cells; altered nuclear transfer. **Cell Proliferation,** *41 (Suppl. 1*), 7-19.
25. Guan, W. Wang, G., Scott, S.A., Condic, M.L. (2008). (*Epub Dec 4, 2007*). Shh regulates cell number and neuronal identity in dorsal root ganglia. **Dev. Biol.** *314*, 317-28.
26. Rao, M., Condic M.L. (2009). Musings on genome medicine: is there hope for ethical and safe stem cell therapeutics? **Genome Medicine** *1, 70.*
27. Condic, M.L., Rao, M. (2010). Alternative sources of pluripotent stem cells: Scientific solutions revisited. **Stem Cells and Development** *19*,1121-9.
28. Cadwalader, E. L., Condic, M.L., Yost, H.J. (2012). 2-O-Sulfotransferase Controls Wnt Signaling to Regulate Cell Cycle and Adhesion in Zebrafish Epiboly. **Development** *139*; 1296-1305.
29. Maguire, C.T., Demarest, B, Hill, J, Brothman, A.R., Yost, H.J, Condic, M.L. (2013). Genome-wide RNA sequencing reveals the unique stem cell identity of

human amniocytes. **PlosOne** *8*, e53372.

30. Lemons, M.L, Abanto, M.L, Dambrouskas, N., Clements, C.C., DeLoughery, Z., Garozzo, J., Condic, M.L. (2013). Integrins and cAMP mediate netrin-induced growth cone collapse. **Brain Research**. 6;1537:46-58.
31. Condic, M.L. (2014). Totipotency: What it is and what it is not. **Stem Cells and Development** *23,* 796-812.
32. Condic, M.L. (2016). The role of maternal-effect genes in mammalian development: Are mammalian embryos really an exception? **Stem Cell Reviews and Reports**. Jun;12(3):276-84. PMID: 26892267
33. Colin T. Maguire, Ryan Sunderland, Bradley L Demarest, Bushra Gorsi, Joshua Jackson, Angelica Lopez-Izquierdo, Martin Martin Tristani-Firouzi, H. Joseph Yost, Maureen L Condic (2018). Deriving Cardiomyocytes from Human Amniocytes. bioRxiv 475624; doi: https://doi.org/10.1101/475624

ETHICS AND SCIENCE POLICY ARTICLES (editorially and/or peer reviewed)

1. Condic, M.L. (2002). The basics about stem cells. **First Things** *119,* 30-34. [Reprinted in: *The Human Life Review* (2002) XXVIII,119-126].
2. Condic, M.L. (2002). Stem cells and false hopes. **First Things** *125*, 21-22.
3. Condic, M.L., Condic, S.B. (2003). The appropriate limits of science in the formation of public policy. **Notre Dame Journal of Law, Ethics and Public Policy** *25*, 157-179.
4. Condic, M.L. (2003). Life: Defining the Beginning by the End. **First Things** *133,* 50-54. [Reprinted in: *The Human Life Review* (2003) XXIX, 22-29].
5. Condic, M.L. (2004). The science of wishful thinking. Review: Whose view of life? by Jane Maienschein. **First Things** 145, 69-74.
6. Condic, M.L., Condic, S. B., Hurlbut, W.B. (2005). Producing non-embryonic organisms for stem cells. **National Cath. Bioethics Quart.** *5*, 13-15
7. Condic, M.L., Condic, S. B. (2005). Defining organisms by organization. **National Cath. Bioethics Quart.** *5*, 331-53.
8. Condic, M.L. (2005). Stem cells and babies. **First Things** *155*, 12-13.
9. Arkes H., Austriaco N.P., Berg T., Brugger E.C., Cameron N.M., Capizzi J., Condic M.L., Condic S.B., FitzGerald K.T., Flannery K., Furton E.J., George R.P., George T., Gomez- Lobo A., Grisez G., Grompe M., Haas J.M., Hamerton-Kelly R., Harvey J.C., Hoehner P.J., Hurlbut W.B., Kilner J.F., Lee P., May W.E., Miranda G., Mitchell C.B., Myers J.J., Oleson C., Pacholczyk T., Ryan P.F., Saunders W.L., Stevens D., Swetland S.W., Whelan M.E., Williams T. (2005). Production of pluripotent stem cells by oocyte-assisted reprogramming: joint statement with signatories. **Natl Cathol Bioeth Quart**. *5*, 579-83.
10. Burke WJ, Pullicino P, Richard EJ, Condic M. L. (2005). Stemming the tide of cloning. **First Things** *158*, 6-9.
11. Condic, M.L. (2007). What we know about embryonic stem cells. **First Things** *169*, 25-29.
12. Cameron, N, Condic, M.L., Kelly, J., Ruse, A. (2007). Missouri amendment. **Natl Cathol Bioeth Quart**. *7*, 9-11.
13. Condic, M.L. (2007). The beginning of life: a perspective from science. **DeVos**

Medical Ethics Colloquy. Van Andel Press. Grand Rapids, MI.

14. Condic, M.L., Furton, E.J. (2007). Harvesting Embryonic Stem Cells from Deceased Human Embryos. **Natl Cathol Bioeth Quart**. *7,* 507-525.
15. Condic, M.L. (2008). Getting Stem Cells Right. **First Things** *180*, 10-12.
16. Anderson, R.T., Condic, M.L. (2008). Professor Lee Silver's Vast Scientific Conspiracy. **First Things**, on the square p. 946 (http://www.firstthings.com/onthesquare/?p=946).
17. Berg, T.V., Condic, M.L. (2008). Emerging Biotechnologies, the Defense of Embryonic Human Life, and Altered Nuclear Transfer. **Linacre Quarterly** *75,* 269-291.
18. Condic, M.L. (2008). When does human life begin? A scientific perspective. **Westchester Institute White Paper** *1*, 1-18. Westchester Institute for Ethics & the Human Person, Thornwood, NY. (available at: http://www.bdfund.org/whitepapers). [Reprinted in: **Natl Cathol Bioeth Quart.** *9,* 127-208.]
19. Condic, M.L., Lee, P., George, R.P. (2009). Ontological and Ethical Implications of Direct Nuclear Reprogramming. **Kennedy Institute Ethics Journal** *19*, 33–40.
20. Condic, M.L., Lee, P. and George, R.P. (2009). The Grail Searchers, **National Review** (online), July 20, 2009. (Available at: http://article.nationalreview.com/?q=ZDFkM2ZiOGEwOWVkY2Y2ZTlhNDk2MjdkMWQ3NzZ hNmY)
21. Condic, M.L. (2009). Stem cells: reviewing the science and the ethics. **Ethics and Medicine** *34, 1-3.*
22. Condic, M.L., Lee, P., George, R.P. (2009). Rejoinder to Magill and Neaves on Stem Cells vs. Organisms. **Kennedy Institute Ethics Journal** *19,* 33-40.
23. Alvaré, H., Anderson, R.T., Bottum, J., Bradley, G.V., Cohen, E., Condic, M.L., Curlin, F.A., Elshtain, J.B., Franck, M.J., George, R.P., Glendon, M.A., Hurlbut, W.B., Landry, D.W., Lee, P., Levin, Y., Novak, M., Ponnuru, R., Snead, C., Stoner, J.R., Tollefsen, C., Watson, M.J. (2010). *Embryos in the Age of Obama.* The First Annual Neuhaus Colloquium calls for a permanent reversal of a misguided stem-cell policy. **First Things** *206*, 57-62.
24. Condic, M.L. (2012). Science and the politics of personhood. **Public Discourse** (available: http://www.thepublicdiscourse.com/2012/12/7300/).
25. Condic, M.L. (2013). The Science and Politics of Cloning: What the News Was All About. **Charlotte Lozier Institute**. On point, 4 June 2013. http://www.lozierinstitute.org/cloning/
26. Condic, M.L. (2013). A scientific view of when life begins. Educational series material. Vol.(1). **Human Life International**. Front Royal, VA.
27. Condic, M.L., Prentice, D. (2013). Stage-Specific Embryonic Antigen-1 (SSEA-1): What it is and what it is not. 4 Sep, 2013. **LifeNews** (available: http://www.lifenews.com/2013/09/04/science-101-induced-pluripotent-stem-cells-are-not- human-embryos/).
28. Condic, M.L., Flannery, K. (2014). A contemporary Aristotelian embryology. **Nova and Vetera**, English Edition, Vol. 12, No. 2: 495-508.
29. Condic, M.L. (2014). When does human life begin? The scientific evidence and

terminology revisited. **Journal of Law and Public Policy.** Vol. 8 No. 1: 44-81.

30. Condic, M.L (2014). Human embryology: science politics versus science facts. **Quaestiones Disputatae**. Vol. 5 No. 2: 47-60.
31. Condic, M.L. (2014). Confusions about Totipotency: Stem Cells are not embryos. **Public Discourse (**available: http://www.thepublicdiscourse.com/2014/03/12361/).
32. Condic, M.L. (2014). We Are Not Just Our DNA: The Ethical Dangers of Three-Parent Embryos. **Public Discourse** (available: http://www.thepublicdiscourse.com/2014/03/12897/).
33. Condic, M.L. (2017). Virtues beyond a utilitarian approach in biomedical research. In *Virtues in the Ethics of Life*, ed. Ignacio Carrasco de Paula, Vincenzo Paglia and Renzo Pegoraro. Pontifical Academy for Life. **Liberia Editrice Vaticana**. Rome, Italy. 99-113.
    Commentary on Manuscript:
    Banfi, G. (2016). Quante virtù necessarie a medicina e scienza. **Avvenire**, p. A16. Rome, Italy. 10 March, 2016.
34. Condic, M.L. (2016). Determination of Death: A scientific perspective on biological integration. **Journal of Medicine and Philosophy**. Jun;41(3):257-78. PMID: 27075193
35. Moschella, M. and Condic, M.L. (2016) Symposium on the Definition of Death: Summary Statement. **Journal of Medicine and Philosophy**. Jun;41(3):351-61. PMID: 27102243.
36. Condic, M.L. (2017). Anencephalic Children and Zombies. **Public Discourse (**available: http://www.thepublicdiscourse.com/2017/07/19599/)
37. Condic, M.L., Harrison, D. (2018). Treatment of an ectopic pregnancy: An ethical re-analysis. **Linacre Quarterly**; 85(3): 241-251.
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39. Condic, M.L. (2023). Actually, We Do Know When Human Life Begins. **National Review.** January 8, 2023. (available: https://www.nationalreview.com/2023/01/actually-we-do-know-when-human-life-begins/)
40. Condic, M.L. (2023). The Principle of Contribution: On the Nature of Human Body Parts. *In review*.
41. Condic, M.L. (2023). Let's Talk About Death. *In review*.

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1. Condic, S.B., Condic, M.L. (2018). *Human Embryos, Human Beings*. **Catholic University of America Press**. Washington, D.C.
2. Condic, M.L. (2020). Untangling Twinning; Identity; Totipotency and the value of human embryos. **University of Notre Dame Press**. Notre Dame, IN.
3. Condic, M.L. The making of man; what modern embryology tells us about the

nature of human individuality *(in preparation)*

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2. Condic, M.L. (2005). Chapter 12: Regeneration and repair. *Developmental Neurobiology, 4th Edition*. *Eds.* M. S. Rao and M. Jacobson. Plenum Press, New York, NY.
3. Condic, M.L. (2011). Chapter 3: Pre-implantation stages of human development: the biological and moral status of early embryos. *Is this cell a human being?: Exploring the status of embryos, stem cells and human-animal hybrids. Eds.* Antoine Suarez, Joachim Huarte. *Social Trends Institute Monograph Series.* Barcelona, Spain. Springer, New York, NY.
4. Condic, M.L. (2011). Chapter 10: A biological definition of the human embryo. *A Critical Analysis of Pro-Choice Arguments: Persons, Moral Worth, and Embryos. Ed.* Stephen Napier. *Philosophy and Medicine Series*, Springer, New York, NY.
5. Condic, M.L. (2017). Embryos and integration. In: **Life and Learning XXVI.** *Proceedings of the twenty-sixth University Faculty for Life Conference. Ed*. Joseph W. Koterski. Fordham University Press. Bronx, NY. p. 295-323. (available here: http://www.uffl.org/pdfs/vol26/UFL_2016_Condic.pdf).
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2. Condic, M.L. (2010). "Feminists choosing life of New York v. Empire state stem cell board," Report. **State of New York Supreme Court: County of Albany**. Index No. 8594/2009.
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4. Condic, M.L. (2011). "Planned Parenthood of Indiana v. Commissioner." Report. **United States District Court, Southern District of Indiana.** No. 1:11-cv-630-TWP-TAB.
5. Condic, M.L. (2012). "Personhood Oklahoma v. Brittany Mays Barber et al." Affidavit, Appendix A, Brief, *AMICUS CURIAE*, AAPLOG. **Supreme Court of the United States.** NO. 12-145.
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12. Condic, M.L. (2015). Joint Public Hearing: Pain-Capable Unborn Child Protection Act. (SB 179/AB 237). **State of Wisconsin Senate Committee on Health and Human Services and Assembly Committee on Health**. Oral testimony on fetal development.
13. Condic, M.L. (2016). "Nova Health Systems, D/B/A Reproductive Services vs. E. Scott Pruit, Attorney General of Oklahoma et al." Affidavit. Case No. CV-2015-1838. **District Court of Oklahoma County**, State of Oklahoma.
14. Condic, M.L. (2017). "Gloria Kato Kariungi vs. Rondalee Ejalu, Custody of the Embryos." Affidavit. Case No. 2016-841198-DS. **State of Michigan**.
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19. Condic, M.L. (2019) "Whole Woman's Health Alliance v. Hill." Report. Case No.: 1:18-cv-01904-SEB-MJD. **United States District Court, Southern District of Indiana**, Indianapolis Division.
20. Condic, M.L. (2019) "Reproductive Health Services of Planned Parenthood v. Parson." Report. Case No.: 2:19-cv-4155. **United States District Court for the Western District of Missouri**, Central Division.
21. Condic, M.L. (2019) "Planned Parenthood Association of Utah v. Miner." Report.

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22. Condic, M.L. (2020) "Memphis Center for Reproductive Health v. Slatery." Declaration. Case No.: 3:20-cv-00501. **United States District Court for the Middle District of Tennessee**.
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25. Condic, M.L. (2021). "Planned Parenthood South Atlantic v. Wilson." Report. Case No.: 3:21-cv-00508-MGL. **United States District Court for the District of South Carolina,** Columbia Division.
26. Condic, M.L. and Charlotte Lozier Institute. (2021). "Thomas E. Dobbs, et al., v. Jackson Women's Health Organization, et al." Brief, *AMICUS CURIAE*, **Supreme Court of the United States.** NO. 19-1392.
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1. Condic, M.L. (2001). Stem cell facts. **Salt Lake Tribune**. 15 August, 2001.
2. Condic, M.L. (2006). Sliding Down the Slope: Where Kinsley's stem-cell illogic will take us. **National Review Online.** 20 July, 2006 (http://article.nationalreview.com/) [Reprinted.in: *The Human Life Review* (2006) XXXII,145-146]
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4. Condic, M.L. (2007). Brave New Future; working together with stem cells. *Invited contribution*: **National Review Online symposium.** 21 November, 2007 (http://www.nationalreview.com/article/222904/brave-new-future-nro-symposium)
5. Condic, M. L. (2007). Unlikely stem cell therapies. **Nature Neurosci.** *10*, 803.
6. Condic, M.L. (2007). Ethical Research. **Omaha World-Herald.** December 17, 2007.
7. Scolding, N., Chopp, M., Franz, W.M., Alan Mackay-Sim, A., Martin, T. J., Rietze, R., McGonagle, D., Eckehard Strauer, B., Gianni Angelini, G., Barker, R., Condic, M.L., Ursula Just, U., Karussis, D., Mazzini, L., Peduzzi-Nelson, J., Lima, C., (2008). Stem-cell therapy is no miracle cure. **The Times** (**London)**. 16 May, 2008.
8. Condic, M.L. (2009). Does Research Really Need Human Embryos and Cloning? **The Daily Beast**. (http://www.thedailybeast.com/articles/2009/04/16/does-research-really-need-human-embryos-and-cloning.html)
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10. Condic, M.L. (2015). The sky is not going to fall. **National Review Online.** 30 July, 2015. (http://www.nationalreview.com/article/42178/planned-parenthood-womens-health).
11. Fava, J.P., Condic, M.L. (2018) .The embryonic human. **The Malta Independent**. 22 April, 2018. (http://www.independent.com.mt/articles/2018-04-22/newspaper-letters/The-Embryonic-Human-Being-6736188534).
12. Ryan T. Anderson, R.T., Austriaco, N.P.G., Condic, M.L., Flannery, K, George, R.P., Snead, O.C., Tollefesen, C., and White, T.J. (2021). Statement from Pro-Life Catholic Scholars on the Moral Acceptability of Receiving COVID-19 Vaccines. 5 March, 2021. **Ethics and Public Policy Center.** (available at: https://eppc.org/news/statement-from-pro-life-catholic-scholars-on-the-moral-acceptability-of-receiving-covid-19-vaccines/)

ABSTRACTS

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2. Condic, M.L., Bentley, D. (1986). Effects of proteolytic, glycolytic and basal lamina directed enzymes on pathfinding by grasshopper pioneer neurons. **Soc. Neurosci.** *12,* 195.
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4. Condic, M.L. (1989). Selective aggregation of dissociated afferent grasshopper neurons. **Soc. Neurosci.** *15,* 649.
5. Condic, M.L., Fristrom, D., Fristrom, J.W. (1990). A novel mechanism of epithelial morphogenesis in *Drosophila*. **Society for Developmental Biology.** *49,* 44.
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7. Fessler, L. I., Garrison, K., Nelson, R. E., Yuhasz, M. P., Gullberb, D., Takagi, Y., Condic, M.L., Fristrom, J.W., Fessler, J.H. (1992). Building and remodeling the Drosophila extracellular matrix. **Keystone Symposium:** Extracellular Matrix in Development.
8. Condic, M.L., Snow, D., Letourneau, P.C. (1993). Regulation of laminin receptors by sensory neurons in response to chondroitin sulfate proteoglycan. **Soc. Neurosci.** *19,* 436.
9. Condic, M.L., Letourneau, P.C. (1995). Posttranscriptional regulation of laminin receptors in sensory neurons is determined by ligand concentration. **Soc. Neurosci.** *21,* 1021.
10. Condic, M.L., Snow, D.M. (1997). Increased laminin receptor expression in response to chondroitin sulfate proteoglycan affects neuronal cell adhesion and axon outgrowth. **Soc. Neurosci.** *23,* 31.
11. Condic, M.L. (1998). Adult neurons lose the ability to adapt to low laminin substrata. **Soc. Neurosci.** *24,* 1767.
12. Guan, W., Condic, M.L. (1999). Axon outgrowth from early chick dorsal root ganglia (DRG) is independent of neurotrophin-3 (NT3). **Soc. Neurosci.** *25,*

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13. Strachan, L., Condic, M.L. (2000). Differences in integrin expression contribute to distinct patterns of migration in cranial and trunk neural crest. **Soc. Neurosci.** *26,* 58.
14. Strachan, L., Condic, M.L. (2001). Surface integrin regulation contributes to neural crest migration. **Keystone Symposium**: Cell Migration and Invasion D3. *346*, p. 84.
15. Lemons, M.L., Condic, M.L. (2001). Cytoplasmic cAMP levels influence neurite outgrowth on growth-influential CNS proteins. **Soc. Neurosci.** *27*, 794.12.
16. Guan, W. Puthenveedu, M., Condic, M.L. (2001). Sensory neuron subtypes have unique substratum preference and receptor gene expression prior to target innervation. **Soc. Neurosci.** *27*,136.18.
17. Strachan, L., Condic, M.L. (2002). The role of integrin recycling in neural crest cell motility. **Keystone Symposium**: Development of the Spinal Cord and Neural Crest X4. *411,* p.177.
18. Guan, W., Condic, M.L. (2002). The differential expression of netrin 1-neogenin/unc5 signals affects axon fasciculation of different subtypes of DRG neurons. **Soc. Neurosci.** *28,* 528.3.
19. Lemons, M.L., Condic, M.L. (2002). Effects of Cyclic AMP upon Neurite Outgrowth and Integrins. **Soc. Neurosci.** *28,*729.13.
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21. Strachan, L.R., Condic, M.L. (2003). Cranial neural crest motility is promoted by substratum-dependent integrin recycling. **Am. Soc. Cell Biol.** 1824: B293.
22. Lemons, M.L., Condic, M.L. (2003) Intracellular cAMP and integrin activation determine growth cone response to laminin-1. **Soc. Devel. Biol.** 17, 24.
23. Strachan, L.R., Condic, M.L. (2003) Integrin recycling is required for proper cranial neural crest migration. **Soc. Devel. Biol.**15, 22.
24. Guan, W., Condic, M.L. (2003) Shh induce the patterning of ventral cell fates in chick dorsal root ganglia. **Soc. Devel. Biol.**1, 35.
25. Strachan, L.R., Condic, M.L. (2003) Cranial Neural Crest Motility is Promoted by Substratum-dependent Integrin Recycling. **Am. Soc. Cell Biol.** 1824: B293.
26. Lemons, M.L., Condic, M.L. (2004). Growth cone response to laminin is reversed by a combination of integrin activation and cAMP. **Soc. Neurosci.** *30*, 23.14
27. Lemons, M.L., Condic, M.L. (2005). Integrins, cAMP and netrin-1 interact and influence growth cone behavior. **Soc. Neurosci.** *31.*
28. Lemons, M.L., Abanto, M., Dambrauskas, N., Duke, V., Clements, C., Condic, M.L. (2008). Netrin-1 induced growth cone collapse is mediated by integrins. **Soc. Neurosci.** *33.*
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30. Maguire, C.T., Demarest, D., Akiona, J., Hill, J., Palmer, J. Brothman, A.R., Yost, H.J., Condic, M.L. (2012). Human amniocytes contain subpopulations of stem cells that have a repressed cardiogenic status. **Weinstein Cardiovascular Conference**.

31. Maguire, C.T., Demarest, D., Hill, J., Brothman, A.R., Yost, H.J., Condic, M.L. (2013). Human amniocytes express a distinct multilineage phenotype that has a repressed cardiogenic status. **Southwest Developmental Biology**.
32. Maguire, C.T. Jackson, J., Demarest, B., Hill, J., Brothman, A.R., Yost, H. J., Condic, M. L. (2013). Minicircle DNA vectors to reprogram human amniocytes into cardiomyocytes. **Keystone Symposium:** Cardiac Remodeling, Signaling, Matrix and Heart Function (D4).
33. Maguire, C.T., Gorsi, B., Demarest, B., Jackson, J., Sunderland, R., Hill, J., Yost, H.J., Condic., M.L. (2014). Reprogramming transcriptionally repressed human amniocytes into cardiomyocytes by manipulating DNA demethylation. **Southwest Developmental Biology**.
34. Maguire, C.T., Demarest, B. Jackson, J., Sunderland, R., Jou, C.J., Tristani-Firouzi, M., Yost, H.J., Condic, M.L. (2015). Whole-genome analyses reveal developmental regulators of cardiomyocyte subtype differentiation in human amniocytes. **Keystone Symposium:** Cardiac Remodeling, Signaling, Matrix and Heart Function (D4).

ORAL PRESENTATIONS

Symposia and Conferences: Keynote or Plenary Presentations

International

1. 3/2005 Plenary Speaker: *Global state of stem cells and cloning in science, ethics and law* Regina Apostolorum Pontifical University, Rome, Italy.
2. 11/2005 Keynote Speaker. *Suffering and Hope: The ideas behind the medical specialty of palliative care*. The University of Texas MD Anderson Cancer Center and the University of St. Thomas, Houston TX. (CME)
3. 9/2006 Plenary speaker. *1st International Conference on Responsible Stem Cell Research Stem cells: What future for therapy? Scientific aspects and bioethical problems*. Azienda Ospedaliera Santa Maria della Misericordia, FIAMC (Fédération Internationale des Associations Médicales Catholiques) and the Pontifical Academy for Life. Rome, Italy. (CME)
4. 1/2009 Plenary Speaker, Scientific criteria for the organismal status of the embryo. *Focus on The Embryo.* Social Trends Institute. Barcelona, Spain.
5. 2/2011 Plenary Speaker, *Embryonic stem cell research.* NCBC bi-annual workshop on Bioethics. Dallas, TX.
6. 9/2013 Invited Debate participant. "The acquisition of human rights." Aggiornamento Institute and Colorado State University. Fort Collins, CO.
7. 10/2013 Plenary Speaker, "*Stem cell research and ethics*." Council of the European Union conference, Human stem cell research, therapeutic applicability, ethical and legal issues of stem cell technologies in the EU. Kaunas, Lithuania.

8. 11/2013 Plenary Speaker, "*When does life begin?"* Human Life International's 19th Asia- Pacific Congress. Kota Kinabalu, Malaysia.
9. 11/2013 Plenary Speaker, "*Stem cell research and ethics."* Human Life International's 19th Asia-Pacific Congress. Kota Kinabalu, Malaysia.
10. 6/2014 Plenary Speaker, "Determination of death: A scientific perspective." Catholic University-Bioethics Defense Fund 1st Annual Conference. Washington, DC.
11. 4/2015 Plenary Speaker and Session Co-chair. *Healing or Human Enhancement? The Future of Medicine.* Maryland Nurses Association, Providence Hospital and the John Paul II Pontifical Institute. Washington, DC. (CME)
12. 6/2015 Plenary Speaker, The Center for Bioethics & Human Dignity's 22nd annual summer conference, "Science, Research, and the Limits of Bioethics." Deerfield, IL. (CME)
13. 7/2015 Plenary Speaker, "The science of fetal pain development." International Symposium, "Fundamental Ideas of Modern Science on the Beginning of Human Life." Moscow, Russia.
14. 3/2016 Plenary Speaker, "Virtues beyond the utilitarian approach in biomedical research." in The role of virtues in the ethics of life. Pontifical Academy for Life. Rome, Italy.
15. 9/2016 Plenary Speaker, "Twinning and Individuality," Science and Religion conference, Fellowship of Catholic Scholars. Washington, DC.
16. 11/2016 Plenary Speaker, 3rd International Conference on Responsible Stem Cell Research, Pontifical Academy for Life and the University of Padua, Padua, Italy. (CME)
17. 2/2017 Plenary Speaker, "Biotechnology and human life," National Catholic Bioethics Center Bishop's Workshop. Dallas, TX.
18. 6/2019 Keynote Speaker, "Human life is defined by organization," *What does it mean to be human?* Society for Catholic Scientists, 3rd annual conference. Notre Dame University, South Bend, IN.
19. 6/2019 Plenary Speaker, "The scientific potential and limitations of genome editing," *New Challenges for Law: Genetic Editing, Human Ecology, and Human Dignity in Life and Death*. Real Colegio Complutense. Harvard University, Institute for Global Law and Policy. Harvard University, Boston, MA.
20. 11/2019 Keynote Speaker, "Human twinning and individuality." *Anscombe Memorial Lecture*. Oxford University, Oxford, UK.
21. 12/2020 Invited Panelist. "Coronavirus and Expanded Reason." Universidad Francisco de Vitoria. Madrid, Spain.
22. 6/2021 Plenary Speaker. "Chance and Indeterminacy in Biologic Systems." *The 3rd Annual Thomistic Philosophy and Natural Science Symposium*. Thomistic Institute, Washington, DC.
23. 5/2022 Keynote Speaker, "Human Embryos, Human Beings." Expanded Reason Congress. Universidad Francisco de Vitoria. Madrid, Spain.
24. 10/2022 Plenary Speaker. "Life in the Cosmos: Contemporary Science, Philosophy, and Theology on the Origin and Persistence of Life on Earth

(and Beyond?)." October 13-16 *The 4rd Annual Thomistic Philosophy and Natural Science Symposium*. Thomistic Institute, Washington, DC.

25. 6/2023 Plenary Speaker. "Defense of life." Angelicum, the de Nicola Center for Ethics and Culture at the University of Notre Dame, and the Ethics Hub at Australian Catholic University. Rome, Italy.

National

26. 9/2002 Plenary speaker. *Scientific basis of pediatric practice*. University of Utah, Salt Lake City, UT. (CME)
27. 3/2003 Plenary speaker. *Bioethics*. Notre Dame Law School, Thomas J. White Center on Law and Government. South Bend, IN.
28. 6/2004 Plenary speaker. *Integrins and cAMP in neuronal regeneration.* McKnight Conference on Neuroscience. Aspen Institute, Aspen Meadows, CO.
29. 4/2005 Plenary speaker. *Altered nuclear transfer*. Westchester Institute Scholars Forum. Washington, DC.
30. 6/2005 Plenary speaker. *Human embryonic stem cell research.* Center for Ethics in Science and Technology, University of San Diego. San Diego, CA.
31. 8/2005 Plenary speaker. *Stem cells: the state of the science.* United States Conference of Catholic Bishops, National Conference of diocesan pro-life coordinators annual meeting. Phoenix, AZ.
32. 9/2005 Plenary speaker. *Science of stem cells and embryology.* United States Conference of Catholic Bishops, Committee on Science and Human Values. Washington, D.C.
33. 3/2006 Plenary speaker. *On the human embryo*. Westchester Institute Scholars Forum. Washington, DC.
34. 10/2006 Plenary speaker. *The beginning of life: Human embryology*. DeVos Medical Ethics Colloquy. Grand Valley State University, Spectrum Health Hospitals, St. Mary's Hospital, Metropolitan Hospital, Calvin College, Aquinas College and the Van Andel Research Institute. Grand Rapids, MI. (CME)
35. 3/2007 Keynote speaker. *Embryonic and non-embryonic stem cell research; the state of the science.* Scientific address to members of the Florida State Legislature. Tallahassee, FL.
36. 5/2007 Plenary speaker. *Defining embryos*. Westchester Institute Scholars Forum. Washington, DC.
37. 10/2007 Keynote speaker. *Stem cells; opportunities and challenges.* Scientific address to members of the Ohio State Legislature. Columbus, OH.
38. 11/2007 Keynote speaker. *Stem cells and human cloning; state of the science.* Scientific address to members of the Nebraska State Legislature. Lincoln, NE
39. 4/2008 Keynote speaker. Alice D. and Frederick C. LaBrecque Lecture in Medical Ethics. *The nature of human embryos.* Boston College. Boston, MA. (CME).

40. 4/2008 Plenary speaker. Witherspoon Institute University Colloquium. *The nature of university education and the pursuit of truth in academic science*. Princeton University, Princeton, NJ.
41. 4/2008 Plenary speaker. *When Do We Die: Brain Death, Irreversible Circulatory Cessation, and the Debate over the End of Life.* Westchester Institute Scholars Forum. Washington, DC.
42. 8/2008 Keynote speaker. *Human Embryology and organismal function.* Newman Seminar Series. Kalamazoo MI.
43. 10/2008 Plenary speaker. *Human embryology and science politics*. Moral Conviction vs. Political Pressure. Allegheny General Hospital and Franciscan University of Steubenville. Steubenville, OH. (CME)
44. 4/2010 Keynote Speaker. Student Affairs. *When does life begin?* Notre Dame University. South Bend, IN.
45. 7/2010 Plenary Speaker. *Who is human and what is not?* "Beyond Therapy: Exploring Enhancement and Human Futures." The Center for Bioethics & Human Dignity, Deerfield, IL. (CME)
46. 9/2011 Plenary Speaker. *Human reproductive embryology.* Biologic Basis of Pediatric disease. Department of Pediatrics. Salt Lake City, UT. (CME)
47. 2/2012 Keynote Speaker. Cuthbert Allen Lecturer. Stem cell research; ethics and science. Belmont Abbey College, Belmont, NC.
48. 2/2012 Plenary Speaker. *Human development.* National AAPLOG meeting. (Public) Washington, D.C. (CME)
49. 2/2012 Plenary Speaker. *Stem cell research.* National AAPLOG Research meeting. (Invitation only) Washington, D.C.
50. 6/2012 Plenary Speaker. *Scientific evidence for when life begins.* National UFL Life and Learning XX. J. Reuben Clark Law School, Brigham Young University. Provo, UT.
51. 7/2012 Plenary Speaker. *Early human development.* American Academy of Fertility Care Professionals. Salt Lake City, UT. (CME)
52. 10/2013 Plenary Speaker. *Human development and human rights.* Journal of Law & Public Policy at the University of St. Thomas. National Symposium. Minneapolis, MN.
53. 1/2014 Keynote Speaker. *Scientific evidence for when life begins.* Catholic Medical Association. St. Paul, MN. (CME)
54. 10/2014 Keynote Speaker. Texas A&M medical school. Definition of death. College Station, TX. (CME)
55. 10/2014 Keynote Speaker. *When life begins*. Conference of State Legislators and Aides, Austin, TX.
56. 6/2015 Plenary Speaker. "Pain Capable Child Protection Act." State of Wisconsin Senate Committee on Health and Human Services and Assembly Committee on Health. Madison, WI.
57. 9/2015 Plenary Speaker and Panelist. "A Medical Perspective on Embryo Adoption." LCMS International Center, St. Louis, MO.
58. 9/2015 Plenary Speaker. "Fetal Pain". Briefing for Senate Staff, sponsored by the Charlotte Lozier Institute. Washington, DC
59. 3/2016 Plenary Speaker. "Mitochondrial disease and early human

development" in: The Intellectual Tasks of the New Evangelization 2016: Science and Religion United States Conference of Catholic Bishops, Secretariat of Doctrine. Washington, D.C.

60. 6/2016 Plenary Speaker. "Integration and the human embryo." University Faculty for Life, National conference, Marquette University, Milwaukee, WI.
61. 9/2016 Plenary Speaker, "When human life begins," Northwestern University and Students for Life, Illinois. Evanston, IL.
62. 10/2016 Plenary Speaker, "Fetal pain," 20/20 Vision Conference, Archdiocese of Newark and Lifenet. Scotch Plains, NJ.
63. 4/2017 Plenary Speaker, "When does life begin: the science." 9th Annual Converging Roads Conference, St. John Paul II Foundation. Houston TX. (CME)
64. 10/2017 Plenary speaker, "Notes from the front." Science and the contest over human meaning. Alliance Defending Freedom. Scottsdale, AZ.
65. 10/2017 Plenary Speaker, "When does life begin: the science." 10th Annual Converging Roads Conference, St. John Paul II Foundation. Nashville, TN. (CME)
66. 2/2018 Plenary Speaker, "Virtues and the utilitarian frontiers of science." True Family Lecturer, University of Oklahoma, Norman OK.
67. 3/2018 Plenary Speaker, "Emerging technologies and human embryos." Bioethics Colloquium, University of Mary, Tempe AZ.
68. 9/2018 Plenary Speaker, "Stem cell therapies for spinal cord injury." 6th Annual Midwest Conference on Cell Therapy and Regenerative Medicine. Kansas University. Kansas City, KS.
69. 11/2018 Plenary Speaker, "Science and embryology," and "Emerging technologies." Wyoming Pastors Network. Casper, WY.
70. 10/2018 Plenary Speaker, "Ethics and the beginning of life." Humanae Vitae Conference, Archdiocese of Saint Paul and Minneapolis. Minneapolis, MN.
71. 1/2019 Plenary Speaker, "When does life begin?" Vita Institute, St. Mary Seminary, Houston and Center for Ethics and Culture, Notre Dame University. Houston, TX.
72. 4/2019 Plenary Speaker, "Human Embryology." 2nd Annual Converging Roads Conference, St. John Paul II Foundation. Charlotte, NC. (CME)
73. 7/2019 Invited speaker, "When does life begin?" Texas Right to Life, Dallas TX.
74. 10/2019 Invited Panelist, "Science, Medicine and Life." Georgetown University, Washington, DC.
75. 7/2020 Invited speaker, "When does life begin?" Texas Right to Life, Dallas TX.
76. 11/2021 Keynote Speaker, "Embryo ethics." Romanell Center Workshops and Conference. University at Buffalo. Buffalo, NY.
77. 10/2022 Keynote Speaker, "Human embryos are defined by organization." University of Alabama and SCS Alabama. Birmingham, AB.
78. 1/2023 Keynote Speaker, "Human embryos are defined by organization." University of New Mexico and SCS NM. Los Alamos, NM.
79. 1/2023 Keynote Speaker, "Human embryos are defined by organization."

University of New Mexico and SCS NM. Albuquerque, NM

80. 2/2023 Keynote Speaker, webinar, “When does human life begin? The science.” Christian Medical and Dental Associations and Wisconsin Right to Life, Madison, WI.
81. 3/2023 Keynote Speaker, “Keynote Speaker, “When does human life begin? The science.” Christian Medical and Dental Associations, Converging Roads and Aquinas College, Grand Rapids, MI. (CME)
82. 4/2023 Keynote Speaker, “When does human life begin? The science.” Christian Medical and Dental Associations and Wisconsin Right to Life, Madison, WI. (CME)
83. 4/2023 Keynote Speaker, “Stem cell research and embryos.” University of New Mexico and SCS NM. Los Alamos, NM.
84. 4/2023 Keynote Speaker, “Human embryos are defined by organization.” SCS Tennessee. Nashville, TN.
85. 11/2023 Keynote Speaker, “Twinning.” Notre Dame University and SCS Indiana, South Bend, IN.
86. 2/2024 Plenary Speaker, “Human life.” AAPLOG/ACPeds Matthew Bulfin Educational Conference. Dallas, TX.

Regional/Local

87. 10/1998 Plenary Speaker. Interdepartmental Neuroscience program symposium, University of Utah. Salt Lake City, UT.
88. 8/1999 Plenary Speaker. Combined program in Molecular Biology and Biological Chemistry Student Orientation Seminar, University of Utah. Salt Lake City, UT.
89. 10/2004 Plenary Speaker. *Control of sensory neuron fate.* Neuroscience Program Snowbird Scientific Symposium, Salt Lake City, UT.
90. 2/2005 Plenary Speaker. *Growth cone motility and regeneration.* Spinal cord research interest group, The Brain Institute, University of Utah, Salt Lake City, UT.
91. 3/2006 Plenary Speaker. *Growth cone motility and regeneration*, The Brain Institute, University of Utah, Salt Lake City, UT.
92. 9/2014 Plenary Speaker, "The beginning and end of life: An organismal definition." Diocese of Salt Lake Annual Congress, Park City, UT.
93. 9/2014 Keynote Speaker. *Stem cells and medicine*. Catholic Medical Association and Diocese of Salt Lake. Salt Lake City, UT. (CME)
94. 10/2014 Keynote Speaker. The beginning and end of life. Diocese of Salt Lake annual convocation. Park City, UT.
95. 1/2015 Keynote Speaker. Human embryology and the politics of human value. In: Roe v. Wade: 42 Years of Abortion-on-Demand Colloquium. Brigham Young University, School of Law. Provo, UT.

Symposia and Conferences: Invited Presentations

International

96. 4/2004 Symposium Speaker. *Integrative Master Class in Anatomy: The Gastrointestinal System*. Experimental Biology National Meeting. Washington, D.C. (CME)
97. 10/2004 Panelist, Comparative Law Colloquium: *The Legal Regulation of Stem Cell Research in the United States and the Federal Republic of Germany*. The Catholic University of America. Washington, D.C.
98. 3/2006 Symposium speaker. *Axonal Growth in the Complex Environment Surrounding Spinal Cord Injury*. American Society for Neurochemistry National Meeting. Portland, OR.

National

99. 7/2002 Invited conference participant. McKnight Conference on Neuroscience. Aspen Institute, Aspen Meadows, CO.
100. 6/2005 Invited conference participant. McKnight Conference on Neuroscience. Aspen Institute, Aspen Meadows, CO.
101. 11/2007 Invited panelist. *Bioethics panel discussion*. Witherspoon Institute conference. Princeton University, Princeton, NJ.
102. 3/2009 Invited speaker. *The Politics of Knowledge; science and technology*. Women's and Gender Studies, University of South Carolina, Columbia, SC.
103. 9/2009 Invited colloquium participant. The Neuhaus Colloquium on Ethics and Public Affairs. Human life and scientific research. The Witherspoon Institute, Princeton University. Princeton, NJ.
104. 3/2011 Invited Panelist. *Scientific perspective on early embryogenesis.* Student Affairs. Notre Dame University. South Bend, IN.
105. 2/2012 Invited President's Roundtable participant. *The use of fetal cell lines in research.* The Catholic University of America. Washington, DC.
106. 11/2021 Invited speaker. St. Albert Conference for High School students and educators. Society for Catholic Scientists and The Catholic University of America. Washington, DC.
107. 2/2022 Invited speaker. St. Albert Conference for High School students and educators. Society for Catholic Scientists and The University of St. Mary. Mundelein, IL.
108. 4/2022 Invited Panelist. "CRISPR and human genome editing." *Conversations that Matter: The Crossroads of Science and Human Dignity*. McGrath Institute for Church Life. University of Notre Dame. Notre Dame, IN.
109. 3/2023 Invited speaker. St. Albert Conference for High School students and educators. Society for Catholic Scientists and St. Charles Borromeo Seminary. Philadelphia, PA.

Regional/Local

110. 3/2001 Invited educational lecture, Birth defects registry staff, University of Utah Hospital. General lecture for non-scientific staff on human development

and the causes of birth defects. Salt Lake City, UT.

111. 5/2001 Invited scientific panelist, "Stem cell research, panel discussion" Women's State Legislative Council of Utah. Salt Lake City, UT.

112. 9/2002 Invited educational lecture. *Stem Cells and Human Life.* Newman Center, Salt Lake City, UT.

113. 9/2004 Symposium series speaker. *"People need a fairy tale"; Stem cells and human life.* Educational Resource Development Council. University of Utah School of Medicine. Salt Lake City, UT.

114. 3/2006 Invited educational lecture for spinal cord injured patient population, *Growth Cone Motility and Regeneration.* Spinal Cord forum, Salt Lake City, UT.

115. 3/2007 Invited educational lecture for spinal cord injured patient population, *Growth Cone Motility and Regeneration.* Spinal Cord forum, Salt Lake City, UT.

116. 2/2008 Symposium series speaker. *Stem cell hope and hype.* Educational Resource Development Council. University of Utah School of Medicine. Salt Lake City, UT.

117. 3/2008 Invited educational lecture for spinal cord injured patient population, *Stem Cells and Spinal Injury Update.* Spinal Cord forum, Salt Lake City, UT.

118. 3/2009 Invited educational lecture for spinal cord injured patient population, *Stem Cells and Spinal Injury Update.* Spinal Cord forum, Salt Lake City, UT.

119. 3/2010 Invited educational lecture for spinal cord injured patient population, *Stem Cells and Spinal Injury Update.* Spinal Cord forum, Salt Lake City, UT.

120. 11/2010 Invited educational lecture, Gastrointestinal development. Pediatric Gastroenterology, Department of Pediatrics. University of Utah. Salt Lake City, UT.

121. 3/2011 Invited educational lecture for spinal cord injured patient population, *Stem Cells and Spinal Injury Update.* Spinal Cord forum, Salt Lake City, UT.

122. 4/2011 Invited speaker. Amniotic fluid stem cells and congenital heart defects. Department of Pediatrics. University of Utah, Salt Lake City, UT. (CME).

123. 4/2012 Invited educational lecture for spinal cord injured patient population, *Stem Cells and Spinal Injury Update.* Spinal Cord forum, Salt Lake City, UT.

124. 1/2013 Invited speaker, Diocese of Salt Lake. When does life begin? A scientific perspective. Taylorsville, UT.

125. 4/2013 Invited educational lecture for spinal cord injured patient population, *Stem Cells and Spinal Injury Update.* Spinal Cord forum, Salt Lake City, UT.

126. 5/2013 Invited speaker, Parish Council, Our Lady of Lourdes. When does life begin? A scientific perspective. Magna, UT.

127. 9/2013 Invited speaker, Diocese of Salt Lake Annual educational conference. Beginning of life and end of life. Draper, UT.

128. 2/2014 Invited panelist, Public Forum on abortion. St. Luke's Episcopal, Park City, UT.
129. 3/2014 Invited educational lecture for spinal cord injured patient population, *Stem Cells and Spinal Injury Update.* Spinal Cord forum, Salt Lake City, UT.
130. 4/2015 Invited educational lecture for spinal cord injured patient population, *Stem Cells and Spinal Injury Update.* Spinal Cord forum, Salt Lake City, UT.
131. 4/2015 Invited speaker, Leadership Development Program. *Principles of Ombudsman Practice and Informal Dispute Resolution*. Human Resources, University of Utah. Salt Lake City, UT.
132. 4/2016 Invited educational lecture for spinal cord injured patient population, Stem Cells and Spinal Injury Update. Spinal Cord forum, Salt Lake City, UT.
133. 10/2018 Invited speaker, *Principles of Ombudsman Practice*. Council of Academic Deans, University of Utah. Salt Lake City, UT.
134. 5/2017 Invited educational lecture for spinal cord injured patient population, Stem Cells and Spinal Injury Update. Spinal Cord forum, Salt Lake City, UT.
135. 9/2018 Invited lectures (2) for local community groups. *When does life begin?* and *Emerging scientific technologies*. Jackson Hole, WY and Etna, WY.
136. 10/2018 Invited lectures (2). *When does life begin?* and *Emerging scientific technologies*. Wyoming Pastors Network Annual Convention. Casper, WY.
137. 1/2019 Invited speaker, *Principles of Ombudsman Practice*. Communication Department, University of Utah. Salt Lake City, UT.
138. 2/2019 Invited speaker, *Principles of Ombudsman Practice*. Academic Leaders meeting, University of Utah. Salt Lake City, UT.
139. 4/2019 Invited speaker, *Principles of Ombudsman Practice*. Two lectures. Directors of Graduate Studies meeting, University of Utah. Salt Lake City, UT.
140. 9/2019 Invited speaker, *Principles of Ombudsman Practice*. Career and Professional Development Center, Graduate Student lecture series. University of Utah. Salt Lake City, UT.
141. 10/2019 Invited speaker, *Principles of Ombudsman Practice*. University of Utah Staff Counsel. Salt Lake City, UT.
142. 10/2019 Invited speaker, *Mentoring Up: Communicating with your Advisor*. University of Utah, Graduate School. Graduate Student meeting. Salt Lake City, UT.
143. 10/2019 Invited speaker, When does human life begin? A scientific perspective. St. Andrew Parish. Riverton, UT.

Invited Visiting Professor Presentations

144. 1/1996 Columbia University, Department of Pathology. New York, NY.
145. 2/1996 University of Maryland, Biology Department. College Park, MD.

146. 3/1996 University of Minnesota, Genetics and Cell Biology. Minneapolis, MN.
147. 4/1996 Mount Sinai School of Medicine, Brookdale Center for Molecular Biology. New York, NY.
148. 5/1996 University of Minnesota, Department of Cell Biology and Neuroanatomy. Minneapolis, MN.
149. 11/1996 University of Utah, Department of Neurobiology and Anatomy. Salt Lake City, UT.
150. 2/1997 University of Illinois at Chicago, Department of Anatomy and Cell Biology Department of Biochemistry. Joint-Departmental seminar speaker. Chicago, IL.
151. 4/1997 University of Texas, Southwestern Medical Center, Department of Neurobiology. Dallas, TX.
152. 5/2000 University of Virginia, Department of Cell Biology. Charlottesville, VA.
153. 10/2000 Case Western Reserve University, Department of Neuroscience. Cleveland, OH.
154. 12/2000 University of Kentucky, Anatomy and Neurobiology. Lexington, KY.
155. 4/2001 University of Rochester, Aab Institute of Biomedical Sciences. Center for Human Genetics and Molecular Pediatric Disease. Rochester, NY.
156. 1/2002 University of Washington, Seattle. Graduate student invited seminar speaker. Program in Neurobiology and Behavior. Seattle, WA.
157. 3/2002 University of Arizona, Tucson. Department of Cell Biology. Tucson, AZ.
158. 10/2003 University of Utah, Departmental Seminar. *The role of adaptive motility in sensory neuron development.* Department of Neurobiology. Salt Lake City, UT.
159. 11/2004 Michigan State University. *Integrin function in sensory development and regeneration.* Neuroscience Program and Department of Physiology. East Lansing, MI.
160. 12/2004 Medical College of Ohio. *Control of cell motility and guidance in neural development.* Molecular and Cellular Neuroscience Program. Toledo, OH.
161. 9/2005 University of Iowa. *Mechanisms of integrin dependent growth cone motility*. Biology Department Seminar speaker. Iowa City, IA
162. 1/2006 Expert witness; Missourian's against human cloning. Challenge to wording of Amendment 2 ballot title. Jefferson City, MO.
163. 4/2007 Invited speaker. *Conceptualizing conception*. Graduate Student invited seminar speaker. Phi Sigma Tau, The University of St. Thomas. Houston, TX.
164. 4/2007 University of Utah, Departmental Seminar. *Alternative sources of pluripotent stem cells*. Department of Neurobiology and Anatomy. Salt Lake City, UT.
165. 6/2007 University of Utah, Departmental Seminar. *Mechanisms of integrin dependent growth cone motility*. Dept. of Neurobiology and Anatomy. Salt Lake City, UT.
166. 10/2008 Invited speaker. *Stem cells and human health.* St. Monica Parish. Diocese of Kalamazoo. Kalamazoo, MI.
167. 1/2009 Invited speaker. Departmental seminar series. Department of

Philosophy. Notre Dame University. South Bend, IN.

168. 1/2009 Invited speaker. Departmental seminar series. *Mechanisms of motility in neural development.* Department of Biology. Notre Dame University. South Bend, IN.

169. 10/2009 Invited speaker. Office of the Vice President and Department of Biology. *Science policy.* Colorado State University. Boulder, CO.

170. 6/2011 Invited Visiting Professor (six lectures). Human embryology, stem cell research, beginning of life, end of life and definition of an embryo. Notre Dame University, South Bend, IN.

171. 2/2012 Invited Speaker. Amniotic Stem cells and congenital heart disease. Belmont Abbey College, Belmont, NC.

172. 3/2012 Invited speaker. Stem cell research; ethics and science. Vanderbilt University and the Catholic Diocese of Nashville. Nashville, TN.

173. 3/2012 Invited speaker. When does life begin? Vanderbilt University. Department of Pharmacology. Nashville, TN.

174. 6/2012 Invited Visiting Professor (six lectures). Human embryology, stem cell research, beginning of life, end of life and definition of an embryo. Notre Dame University, South Bend, IN.

175. 9/2012 Invited speaker. Medical embryology. Texas A&M University, School of Medicine, College Station, TX.

176. 10/2012 Invited Speaker. Why does the embryo matter? Office of Undergraduate Activities. Princeton University, Princeton, NJ.

177. 3/2013 Invited Speaker. Stem cell research and Ethics. Arizona State University, Sandra Day O'Connor School of Law. Phoenix, AZ.

178. 6/2013 Invited Visiting Professor (six lectures). Human embryology, stem cell research, beginning of life, end of life and definition of an embryo. Notre Dame University, South Bend, IN.

179. 10/2013 Invited Speaker. Aristotelian Embryology. The Pontifical Gregorian University. Rome, Italy.

180. 10/2013 Invited Visiting Professor. Stem cell research and ethics. St. John's University. Rome, Italy.

181. 11/2013 Invited Visiting Professor (four lectures). Organismal criteria for the beginning and the end of life. The Catholic University of America. Washington, DC.

182. 11/2013 Invited Panel Participant. The brain death criteria. The Catholic University of America. Washington, DC.

183. 6/2014 Invited Visiting Professor (five lectures). Human embryology, stem cell research, beginning of life, end of life and definition of an embryo. Notre Dame University, South Bend, IN.

184. 4/2015 Invited Visiting Professor. University of Texas, Austin. Coalition of student groups. Human embryology and ethics. Austin, TX.

185. 6/2015 Invited Visiting Professor (four lectures). Human embryology, stem cell research, beginning of life, end of life and definition of an embryo. Notre Dame University, South Bend, IN.

186. 10/2015 Invited Visiting Professor. "When does life begin? Human biology and human value." Newman Lecture Series. Utah State University, Logan

UT.

187. 3/2017 Invited Visiting Professor. “Human embryology,” Our Lady of the Lake College, Baton Rouge, LA.

188. 6/2018 Invited Visiting Professor (four lectures). Human embryology, stem cell research, beginning of life, medical technologies and human twinning. Notre Dame University, South Bend, IN.

189. 6/2019 Invited Visiting Professor. Human embryology. Notre Dame University, South Bend, IN.

190. 8/2019 Invited Speaker, University of St. Thomas and Prolife Action Ministries. St. Paul, MN.

191. 10/2019 Invited Speaker, University of St. Thomas and Catholic Health Association. St. Paul, MN.

192. 11/2019 Invited Speaker, “Emerging medical technologies.” University of Arizona Political History and Leadership certificate program. Phoenix, AZ.

193. 10/2020 Invited Speaker, “Stem cell biology and emerging medical technologies.” (2 lectures) Catholic University of America, Washington, DC.

194. 4/2021 Invited Speaker. “When does live begin?” Horns for Life Student Association. University of Texas at Austin, Austin, TX.

195. 6/2021 Invited Seminar speaker. “Order in embryology.” Harvard Catholic Forum. Harvard University, Boston, MA.

196. 6/2021 Invited Panelist. “Chance and chaos in biology.” Thomistic Institute Conference on Philosophy and Natural Science. Washington, D.C.

197. 7/2021 Colloquium Speaker. “Order in embryology.” Fermilab Colloquium Series. Batavia, IL.

198. 6/2021 Conference Speaker. “When does life begin?” Society for Catholic Scientists Annual conference. Washington, D.C.

199. 10/2021 Invited Speaker, “Stem cell biology and emerging medical technologies.” (2 lectures) Catholic University of America, Washington, DC.

200. 6/2022 Invited Visiting Professor, Human embryology. Notre Dame University, South Bend, IN.

201. 6/2023 Invited Visiting Professor, Human embryology. Notre Dame University, South Bend, IN.

Grand Rounds Presentations

202. 12/1996 Baylor College of Medicine, Department of Surgery. Houston, TX.

203. 11/1998 University of Utah, Grand Rounds seminar. *Stem cells in Pediatrics Medicine*. Department of Pediatrics. Salt Lake City, UT.

204. 4/2001 University of Utah, Grand Rounds. *Integrins in sensory neuron development and regeneration.* Pediatrics Department. Salt Lake City, UT.

Public Education

<u>Scientific and Ethics Interviews (Radio, Print, Television)</u>

205. 2001 Radio interview, WWJ (Detroit, MI); Current scientific research on spinal cord injury.

206. 2001 Radio interview, WMUK (Kalamazoo, MI); Gene manipulation as a treatment for spinal cord injury.

207. 2001 Newspaper interview, Salt Lake Tribune (Salt Lake City, UT) 29 July; Troy Goodman "Utah Leaders in debate over ethics, possibilities of stem cell research".

208. 2002 Radio interview, KUER (Salt Lake City, UT); Research on spinal cord injury and therapeutic approaches to rehabilitation.

209. 2002 Radio interview, KCPW, Talk of the City Science Friday (Salt Lake City, UT); Current brain research at the University of Utah.

210. 2002 Newspaper interview; Our Sunday Visitor (National circulation); Woodeene Koenig-Bricker. Scientific issues surrounding stem cells.

211. 2004 Interview, Science and Theology News, Templeton Foundation (National circulation); Chhari Sadhcev. Science Policy and Science funding.

212. 2005 Interview, Health Sciences Report, University of Utah, Salt Lake City, UT; Phil Sahm. Current research on Neural Crest development.

213. 2005 Interview, Wired Magazine (National circulation); Clive Thompson. Scientific and ethical issues surrounding altered nuclear transfer.

214. 2006 Interview, The Weekly Standard (National Circulation) 3 July; Colleen Carroll Campbell. A clone by any other name; Missouri's deceptively worded ballot measure.

215. 2006 Interview, National Review Online (National Circulation) 7 July; Fr. Thomas Berg. A Step Toward Clarity. Recent cloning headlines may herald the end of embryo name games.

216. 2006 Radio Interview, KSL, The Doug Wright Show (Salt Lake City, UT); Potential of stem cell research.

217. 2006 Interview, Catholic News Service (International Circulation) 18 September; Carol Glatz. Pope endorses adult stem-cell research.

218. 2006 Interview, Brain Institute news (Utah); Julie Kiefer. Two research papers report “ethical” means to derive embryonic stem cells; The debate rages on.

219. 2007 Interview, KVSS, The Spirit Morning Show (Omaha, Nebraska) 10 January; Kris McGregor, The science of stem cell research.

220. 2007 Interview, Representative Rob Inglis (South Carolina), 10 January; Discussion with Rep. Inglis staff of human development, embryonic and adult stem cell research. Dr. Willy Lensch (Harvard Medical School), co-participant.

221. 2007 Interview, Dr. David Stevens, CEO for the Christian Medical & Dental Associations (National membership) 12 February; Science of stem cell research.

222. 2007 Interview. Scientist hopeful about new stem cell studies. 6 June; Carrie Gress. Zenit, (International circulation). Rome Italy.

223. 2007 Radio Interview. Induced Pluripotent Stem cells. Family news in focus (National syndication). 20 June. Steve Jordahl. Colorado Springs, CO.

224. 2007 Radio Interview. Cloning legislation. Chip Maxwell. KKAR. Omaha, NE.

225. 2007 Interview. Stem Cell Breakthrough Hailed. 20 November; Carrie Gress. ZENIT news agency, (International circulation). Rome Italy.

226. 2007 Interview. Scientist hopeful about new stem cell studies. 6 June; Carrie Gress. ZENIT news agency, (International circulation). Rome Italy.

227. 2008 Interview. Ethical concerns with the iPS approach. 22 January; Tom McFeely, Contributing Editor. National Catholic Register (National Circulation). North Haven, Connecticut.

228. 2008 Interview. Science of direct reprogramming. 30 January; Jim Schwarz. KFUO radio. St. Louis, MO.

229. 2008 Interview. Primate cloning and induced pluripotent stem cells. 19 February; Ted Katauskas, Editor-at-Large, Portland Monthly. Portland, OR.

230. 2008 Interview. Pluripotent stem cells and infertility treatments. Jane Bosveld, Contributing Editor, Discover Magazine. New York, NY.

231. 2008 Interview. Trends in Embryonic stem cell research. Anna Persky, Contributing journalist, Washington Lawyer. Washington, DC.

232. 2008 Interview. Westchester inaugural White Paper. Karna Swanson Lozoya, Editor. ZENIT news agency, (International circulation). Rome Italy.

233. 2008 Interview. Westchester inaugural White paper. Alton J. Pelowski, Managing Editor. Columbia magazine (International circulation). New Haven, CT.

234. 2008 Interview. Biological issues raised by Congregation for the Doctrine of the Faith *Dignitas Personae*. 10 December; Ann Rodgers, Pittsburgh Post-Gazette.

235. 2008 Interview. Biological issues raised by Congregation for the Doctrine of the Faith Instruction *Dignitas Personae*. 10 December; Rob Stein, The Washington Post (National Circulation).

236. 2009 Interview. Uso clínico de célula iPS será difícil, diz cientista. 29 January; Herton Escobar, O Estado de S. Paulo. São Paulo, Brazil.

237. 2009 Interview. Scientific Community Differs About Stem Cells. 12 March; Michael P. Tremoglie. The Philadelphia Bulletin. Philadelphia, PA.

238. 2009 Interview. When does life begin? 15 June; Sue Ellen Browder. The National Catholic Register (National Circulation). North Haven, CT.

239. 2009 Interview. Chinese stem cell breakthrough. Joan Desmond. December 13-19, 2009. The National Catholic Register (National Circulation). North Haven, CT.

240. 2009 Interview. Patient specific model of type-1 diabetes. Nima Reza. Family News and Focus (National Syndicate). Colorado Springs, CO.

241. 2010 Interview. Newly approved stem cell lines. Audrey Bright. 12 December, 2010. Family News and Focus Radio (National Syndicate). Colorado Springs, CO.

242. 2013 Interview/panel discussion. When does life begin? Huffington Post Live. (National Circulation) Josh Zepps. 15 May, 2013. New York, NY.

243. 2013 Interview. "When does life begin?" Through the Wormhole. 5 June 2013. Discovery Channel (National circulation).

244. 2013 Interview. Advances in stem cell research. Christianity today. (National

Circulaiton) Bob Smietana. 23 August, 2013. Carol Stream, Illinois.

245. 2013 Interview. Controversies over embryology. Prolife Magazine. Brett Attebery. 4 July 2013.

246. 2013 Interview. Small survivors: How the disputed science of fetal pain is reshaping abortion law. Eric Schulzke, Deseret News. Published: Monday, 2 September, 2013. Salt Lake City, UT.

247. 2014 Interview. Stem cell research, recent developments. Theresa Laurance.Tennessee Register. Nashville, TN. 25 Feb, 2014.

248. 2014 Interview. Ethics and the Pontifical Academy for Life. Marie Mischel. Editor, Intermountain Catholic, Utah. 3 December, 2014.

249. 2015 Interview. Patrick Madrid show. "Is It Ethical to Create Babies From Three DNA Sources?" Immaculate Heart radio (national syndication). 5 February, 2015

250. 2015 Interview. Sheila Liaugminas, A closer look. Relevant Radio. "Fetal pain, the scientific evidence." 5 August 2015.

251. 2016 Interview. Janet Morana. The Catholic view for women. EWTN. "Controversies in medicine." 3 March 2016.

252. 2016 Interview. Jan Bentz. Catholic News Agency EWTN news. "Biomedical ethics." 4 March 2016.

253. 2018 Interview and Podcast. Nathan Apodaca. Life Training Institute. "Science and the embryo" 29 March 2018.

254. 2018 Interview and Podcast. Morgan Korth. weDignify. "When does human life begin?"

255. 2018 Interview. National Science Board. Jeffrey Mervis. Science Magazine.

256. 2018 Interview. KUER. National Public Radio. Erik Neumann. National Science Board appointment.

257. 2018 Interview. Salt Lake Tribune. Courtney Tanner. National Science Board appointment.

258. 2019 Interview. Podcast: That's so second millennium. Paul Giesting. SCS conference at University of Notre Dame. 7 June 2019.

259. 2019 Interview. McGrath Institute: Church Life Today (National broadcast). Leonard J. DeLorenzo. SCS conference at University of Notre Dame. 7 June 2019.

<u>Educational Interviews and Lectures</u>

260. 2007 Interview; Catherine Caine, Undergraduate student, Brigham Young University UT. Regenerative medicine.

261. 2007 Interview; Maria Stone, Undergraduate student, Carlton College MN. Regenerative medicine.

262. 2007 Interview; Heather Borck, HS student, Nashville, TN. Stem cell therapies.

263. 2007 Lecture; Junior High School, Salt Lake City, UT. Presentation to 7th and 8th grade students about the scientific method.

264. 2008 Interview; Jessica Rump, Nashville, TN. High School AP honors paper. Induced Pluripotent Stem Cells.

265. 2010 Interview; Iris Xu, Leal Elementary, Cerritos, CA, 6th grade. Neuroscience careers.

266. 2012 Interview, Cierra Pieper, Dakota State University, Madison, SD. Scientific evidence regarding early human development.

267. 2013 Interview (email), James McTavish, Manila, Philippines. Early embryo death; medical evidence.

268. 2013 Interview (email), Maria Wanchc, Bismark, North Dakota. Scientific evidence on when life begins.

269. 2013 Interview (email), Maddalena Togliani, Italy. ALS clinical research.

270. 2013 Interview (email). Ismael Hernandez, Executive Director, Freedom & Virtue Institute, Fort Myers, FL. Scientific evidence on when life begins.

271. 2013 Interview (email), Rose Hershenov, Niagra University, Niagara NY. Scientific definition of the zygote.

272. 2014 Interview (email), Sri Talia, University California, Los Angeles. Human embryology.

273. 2014 Interview (email), Paulina Knobloch, Jagiellonian University, Kraków, Poland. STAP cells and totipotency.

274. 2014 Interview, Dennis M. Sullivan, Cedarville University, Cedarville, OH. Human embryology.

275. 2014 Interview (email), Rita K. Vaughn, Minot, ND. Fetal pain.

276. 2014 Interview (email), Eric Andre, Saskatoon, Canada. Scientific evidence for when life begins.

277. 2014 Interview (email). Erika Bachiochi, Boston, MA. Abortion and contraception.

278. 2014 Interview (email). Ashlen Sandoz, Louisiana. High School anatomy project. Brain circuitry and fetal pain.

279. 2015 Interview (email). Ernie Ramos. When does life begin? Juneau Douglas High School, Juneau, AK.

EXHIBIT #7

IN THE DISTRICT OF JOHNSON COUNTY, KANSAS
CIVIL COURT DEPARTMENT

HODES & NAUSER, MDs, P.A., on behalf of itself, its patients, physicians, and staff; TRACI LYNN NAUSER, M.D.; TRISTAN FOWLER, D.O.; and COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, on behalf of itself and its patients, physicians, and staff, Plaintiffs, v. KRIS KOBACH, in his official capacity as Attorney General of the State of Kansas; STEPHEN M. HOWE, in his official capacity as District Attorney for Johnson County; MARCH BENNETT, in his official capacity as District Attorney for Sedgwick County; SUSAN GILE, in her official capacity as Executive Director of the Kansas Board of Health Arts; and RONALD M. VARNER, D.O., in his official capacity as President of the Kansas Board of Healing Arts, Defendants.	Case No. 23CV03140 Division No. 12 K.S.A. Chapter 60

DECLARATION OF GEORGE MULCAIRE-JONES, M.D.

I, George Mulcaire-Jones, M.D., pursuant to the provisions of Kan. Stat. Ann. § 53-601, do hereby declare as follows:

1. I am at least 18 years of age and competent to testify. I have personal and professional knowledge of the statements contained in this declaration. The opinions I express in this declaration are based on my education, training, experience, and ongoing familiarity with the medical literature. These opinions are my own, and do not represent any group with which I am affiliated.

I. Introduction and Professional Background

2. I attended Carroll College in Helena, Montana, majoring in Biology and entered Medical School at the University of Washington after three years. Upon completion of Medical School, I completed a Flexible Internship at Deaconess Hospital in Spokane, Washington, and a Family Residency Program at the University of Minnesota. After two years of practice in West Africa I completed an Obstetrical Fellowship in Spokane, Washington.

3. I am a board-certified in Family Medicine. I provided obstetrical, pediatric, primary and hospital-based care for over 29 years at St. James Hospital in Butte, Montana. I am the founder and director of Maternal Life International, a non-profit organization that provides training and resources for improving obstetrical and perinatal care in Africa. I also work with the State of Montana as a consultant for the Montana Perinatal Quality Collaborative.

4. In my practice in Butte, Montana I delivered between 60 and 110 babies a year. Over the course of my career, I have delivered over three thousand babies. My practice includes Cesarean sections, care of miscarriages/fetal demise, external cephalic version, repair of 3rd and 4th degree lacerations and assisted vaginal deliveries with vacuum extraction.

5. I have considerable experience in developing safe birth training programs for midwives, nurses, and physicians in low resource settings in Africa.

6. I have been the physician lead in implementing a perinatal behavioral health and support program (A Healthy 1st Thousand Days of Life) for pregnant

women with substance use and mental health conditions at SCL Health St. James. The 1000 Day model has also been adapted for use at other Montana hospital sites.

7. As part of my family medicine and obstetrical practice, I have provided holistic care for women and families. As part of that holistic care, I have a deep awareness of the social determinants of health and the impact of adverse childhood experiences, mental illness, unemployment, domestic violence, substance use, and dysfunctional intimate partner relationships have on the health and well-being of women.

8. As a part of my obstetrical practice, I manage miscarriages (spontaneous abortion), fetal demise, stillbirth, retained products of conception and retained placenta. In so doing, I perform the same procedures as do abortion providers with two exceptions:

a. When I perform a surgical evacuation of the uterus or medical induction of a miscarriage or stillbirth the fetus is already dead or the embryo/fetus never developed (i.e. an anembryonic pregnancy or a molar pregnancy). Thus, I am well-acquainted with techniques, risks, and complications inherent with both surgical and medical evacuation of the uterus.

b. As a part of my practice, I performed dilation and curettage of the uterus and induction of later fetal demise and stillbirths in a hospital setting which is fully equipped and capable of responding to any complications including management of hemorrhage, shock, retained placenta,

retained products of conception and any complications related to anesthesia.

9. As a part of my obstetrical care, I have cared for patients who have had hemorrhage, shock, and complications of both spontaneous and induced miscarriages as well as women who have had secondary infertility and ectopic pregnancies as a sequela of pelvic inflammatory disease—including several cases which occurred after an elective abortion.

10. As part of my practice, I have managed early pregnancy losses with embryonic/fetal demise and/or an anembryonic pregnancy with misoprostol—which is part of the standard medication protocol for chemical termination of pregnancy. While I am inducing a non-viable fetus or an anembryonic pregnancy, an elective chemical abortion is used to terminate a live embryo/fetus. According to ACOG, "[a] misoprostol-only regimen is an acceptable alternative for inducing uterine evacuation when mifepristone is not available."

11. When I care for a patient with a fetal demise, I present options of expectant management, medical induction with misoprostol, or surgical evacuation with ultrasound guidance. If they meet gestational age requirements for medical induction (which can only be accurately determined by ultrasound), I administer misoprostol in the office if that is their choice. Every patient is counseled about side effects and warning signs inherent in a medically induced miscarriage. Every patient is counseled about my immediate availability to manage any complications and is given both my phone number and if I am not available, the phone number for the

obstetrical provider on call. If I know I am not going to be available, I contact the obstetrical provider on-call notifying them of the patient who has had misoprostol administered. Every patient is given instructions to go the Emergency Room if they have heavy bleeding, worsening abdominal or pelvic pain, fever, worsening diarrhea or vomiting, or any other symptoms that are concerning for them.

12. Every patient with a medically induced miscarriage has ongoing careful follow up. (The same applies to women who are being followed for expectant management of a fetal demise or women who have had a surgical evacuation for a fetal demise.) As a part of this follow up, the patient is called by my nurse the next day to assess the patient's status and if the miscarriage is completed or not. In cases of continued bleeding or pain, the patient is seen, and a repeat ultrasound done to determine if there has been a complete evacuation or not. In cases where there is an incomplete evacuation and ongoing bleeding, I perform a surgical evacuation with suction under ultrasound guidance.

13. Patients are seen again in follow up 1 to 2 weeks after the miscarriage is completed. At that time, we assess the patient's medical and obstetrical/reproductive health status and needs. At that time, patients who have a history of depression, mental illness, substance use, domestic violence and may have compromised housing and living situations are seen not only by myself, but also by a social worker and/or counselor. Frequently patients will be seen at another post-miscarriage visit, especially if there are concerns about depression and/or ongoing grief following the pregnancy loss. At these follow up visits we also address family

planning, pre-conception care and in the case of recurrent pregnancy loss, options for further testing, and referral.

14. During the course of my career, I have served as a supervising physician and consultant to certified nurse-midwives who have practiced at St. James Health Care in Butte, Montana.

15. I have been a part of a collaborative call group of obstetricians and family medicine physicians with Cesarean-section privileges which provide backup for a nurse midwife as well as call coverage for the nurse midwife.

16. I have also served as the medical director for the New Hope Pregnancy Center in Butte and at present read ultrasounds for the Options Pregnancy Support Center in Helena, Montana.

17. My experience and qualifications are set forth in further detail in my *curriculum vitae*, attached hereto as Exhibit A.

II. Expert Opinions and Reasons for Them

A. The Ethics of Abortion

18. In response to the plaintiff's witness and their claims as to the burden imposed on their abortion practice by the "Woman's Right to Know Act," several narratives critical of the initiative emerge, each of which has another side to the story. Before addressing these narratives, it is important to recognize the overarching context in which abortion takes place. Unlike any other surgical or medical procedure in medicine, abortion involves the deliberate killing of another human. Dr. Warren Hern, a well-known and respected abortion provider reflected on performing Dilation and Evacuation abortions (D and E) in these words:

> Some part of our cultural and perhaps even biological heritage recoils at a destructive operation on a form that is similar to our own. . . . We have reached a point in this (abortion) technology where there is no possibility of denying an act of destruction. It is before one's eyes. . . . The sensation of dismemberment flows through the forceps like an electric current.[1]

19. According to their testimony, D and E abortions are performed by Dr. Traci Nauser and Dr. Iman Alsaden, through 21 weeks and 6 days.

20. Given that abortion deliberately kills a fetus through "a destructive operation on a form that is similar to our own,", it is no surprise that few physicians want to perform them. In a study published by the Guttmacher Institute, the research arm of Planned Parenthood, only 7% of obstetrician/gynecologists had provided an abortion in the previous year or two years[2]. The vast majority of physicians went into medicine to prevent disease or provide care and healing—and not to kill. Such an ethos was well-expressed by the plaintiff's bioethicist, Dr. Matthew Wynia, in paragraph 49 of his report:

> Beneficence and non-maleficence are complementary ethical principles, with ancient roots in medical ethics, dating from the Hippocratic dictum that physicians must "make a habit of two things-to help, or at least, to do no harm" Beneficence requires physicians to act in ways that best benefits their patients, while non maleficence requires physicians to minimize potential harms to patients

21. According to the witnesses, the principles of beneficence and non-maleficence expounded by Dr. Wynia are not applied to the fetus. They recoil at the

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[1] What about us? Staff reactions to D and E. Warren Hern, M.D., Advances in Planned Parenthood. Vol. XV, No. 1. Excerpta Medica, 1980. https://www.academia.edu/45269734/What_about_us_Staff_reactions_to_D_and_E. Accessed 7/3/2023.

[2] Desai S, Jones RK, Castle K. Estimating abortion provision and abortion referrals among United States obstetrician-gynecologists in private practice. *Contraception*. 2018;97(4):297-302. doi:10.1016/j.contraception.2017.11.004

term "unborn child." They deny that the fetus in utero even up to term can experience pain. They state that having an abortion is safer than taking Tylenol or Viagra. Is it beneficence to dismember the fetus at 21 weeks? Starting between 18 and 20 weeks, a woman generally feels the movement of the fetus—commonly described as "the baby kicking." Do we have some duty to the unborn to "help, and at least, to do no harm," or are principles of beneficence and non-maleficence solely the province of a woman, no matter the sex, the gestational age, or the life potential of a pre-born child.

B. Informed Consent for Abortion

22. The ethical principles of beneficence and non-maleficence apply equally to women and informed consent. Pregnant women considering abortion need to know that there is potential harm. According to the National Abortion Federation (the professional association of abortion providers) 2022 Clinical Guidelines the "following risks, **at a minimum** must be addressed for all abortion procedures (medical and surgical)":[3]

a. Hemorrhage;

b. Infection;

c. Continuing Pregnancy;

d. Death.

23. The guidelines further note that "For abortion procedures (uterine aspiration or dilation and evacuation), the additional risks must be included":

e. Perforation;

[3] National Abortion Federation. 2022 Clinical Policy Guidelines for Abortion Care. https://prochoice.org/wp-content/uploads/2022-CPGs.pdf. Accessed 12/17/2022.

f. Damage to organs including hysterectomy.

24. Other risks related to abortion that have been documented include *Clostridium sordelli* sepsis and death secondary to medical abortions,[4] anesthesia related deaths,[5] deaths from pulmonary or amniotic embolism,[6] cervical lacerations, incomplete abortion with retained products,[7] and increased risk of preterm birth.[8]

25. Informed consent must be in line with the science and evidence base in regard to fetal development and to risks related to abortion. In their evidence-base, I find it disturbing that the petitioner's state abortion to be 'substantially safer than aspirin, Tylenol, and Viagra." (Page 21) A woman who has contracted post-abortal pelvic inflammatory disease or a woman rushed to the hospital in ambulance hemorrhaging from an abortion may disagree with these comparisons.

26. The best studies about abortion complications come from Scandinavia where the national health care systems, abortion providers, and researchers are able to obtain complete reporting data. A 2018 study from Sweden stated, "The rate of complications associated with medical abortions < 12 weeks has increased from 4.2%

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[4] Fischer M, Bhatnagar J, Guarner J, Reagan S, Hacker JK, Van Meter SH, Poukens V, Whiteman DB, Iton A, Cheung M, Dassey DE, Shieh WJ, Zaki SR. Fatal toxic shock syndrome associated with Clostridium sordellii after medical abortion. N Engl J Med. 2005 Dec 1;353(22):2352-60. doi: 10.1056/NEJMoa051620. PMID: 16319384

[5] Atrash HK, Cheek TG, Hogue CJ. Legal abortion mortality and general anesthesia. Am J Obstet Gynecol. 1988 Feb;158(2):420-4. doi: 10.1016/0002-9378(88)90169-x. PMID: 2829630.

[6] Lawson HW, Atrash HK, Franks AL. Fatal pulmonary embolism during legal induced abortion in the United States from 1972 to 1985. Am J Obstet Gynecol. 1990 Apr;162(4):986-90. doi: 10.1016/0002-9378(90)91301-r. PMID: 2327467.

[7] Carlsson, I., Breding, K. & Larsson, PG. Complications related to induced abortion: a combined retrospective and longitudinal follow-up study. *BMC Women's Health* **18**, 158 (2018). https://doi.org/10.1186/s12905-018-0645-6

[8] Brittain JJ, Wahl SE, Strauss JF 3rd, Romero R, Wolf HM, Murphy K, Cyrus JW, York TP. Prior Spontaneous or Induced Abortion Is a Risk Factor for Cervical Dysfunction in Pregnant Women: a Systematic Review and Meta-analysis. Reprod Sci. 2023 Jul;30(7):2025-2039. doi: 10.1007/s43032-023-01170-7. Epub 2023 Feb 13. PMID: 36781584; PMCID: PMC10310603.

in 2008 to 8.2% in 2015. The cause of this is unknown but it may be associated with a shift from hospital to home medical abortions."[9]

27. A recently published study from an abortion center in South Carolina performing D and E procedures between 14- and 24-weeks' gestation noted the following: 37% of patients had a blood loss equal to or greater than 500 mL (the standard definition for postabortion hemorrhage and the generally recognized threshold for postpartum hemorrhage following a vaginal delivery). They further noted that "[p]atients whose uterine evacuation was indicated for pregnancy termination had an 80.6% increase in blood loss compared with those with preoperative fetal demise."[10]

28. A Canadian review of post-abortal infection states, "Postabortion infection after therapeutic abortion, although uncommon, may have devastating consequences including infertility, ectopic pregnancy, and pelvic pain syndrome." The review further notes,

> After an abortion, the main risk to fertility is the development of pelvic inflammatory disease (PID), an inflammation of the endometrium, fallopian tubes, pelvic peritoneum and/or contiguous structures. PID is thought to be caused by the ascending spread of microorganisms from the vagina and cervix into the genital tract. Any instrumentation of the cervix (including surgical abortion) enhances the ascending spread of these organisms and, hence, the risk of PID. . . The consequences of untreated PID are significant. In addition to being a cause of chronic pelvic pain and dyspareunia, many women will go on to have problems with infertility and ectopic pregnancy. One study showed that 11% of

[9] Carlsson I, Breding K, Larsson PG. Complications related to induced abortion: a combined retrospective and longitudinal follow-up study. BMC *Womens* Health. 2018 Sep 25;18(1):158. doi: 10.1186/s12905-018-0645-6. PMID: 30253769; PMCID: PMC6156848.

[10] Bridges KH, Wolf BJ, Dempsey A, Ellison WB, Williams DY, Wilson SH. Maternal and procedural factors associated with estimated blood loss in second trimester surgical uterine evacuation: a retrospective cohort analysis. Int J Obstet Anesth. 2020 Aug;43:65-71. doi: 10.1016/j.ijoa.2020.03.001. Epub 2020 Mar 6. PMID: 32216983; PMCID: PMC7363525.

> women with PID developed infertility after one episode, 23% after two episodes, and 54% developed infertility after three or more episodes of PID. The risk of ectopic pregnancy is increased eight- to tenfold in women who have had an episode of PID as compared to women who have never had the disease. Evidence is increasing that acute PID with abdominal pain as the chief complaint may represent the tip of the iceberg, with many more women having asymptomatic PID.[11]

29. According to a study promoted by the abortion lobby, 1 in 16 women present to the Emergency Room after an abortion within 6 weeks of having either a medical or surgical abortion.[12]

30. In fact, if we look an expert review, "APAP (Tylenol) is reported to be regularly consumed by over 60 million Americans on a weekly basis, making it the most widely utilized analgesic and antipyretic in the United States. Advertised as safe in doses up to 4000 mg every 24 hours by the United States Food and Drug Administration (FDA), consumption at this dose generally does not yield any toxic effects."[13] And, in terms of Viagra, "According to a recent study, men who regularly took a specific type of erectile dysfunction medication (Viagra) had a 25 percent lower chance of dying prematurely than men with ED who did not take these pills, including a 39 percent decrease in death from heart disease."[14]

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[11] Antibiotic prophylaxis at the time of induced abortion. BCMJ, vol. 44 , No. 7 , September 2002. Pages 367-373 Clinical Articles: Carolyn A. Montgomery, MB Wendy V. Norman, MD, FCFP Deborah M. Money, MD, FRCSC Michael L. Rekart, MD, DTM&H, MHSc. https://bcmj.org/articles/antibiotic-prophylaxis-time-induced-abortion. Accessed 9/18/2022.

[12] Upadhyay UD, Desai S, Zlidar V, Weitz TA, Grossman D, Anderson P, Taylor D. Incidence of emergency department visits and complications after abortion. Obstet Gynecol. 2015 Jan;125(1):175-183. doi: 10.1097/AOG.0000000000000603. PMID: 25560122.

[13] Yoon E, Babar A, Choudhary M, Kutner M, Pyrsopoulos N. Acetaminophen-Induced Hepatotoxicity: a Comprehensive Update. J Clin Transl Hepatol. 2016 Jun 28;4(2):131-42. doi: 10.14218/JCTH.2015.00052. Epub 2016 Jun 15. PMID: 27350943; PMCID: PMC4913076.

[14] Robert A Kloner, MD, PhD and others, Effect of phosphodiesterase type 5 inhibitors on major adverse cardiovascular events and overall mortality in a large nationwide cohort of men with erectile dysfunction and cardiovascular risk factors: A retrospective, observational study based on healthcare

31. Accurate information in regard to possible risks and harms is essential to ethical informed consent. It is disturbing to think abortion providers share comparisons of Tylenol and Viagra's supposed safety relative to induced abortion with patients as readily as they do in an expert witness testimony. A woman's right to know is hardly enhanced by such misleading comparisons and by casual dismissal of potential complications from abortion. The figures speak for themselves: 8.2% complication rate, 1 in 16 women going to the Emergency Room within 6 weeks of an abortion, 38.7% of D and E abortions with excess blood loss, and the risk of life-long infertility and chronic pelvic pain from pelvic inflammatory disease.

C. Is abortion really safer than pregnancy?

32. The mantra, "abortion is 12 to 14 times safer than pregnancy" is repeated over and over as part of legitimizing abortion—inflating the risks of pregnancy carried to term and minimizing any risk of abortion. The figure is arrived at by the crude comparison of the number of deaths reported for 100,000 abortions relative to the number of pregnancy-related deaths reported for 100,000 live births—using a figure of 8.8 maternal deaths per 100,000 live-born infants and comparing it to 0.6 reported deaths from 100,000 abortions. The number is calculated from abortion and pregnancy related mortality reported to the Center for Disease Control in the United States.

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claims and national death index data, *The Journal of Sexual Medicine*, Volume 20, Issue 1, January 2023, Pages 38–48, https://doi.org/10.1093/jsxmed/qdac005

33. Abortion and pregnancy related deaths are subject to different reporting requirements. According to the American College of Obstetricians and Gynecologists (ACOG), "Every state is required to report all maternal deaths. Mortality statistics compiled from death certificates are used to measure health quality, set public health goals and policy, and to direct research and resources. The death certificate provides important information about the decedent, the circumstances of death, and the cause of death. In particular, maternal deaths are identified when the cause of death is coded according to the World Health Organization's International Classification of Diseases (ICD) for deaths due to complications of pregnancy, childbirth, and the puerperium."[15]

34. While maternal deaths are rigorously accounted for and reviewed, abortion related deaths in many states do not have to be reported, including California where 1 out of 5 abortions take place. The Center for Disease Control specifically notes, "States and areas voluntarily report data to CDC for inclusion in its annual Abortion Surveillance report. CDC's Division of Reproductive Health prepares surveillance reports as data become available. There is no national requirement for data submission or reporting."[16]

35. The lack of reporting on abortions and the exclusion of any linkages to pregnancy-associated deaths from abortion or ectopic pregnancy from many states

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[15] The Importance of Vital Records and Statistics for the Obstetrician–Gynecologist Committee Opinion Number 748 August 2018, *available at* https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/08/the-importance-of-vital-records-and-statistics-for-the-obstetriciangynecologist.

[16] CDCs Abortion Surveillance System FAQs. Center for Disease Control and Prevention. https://www.cdc.gov/reproductivehealth/data_stats/abortion.htm. Accessed 12/19/2022

makes it impossible to determine "abortion safety" from United States data. A much more accurate and evidence-based analysis of pregnancy associated deaths is found in Finland where comprehensive linkages to both birth and abortions exist. The validity of the methodology of linkage data in Finland was previously noted in a publication of the Guttmacher Institute, the research arm of Planned Parenthood.[17] The data from Finland clearly and consistently demonstrate pregnancy associated mortality is higher in induced abortion compared to ongoing pregnancy or live birth. The methodology and results clearly refute the claims made that "abortion is safer than pregnancy:" *The evidence base demonstrates in* comparing age-related mortality rates between induced abortion to ongoing pregnancy and birth, overall mortality was higher for all deaths as well as every category of death. The specific numbers are as follows (deaths per 100,000 pregnancies or 100,000 person years).[18]

Category of Death	Termination of Pregnancy	Ongoing Pregnancy or Live Birth	Relative Mortality Risk of Termination of Pregnancy compared to Ongoing Pregnancy or Life Birth
All deaths	74.6	21.3	3.5 x
Medical	13.4	11.4	1.17 x
All external causes	49.5	8.1	6.1 x

[17] Methodologies for Estimating Abortion Incidence and Abortion-Related Morbidity: A Review. Susheela Singh, Lisa Remez, Alyssa Tartaglione. Guttmacher Institute. December 2010. https://www.guttmacher.org/report/methodologies-estimating-abortion-incidence-and-abortion-related-morbidity-review. Accessed 9/18/2022.)

[18] Karalis, E., V. Ulander, A. Tapper, and M. Gissler. 2017. "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: An International Journal of Obstetrics and Gynaecology 124:1115–21

Accidents	20.4	3.8	5.37 x
Suicides	21.8	3.3	6.6 x
Homicides	6.8	0.9	7.5 x

D. Kansas's Informed Consent Handbook

36. Ethical informed consent requires the provision of accurate information for decision making:

> Many accounts of informed consent in medical ethics claim that it is valuable because it supports individual autonomy. Unfortunately, there are many distinct conceptions of individual autonomy, and their ethical importance varies. A better reason for taking informed consent seriously is that it provides assurance that patients and others are neither deceived nor coerced.[19]

37. From this ethical perspective, I have reviewed the information presented in the Woman's Right to Know handbook. In my professional opinion the information is factual, accurate and evidence based. There is nothing in it that is either deceitful or can be used for coercion. Below are my specific comments regarding the Woman's Right to Know handbook. Several of the comments also respond to criticisms expressed by the plaintiff's witnesses in their written testimony.

38. The cover of the handbook accurately depicts a picture of a 9-week-old fetus.

39. The handbook accurately states that at 20 weeks an unborn child is pain sensitive. A recent review of fetal pain states, "Current neuroscientific evidence

[19] O'Neill O. Some limits of informed consent. J Med Ethics. 2003 Feb;29(1):4-7. doi: 10.1136/jme.29.1.4. PMID: 12569185; PMCID: PMC1733683.

supports the possibility of fetal pain before the "consensus" cutoff of 24 weeks. Overall, the evidence, and a balanced reading of that evidence, points towards an immediate and unreflective pain experience mediated by the developing function of the nervous system from as early as 12 weeks."[20]

40. In the obstetrical and reproductive health literature, there are varying rates of miscarriage reported. The Woman's Right to Know handbook states that "Less than 5% of all natural pregnancies end in spontaneous miscarriage after detection of cardiac activity and a fetal heartbeat is, therefore, a key medical indicator that an unborn child is likely to achieve the capacity for live birth This statement is consistent with evidence-based studies. For example, in a study of women presenting for their first visit from 6 weeks (when fetal heartbeat can be detected) up to 11 weeks. "The risk of miscarriage among the entire cohort was 11 of 696 (1.6%). The risk fell rapidly with advancing gestation; 9.4% at 6 (completed) weeks of gestation, 4.2% at 7 weeks, 1.5% at 8 weeks, 0.5% at 9 weeks and 0.7% at 10 weeks."[21] A second study examining racial disparities in miscarriage rates showed that amongst 4070 pregnant patients there were 537 miscarriages.[22] The patients were enrolled either before pregnancy or early in pregnancy and the majority had ultrasound exams beginning after 5 weeks of gestation. There were 4070 women enrolled in the study. 537 of them

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[20] Clinical Ethics Derbyshire SW, Bockmann JC. Reconsidering fetal pain. J Med Ethics. 2020 Jan;46(1):3-6. doi: 10.1136/medethics-2019-105701. PMID: 31937669.

[21] Tong S, Kaur A, Walker SP, Bryant V, Onwude JL, Permezel M. Miscarriage risk for asymptomatic women after a normal first-trimester prenatal visit. Obstet Gynecol. 2008 Mar;111(3):710-4. doi: 10.1097/AOG.0b013e318163747c. PMID: 18310375.

[22] Sudeshna Mukherjee and others, Risk of Miscarriage Among Black Women and White Women in a US Prospective Cohort Study, *American Journal of Epidemiology*, Volume 177, Issue 11, 1 June 2013, Pages 1271–1278, https://doi.org/10.1093/aje/kws393

had miscarriages. Of the 537 miscarriages, only 137 had a normal fetal heart rate after 6 weeks. 400 of the miscarriages occurred in women either before their ultrasound was done (153), or the ultrasound showed an anembryonic pregnancy (145) or there was an abnormal or absent heart rate. (153). Thus, in this study only 3.36% (137 out of 4070) had a miscarriage after a normal fetal heart rate.

41. The handbook also gives information about alternatives to abortion as well as the availability of support services during pregnancy and postpartum. Providing alternatives to a given medical or surgical intervention is a recognized and necessary part of informed consent.

42. The introduction and the remaining tract of the Woman's Right to Know Act handbook uses the term "unborn child"—a term rejected by the plaintiff's witnesses. The witnesses also reject other terms that humanize the fetus. For example, Dr. Wynia states, "Likewise the use of the terms "unborn child" and "fetal heartbeat" in the Biased Counseling Requirements are not grounded in medical science and convey an ideological viewpoint that the clinician might not share." (Testimony of Dr. Wynia, pages 12–13).

43. Throughout prenatal care, we listen to the "baby's heartbeat." During a woman's labor we monitor the "fetal heart rate" and not the "fetal cardiac activity." In the case of a fetal demise or stillbirth, a mother or both parents see on the ultrasound there is no heartbeat. In this circumstance I have never heard a nurse, a midwife or another physician explain to the grieving parents, "there is an absence of cardiac activity."

44. Language has power—to reveal or to obfuscate. The embryo, the fetus, the infant, and the baby are on a continuum of being a child.

45. The word "child" is specific to human beings. Dogs have puppies, cats have kittens, ducks have ducklings. While mammals have unborn fetuses, they do not have unborn children. In fact, the English language does use the term "child" for an unborn developing fetus. According to the Collins Dictionary a child is defined as "1. An infant, baby; 2 An unborn offspring, fetus, 3. A boy or girl before puberty; 4 A son or daughter."[23]

46. A child's sex is determined at fertilization. At 10 weeks gestation, cell-free DNA testing can reveal the sex of the fetus. Parents can find out if the baby has XX sex chromosomes, a female or XY sex chromosomes, a male—the implicit meaning to parents is they are having a child that is either a boy or a girl.

47. An unborn child is not a coercive or deceitful term. It is a term unique to humans, and unlike the verbiage of many abortion proponents, describes the reality of a human life stage. While more specific terms can be used to describe the development of a child: embryo, fetus, newborn, infant, toddler, adolescent—none of these terms take away from the reality that in-utero, the essence and potential of human life can be described as an "unborn child."

48. The handbook's section on human development accurately describes and depicts the unfolding development of a human life. There are no inaccuracies in

[23]Collins Dictionary. Definition of child. https://www.collinsdictionary.com/us/dictionary/english/child. Accessed 7/3/2023.

presenting the anatomic, physiological, and behavioral features present at successive gestational ages.

49. The handbook accurately informs the patient of the need for and requirement of an ultrasound for establishing gestational age. The use of ultrasound safeguards both the women and provides essential information for an abortion provider—establishing the presence or absence of a viable fetus, the possibility of an ectopic pregnancy, the presence of a singleton or twin pregnancy and the placental location.

50. All risks described by the handbook for both early medical abortion and vacuum abortion are recognized complications of abortion that are documented in the medical literature and are listed as "adverse reactions" of the manufacturers of mifepristone[24] and misoprostol.[25]

51. The handbook accurately describes the D and E procedure including use of laminaria, suction, and forceps. It notes that D and E involves dismemberment of the fetus. All of these are factual and accurate statements.

52. The document accurately reflects a consensus of increased complications related to induction of labor at later gestational ages. It accurately states that a surgical evacuation is sometimes needed to complete a medically induced abortion and remove any retained placental fragments.

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[24] Mifepristone Side Effects. https://www.drugs.com/sfx/mifepristone-side-effects.html. Accessed 7/1/2023.

[25] Misoprostol Side Effects. https://www.drugs.com/sfx/misoprostol-side-effects.html. Accessed 7/1/2023.

53. All the complications of abortion that are noted are well-established and reported in the literature. The major complications noted are part of the National Abortion Federation Clinical Care guidelines from 2022.

54. The document accurately notes that labor induction may result in the birth of a live baby. This is one reason that abortion providers prefer a surgical abortion to a medical abortion during the late second trimester. Specifically, the American College of Obstetricians and Gynecologists state in their bulletin on second trimester abortion notes, "With medical induction after 20 weeks, induced fetal demise may be preferred by the woman or provider, in order to prevent transient fetal survival after expulsion."[26]

55. The procedure of a D and X is accurately presented as well as its illegality. The exception of performing a D and X to save the life of the mother is accurately presented.

56. The information on methods and medical risks from 22 to 38 weeks is accurately presented.

57. As noted by ACOG, medical abortion at later gestations (20 or more weeks) can result in the "expulsion" of a live baby. This is most likely to occur in the situation of late prenatal care and uncertain dating parameters or in a condition of Intrauterine Growth Restriction. In these circumstances, a fetus thought to be 21 weeks by ultrasound dating parameters, may be 23 weeks when it is "expulsed." The

[26] ACOG Practice Bulletin No. 135: Second-trimester abortion. Obstet Gynecol. 2013 Jun;121(6):1394-1406. doi: 10.1097/01.AOG.0000431056.79334.cc. PMID: 23812485.

section on fetal viability with medical abortion accurately describes the responsibilities of the attending physician.

58. The handbook lists abortion complications, including pelvic infection, incomplete abortion, blood clots in the uterus, heavy bleeding (hemorrhage), cut or torn cervix, perforation of the uterine wall, anesthesia-related complications, and RH isoimmunization. All of these are all documented complications of abortion. None of the risks are exaggerated and all are recognized complications reported in the abortion literature.

59. The handbook states that "[s]ome complications associated with an abortion, such as infection or a cut or torn cervix, may make it difficult or impossible to become pregnant in the future or carry a pregnancy to term." As is noted in the National Abortion Federation Guidelines for Clinical Care, "infection" is a complication of abortion and is part of informed consent. A woman who contracts pelvic-inflammatory disease (PID) after an abortion has a 11% risk of infertility after 1 episode and 23% after two episodes of PID."[27]

60. The handbook cites an increased risk of preterm birth in association with induced abortion. And correctly notes that, "Preterm babies, who have higher risk of death, also have the highest risk for lasting disabilities, such as cerebral palsy, mental retardation, and visual and hearing impairment." The relationship between induced abortion and preterm birth is well-documented in the obstetrical literature.

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[27] Antibiotic prophylaxis at the time of induced abortion. BCMJ, vol. 44 , No. 7 , September 2002. Pages 367-373 Clinical Articles: Carolyn A. Montgomery, MB Wendy V. Norman, MD, FCFP Deborah M. Money, MD, FRCSC Michael L. Rekart, MD, DTM&H, MHSc. https://bcmj.org/articles/antibiotic-prophylaxis-time-induced-abortion. Accessed 9/18/2022.

For example. A 2023 study entitled, "Prior Spontaneous or Induced Abortion Is a Risk Factor for Cervical Dysfunction in Pregnant Women: A Systematic Review and Meta-analysis."[28] noted the following:

a. "All three meta- analyses demonstrate an increased risk of reproductive health complications with increased number of prior abortions. Specifically, the dose-response relationship of prior abortion with both cervical dysfunction and preterm birth supports a causal interpretation."

b. "Subgroup analyses with only induced abortions (surgical/medical) estimated an a OR of 2.54 while studies limited to surgical abortions had an a OR of 4.08 The risk of cervical dysfunction in the current pregnancy was also found to be dependent on the number of previous abortions. In this meta-analysis, a prior history of abortion, and specifically induced abortions, was associated with cervical dysfunction." (In other words, the risk of cervical dysfunction leading to increased risk of preterm birth were 2.5 times greater in women who had an abortion and 4 times greater when a woman had a previous surgical abortion.)

c. "These studies are characterized by a heightened risk of preterm birth with a history of abortion procedures and an observed dose–response relationship."

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[28] Brittain JJ, Wahl SE, Strauss JF 3rd, Romero R, Wolf HM, Murphy K, Cyrus JW, York TP. Prior Spontaneous or Induced Abortion Is a Risk Factor for Cervical Dysfunction in Pregnant Women: a Systematic Review and Meta-analysis. Reprod Sci. 2023 Jul;30(7):2025-2039. doi: 10.1007/s43032-023-01170-7. Epub 2023 Feb 13. PMID: 36781584; PMCID: PMC10310603.

d. The study was done by multiple investigators in the United States and was sponsored in part by the "Perinatology Research Branch, Division of Obstetrics and Maternal–Fetal Medicine, Division of Intramural Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, US Department of Health and Human Services."

61. Another study and commentary on the relationship of induced abortion to preterm birth, concluded with this statement: "Women who have had a termination of pregnancy have an increased risk of preterm delivery, cervical incompetence treated by cerclage, placental problems and PPH, although absolute risks are low. Medical termination may be safer for future pregnancies than surgical termination. For future research, we recommend including the technique of pregnancy termination in perinatal registries, as well as gestational age at termination and number of terminations. The issue of possible harm to future reproduction is not routinely addressed when informing patients about various alternatives for terminating pregnancy."[29]

62. As these studies demonstrate, the handbook correctly provides the right to know about possible harm to future reproduction, including preterm birth.

[29] The influence of pregnancy termination on the outcome of subsequent pregnancies: a retrospective cohort study BMJ Open 2013;3:e002803. doi: 10.1136/bmjopen-2013-002803

63. The information on breast cancer is from the National Cancer Institute. According to the NCI, pregnancy carried to term has a protective effect against breast, uterine and ovarian cancer.[30]

64. The information noting the possible psychological effects of having an abortion is accurate. While there is controversy in regard to the psychological effects of induced abortion, the abortion experience can directly contribute to mental health problems and should be included in a Woman's Right to Know.[31]

65. As with abortion, complications related to pregnancy and childbirth are accurately represented in the handbook.

66. The handbook's information on pregnancy, childbirth, and newborn care is accurate, supportive, and non-directive

67. The handbook's information on adoption is a necessary part of informed consent and is presented in an accurate and supportive manner.

68. The handbook's information on the father's responsibility is important for women and clearly and non-judgmentally outlines the responsibility of the father and his respective rights and obligations.

69. The contact information is presented in a supportive, non-directive manner and simply outlines support services if a woman decides to continue the pregnancy or consider adoption.

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[30] National Cancer Institute. Reproductive History and Cancer. https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/reproductive-history-fact-sheet. Accessed 7/3/2023.

[31] Fergusson DM, Horwood LJ, Boden JM. Abortion and mental health disorders: evidence from a 30-year longitudinal study. Br J Psychiatry. 2008 Dec;193(6):444-51. doi:. 10.1192/bjp.bp.108.056499. PMID: 19043144 (emphasis added).

III. Conclusion

70. The boundaries of informed consent and the ethics that mark them are contentious, especially with induced abortion, where the boundaries circumscribe both a woman and an unborn child. We should err on the side of caution in setting those boundaries by providing women with full and factual information. The claims of the plaintiff's witnesses such as "abortion is "safer than aspirin, Tylenol, or Viagra," (Page 21 Dr. Iman Alsaden), to a "fetus up to term is not capable of experiencing pain," (Paragraph 58 Dr. Iman Alsaden), to "myths like the impact of a previous abortion on future preterm birth." (Paragraph 18, Page 12 Dr. Traci Nauser) collapse those boundaries. Within the self-defined boundaries of the abortion providers, the fetus has no rights, and the abortion providers are the ones to control the information given to women, even when it is inaccurate and dismissive of any potential harm.

71. A "Woman's Right to Know Act" marks a boundary that should be respected by both sides. It provides accurate information about abortion and pregnancy continued to term and risks related to both. It provides referrals and support for the option of continuing the pregnancy and the right and opportunity to change their mind about the choice of abortion. It is neither coercive nor deceitful and marks the boundaries of what is just, necessary, and vital regarding the States' role and responsibility in protecting human life. To gut it, as proposed by the plaintiff's witnesses, would only further collapse the protections surrounding women and the unborn.

I declare under penalty of perjury under the laws of the state of Kansas that the foregoing is true and correct. Executed on July 5, 2023.

George Mulcaire-Jones, M.D.

EXHIBIT A

George Mulcaire-Jones, M.D.
107 High Park Way
Missoula, Montana
(406) 490-1998
gmuljones@gmail.com

PERSONAL

Spouse: Mary

Children: Mark, Megan, Katherine, John, Matthew, Liam

EDUCATION

1971-74: Helena High School, Helena, Montana.

1974-77: Biology Major, Carroll College, Helena, Montana.

1977-1981: University of Washington School of Medicine, Seattle, Washington

1981-1982: Flexible Internship, Deaconess Hospital, Spokane, Washington

1982-1984: Family Practice Residency, University of Minnesota Affiliated Hospitals, St. Paul, Minnesota

1989-1990: Obstetric Fellowship, Family Medicine Spokane, Deaconess and Sacred Heart Hospitals, Spokane, Washington

PROFESSIONAL EXPERIENCE

Employment

1985-1987: General Medical, Surgical and Obstetrical Practice, Shisong Hospital, Cameroon, West Africa, through Mission Doctors Association, Los Angeles, CA

1987-1988: Emergency Room Physician, Spectrum Emergency Services, Tulare, California

1988-1989: Family Practice and Obstetrics, Obstetrics Coordinator: Highpoint Clinic, West Seattle Housing Project, Puget Sound Neighborhood Health Centers, Seattle, Washington

1990-1991: Family Practice and Obstetrics: Providence Factoria, Seattle, Washington.

1991- 2010 Family Practice and Obstetrics, Rocky Mountain Clinic, Butte, Montana

2010 – 2014: Family Practice and Obstetrics, Community Health Center, Butte, Montana

2014- 2021: Family Practice and Obstetrics, St. James Health Care/Rocky Mountain Clinic, Butte, Montana

1997-present: President and Medical Director, Maternal Life International

2021 to present: Project Director Southwest Montana Substance Use/Opioid Use Community Coalition (Rural Community Opioid Response Program)

2021 to present: Ultrasound Supervision/Reading, Options Pregnancy Support Center. Helena, Montana.

Hospital and Community Affiliations

St. James Health Care, Member Integrated Strategic Leadership Team, 2012 to 2021

Maternal/Newborn Council Head, 2012 to 2021

Chair and founder of D.J. Memorial Ethics Conference, 2014, St. James Health Care

Founder of Butte Community Fitness Foundation and Snoflinga Winter Festival, Butte, Montana, 2015 to present

Lead Physician, Meadow Lark Initiative and 1st 1000 Days of Life Perinatal Program at SCL St. James, 2017 to 2021

2021 Physician consultant to Montana Perinatal Quality Collaborative

International Health Care Development and Training

1985-1987: General Medical, Surgical and Obstetrical Practice, St Elizabeth's Hospital, Shisong, Cameroon

1985- 1987: Training Nurses, Nurse-Midwives at Shisong Nursing and Midwifery School, Cameroon

1985- 1987: Developed training program for compound and consulting nurses; assisted in primary health care program training for village health care workers, Cameroon

1997 -1999: Developed bead system of fertility awareness with pilot training in Cameroon, Ghana and Mexico. Patent issued for bead system by National Patent Office, Washington, D.C. September 2009

2000- 2001: Developed parish nurse model for community based HIV Prevention and Care in Africa; piloted first ever parish nurse program in Africa, Swaziland.

2001-2002: Developed “Circles of Life” Program for Integration of AIDS Prevention with Fertility Awareness, piloted programs in Cameroon, Malawi, and Uganda.

2003: Started Maternal Life Uganda.

2003: Developed “Safe Passages: Emergency Obstetrical Care in A Time of AIDS” maternal health care training model. Piloted Safe Passages Training in collaboration with Catholic Medical Mission Board at two sites in Nigeria, August, 2003.

2003: Expanded Parish Nurse training to eight Christian denominations; developed training workshop for parish nurses and home-based providers, presented training workshop, Swaziland.

2003 –2007: Writing and Publication of quarterly “Safe Passages Bulletin” for obstetrical providers in Nigeria in collaboration with Catholic Secretariat of Nigeria

2005- present: Developed “The Faithful House” HIV Risk Avoidance Program in collaboration with Catholic Relief Services. Program operative in multiple countries in Africa.

2006: Developed South African Parish Nurse Training Manual and introduced parish nurse program in Mbupalongo and Kwa-Zulu-Natal provinces in collaboration with CATHCA (Catholic Health Care Association of South Africa)

2007: Developed, in collaboration with National Center for Health Care Informatics, AFMED (African Family Medicine Education and Development Initiative) with pilots in Jos, Nigeria (2008) and Sierra Leone (2009)

2008: Developed training manual for CRS Faithful House program for HIV Risk Avoidance for PMTCT programs

2008-2009: Adapted and introduced *The Faithful House* program and Bead System of Fertility Literacy in Haiti in collaboration with CRUDEM foundation and Archdiocese of Boston NFP office

2009: Developed training manual for Faithful House “Training of Facilitators” with multi-country training Kampala, Uganda.

2011: Developed Faithful House adaptation for couples living with HIV and for PMTCT (Prevention of Mother to Child Transmission)

2012: Began conception and design work for mobile surgical unit for Cesarean-sections in collaboration with Montana Tech University Engineering Department. Unit constructed out of 40 foot shipping container and prototype built and is now being equipped.

2012: Consultant and trainer for Catholic Relief Services for development of Faithful House adaptations for fertility education, PMTCT, Couples living with HIV. Presented training workshop for CRS program coordinators from multiple countries, Arusha, Tanzania, October 2012.

2013: Started Maternal Life Haiti affiliate with continued operations and a staff of three to present.

2014: Started Maternal Life Tanzania affiliate with continued operations and a staff of two to present.

2012-2015: Supported development of training model for Natural Family Planning for use in Somalia and adaptations of programs for Muslim beneficiaries.

2013 -2015: Revised bead method of natural family planning in collaboration with Dr. Richard Fehring (Published May 2016 as *Couple Beads: An integrated method of natural family planning.* Mulcaire-Jones, G., Fehring R., Bradshaw M., Brower K., Lubega G., Lubega P. The Linacre Quarterly 83 (1) 2016, 69-82.

2015 to present: Development and piloting of "The Journey of a Thousand Days" in Uganda and Kenya.

2016: Developed and piloted training programs for post-partum hemorrhage and infant resuscitation in collaboration with Uganda Catholic Medical Bureau. (August 2016 with pilots in Masaka and Kabuli)

2018 to present: Expanded Family Life Programs to sites and teams in Rwanda and Kenya. Ongoing program development and training in Haiti, Uganda, Kenya, Nigeria, Tanzania and Rwanda

Professional Affiliations

American Academy of Family Practice

Montana Medical Association

Mission Doctors Association, Los Angeles, California

Catholic Medical Association

American Academy of Pro-Life Obstetricians and Gynecologists (AAPLOG)

Board Certification

American Board of Family Medicine

PUBLICATIONS:

Safe Passages: Emergency Obstetrical Care in a Time of AIDS, A Training Manual for African Obstetrical Providers, Maternal Life International. 2003.

A New Robe: Parish Nursing in AIDS Prevention and Care, A Training Manual for Nurses in Swaziland and South Africa, Maternal Life International, 2001 and 2006.

Circles of Life: Integrating HIV Risk Avoidance and Fertility Literacy. Maternal Life International. Nujbass Press. Lagos, Nigeria, 2005.

The Faithful House: Affirming Life and Avoiding Risk; Catholic Relief Services, USAID, 2006.

The Faithful House PMTCT Training Manual; CRS, 2008

The Faithful House Training of Facilitators Manual, CRS, 2009.

The Faithful House CALL manual (Couples Affirming Live and Love) CRS 2010

Windows to Ordinary Souls: A Poetic Reflection on the Spiritual Journey, 1997.

The Bead System of Fertility Awareness, Maternal Life International, 2009.

Apparatus and Method of Fertility Awareness, US Patent Office Number 7,588,544 B2, Date of Issue September 15, 2009.

Couple Beads: An integrated method of natural family planning. Mulcaire-Jones, G., Fehring R., Bradshaw M., Brower K., Lubega G., Lubega P. The Linacre Quarterly 83 (1) 2016, 69-82.

Safe Passages, A Pro-Life Response to the Tragedy of Maternal Deaths. Mulcaire-Jones G., Scanlon R., The Linacre Quarterly 78 (2) (May 2011) : 202-210

The First Thousand Days of Life: Issues in Law & Medicine. Fall 2022, Vol. 37 Issue 2, p249-256. 8p.

AWARDS AND RECOGNITIONS

Carroll College Charles Borromeo Humanitarian Award, 2000

St. James Health Care Community Advocacy Award, 2001

1995 Advocate of the Year, State Award for Excellence, Montana Advanced Practice Registered Nurses Association

Finalist, Family Physician of the Year 2005, American Academy of Family Practice

Dr. George Saari Humanitarian Award, University of Washington Medical School, WWAMI Program, September 2007

EXHIBIT #8

IN THE DISTRICT OF JOHNSON COUNTY, KANSAS
CIVIL COURT DEPARTMENT

HODES & NAUSER, MDs, P.A., on behalf of itself, its patients, physicians, and staff; TRACI LYNN NAUSER, M.D.; TRISTAN FOWLER, D.O.; and COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, on behalf of itself and its patients, physicians, and staff, Plaintiffs, v. KRIS KOBACH, in his official capacity as Attorney General of the State of Kansas; STEPHEN M. HOWE, in his official capacity as District Attorney for Johnson County; MARCH BENNETT, in his official capacity as District Attorney for Sedgwick County; SUSAN GILE, in her official capacity as Executive Director of the Kansas Board of Health Arts; and RONALD M. VARNER, D.O., in his official capacity as President of the Kansas Board of Healing Arts, Defendants.	Case No. 23CV03140 Division No. 12 K.S.A. Chapter 60

DECLARATION OF JONATHAN SCRAFFORD, M.D.

I, Jonathan Scrafford, M.D., pursuant to the provisions of Kan. Stat. Ann. § 53-601, do hereby declare as follows:

1. I am at least 18 years of age and competent to testify. I have personal and professional knowledge of the statements contained in this declaration. The opinions expressed in this document are my own and do not represent the views of any organization with which I am associated.

Professional Background

2. I received my medical degree (M.D.) from the University of Minnesota in 2013. I completed my residency training in obstetrics & gynecology at the University of Minnesota in 2017. I completed my board certification with the American Board of Obstetrics and Gynecology in 2019 and have maintained board certification since then.

3. I have been practicing as an obstetrician-gynecologist in my hometown of Wichita, Kansas, since 2017. I provide medical care to women facing crisis pregnancies, those considering abortion, and those who are post-abortive, including women facing complications from their abortions. I also care for women who regret their decision to procure an abortion, including those who have sought to reverse the medication abortion process soon after starting it. Moreover, I have provided care to women through the abortion pill reversal process, including multiple women who went on to successfully deliver healthy babies after abortion pill reversal and one woman whose delivery I had the honor to attend myself after undergoing abortion pill reversal.

4. My experience and qualifications are set forth in further detail in my *curriculum vitae*, attached hereto as Exhibit A.

Medication Abortion

5. Medication abortion involves the use of abortion-causing drugs to terminate a pregnancy. A commonly used protocol for medication abortion involves the oral administration of mifepristone, followed—usually about 1 to 2 days later—

by the vaginal administration of misoprostol. Mifepristone works by competing with progesterone at a molecular level to bind to progesterone receptors in and around the uterus. This phenomenon—competitive receptor antagonism—diminishes the effect of progesterone in those tissues. Because progesterone works by several mechanisms to sustain the healthy development of a pregnancy within the uterus, its disruption by mifepristone works to interfere with said development. As such, mifepristone disrupts the development of an early pregnancy, and often results in the death of an embryo or fetus.

6. Misoprostol is a prostaglandin which works at a molecular level to—among other effects—soften the cervix, facilitate its dilation, and cause uterine contractions sufficient to evacuate the uterus. The combination of mifepristone and misoprostol thus causes the termination of pregnancy first by halting the development of an early pregnancy, and then by expelling the uterine contents including placental tissue and embryo or fetus.

Abortion Pill Reversal

7. Progesterone is a natural hormone which promotes the early development of a pregnancy within the uterus. Abortion pill reversal (APR) is based on the biologic phenomenon of reversible competitive inhibition. At the molecular level, the inhibition that one agent would have on a receptor—in this case mifepristone acting on progesterone receptors—can be reversed if enough of another agent acting on the same receptor—in this case, progesterone—is present to displace the inhibiting agent. APR involves the use of progesterone to compete with

mifepristone at progesterone receptors, counteracting the effects of mifepristone and enhancing the natural effects of progesterone in supporting the development of a healthy pregnancy. Although mifepristone does not directly affect the amount of progesterone in the body, it competes with progesterone molecules to exert its effect on progesterone receptors, which ultimately drive the biological effects of progesterone in supporting an early pregnancy. Thus, by supplementing progesterone, the APR protocols aim to outcompete mifepristone at the progesterone receptors, and thus to restore the healthy function of progesterone receptors, supporting normal placental and fetal development.

8. APR is a safe and effective option for pregnant women who have taken mifepristone recently but have not taken misoprostol. As of 2022, the APR protocol has been used in all 50 states and in 86 countries and data indicates that it has resulted in over 4,000 lives being saved from the fatal effects of medication abortion on the living human fetus.[1]

9. The best available clinical research demonstrates that using progesterone to counter the effects of mifepristone and to stop the medication abortion process is safe and effective:

a. Drs. Delgado and Davenport reported a case series of six women who sought abortion reversal with the use of progesterone and found that four of those women went on to deliver healthy children.[2]

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[1] https://www.heartbeatinternational.org/images/ImpactReports/APRN_Impact_Report_2022.pdf

[2] George Delgado & Mary L. Davenport, Progesterone Use to Reverse the Effects of Mifepristone, 46 Annals of Pharmacotherapy n.13 (2012).

b. Drs. Garrett and Turner, a few years later, described reports of three women who used progesterone in attempts to reverse medication abortion. Similarly, two of the three successfully reversed the process and went on to deliver.[3]

c. In 2018, Dr. Delgado published what remains to date the largest clinical study describing outcomes of over 700 patients who attempted APR. The overall reversal success rate was 48% and as high as 68% in subgroups receiving the progesterone doses and schedule typically used now in contemporary APR protocols. Safety analyses revealed no increased risks of birth defects or preterm labor compared to the general population baseline rates.[4]

d. In 2019, Drs. Creinin and colleagues published the first randomized controlled trial studying APR outcomes and found similar success and safety profiles for women undergoing APR. In particular, four of the five women (80%) receiving progesterone for abortion reversal had successful treatment defined as continuation of a living pregnancy 2 weeks following reversal. One woman in the study undergoing APR presented to the emergency room for heavy bleeding but was found to have completed the abortion process and required no treatment.

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[3] D. Garratt D, J.V. Turner, Progesterone for Preventing Pregnancy Termination After Initiation of Medical Abortion with Mifepristone, Eur. J. Contraception & Reprod. Health Care, 472–75.

[4] George Delgado, et al., A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone, 33 Issues Law Med. 21–31 (Spring 2018)

> Unfortunately, the study was halted because of safety concerns, especially among women who did not receive APR; in particular, the study included a control arm who received mifepristone monotherapy (that is, mifepristone, but neither the misoprostol to complete the medication abortion thereafter, nor progesterone to reverse it). Two of the five women (40%) in that group required emergency treatment for hemorrhage. Although the study was brief, its findings were generally consistent with aforementioned clinical research findings by Dr. Delgado and others; in particular, the study indicates that mifepristone monotherapy is not safe or effective but that APR is.

10. In addition to the above clinical research describing the safety and effectiveness of APR, exploratory research has been published describing patients' experience with APR. In my opinion, the findings of such emergent literature support the claim that APR is an option about which patients undergoing medication abortion should be informed. A survey of women who had completed the APR protocol between 2018 and 2022 found significantly lower self-reported difficulty in the decision to proceed with abortion pill reversal, compared to the greater difficulty in the decision to proceed with medication abortion. Additionally, women self-reported more satisfaction and higher quality interactions with their APR provider than with their

abortion provider, as reflected in Quality of Physician Patient Interaction (QQPPI) scores, a clinically validated questionnaire for patient-physician interactions.[5]

Experience with APR

11. Since practicing independently as an obstetrician-gynecologist in 2017, I would estimate that approximately 10 women have sought abortion pill reversal with me. Of those, I would estimate that about half were lost to follow up before beginning the protocol (either due to establishing with another provider to complete APR or due to uncertainty about proceeding with APR). Of the remaining five:

a. 2 went on to deliver healthy babies, having transferred to another obstetrical provider after completion of APR;

b. 1 went on to deliver a healthy baby, continuing care with me such that I was able to be present for the delivery;

c. 1 was lost to follow up after the first two weeks (failed to answer phone calls or return for clinic visits);

d. 1 went on to have a miscarriage.

The Value of Fully Informing Patients

12. As a physician, I believe that patients should remain fully informed of the risks, benefits, and alternatives to interventions they are undergoing. In the case of an ongoing medical intervention, such as that outlined for medication abortion, informed consent should be maintained to the greatest degree feasible. This should

[5] Rafferty and Longbons. "Understanding women's communication with their providers during medication abortion and abortion pill reversal: an exploratory analysis." *The Linacre Quarterly*. Vol 90, No 2. May 2023.

include information about the risks, benefits, and alternatives to continuing or stopping the medication abortion process once it has begun.

13. A recently published article in a bioethics journal outlines this well:

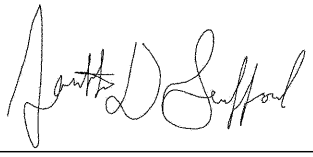
> "In general, patients are permitted to withdraw their consent for an intervention throughout the process, and the same should be the case with abortion . . . [If] we respect a woman's choice, this should be throughout every stage of the abortion process. Women with capacity are currently free to take the calculated risk of not taking the second abortion pill, even if it might be associated with a higher risk of hemorrhage. But it would be suboptimal care for such women not to be offered progesterone if the pregnancy is still potentially viable, given that it has not been associated with any increased risk compared to not taking misoprostol, and is likely to increase the chances of keeping the pregnancy . . . As such, the pro-choice advocate, committed to both expanding women's reproductive choices and increasing the safety profile of those choices, is consequently committed to supporting APR—and certainly not opposing it."[6]

Conclusion

14. Because there is a safe and effective reversal process available, and because some women change their minds about procuring an abortion after receiving mifepristone, it is reasonable to offer this life-saving treatment to women. Moreover, it is reasonable to ensure that women procuring a medication abortion—some of whom may regret their decision—be informed of the possibility to reverse the process as outlined above.

[6] Pruski, Whitehouse, and Bow. "The right to choose to abort an abortion: should pro-choice advocates support abortion pill reversal?" *The New Bioethics*. 2022.

I declare under penalty of perjury under the laws of the state of Kansas that the foregoing is true and correct. Executed on June 29, 2023.



Jonathan D. Scrafford, M.D.

EXHIBIT A

Jonathan Scrafford, MD, FACOG

403 N Cyrilla St | Wichita, KS 67235
316-882-7362 (H) | 316-737-4138 (C)
scraf003@umn.edu

EDUCATION AND TRAINING

University of Minnesota **2013 - 2017**
Minneapolis, MN
Residency in Obstetrics & Gynecology
Honors: Class Representative (Class of 2017) **2013-2017**
Chief Resident **2016-2017**
Leon L Adcock Award **2015, 2016**
Hardin E. Olson Award **2016, 2017**
Raymond J Albrecht Award **2017**

University of Minnesota Medical School **2009 - 2013**
Minneapolis, MN
Medical Degree (MD): 3 May 2013
Honors:
- Alpha Omega Alpha (Class of 2013)
- Dean's Scholarship (2009-2013)

Stanford University **2005 - 2009**
Palo Alto, CA
Major Degree: Biological Sciences (Bachelor of Science)
Minor Degree: Spanish
Graduated with Distinction

Bishop Carroll High School **2001 - 2005**
Wichita, KS
Honors: Valedictorian, Student Body President, Varsity Tennis Team Captain

EMPLOYMENT HISTORY

Obstetrician / Gynecologist **July 2017 - Present**
Ascension Health - Via Christi | Wichita, KS

Course Assistant / Course Coordinator **October 2007 – June 2009**
Stanford University | Palo Alto, CA

Research Assistant, Stowers Scholar **June 2007 – September 2007**
Stowers Institute for Medical Research | Kansas City, MO

Camp Counselor **June 2006 – August 2006; June 2008 – August 2008**
Bay Cliff Health Camp | Big Bay, MI

AWARDS

Volunteer Faculty Teaching Award **2018, 2019, 2020, 2021, 2022**
Awarded by residents for excellence in teaching, selected among volunteer faculty for the Via Christi Family Medicine residency program in Wichita, KS

Leon L. Adcock Award **2015, 2016**
University of Minnesota Department of Obstetrics, Gynecology, and Women's Health | Minneapolis, MN
Presented each year to a resident physician for excellence in teaching obstetrics and gynecology to medical students

Hardin E. Olson Award **2016, 2017**
University of Minnesota Department of Obstetrics, Gynecology, and Women's Health | Minneapolis, MN
Presented each year to the resident with the top research presentation, and the resident with the top research poster

Raymond J Albrecht Award **2017**
University of Minnesota Department of Obstetrics, Gynecology, and Women's Health | Minneapolis, MN
Presented each year to the resident whose activities in clinical care & teaching approach the highest values of the practice

Alpha Omega Alpha **2012**
University of Minnesota Medical School | Minneapolis, MN
The national medical honor society, for academic performance in the top 15% of the UMN graduating class of 2013

Dean's Scholarship **2009 - 2013**
University of Minnesota Medical School | Minneapolis, MN
For high academic achievement and potential, evidence of outstanding leadership, and community involvement

Hoefer Prize for Excellence in Undergraduate Writing in the Major **2008**
Stanford University | Palo Alto, CA
For top undergraduate written work related to an academic degree.

RESEARCH, PUBLICATIONS, AND PRESENTATIONS

Opportunistic Salpingectomy during Cesarean Section
Publication: *National Catholic Bioethics Quarterly*. Vol 18, Issue 3, pp 487-500. 2018

Overcoming Technocracy in Obstetrics: The Birth Center as a Model of Compassionate Care
Oral presentation: Catholic Medical Association, National Meeting, Dallas, TX. 2018

"Mirror of Patients": A reflection on the honor of serving as a male obstetrician-gynecologist
Publication: *Linacre Quarterly*. Vol 85, Issue 3, pp 202-203. 2018

***Celebrating 50 Years of* Humanae Vitae**
Oral presentation: Catholic Medical Association, Twin Cities Guild Winter Symposium, Saint Paul, MN, 2018

FEMM: Fertility Education and Medical Management
Oral presentation: World Youth Alliance Emerging Leaders Conference, Benedictine College, Atchison, KS, 2017

Salt, Light, and Leaven: Preserving the Ethical and Religious Directives in the medical training environment
Oral presentation: Annual education conference of the Catholic Medical Association (CMA), Denver, CO, 2017

Effect of Changing Gloves During Cesarean Section on Post-Operative Infectious Morbidity
Publication: Scrafford, Reddy, Rivard, and Isaksson Vogel. "Effect of intra-operative glove changing during cesarean section on post-operative complications: a randomized controlled trial." *Archives of Gynecology and Obstetrics*. Vol 297, Issue 6, pp 1449-1454. June 2018
Oral presentation: National meeting of the American College of Obstetricians & Gynecologist (ACOG), San Diego, CA, 2017

Maternal Experience with Cesarean Section at Periviable Gestation
Elizabeth Johnson (MS4), Jonathan Scrafford (MS2), Lois Gilmore (RN), Stacy Svobodny (ART), Ronald Hoekstra (MD), Steven Calvin (MD)
Research Abstract, completed 2010

Human Rap1 Inhibits Non-Homologous End-Joining at Telomeres.
Jay Sarthy (BS), Nancy S Bae (PhD), Jonathan Scrafford, Peter Baumann (PhD)
Original Research Article
Published: *European Molecular Biology Organization (EMBO Journal)*. 2009 November 4; 28(21):3390-3399.

La Globalización de la Ética: Análisis filosófico de la universalidad de la ética humana
Original Composition, Spanish Language
Published: Stanford University, Hoefer Prize compilation, 2008

PROFESSIONAL QUALIFICATIONS

National Board of Physicians and Surgeons
Board certification in obstetrics & gynecology through the NBPAS. Certification maintained since 2022

Fellow of the American Congress of Obstetrics and Gynecology
Board certification through the American Board of Obstetrics & Gynecology. Certification maintained since January 2019

Natural Family Planning Medical Consultant (NFPMC)
Completed medical consultant training integrating the Creighton Model system of natural family planning and FertilityCare, through the Pope Paul VI Institute (Omaha, NE) in April 2018.

FEMM Medical Consultant
Certified in FEMM (Fertility Education & Medical Management), a mode of functional restorative reproductive medicine
Certified June 2017

PROFESSIONAL AND ACADEMIC MEMBERSHIPS

Alpha Omega Alpha
Member since 2012
Alpha Omega Alpha is the national medical honor society. Nomination to the AOA represented academic performance in the top 15% of the graduating class of 2013 at the University of Minnesota Medical School

Via Christi Ethics Integration Committee
Wichita, KS Member 2017-2018
Vice Chair 2018

Catholic Medical Association
National Organization: Member since 2009
Minneapolis / St. Paul Guild:
- Member / Officer from 2009 to 2017
- Board Member from 2011 to 2017

Wichita St. Gianna Guild:
- Member since 2017
- Vice President 2018-2021
- President since 2021

Medical Students for Human Life
University of Minnesota
Officer, 2010-2013
President, 2010-2011

Twin Cities Fertility Care Center
Saint Paul, MN
Board Member from 2013 to 2017