In The Supreme Court of the United States

TERRY CLINE, in his official capacity as Oklahoma Commissioner of Health, ET AL.,

Petitioners,

v.

OKLAHOMA COALITION FOR REPRODUCTIVE JUSTICE, ET AL.,

Respondents.

On Petition For A Writ Of Certiorari To The Supreme Court Of Oklahoma

BRIEF OF WOMEN AND FAMILIES HURT BY RU-486 AS AMICI CURIAE IN SUPPORT OF PETITIONERS

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The Amici respectfully submit this amicus curiae brief in support of Petitioners. Consent to file the amicus curiae brief was given by both parties. This brief supporting Petitioner was prepared by counsel for Amici.¹

STATEMENT OF INTEREST OF THE AMICI CURIAE

This case is of great national importance and consequence because it goes to the heart of this Court's decision in *Planned Parenthood v. Casey*. The State may impose reasonable regulations that do not create an undue burden on a woman's right to decide. In addition, a woman must be given full, accurate, and truthful information so that she can make an informed decision whether to abort her unborn child. The women Amici who have taken RU-486, their families, and former abortion facility workers have personal knowledge as to how RU-486 affects women

¹ The parties were notified ten days prior to the due date of this brief of the intention to file. The parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. Trinity Legal Center is a nonprofit corporation and is supported through private contributions of donors who have made the preparation and submission of this brief possible. No person other than Amici, their counsel, or donors to Trinity Legal Center made a monetary contribution to its preparation or submission.

and how they are not adequately warned of the dangers of the drug regimen. The Amici are Jennifer Baros (Colorado); Carol Everett (Texas); Abby Johnson (Texas); Monty Patterson, father of Holly Patterson (California); Lindsey Poe (Arkansas); and, Leslie Wolbert (New York). They urge this Court to grant certiorari and reverse the Oklahoma Supreme Court's decision.

Amici Concerned Women of America (CWA) is a 501(c)(3) public policy women's organization. It is the nation's largest public policy women's organization which was founded in the 1970's. CWA's membership consists of half a million women with nearly 500 chapters in almost every state. CWA of Oklahoma has more than 5,000 members. Two of CWA's six core issues are the family and the sanctity of human life which includes the abortion issue.

SUMMARY OF THE ARGUMENT

I.

The Oklahoma Legislature enacted legislation to ensure that the FDA guidelines for RU-486 would be followed. This was a reasonable regulation that does not impose an undue burden on a woman's right to decide. The Oklahoma Supreme Court erred in summarily holding the provision unconstitutional as this Court allows reasonable regulations that do not impose an undue burden on the woman's right to decide. Furthermore, this Court requires that women are

given accurate and truthful information to make an informed decision. The Oklahoma Supreme Court based its decision on this Court's decision in *Planned Parenthood v. Casey*, but it misinterpreted and misapplied *Casey*. Therefore, Amici urge this Court to grant the writ of certiorari.

II.

The RU-486 regimen and other drugs that are used in medical abortions expose women to an increased risk of both physical and psychological harm. This is supported by scientific and medical studies that demonstrate this increased risk. In addition, the women Amici attest to the physical and psychological trauma as a result of taking RU-486. Therefore, the Oklahoma Legislature was justified in providing for safety measures as articulated by the FDA to protect women. This was within the State's authority under the rulings of this Court.

ARGUMENT

- I. THIS CASE IS CERTWORTHY BECAUSE THE OKLAHOMA SUPREME COURT MISAPPLIED THIS COURT'S DECISION IN PLANNED PARENTHOOD V. CASEY AND ONLY THIS COURT CAN CORRECT THE ERROR.
 - A. The State Has the Right to Provide Reasonable Regulations for the Health and Safety of Women, and Therefore, the Oklahoma Supreme Court Erred.

Because this Court found a constitutional right to decide in *Roe v. Wade*² and *Doe v. Bolton*,³ only this Court can correct the lower court's errors in interpretation and application. The Oklahoma Supreme Court, relying on this Court's decision in *Planned Parenthood v. Casey*,⁴ held House Bill 1970, 2011 Okla. Sess. Laws 1276 (codified at 63 Okla. Stat. § 1-729a) unconstitutional and placed it squarely within the constitutional framework that this Court would have to decide.

The Oklahoma Supreme Court erred in its interpretation and application of *Casey*. This Court recognized in *Casey* that because the State has a substantial interest in the life of the unborn child, the State may promulgate regulations that do not create

² 410 U.S. 113 (1973).

³ 410 U.S. 179 (1973).

⁴ 505 U.S. 833 (1992).

an undue burden on the woman's right to decide.⁵ In particular, regulations that are "designed to foster the health of a woman seeking an abortion are valid if they do not constitute an undue burden." This Court stated:

As with any medical procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion. Unnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right.⁷

Furthermore, this Court has upheld abortion regulations that "are not efforts to sway or direct a woman's choice, but rather are efforts to enhance the deliberative quality of that decision or are neutral regulations on the health aspects of her decision." In a case interpreting an Ohio statute virtually identical to the Oklahoma provision, the Court of Appeals for the Sixth Circuit concluded that there was no evidence the Act would impose an undue burden on a woman's ability to decide whether to have an abortion, and therefore, the statute was

⁵ Planned Parenthood v. Casev. 505 U.S. 833, 876 (1992).

⁶ *Id.* at 877.

⁷ *Id.* at 878.

 $^{^{8}}$ Id. at 917 (Stevens, J., concurring in part and dissenting in part) (providing examples of valid regulations including written informed consent, recordkeeping and reporting, pathology reports, and licensing and qualification provisions).

constitutional.⁹ Unlike the Court of Appeals for the Sixth Circuit that provided a detailed analysis for its conclusion, the Oklahoma Supreme Court summarily concluded that the Oklahoma provision was unconstitutional without analysis or explanation.

As long as there is a "commonly used and generally accepted method" of abortion, there is not a "substantial obstacle to the abortion right." Specifically, this Court stated in *Gonzales v. Carhart*: 11

Considerations of marginal safety, including the balance of risks, are within the legislative competence when the regulation is rational and in pursuit of legitimate ends. When standard medical options are available, mere convenience does not suffice to displace them; and if some procedures have different risks than others, it does not follow that the State is altogether barred from imposing reasonable regulations.¹²

The RU-486 regimen poses a substantial risk to the physical health of women including the risk of death. Both the FDA¹³ and Danco, the drug

 $^{^{\}rm 9}$ Planned Parenthood v. DeWine, 696 F.3d 490, 513-14 (6th Cir. 2012).

¹⁰ Gonzales v. Carhart, 555 U.S. 124, 165 (2007).

^{11 555} U.S. 124 (2007).

¹² *Id*. at 166.

¹³ Congressional Staff Report, The FDA and RU-486: Lowering the Standard for Women's Health, prepared for the Chairman of the House Subcommittee on Criminal Justice, Drug (Continued on following page)

manufacturer,¹⁴ have acknowledged that RU-486 poses health risks for women. The Mifeprex drug label acknowledges that "[n]early all of the women who receive Mifeprex and misoprostol [the RU-486 regimen] will report adverse reactions, and many can be expected to report more than one such reaction."¹⁵ These adverse reactions include abdominal pain, uterine cramping, nausea, vomiting, diarrhea, pelvic pain, fainting, headache, dizziness, and asthenia.¹⁶

The Congressional Staff Report on RU-486 cited FDA findings concerning the physical risks to women taking RU-486 regimen.¹⁷ These included: "abdominal pain; uterine cramping; nausea; headache; vomiting;

Policy and Human Resources, at page 30 (Oct. 2006), available at http://old.usccb.org/prolife/issues/ru486/SouderStaffReportonRU-486.pdf (citing FDA findings and reporting adverse reactions).

 $^{^{^{14}}}$ See MIFEPREXTM Label, available at http://www.access data.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm.

¹⁵ See MIFEPREXTM Label, available at http://www.access data.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm; Congressional Staff Report, The FDA and RU-486: Lowering the Standard for Women's Health, prepared for the Chairman of the House Subcommittee on Criminal Justice, Drug Policy and Human Resources, at page 30 (Oct. 2006), available at http://old.usccb.org/prolife/issues/ru486/SouderStaffReportonRU-486.pdf.

 $^{^{\}mbox{\tiny 16}}$ MIFEPREXTM Label, available~at http://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm.

¹⁷ Congressional Staff Report, *The FDA and RU-486: Lowering the Standard for Women's Health*, prepared for the Chairman of the House Subcommittee on Criminal Justice, Drug Policy and Human Resources, at page 30 (Oct. 2006), *available at* http://old.usccb.org/prolife/issues/ru486/SouderStaffReportonRU-486.pdf.

diarrhea; dizziness; fatigue; back pain; uterine hemorrhage; fever; viral infections; vaginitis; rigors (chills/shaking); dyspepsia; insomnia; asthenia; leg pain; anxiety; anemia; leucorrhea; sinusitis; syncope; endrometritis/salpingitis/pelvic inflammatory disease; decrease in hemoglobin greater than 2 g/dL; pelvic pain; and fainting."¹⁸

The FDA's Medical Officer's review indicated that, "[m]ore than one adverse event was reported for most patients. . . . Approximately 23% of the adverse events in each gestational age group were judged to be severe." The Congressional Staff Report calls these "startling adverse effects," which the FDA knew during the RU-486 NDA review process. 20

Also of concern was "the incredibly high failure rate of the drug." The FDA knew the failure rate was averaging 14.6% in the U.S. trial testing the drug through 63 days gestation. The findings were that 27% had ongoing pregnancies, 43% had incomplete abortions, 10% requested and had surgical terminations, and the remaining 20% of patients had surgical terminations performed because of medical indications directly related to the medical procedure. ²²

 $^{^{^{18}}}$ Id.

¹⁹ *Id*.

 $^{^{20}}$ Id.

 $^{^{21}}$ Id.

 $^{^{22}}$ Id.

The Report stated the "best" outcome was in the patient group where the pregnancies were less than or equal to 49 days.²³ In this group, the Report stated that 7.9% of patients required surgical intervention after taking RU-486.²⁴ The Report also stated that as "the gestational age increases, the failure rate of RU-486 increases rapidly, to 17% in the 50-56 days gestation group, and 23% in the 57-63 days gestation group," The Congressional Staff Report concluded that "By any objective standard, a failure rate approaching eight percent and requiring subsequent surgical intervention as the 'best' outcome is a dismal result." Indeed, this is a dismal result.

In 2011, the FDA issued a report on the post-marketing events of RU-486.²⁷ The FDA reported that there were 2,207 adverse events (complications) in the United States. related to the use of RU-486, including hemorrhaging, blood loss requiring transfusions, serious infections, and death.²⁸ Among the 2,207 adverse events were 14 deaths, 612 hospitalizations,

²³ *Id*. at 31.

 $^{^{24}}$ Id.

 $^{^{25}}$ Id.

²⁶ *Id*.

²⁷ Food and Drug Administration, *Mifepristone U.S. Post-marketing Adverse Events Summary Through 04/30/2011* (July 2011), *available at* http://www.fda.gov/downloads/Drugs/Drug Safety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf.

 $^{^{28}}$ Id.

339 blood transfusions, and 256 infections (including 48 "severe infections"). 29

In accordance with this Court's decision in *Casey* and *Gonzales*, providing for the safety of drugs and medical procedures are within the legitimate function of the State, and therefore, the Oklahoma Supreme Court should have held that House Bill 1970 is constitutional.

B. This Court Requires That Women Must Be Given Accurate and Truthful Information, and Therefore, the Oklahoma Supreme Court Misapplied *Casey*.

In *Casey*, this Court emphasized the need for a woman to have full, accurate, and truthful information so that she could make an informed decision.³⁰ House Bill 1970 provides reasonable protections for women considering taking the RU-486 regimen based on FDA guidelines for the drug regimen. Off-label use of RU-486 regimen misleads women into thinking that it is safe and approved by the FDA.

This Court correctly stated that it is important for a woman to have full and accurate information to make an informed decision because of the psychological consequences of later realizing that she did

²⁹ Id

 $^{^{\}scriptscriptstyle 30}\,$ Planned Parenthood v. Casey, 505 U.S. 833, 882 (1992).

not have accurate information or know the truth.³¹ This Court stated in *Casey*:

In attempting to ensure that a woman apprehend the full consequences of her decision, 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. If the information the State requires to be made available to the woman is truthful and not misleading, the requirement may be permissible.³²

Approximately 1.2 million abortions are performed each year in the United States.³³ Of that number, seventeen percent of all abortions are medical abortions.³⁴ For pregnancies within the first nine

 $^{^{\}scriptscriptstyle 31}$ Id.

 $^{^{32}}$ Id.

³³ Guttmacher Institute, *Fact Sheet: Facts on Induced Abortions in the United States* (Aug. 2011), *available at* http://www.guttmacher.org/pubs/fb_induced_abortion.html (stating "In 2008, 1.21 million abortions were performed, down from 1.31 million in 2000. However, between 2005 and 2008, the long-term decline in abortions stalled. From 1973 through 2008, nearly 50 million legal abortions occurred.").

³⁴ *Id.* (stating "In 2008, 59% of abortion providers, or 1,066 facilities, provided one or more early medication abortions. At least 9% of providers offer only early medication abortion services. Medication abortion accounted for 17% of all nonhospital abortions, and about one-quarter of abortions before nine weeks' gestation, in 2008.").

week, that percentage rises to one-quarter of the abortions are medical abortions.³⁵ Therefore, approximately 200,000 women are at risk each year for physical and psychological harm from medical abortions such as the RU-486 regimen. These women are entitled to have drugs approved by the FDA instead of off-label use of the drugs. Furthermore, women need to know accurate and truthful information about the drugs that they are taking and what side effects and risks may occur. To do any less would not be informed consent.

The Oklahoma Supreme Court has set a bad precedent based on a misinterpretation and misapplication of this Court's decision in *Casey*. Therefore, the Amici urge this Court to grant certiorari.

 $^{^{35}}$ Id. (stating one-quarter were medication abortions).

- II. MEDICAL ABORTIONS EXPOSE WOMEN TO INCREASED RISKS OF PHYSICAL AND PSYCHOLOGICAL HARM, AND THERE-FORE, THE OKLAHOMA LEGISLATURE WAS PROPER IN PROVIDING SAFETY MEASURES TO PROTECT WOMEN.
 - A. Scientific and Medical Studies Demonstrate that Medical Abortions Present Increased Risks Physical and Psychological Problems.

Physical Risks of RU-486

A woman should be given factual information about the physical and psychological risks of the RU-486 regimen. The purpose of "[i]nformed consent provisions serve not only to communicate information that would not necessarily be known to the patient, but also help the woman to make a fully informed decision." Therefore, women should be given information that they are exposed to increased risk of physical and psychological problems by taking the RU-486 regimen.³⁸

 $^{^{\}rm 36}$ Planned Parenthood of Indiana, Inc. v. Commissioner, 794 F. Supp. 2d 892, 918 (S.D. Ind. 2011).

³⁷ *Id*.

³⁸ Planned Parenthood v. Rounds, 686 F.3d 889, 898 (8th Cir. 2012) (holding disclosure that an increased risk of suicide ideation and suicide is non-misleading and relevant to the patient's decision to have an abortion and other psychological distress was not challenged).

The Oklahoma State Board of Medical Licensure and Supervision produced the Woman's Right to Know Booklet³⁹ to provide women accurate and truthful information.⁴⁰ The booklet discusses the RU-486 procedure and side effects. Included in the list of side effects are: incomplete abortion, heavy bleeding, painful cramping, allergic reaction to the drugs, nausea and/or vomiting, diarrhea, fever, infection, fertility can be diminished, birth defects if the pregnancy does not end, death, and emergency treatment.⁴¹ Since the booklet was produced in 2006, more scientific information is available on the risks and side effects of the RU-486 regimen and that those risks are greater than with surgical abortion.

In reviewing and assessing the scientific literature, researchers have concluded that there are increased risks of physical problems with the RU-486 regimen. These include: more pain, more nausea or vomiting, higher failure rate, greater risks of acute bleeding requiring surgery, post-procedure bleeding continues for a longer period of time, more women require surgery for persistent bleeding, more

³⁹ Oklahoma Woman's Right to Know Booklet (2d ed. 2006) available at http://www.awomansright.org/pdf/AWRTK_Booklet-English-sm.pdf.

 $^{^{\}scriptscriptstyle 40}$ Id. at 3 (stating that it gives "current and medically reliable" information).

⁴¹ *Id*. at 10.

 $^{^{^{42}}}$ Shuping, Harrison, Gacek, *Medical Abortion with Mifepristone (RU-486) Compared to Surgical Abortion*, available at http://rachelnetwork.org/images/Medical_Abortion_with_Mifepristone.pdf.

total blood loss, and greater risk of massive, life-threatening hemorrhage.⁴³ They also report that "Mifepristone abortion has 10 times more risk of death from infection than surgical abortion and 50 times more risk of death from infection compared to childbirth."⁴⁴

The risks of RU-486 are not only with the current pregnancy but may be transgenerational. Dr. Bernard Nathanson, co-founder of the National Association for the Repeal of Abortion Laws (NARAL) and who presided over 60,000 abortions, warned that if a woman starts taking the regimen but then changes her mind and wants to carry the baby to term, the newborn may have serious deformities.⁴⁵

In addition, Dr. Nathanson warned there may be the possibility that disorders could be passed down to surviving offspring of women who have taken the drug.⁴⁶ "RU-486 is the drug which acts on the female reproductive system, and anything that does that we have to be keenly aware of what are called transgenerational effects."⁴⁷

 $^{^{43}}$ Id.

⁴⁴ *Id.* (citations omitted).

 $^{^{\}scriptscriptstyle 45}$ The Silent Scream, Former Abortionist Bernard Nathanson, M.D. Warns of RU-486 Dangers, available at http://www.silentscream.org/ru486-drnat.htm.

⁴⁶ *Id*.

⁴⁷ *Id*.

Psychological Risks of RU-486

The RU-486 regimen also has increased risks for psychological problems. In scientific studies, women rated medical abortions more stressful and experienced more disruptions in their lives.⁴⁸ They also experienced a significant decline in self-esteem and higher PTSD intrusion scores.⁴⁹

There are at least five major reasons why women are at greater risk of more severe psychological trauma with the RU-486 regimen than with a surgical abortion. First, the woman has a participatory role with a medical abortion which may cause greater psychological trauma. This is because the woman is directly responsible for the abortion which may exacerbate guilt and other negative feelings.

The RU-486 regimen is a very difficult process and simply adds to emotional consequences. Unlike surgical abortion, the woman acts as the abortionist.⁵³ The drug is self-administered by her own hand and

 $^{^{\}mbox{\tiny 48}}$ Affidavit of Dr. Priscilla Coleman, attached as App. E (citing scientific studies).

 $^{^{49}}$ Id.

⁵⁰ *Id*.

 $^{^{51}}$ Id.

 $^{^{52}}$ Id.

Dr. Theresa Burke, Psychotherapist and founder of Rachel's Vineyard, Address at the American Association of Pro-Life OB-GYNS (AAPLOG) meeting entitled "Medical Abortion: New Emotional and Psychological Landscape" (Jan. 28, 2011).

there is no one else to blame or project anger on such as the abortionist or others. Because the woman plays an active role in the procedure and is conscious of each step, it is more likely that there will be psychological consequences. Here is one of the profound differences between surgical and medical abortion. In a surgical abortion, the woman is usually given drugs to be relaxed or to wake up after the procedure is complete. With RU-486, however, "she will have a memory of each step and its effects on her body and the body of her child. She cannot close her eyes to the process and tell herself that someone else is doing this to her . . . Simply looking in the mirror can become a triggering event."

Second, medical abortion requires the woman to be more alert and involved during the process.⁵⁷ Therefore, it is impossible for her to distance herself psychologically from the abortion.⁵⁸

Third, there is a greater potential for the woman to see her expelled unborn child.⁵⁹ There is no doubt in her mind that she has taken the life of her unborn child.

 $^{^{54}}$ Id.

 $^{^{55}}$ Id.

 $^{^{56}}$ *Id*.

⁵⁷ Affidavit of Dr. Priscilla Coleman, attached as App. E.

 $^{^{58}}$ Id.

⁵⁹ *Id*.

Fourth, although women usually say that they choose a medical abortion because it is in the privacy of her home, it is that privacy that can also lead to greater trauma. This is because the woman is more likely at home and alone. Thus, it is likely that she is without emotional support at the time of the abortion.

Fifth, the woman's home becomes a trigger point for negative emotions instead of being a place of refuge. ⁶² This is because she is at home and more specifically in the bathroom. Therefore, her home and the bathroom are associated with the abortion that she participated in a major and very visual way.

⁶⁰ *Id*.

 $^{^{61}}$ Id.

 $^{^{62}}$ Id.

⁶³ Dr. Theresa Burke, Psychotherapist and founder of Rachel's Vineyard, Address at the American Association of Pro-Life OB-GYNS (AAPLOG) meeting entitled "Medical Abortion: New Emotional and Psychological Landscape" (Jan. 28, 2011).

 $^{^{64}}$ *Id*.

reality of what she has done." Therefore, this "traumatic scene will be accessible each time a woman uses her bathroom, lays on her bed, or any other associations they make while waiting for the pill to do its job. Her very home becomes a daily trigger to traumatic feelings and sensations."

The courts also have recognized the negative psychological impact that abortion has on women. For example, the Court of Appeals for the Fifth Circuit cited testimony that abortion as practiced is "almost always a negative experience for the patient..."

This Court has recognized that abortion:

Is an act fraught with consequences for others; for the woman who must live with the implications of her decision; for the persons who perform and assist in the procedure; for the spouse, family, and society which must confront the knowledge that these procedures exist, procedures some deem nothing short of an act of violence against innocent human life; and depending on one's beliefs, for the life or potential life that is aborted.⁶⁸

More recently, this Court recognized, "whether to have an abortion requires a difficult and painful

⁶⁵ *Id*.

⁶⁶ *Id*.

 $^{^{\}mbox{\tiny 67}}$ Women's Medical Center v. Bell, 248 F.3d 411, 418 (5th Cir. 2001).

⁶⁸ Planned Parenthood v. Casey, 505 U.S. 833, 852 (1991).

moral decision" and is "fraught with emotional consequences." In addition, women can suffer from depression, regret, guilt, and a loss of self-esteem following an abortion. As Justice Ginsburg wrote, "The Court is surely correct that, for most women, abortion is a painfully difficult decision."

The RU-486 medical abortion regimen creates greater risks of both physical and psychological harm to women than surgical abortion. The Oklahoma Legislature was correct in providing for the protection of women considering the RU-486 regimen and requiring the FDA guidelines be followed instead of the off-label use that abortionists are prescribing. This Court has allowed these reasonable medical regulations, and therefore, the Oklahoma Supreme Court misinterpreted and misapplied this Court's decisions.

B. Women Attest of the Trauma They Experience as a Result of the RU-486 Regimen.

The courts and the scientific research support the conclusion that there are negative physical and psychological consequences of abortion on women and particularly the RU-486 regimen. But it is the real

⁶⁹ Gonzales v. Carhart, 550 U.S. 124, 159 (2007).

⁷⁰ *Id*

 $^{^{71}}$ Id. at 184 n.7 (Ginsburg, J., dissenting).

life experiences of women that bring to light the true impact of this dangerous drug regimen.⁷²

The RU-486 regimen process is generally over a two week period, and therefore, much longer than a surgical abortion which is completed on the same day in approximately fifteen minutes. On Day 1, the patient reads the *Medication Guide*, reads and signs the *patient agreement*, and then swallows three tablets of Mifeprex in the presence of a health professional. On Day 3, she is supposed to return to the abortion facility and be examined to determine if she is still pregnant. If she is pregnant, she is given two tablets of misoprostol. However, this is not the experience of these post-abortive women as they are

⁷² See Affidavit of Leslie Wolbert, attached as App. A and Affidavit of Abby Johnson, attached as App. B.

⁷³ Dr. Theresa Burke, Psychotherapist and founder of Rachel's Vineyard, Address at the American Association of Pro-Life OB-GYNS (AAPLOG) meeting entitled "Medical Abortion: New Emotional and Psychological Landscape" (Jan. 28, 2011).

⁷⁴ CRS Report for Congress, Abortion: Termination of Early Pregnancy with RU-486 (Mifepristone) at 14 (Feb. 23, 2001), available at http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL30866.pdf (discussing the process and history of RU-486), see also National Abortion Federation, Facts About Mifepristone (RU-486), available at http://www.prochoice.org/about_abortion/facts/facts_mifepristone.html (describing the process).

⁷⁵ CRS Report for Congress, Abortion: Termination of Early Pregnancy with RU-486 (Mifepristone) at 14 (Feb. 23, 2001) (discussing the process and history of RU-486), *available at* http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL30866.pdf.

 $^{^{76}}$ *Id*.

given a "brown bag of pills" to be taken at home.⁷⁷ On Day 14, she is supposed to return to the abortion facility for a follow-up visit to confirm the pregnancy has been terminated and assess the level of bleeding.⁷⁸ This also may not be the case if she has had to go to the emergency room due to hemorrhaging or infection. Just by the mere method of the RU-486 regimen, the woman's ordeal is prolonged over at least a two week period in contrast to the surgical abortion procedure which is usually over in 10-15 minutes.

Although the abortion facility may generally tell a woman what the regimen will be, the women are not prepared for what is truly involved. For example, Leslie attests that "Nothing could have prepared me for what I would experience, or the emotional pain that I would carry for years." She "trusted the clinic." They referred to the baby as "just a blob of tissue." When the clinic workers counseled her, they

⁷⁷ Affidavit of Abby Johnson, attached as App. B. The National Abortion Federation admits that there may not be a second visit to the clinic but that the drugs may be taken at home. National Abortion Federation, Facts About Mifepristone (RU-486), *available at* http://www.prochoice.org/about_abortion/facts/facts_mifepristone.html

⁷⁸ CRS Report for Congress, Abortion: Termination of Early Pregnancy with RU-486 (Mifepristone) at 14 (Feb. 23, 2001) (discussing the process and history of RU-486), *available at* http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL30866.pdf

⁷⁹ Affidavit of Leslie Wolbert, attached as App. A.

 $^{^{80}}$ *Id*.

⁸¹ *Id*.

told her about the abortion pill and "how 'simple' it was and that you didn't have to go through surgery, but that you would have a heavy period instead."⁸²

But Leslie quickly learned that what she had been told was not accurate or truthful information. "It was the second day that I experienced the worst pain I've ever felt in my life. The experience wasn't just a heavy period. I was bleeding like I never knew possible." She goes on to say that "... the cramps were not just severe – I thought I was dying because they were so intense. I was crying hysterically and begging to die because the pain was more than I could handle. I was sweating like crazy and on the toilet while throwing up too." She "was alone, and afraid" and too ashamed to share with anyone what was truly causing her physical and emotional pain. 85

Leslie also experienced severe hemorrhaging. She states: "I bled so much that it clogged the drain . . . It was my baby that was clogging the drain of the shower. I had to turn off the water, get out, and clean it up myself and then I flushed it down the toilet. It was even more horrifying than it sounds."

In addition, Leslie experienced the trigger problems associated with the RU-486 regimen. She

 $^{^{82}}$ Id.

⁸³ *Id*.

⁸⁴ *Id*.

⁸⁵ *Id*.

attests: "This was all done in my own home, in the family bathroom, the family shower, the home where I had to live after this experience. The emotional pain this caused made it almost unbearable to be at home after that. I hated showering and I hated sleeping in my bed, I hated being around my family, I didn't want to be there anymore and tried my best to avoid being home."

Leslie's experience is not unusual.⁸⁷ Abby Johnson, a former Director of Planned Parenthood who took the RU-486 regimen, had a similar experience. She attests that what she experienced was different from what Planned Parenthood told her and "was totally unexpected."⁸⁸ She states: "...I started to feel pain in my abdomen unlike anything I had ever experienced. Then the blood came. It was gushing out of me... The only thing I could do was sit on the toilet. I sat there for hours ... bleeding, throwing up into the bathroom trashcan, crying, and sweating."

Abby attests that blood clots the size of lemons were being expelled. She knew the huge clot was not going to go down the drain, so I reached down to pick it up. I was able to grasp the large clot with both hands and move it to the toilet. She thought that

⁸⁶ *Id*.

⁸⁷ For example, *see* Affidavit of Carol Everett, attached as App. C and Affidavit of Abby Johnson, attached as App. B.

⁸⁸ Affidavit of Abby Johnson, attached as App. B.

⁸⁹ *Id*.

⁹⁰ *Id*.

this could not be normal because Planned Parenthood never told her that this kind of severe hemorrhaging could happen. 91 "This must be atypical. I decided that I would call them in the morning . . . if I did not die before then." 92

The next morning, Abby called Planned Parenthood. What was even more shocking to her was the response that she got from the Planned Parenthood nurse. She told Abby, that it "'is not abnormal.' I was shocked. She could not be serious. All of the bleeding, the clotting, the pain . . . that was NORMAL! 'Yes,' she said . . . I was angry. How could they not tell me the side effects? I felt so betrayed."

When Abby worked at Planned Parenthood, she told women of her experience. He are Planned Parenthood did not want Abby around women considering the RU-486 regimen and said "Don't let Abby see the MAB (medication abortion) clients. She will change all of them to surgical abortions and we will be here all day." Abby did not believe that there was anything natural about this type of abortion, she personally hated it, and had seen too many women hurt by it. He are to be surgical abortion.

 $^{^{91}}$ *Id*.

 $^{^{92}}$ *Id*.

⁹³ *Id*.

 $^{^{94}}$ Id.

⁹⁵ *Id*.96 *Id*.

One woman who was hurt by RU-486 was Holly Patterson who was the first woman in the United States to die of the drug regimen. Planned Parenthood had given Holly the unapproved, off-label RU-486 medical abortion regimen. Holly tragically died from an infection known as Clostridium sordellii toxic shock syndrome that was associated with a medically induced abortion. Holly had not been given accurate and truthful information concerning the RU-486 regimen so that she could make an informed decision. Mr. Patterson, Holly's father, attests to how painful this abortion experience has been for his family and that it was the worst day of his life as he watched his daughter die.

The Oklahoma Legislature was correct in requiring use of RU-486 in accordance with FDA guidelines to protect women. It is even more critical that the law is upheld because "Planned Parenthood is planning to expand their medication abortion protocols to EVERY family planning clinic in the country in the next 5 years." Abby states: "Women need to know the truth so that they can make the right decision. Women do not have to die. They do not need to be hurt by

⁹⁷ Affidavit of Monty Patterson, attached as App. D.

⁹⁸ *Id*.

⁹⁹ *Id*.

¹⁰⁰ Id

¹⁰¹ Affidavit of Abby Johnson, attached as App. B.

abortion. I wish I had known the truth about medication abortion." 102

CONCLUSION

This Court has held that the State can make reasonable regulations to protect women, and therefore, the Oklahoma Supreme Court misinterpreted and misapplied this Court's decisions in *Casey* and *Gonzales*. RU-486 creates greater risks of both physical and psychological harm to women than surgical abortion. Thus, the Oklahoma Legislature was correct in providing for the protection of women who are considering the RU-486 regimen and requiring the FDA guidelines be followed when RU-486 is used. Women deserve to have accurate and truthful information so that they can make an informed decision about the abortion procedure. Amici urge this Court to grant certiorari.

Respectfully submitted,

LINDA BOSTON SCHLUETER
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 $^{^{102}}$ *Id*.

Affidavit of Leslie Wolbert

STATE OF NEW YORK \$ KNOW ALL MEN BY THESE PRESENTS

BEFORE ME, the undersigned authority on this day personally appeared Leslie Wolbert who is personally known to me, and after being by me first duly sworn according to law on her oath did depose and say that:

- 1. "My name is LESLIE WOLBERT. I am over the age of eighteen (18) years of age and I am fully competent to make this Affidavit. I reside in Lockport, New York. I have personal knowledge of the facts stated herein and the following is true and correct.
- 2. It is a bittersweet thing to share a piece of my story with you. I was 21 years old when I took the "abortion pill" (RU-486), seven years ago. Nothing could have prepared me for what I experienced during the time of the abortion or the emotional pain that I would carry for years following.
- 3. I had always vowed as a young teen to never have sex before marriage, yet choices I made along the way and half-hearted convictions led me to choose to be sexually active. Over the course of five years, I had gone to a clinic three times and took the "morning after pill." I chose Planned Parenthood clinic because it was portrayed as safe, friendly and was well established, with the bonus of me not having to tell my mom I

was visiting. The morning after pill was painful yet bearable and I kept reminding myself what the nurse had told me, that it was only speeding up my period.

- 4. Since I had come to trust the clinic for years and had taken the morning after pill a few times without problems, I chose the same clinic to go to for counsel when I found out I was pregnant. I was still completely against abortion at that time and was certain that I could never have a surgical abortion because I knew if they had to perform surgery that meant it really was a baby not just a blob of tissue as they referred to it. When I got counsel from the clinic, they told me about the abortion pill and how "simple" it was and that you didn't have to go through surgery, but that you would have a heavy period instead.
- 5. I wish I could remember all the details of what was said or what wasn't said, but I don't. I was confused and really wanted someone to help me make the best decision. I do remember that nobody ever told me that I could carry my baby to term if I wanted to. It was just assumed that because I was confused and scared, that meant I wanted to abort. I was informed about the different abortion procedures and set up with an appointment at the clinic where abortions were performed.
- 6. At the clinic I was given a routine ultrasound in which the screen was conveniently turned away from me. The nurse asked if I wanted to see, but stated that it was just a mass of tissue. That statement made it easier for me to continue with

the process. I was told RU-486 would be like a really heavy period and that I would have some severe cramping that would last a couple of days. They even prescribed pain medication for when the cramping got too severe. To me, it sounded a lot like the morning after pill, except you could take it up to ten weeks. (Ten weeks is what I was told, however the FDA approved it only up to seven weeks, I was eight weeks pregnant when I took the pill). So I chose the abortion pill. It was the only one that seemed safe to me, and I again was reassured that it was.

- 7. I took the first set of pills at the clinic and then the next day took the last pills. I rented a hotel room on the day that I went to the clinic because I was ashamed of what I was doing and couldn't imagine going through with the abortion at home. I didn't have any problems at the hotel so I decided to go back home the next day.
- 8. It was the second day that I experienced the worst pain I've ever felt in my life. The experience wasn't just a heavy period. I was bleeding like I never knew possible. And the cramps were not just severe I thought I was dying because they were so intense. I was crying hysterically and begging to die because the pain was more than I could handle. I was sweating like crazy and on the toilet while throwing up too.
- 9. I was in my bed for a day straight and told my family members that I was extremely sick feeling too ashamed to tell what really was happening. My younger siblings were scared and stayed

away from me because of how I was acting. I was alone, and afraid, yet too ashamed to share.

- 10. It was the third day when I finally had enough energy to shower. I felt so dirty and shameful that I couldn't wait to clean myself. It was the first time I had stood for more than a minute and I was starting to feel a little better by then. I got about halfway through my shower when I started to bleed again.
- 11. I bled so much that it clogged the drain. It was in that moment, me trying to cleanse myself from my sin of the abortion, that the truth was exposed. It was the "blood clot" or the "blob of tissue" that the clinic talked about. It was my baby that was clogging the drain of the shower.
- 12. I had to turn off the water, get out, and clean it up myself and then I flushed it down the toilet. It was in that moment that I knew I wasn't flushing a mass of tissue down the toilet; I was flushing what was left of the life of my child that was growing inside of me. It was even more horrifying than it sounds.
- 13. This was all done in my own home, in the family bathroom, the family shower, the place where I had to live after this experience.
- 14. The emotional pain this caused me made it almost unbearable to be at home after that. I hated showering and I hated sleeping in my bed, I hated being around my family, I didn't want to be there anymore and tried my best to avoid being home.

- 15. I immediately felt a loss. I didn't want to hear people mention the word baby. I didn't want to see babies the sight of a baby caused me to nearly break down.
- 16. I lived in denial for a period after that trying to pretend that nothing happened, that my life hadn't drastically changed, and that I was ok. It was in that time that Jesus found me. At my lowest and darkest point, He drew me closer to Himself. I am only able to share my story with you now because I know that He has set me free from the guilt and pain of my choice to abort. I have been forgiven.
- 17. RU-486 is not a simple solution to a problem as it is presented to be. It is a horrible drug, and the lasting side effects are not spoken of. If it is made more readily available to women, especially young girls, they will have similar stories as mine. Women who weren't told the truth, women who are full of grief and sorrow, women who wish they knew before they aborted.
- 18. I hate that they say it's safe, or simple. I hate that they don't tell you what you will really experience and the extreme loss and heartache you will feel. I hate that in a place where women should feel the most loved and cared for they are manipulated and lied to. I especially hate that the truth is not being told about RU-486. It indeed will change lives, but not for the better. And the truth is not being told because if it were then women wouldn't be choosing it the way clinics want them to.

- 19. RU-486 isn't a simple solution to an unplanned pregnancy. The truth is that RU-486 is murder. It is not only destroying the lives of babies, but the lives of women. I am sick and tired of women being manipulated and lied to, and never told the whole truth. That's one of the reasons I must share my story, so that others know before it's too late.
- 20. The effects of experiencing an abortion at home are huge. The home is the safest place one should have, and to experience the worst thing of your life at home is a living nightmare.
- 21. No one ever called me from the clinic after I aborted. I never went in for a follow up to make sure I was alright. There was absolutely no contact from the clinic to me after I gave them my money and left that day. I felt that I was just a number, not a human being. It breaks my heart because I am not the only young woman who has walked this path, and with RU-486 being more available there will be more to come after me. Women left to deal with the consequences, pain and heartache of their choices alone. The more this drug is open to the public, the more stories of broken women there will be.
- 22. It's not an easy way out, but is physically the worst pain in the world, and yet the emotional effects that a medical abortion brings are even more painful. No one told me how scary it would be to experience this alone at home, or that I would feel such a deep loss, or that the sound of a baby's cry would bring tears to my eyes for years to come. No one warned me of the pain I would

feel afterwards living at home where the abortion took place. These things just weren't discussed, yet they had great effects on me then and still do today. Women need to be counseled about all of their choices when it comes to an unplanned pregnancy, and not ushered into choosing one that is most convenient at the time. The truth needs to be told, it is far too great of a matter for it to continue to be handled the way it has been.

Further Affiant sayeth not."

/s/ Leslie Wolbert Leslie Wolbert

SWORN TO AND SUBSCRIBED BEFORE ME, the undersigned authority, on this <u>1st</u> day of <u>April</u> 2013.

/s/ Mary Ann Adams NOTARY PUBLIC IN AND FOR THE STATE OF NEW YORK

Notary Public, <u>Niagara</u> County, New York

My Commission Expires: 5/22/14

Affidavit of Abby Johnson

STATE OF TEXAS \$ KNOW ALL MEN BY COUNTY OF WILLIAMSON \$ THESE PRESENTS

BEFORE ME, the undersigned authority on this day personally appeared Abby Johnson who is personally known to me, and after being by me first duly sworn according to law on her oath did depose and say that:

- 1. "My name is ABBY JOHNSON. I am over the age of eighteen (18) years of age and I am fully competent to make this Affidavit. I reside in Round Rock, Texas. I have personal knowledge of the facts stated herein and the following is true and correct.
- 2. I am the former director of a Planned Parenthood clinic in southeast Texas. I worked and volunteered for Planned Parenthood for eight years. During my eight years with Planned Parenthood, I quickly rose in the organization's ranks and became a clinic director. As the clinic's director, my duties included running the family planning and abortion programs.
- 3. On September 26, 2009, I was asked to assist with an ultrasound-guided abortion. This was not part of my regular duties. I watched in horror as a 13 week old unborn child fought, but ultimately lost, its life at the hands of the abortionist. Although I had seen ultrasounds before, I had never seen an ultrasound image during an abortion. At that moment, I fully realized what abortion was

and it changed my heart. The procedure and experience changed me forever.

- 4. I was not interested in promoting abortion. I came to Planned Parenthood eight years before, believing that its purpose was primarily to prevent unwanted pregnancies, thereby reducing the number of abortions.
- 5. During the last year of my employment, I began to question my work and the motivations of the company I had dedicated myself to for eight years. My superiors were pushing clinics that did have an abortion program to bring in more money. I became disillusioned with my job after my bosses pressured me for months to increase profits by performing more and more abortions. For them there is not a lot of money in education. There is not as much money in family planning as there is abortion. It's a very lucrative business and that's why they want to increase numbers.
- 6. On October 6, 2009, I left Planned Parenthood. I felt betrayed by Planned Parenthood.

My RU-486 Experience.

7. In 2003, I was 23 years old, a volunteer at Planned Parenthood, a college student, a woman who was 8 weeks pregnant by her husband . . . a husband she was divorcing. I did not want a baby so I had a solution . . . abortion. I had already had one abortion and it was easy. Surely, this time it would be the same. Instead of a surgical abortion, I thought this time I would choose a

more "natural" way to abort . . . the medication abortion.

- 8. It was all pills and that seemed really simple. Everything was done at home. It was private, on your schedule, under your control and seemed less invasive. It should be nothing worse than a heavy period, according to Planned Parenthood. It sounded pretty easy to me.
- 9. I made an appointment and got the money together. The day came and it really felt like any other day. I wasn't nervous . . . I wasn't having surgery. This was going to be simple, so I thought.
- 10. At the clinic, I filled out paperwork, had some basic lab work done, had an ultrasound (that I don't remember), and got put in a room for abortion counseling. I had brought someone with me, but I, of course, had to do all of this alone. No one except the patient was allowed past the waiting room.
- 11. I remember my "counseling" as if it happened yesterday. "You will have some heavy bleeding and period like cramps. None of it should last too long. You will be back to normal in a couple days," my counselor said. "Sounds good," I remember saying. And I guess it did sound pretty good. I could get rid of my biggest burden for \$400.00 and a little cramping. Not a bad deal, I thought.
- 12. I thought that there did not appear to be any risks or side effects. I thought that if there were side effects or risks, surely the counselor would

go over them. Nothing was said to me about risks and side effects.

- 13. So I gave them \$400.00, and they gave me a Mifeprex pill and a brown bag of pills to take home. After taking the Mifeprex, I felt great! No side effects . . . just like she said. The next day, I did as I was told. I ate a light lunch and took the 4 pills in my brown bag called Misoprostol. They told me these were the pills that would start my bleeding and cramping. At most, I would need a few Ibuprofen which would take care of it.
- 14. I was told after taking the pills at home that I would probably start bleeding in about an hour. So, I made myself comfortable on the bed and turned the TV on.
- 15. What happened next was totally unexpected. Ten minutes later, I started to feel pain in my abdomen unlike anything I had ever experienced. Then the blood came. It was gushing out of me. I could not wear a pad . . . nothing was able to absorb the amount of blood I was losing. The only thing I could do was sit on the toilet. I sat there for hours . . . bleeding, throwing up into the bathroom trashcan, crying, and sweating.
- 16. I used to watch shows about childbirth. I would see these women in labor and they would be covered in sweat. I would always think, "Gosh, do they keep it hot in the delivery room, or what?" But at that moment, sitting on the toilet, I knew it wasn't from heat . . . it was from pain.
- 17. I had vomit all in my hair and on my legs, not to mention how sweaty I was. After several hours

on the toilet, I desperately wanted to soak in the bath tub. I was hoping that would make me feel better. Maybe the warm water would help the cramping. Certainly it would make me smell better.

- 18. I filled the tub and climbed in. It actually did feel pretty good. I remember closing my eyes and leaning my head back. I felt exhausted. The cramps kept coming, but the water helped soothe them somewhat.
- 19. I opened my eyes after 15 minutes and was horrified. My bathwater was bright red. It looked like I was sitting in the middle of a crime scene. And I guess it was . . . I had murdered my child. I knew I had to get up and wash the blood off of me. I stood up slowly and straightened out my body.
- 20. As soon as I was completely upright, I felt a pain worse than any other I had experienced. I began to sweat again and felt faint. I grabbed on to the side of the shower wall to steady myself. Then I felt a release . . . and a splash in the water that was draining beneath me. A blood clot the size of a lemon had fallen into my bath water. Was that my baby?
- 21. I knew this huge clot was not going to go down the drain, so I reached down to pick it up. I was able to grasp the large clot with both hands and move it to the toilet.
- 22. I stood in the warm shower for a few minutes . . . feeling a little relief from the cramping. Then came the excruciating pain again. I jumped out of

the shower and sat on the toilet. Another lemon sized blood clot. Then another. And another. I thought I was dying.

- 23. I thought to myself, this could not be normal. Planned Parenthood did not ever tell me this could happen. This must be atypical. I decided that I would call them in the morning . . . if I did not die before then.
- 24. It was around midnight and I had been in the bathroom for a good 12 hours. I knew I could not leave yet. I did not want to lay in the bed . . . the bleeding was too heavy. And the clots were still coming; not as often, but they were still coming.
- 25. So, I decided to sleep on the bathroom floor that night . . . right by the toilet. The cold floor felt good on my face. I was physically depleted, but I could not sleep.
- 26. The next morning, I called Planned Parenthood as soon as they opened and asked to speak to the nurse. I was told she would call me back soon. She did. I told her about my previous day. She told me, "That is not abnormal." I was shocked. She could not be serious. All of the bleeding, the clotting, the pain . . . that was NORMAL! "Yes," she said. "Use heating pads, soak in a warm tub, and take Ibuprofen." I was angry. How could they not tell me the side effects? I felt so betrayed.
- 27. Eight weeks passed. Eight weeks of blood clots. Eight weeks of nausea. Eight weeks of excruciating cramps. Eight weeks of heavy bleeding. Eight terrible weeks of misery.

- 28. When it was finally over, I went back to volunteer at Planned Parenthood. My anger was gone and had now been replaced by self-reproach. I no longer blamed Planned Parenthood, I blamed myself. And honestly, I was glad that I was not pregnant. So, I just chalked it up to a terrible experience and vowed that I would do my best to never let anyone I know choose medication abortion. I did not want anyone else to experience what I had been through.
- 29. When I started working at Planned Parenthood, I did just that. It actually became a joke around the clinic. "Don't let Abby see the MAB (medication abortion) clients. She will change all of them to surgical abortions and we will be here all day."
- 30. There is nothing natural about medication abortion. I HATED medication abortion. I hated that we were pushing it at all of our clinics. I did not think it was best for our patients. And I told them the risks. I told them my story. I told them about the clots, the cramping, the nausea, the bleeding.
- 31. I had seen too many women that had been hurt by this so-called "natural" abortion method. There was nothing natural about it.
- 32. At a management meeting, I voiced my concerns. Why weren't we talking about the risks? Why hadn't anyone told me? My supervisor said: "Well, we don't want to scare them." I responded: "Oh, like they are scared when they think they are dying from the amount of blood they are losing because we choose not to tell them that is

supposedly normal." That did not go over too well.

- 33. The night of my medication abortion, lying on the cold bathroom floor, I had never been so scared. What if I died there alone? Who would find me? Would my parents find out that their daughter died because she had an abortion? That fear was real.
- 34. Planned Parenthood is scared to give women the real truth. To not give women all of the information about abortion because you think it will "scare" them is actually very offensive. It is not honest. It does not allow women to make an informed decision.
- 35. Here is the truth . . . Planned Parenthood is not worried about women being "scared" . . . Planned Parenthood is scared. They are scared women will walk out the door if they get accurate and thorough information. Every woman that walks out the door, it is lost revenue . . . that is Planned Parenthood's biggest fear. They are scared. They are scared of the truth. They are scared to give women the truth.
- 36. I have compared my medication abortion experience with my tonsillectomy surgery. There was such a difference in what the ENT doctor told me and how I was informed about the risks. Women should have the same benefit when they are considering a medication abortion so that they will know the risks and make an informed choice. It is even more important concerning abortion because of the physical and psychological effects on the woman and the death of the child.

- 37. In 2009, I had my tonsils removed. They had been bothering me for a while, so I figured I might as well have them out. I knew a lot of tonsilless people, so I was not nervous at all about surgery.
- 38. A couple days before I went "under the knife," I had my pre-op visit with my ENT (Ear-Nose-Throat) doctor. We were going over a few things that I already knew. Then, he started talking about the risks. I guess I had not really thought there would be risks with a tonsillectomy. He started talking about the risks of severing vocal cords and being unable to speak . . . damage to teeth . . . extreme blood loss . . . damage to my tongue . . . and even death. I wondered, maybe I should just keep my annoying tonsils. I suddenly became very nervous.
- 39. My doctor assured me that his patients had not had problems . . . he just HAD to tell me those things. Two days later, the tonsils came out. I had no problems. My throat has never been happier.
- 40. Looking back on my tonsillectomy and my abortion, one thing really stands out. When my ENT was going over all of these potential risks, I was thinking, "Can you just NOT tell me any of this." But then I was grateful because if I woke up and I was not able to talk, or if my two front teeth were all busted up, at least I would have known that was a possibility. At least I had the CHOICE to back out. With my abortion, I was not given that CHOICE. Planned Parenthood did not tell me what was really going to happen to

me because they did not want to "scare" me. This is not freedom of choice.

- 41. Here is another glaring contrast. When my ENT was explaining the risks to me, I became nervous. But as he was calming my fears, I remember him saying, "Don't worry, none of this has EVER happened before to any of my patients." That made me feel better. But the same cannot be said of abortion . . . particularly medication abortion. Women have died from medication abortion. Thousands of women have had very serious complications. I saw many of them with my own eyes I was one of them.
- 42. Planned Parenthood is planning to expand their medication abortion protocols to EVERY family planning clinic in the country in the next 5 years. Women need to know the truth so that they can make the right decision. Women do not have to die. They do not need to be hurt by abortion. I wish I had known the truth about medication abortion.

Further Affiant sayeth not."

/s/ Abby Johnson Abby Johnson SWORN TO AND SUBSCRIBED BEFORE ME, the undersigned authority, on this $\underline{28th}$ day of \underline{March} 2013.

/s/ Jennifer Leaver

NOTARY PUBLIC IN AND FOR THE STATE OF TEXAS

Notary Public, <u>Williamson</u> County, Texas

My Commission Expires: 10/11/15

Affidavit of Carol Everett

STATE OF TEXAS \$ KNOW ALL MEN BY COUNTY OF WILLIAMSON \$ THESE PRESENTS

BEFORE ME, the undersigned authority on this day personally appeared Carol Everett who is personally known to me, and after being by me first duly sworn according to law on her oath did depose and say that:

- 1. "My name is CAROL EVERETT. I am over the age of eighteen (18) years of age and I am fully competent to make this Affidavit. I reside in Round Rock, Texas. I have personal knowledge of the facts stated herein and the following is true and correct.
- 2. I know firsthand about pregnancy termination. I have been both a consumer and provider. I was involved in the operation of four pregnancy termination clinics from 1977 to 1983, overseeing 35,000 pregnancy terminations. A fifth clinic was being planned. I was formerly Dallas' largest abortion chain owner.
- 3. Since leaving the abortion industry, I have been committed to safeguarding the health of women and their babies all over this nation. I speak to the men and women who have experienced a pregnancy loss to offer a message of healing and hope.

4. I formed the Heidi Group to help girls and women in unplanned pregnancies make positive, life-affirming choices for themselves and their babies. Our role is to connect girls and women to the best resources available. At the Heidi Group, we affirm the dignity and value of girls, women, and families. It is our goal to make sure that before a girl or a woman walks through the door of an abortion clinic, she sees the full picture of the resource community waiting to embrace her and her unborn baby.

My Abortion Experience

- 5. I was married, had an 8 year-old daughter and a 10 year-old son. I found myself pregnant again. When I told my husband, I was excited about the pregnancy but his initial reaction was, "you'll just have to have an abortion."
- 6. I decided to look for someone to help me. I went to my doctor and told him that my husband didn't want me to have this baby. What he offered was an illegal abortion. I was looking for someone to tell me not to have the abortion, but I ran into an abortion salesman. And that is what happens in our nation today.
- 7. When I woke from that abortion, I picked up the telephone, and literally started working from my hospital bed, not realizing that I was already running from that decision. I know first-hand the devastation of abortion my life rapidly went downhill. Within a month, I was having an affair which I had never done before. Very soon I

started drinking; I had not ever drunk in my life. Shortly thereafter, my marriage broke up.

- 8. Then I started seeing a psychiatrist daily. At the rate of \$125.00 an hour, I could not go on with this very long. So I decided to do what I called, "get hold of myself." I changed everything I could in my life, except my children. I got away from the job I'd had; got away from my husband, and decided I would make it on my own. What I'm telling you is the story about how my life went along at a pretty good level for a while, and the moment I had that abortion, it went straight downhill. I think that is what happens to every woman who has an abortion.
- 9. Abortion is devastating to women and babies, but it also has very negative consequences for fathers. My ex-husband also had to go to counseling trying to deal with the abortion.

The Abortion Business

10. When I did get hold of myself, I went to work for a man who had a medical supply business. At about this time, abortion became legal in the State of Texas, and very soon we had an account online that was very profitable for us. We were making over \$1,000 a month profit out of this account. So he decided that he wanted to look into it to see exactly what sort of business they were — they were an abortion clinic. This man who told me he never wanted to see an abortion, never wanted to know what an abortion really was, opened his first abortion clinic, and soon he had four.

- 11. All this time he kept inviting me to join him. He said that if I would go out and sell abortions for him, he would pay me \$25 an abortion. I kept selling medical supplies, and finally the day came when I needed to make more money. So I told him that I was quitting my job; I wanted to go with another company. So, he got me on the fringe of the abortion industry by asking me to go out and set up referral clinics all over Texas, Oklahoma and Louisiana. And I did that for a while and it was quite profitable.
- 12. Then he asked me to work at one of the clinics for a month. I got involved with the numbers. With just a very few small changes, his abortions went from 190-195 per month to over 400 per month. We booked abortions for the Dallas and Fort Worth clinics. The last month I was with him in those two clinics, he was doing something over 800 abortions a month. I personally participated in approximately 10% of the abortions performed at the two facilities.
- 13. In addition to other duties, I was in charge of training employees who we called "counselors." These counselors were not trained to counsel a woman about her options or to provide accurate, truthful information about an abortion. Information about fetal development or the risks of abortion was not provided. We did not counsel our patients as to the potential emotional consequences of having an abortion. What we did could not be considered counseling. We learned how to exploit their fears. We sold abortions. I believe that states should require full and accurate informed consent counseling and should require

statistical reporting to compile data for accurate informed consent forms.

- 14. The strategy of the abortion industry is to gain the trust of young people by offering secrecy and promiscuity via free and inexpensive birth control, and then banking on their inevitable return when pregnancy occurs. They would deliberately prescribe low-dosage birth control to help ensure that pregnancies occurred. The goal was to get three abortions out of each of their girls by the time they graduated high school. The record was nine from one girl.
- 15. It has been my experience that when a woman or a young girl learns that she is pregnant, she may not want an abortion. She may only want information. The person who answers the phone in an abortion facility is paid and trained to be her friend. Her job is to sell her an abortion by asking questions and leading her to believe an abortion is her only option.
- 16. Since I had doubled his business, I asked for an equity interest in the business. He said no. I placed my Yellow Page ad to come out in six months for my own abortion clinic. We opened the first clinic. And then I opened a second clinic in the Dallas area. We did over 500 abortions a month in those two clinics. I was compensated at the rate of \$25.00 per case, plus one-third of the clinic's, so you can imagine what my motivation was. I sold abortions. I had made \$150,000; was on target in 1983 to make about \$260,000; and when we opened our five clinics, I would have been making about a million dollars a year. I

- expected to make more than that after we were really functioning.
- 17. Abortion is a very lucrative business. Abortion facilities sell abortions. They don't sell keeping the baby. They don't sell giving the baby up for adoption.
- 18. It is becoming more lucrative with the RU-486 regimen. These medical abortions sell pills with minimal oversight and follow-up.
- 19. Since 2000 when the FDA approved the RU-486 regimen, I have met with women who have taken RU-486. They have had more severe physical and psychological complications than women who have had surgical abortions. For example, the physical issues include severe hemorrhaging and pain from RU 486. In addition, some of the most severe post-abortion syndrome occurs because the women actually see the baby being expelled.
- 20. Abortion facilities do not discuss the baby in accurate terms. Even when the women ask if it is a baby, they say no, it's a product of conception; it's a blood clot; it's a piece of tissue. They do not even really tell them it's a fetus because that almost humanizes it too much. It is never a baby.
- 21. This is what causes such psychological trauma certainly with RU-486 because the woman sees for herself that she was lied to and it really is a baby that she has just expelled in the toilet or shower.
- 22. They also mislead women as to what will occur. For example, women ask if it will hurt. They say no and explain that the uterus is a muscle and it

cramps to open it; a cramp to close it; it is a slight cramping sensation. Because every woman has had cramps, they think that it is like what they have experienced before. But women who have taken RU-486 state that it is severe cramping like they have never experienced before.

- 23. As recently as this month, I have worked with a Houston woman who was given RU-486. Ten weeks later, she thought she was pregnant again, but when she went to the abortion facility she learned she had an incomplete abortion. This time a surgical abortion was done and she was sent home with an IV in her arm. When she called the abortion facility, she was told to meet them in a park and they would take it out.
- 24. Many women who had abortions at my clinics had major physical complications requiring hospitalization. Based on my experience, I now believe that women should have been given accurate information about the physical and emotional consequences of abortion so that they could make an informed decision.
- 25. I have seen how abortion affects women, babies, men, and families. I have experienced surgical abortion first-hand and counseled women who have had the RU-486 regimen. This drug regimen can have severe physical and psychological consequences for the women who take it. The State should ensure that the FDA guidelines are being followed by abortion facilities and off-label use of the regimen which can cause greater harm should not be allowed.

Further Affiant sayeth not."

/s/ Carol Everett Carol Everett

SWORN TO AND SUBSCRIBED BEFORE ME, the undersigned authority, on this $\underline{27th}$ day of \underline{March} 2013.

/s/ Nicole Daynelle Noe NOTARY PUBLIC IN AND FOR THE STATE OF TEXAS

Notary Public, <u>Williamson</u> County, Texas My Commission Expires: February 10, 2017

Affidavit of Monty L. Patterson

STATE OF CALIFORNIA \$ KNOW ALL MEN BY THESE PRESENTS

BEFORE ME, the undersigned authority on this day personally appeared MONTY L. PATTERSON who is personally known to me, and after being by me first duly sworn according to law on her oath did depose and say that:

- 1. "My name is MONTY L. PATTERSON. I am over the age of eighteen (18) years of age and I am fully competent to make this Affidavit. I reside in Livermore, California. I have personal knowledge of the facts stated herein and the following is true and correct.
- 2. My daughter Holly was a beautiful 18 year young woman. Unbeknownst to me until that fateful day, Planned Parenthood prescribed my daughter an unapproved/off-label mifepristone (commonly known as RU-486, U.S. trade name Mifeprex, The Abortion Pill) and misoprostol medical abortion drug regimen. I first learned of it when I received a call from the hospital stating that she was there and in serious condition. Later that day, while at her bedside, my daughter tragically died from an infection known as Clostridium sordellii toxic shock syndrome that was associated with a medically induced abortion.
- 3. This has been such a painful experience for our family. I do not want to see any other family go through what we have. Women need to have

accurate and factual information regarding the potential risks of severe and life threatening side-effects. They need a supportive network of providers and physicians assuring them they will be properly prescribed and administered medical abortion drugs, monitored throughout the entire abortion process, and accurately diagnosed and treated with the best of care when they have complications. Women need to make an informed decision that is in their best interest, safety, health and welfare when considering an early pregnancy termination. Holly did not have such information.

4. Since her death, I have learned the true facts of what happened to Holly.

HOLLY'S MEDICAL ABORTION EXPERIENCE

- 5. In August 2003, Holly Patterson, then 17, discovered she had become pregnant by her boyfriend who was seven years her senior. Like most young women who have an unwanted pregnancy, Holly did not want her parents to know about the pregnancy and sought abortion counseling at Planned Parenthood in Hayward, California.
- 6. On September 10, shortly after her 18th birth-day, the couple went to a Planned Parenthood clinic to seek counseling on terminating her seven-week-old pregnancy. At this time, Holly was especially vulnerable and dependent on adequate care and advice from Planned Parenthood about any risks associated with the drug mifepristone and the medical abortion regimen.

- 7. After counseling by Planned Parenthood, Holly decided to terminate her pregnancy with the Mifeprex (mifepristone) abortion procedure and would follow her provider's advice about when to take each drug and what to do in an emergency.
- 8. There, she received the first of two drugs in the mifepristone/misoprostol medical abortion protocol. At the clinic, Holly was administered an unapproved (off-label/modified/alternative/evidence-based) regimen of 200-mg mifepristone orally which blocks the hormone progesterone that is required to maintain a pregnancy.
- 9. At home, 24 hours later, on September 11, she followed the clinics off-label instructions to vaginally insert 800-mcg of misoprostol to induce labor contractions and expel the fetus.
- 10. On September 13, Holly repeatedly called the Planned Parenthood clinic hotline to complain of severe cramping. She was told her symptoms were normal and to take the clinic prescribed Tylenol-Codeine painkiller. Later, Holly called the clinic's hotline again and was told to go to a local hospital's emergency room if the pain continued.
- 11. By September 14, Holly was still experiencing extreme cramping and bleeding, and visited the emergency room of Valley Care Medical Center in Pleasanton on the fourth day after her initial visit to Planned Parenthood. The doctor there, whom she told about her abortion, sent her home after an injection of narcotics and yet more painkillers.

12. The severity of the pain continued. Holly was weak, vomiting, and unable to walk. In the early morning hours of September 17, 2003, she was re-admitted to Valley Care Medical Center. Holly died on the seventh day after starting the mifepristone/misoprostol medical abortion regimen. This was the same day she was scheduled to return to Planned Parenthood for a follow up visit to make sure her abortion had been completed.

THE DAY HOLLY DIED - A FATHER'S EXPERIENCE

- 13. I first heard of the mifepristone abortion pill on September 17, 2003. This was the worst day of my life.
- 14. A call came, earlier that morning, while I was at work. A nurse told me my 18-year-old daughter, Holly, was in the hospital and in very serious condition. I asked "What was wrong?" She said, "Mr. Patterson, we'll explain when you get here, be careful, come as quickly as you can."
- 15. I sped to the hospital which was near the San Francisco suburb of Livermore, where Holly and I lived. Once there, I found her in the intensive care unit, barely conscious, too weak to talk, pale complexion, puffy faced, and struggling to breathe. It absolutely made no sense. Holly, a beautiful, blue-eyed blonde, was a fitness buff in perfect health.
- 16. As I looked into her confused and scared eyes I could see she was trying to say "Dad save me." I

called out and asked her if she could hear me. I tried to comfort and reassure her: "Whatever it is Holly you're going to make it. I know you're strong. Honey, squeeze my hand and let me know you understand."

- 17. Trying to focus, Holly could barely squeeze my hand. I felt so utterly helpless. While standing at her bedside, the doctor came in and briskly explained, "We are doing everything we can for her, but she might not make it. These things sometimes happen as a result of the pill."
- 18. I was completely baffled. "What, the birth control pill?" I asked. "No, the abortion pill," the doctor replied. Shocked, I asked him, "What are you talking about? What abortion pill?" "Oh," the doctor said awkwardly, "No one's told you?" I stared at the doctor, "No, I don't know anything, no one has told me anything!" Holly was pregnant? Abortion?
- 19. The doctor now realized that I was completely in the dark. He briefly explained Holly had undergone an "early medical pregnancy termination" with the two-drug abortion regimen, mifepristone and misoprostol. The doctor said, "Holly was suffering from an incomplete abortion and a massive infection." Her vital organs were starting to shut down and her lungs were filling with fluid. "Septic shock," is what I was told.
- 20. Moments later the crisis had deepened. Holly's condition was deteriorating rapidly; the doctor called for a ventilator, her blood pressure was dropping. The monitors around Holly started beeping in alarm.

- 21. I heard the panicked words "code blue!" and was ushered from the room into the hallway. Staffers, nurses, and doctors raced down the hall and into the room.
- 22. I remember our family crying and calling out "Don't give up! We love you, Holly!" Not being able to take it any longer, I stormed back into the room and threw back the curtain. I will carry that image in my mind for the rest of my life. The hospital staff was working frantically to save Holly's fragile life. Someone was pumping on her chest trying to resuscitate her, drugs were being administered, and the monitors were sounding in alarm. Holly had flat-lined.
- 23. Everyone looked at me in disbelief and sorrow. Holly died just before 2 p.m. on September 17, 2003.

PLANNED PARENTHOOD'S ALTERNATIVE TREATMENT PLAN

- 24. Everything that could go wrong went wrong.
- 25. At 18 years old, Holly had her whole life ahead of her. The decision to terminate an early pregnancy by the mifepristone/misoprostol medical abortion regimen was a fatal choice.
- 26. After Holly's funeral, I learned she had been very worried about continuing her unwanted pregnancy and had relied on Planned Parenthood's advice on the safety and efficacy of medical abortion.
- 27. Planned Parenthood convinced Holly to choose the medical abortion regimen option using

Mifeprex (mifepristone) and misoprostol. Her boyfriend had stated the clinic made it seem that Mifeprex was a "miracle drug" and that medical abortion would be like a "walk in the park." The paperwork they were given did not disclose any serious health risks or deaths with the drug.

- 28. On September 10, 2003, Holly and her boyfriend were shown a video about the benefits of the drug and medical abortion procedure Holly would undergo at Planned Parenthood. The video was also used to inform the patient how to use Mifeprex but it did not actually have a demonstration of the actual off-label procedure for self-administration of misoprostol at home.
- 29. Holly was given materials on the FDA approved Medication Guide and Patient Agreement for administering the approved Mifeprex regimen.
- 30. The FDA's approval in September 2000 of medical abortion for pregnancy up to 49 days involved the protocol: On day 1, the patient would receive three 200-milligram tablets of Mifeprex (mifepristone) orally at the clinic and, on day 3, the patient would return to the provider's office to take two 200-microgram tablets of misoprostol orally. The patient would return to the clinic on day 14 to confirm termination, and if not completed, a surgical (vacuum aspiration) abortion would be scheduled.
- 31. Instead of the FDA approved regimen, Planned Parenthood persuaded Holly to choose an off-label treatment that emphasized: (a) research studies for other treatment plans for mifepristone have been shown to be equally safe and effective

for medical abortion up to 63 days pregnancy; (b) a lower dose of 200 mg of Mifeprex (one pill) can be used instead of the 600 mg (three pills) dose on the package labeling; (c) when the 200 mg dose of Mifeprex is used, the dosage and method of using the second drug misoprostol, must be changed; (d) the dose of misoprostol is then 800 mcg (four pills) and they are selfinserted high into the vagina instead of orally, taking the second medication (misoprostol) at home instead of the clinic, inserting the misoprostol pills at least 24 hours after taking the first pill mifepristone; and (d) the off-label regimen is acceptable to women and has been shown to cause less nausea and vomiting than the FDA approved regimen.

- 32. Holly was provided a consent form for "Alternative Treatment Plans for Mifeprex (mifepristone)" where her consent was sought for the off-label treatment rather than the FDA approved protocol for Mifeprex. Based on these representations, Holly signed the consent form consenting to the off-label procedure.
- 33. Planned Parenthood had failed to disclose and inform Holly that research studies for "Alternative Treatment Plans" were not submitted, reviewed, scrutinized, or approved by the FDA. It would be impossible for the FDA to know if the research was unbiased, evidence supported home use of misoprostol, there was substantial evidence proving off-label medical abortion regimens were safer and more effective than the FDA approved protocol.

- 34. Planned Parenthood not only prescribed an offlabel alternative drug regimen to Holly but was also responsible for full support and tracking of her through the medical abortion process. I do not believe there was proper monitoring, diagnosis of her condition or follow-up considering her calls for help and assistance.
- 35. Alternative Treatment Plans for medical abortion are promoted as safe and effective. The information Holly was able to obtain about mifepristone and medical abortion regimen cost my daughter her life. Holly was an intelligent young woman. She could have made a better informed choice if she had known the accurate facts and the full extent of the risks associated with the procedure to terminate early pregnancy.

A FATHER'S EFFORTS TO BRING SAFETY ISSUES TO THE ATTENTION OF REGULATORY AUTHORITIES, SCIENTISTS AND THE PUBLIC

- 36. The impact of Holly's death on family and friends was devastating. I wanted answers to my questions as to how a perfectly healthy young girl could succumb to death so quickly after a medical abortion procedure. Holly's death left us all in shock. We didn't know what to think except something was terribly wrong. I was going to find out what happened and do something about it.
- 37. Since Holly's death, I have spent thousands of hours on the computer, the phone and traveling to conduct research on mifepristone and the medical abortion procedure. I have talked to and met

with government regulatory and scientific authorities, legislators, scientists, the media, political activists and even women who had experiences with the drug to learn what happened to Holly.

- 38. Over the years I had amassed an archive of information on mifepristone/misoprostol for use in medical abortion. Since Holly's death, I traveled to Washington D.C, to meet with FDA and White House officials to share my findings and pose my questions, attended a CDC/FDA/NIH Clostridium workshop in Atlanta Georgia, testified before the House Subcommittee on Criminal Justice, Drug Policy and Human Resources that was investigating the approval, safety, and handling of mifepristone by the FDA, and was instrumental in getting black box warnings put on the labeling of mifepristone (RU-486).
- 39. On October 31, 2003, the Alameda, California coroner's office issued a report concluding that Holly Patterson died from Septic Shock, due to endomyometritis (uterus related blood infection), due to a therapeutic, drug induced abortion. After receiving the coroner's report, I wanted to know exactly what kind of infection killed Holly. I worked with the coroner, state, and federal agencies to help me get the answers.
- 40. Planned Parenthood & Valley Care Hospital Failure to Report Holly's Death to the State of California: On February 25, 2004, I released a media statement about findings from the State of California Department of Health Services (DHS) which concluded their investigation with Planned

Parenthood of Hayward and Valley Care Medical Center in Pleasanton. The findings were as follows: (a) Valley Care Hospital failed to notify the Department of Health Services of an unusual death of a very young adult who received drugs for early medical abortion. Hospital staff did not report the death because they felt it was not a reportable death and disagreed with the DHS findings; (b) Planned Parenthood's Vice President of External Affairs stated the incident was not reportable to the DHS because Holly died in a hospital. The DHS informed the Vice President that Holly was under the care of the clinic at the time of expiration and the death was due to sepsis following use of prescribed early abortion medication, it was an unusual event and reportable to the Department of Health Services; and (c) Planned Parenthood failed to obtain Holly's signature for the "Request for Provision of Surgery or Other Special Services/Procedures with Medical Abortion." The DHS found that the informed consent was to list the use of mifepristone (Mifeprex) and misoprostol and was not signed.

41. I was appalled by the lack of accountability of Planned Parenthood and Valley Care Medical Center for failure to report Holly's death to the State of California DHS. Hospitals and abortion providers must be accountable and responsible for the reporting of serious adverse events and deaths to the proper State agencies, regulatory authorities, drug manufacturer and the FDA to monitor and evaluate the safe use of medical abortion drugs.

- 42. With respect to Planned Parenthood not obtaining Holly's signature on the proper forms, according the DHS, the clinic had failed to implement its own written policy and procedure. Informed consent is an extremely important issue with these dangerous drugs and it is critical that a patient be fully informed of the procedures, administration, and risks involved with medical abortion.
- 43. On September 15, 2004, I met with top FDA officials in Washington D.C. to discuss my five page list of concerns questioning: (a) FDA action after the death of Holly Patterson; (b) the properties of mifepristone that can suppress the immune system and cause infection; (c) safety issues with off-label Mifeprex (mifepristone) regimens commonly used by the majority of providers; (d) the insufficiencies and lack of adverse event reporting by physicians and providers; (e) drug manufacturer and abortion provider accountability issues; and (f) the controversies of the Mifeprex approval and manufacturing process.
- 44. On October 20, 2004, after persistent and continuous contact with the FDA, the agency informed me the Center for Disease Control and Prevention (CDC) reported that Holly had tested positive for Clostridium sordellii toxic shock syndrome following mifepristone/misoprostol medical abortion.
- 45. Holly's death was the first reported case of a Clostridium sordellii toxic shock infection associated with medical abortion in the United States.

However, two years prior, on September 1, 2001, the first fatality ever reported to the FDA and the medical abortion community was that of a Canadian patient who was prescribed the off-label regimen of 200 mg oral mifepristone, followed by 800 mcg vaginal misoprostol (the same regimen as given the [sic] Holly Patterson) during a clinical trial.

- 46. On November 12, 2004, the FDA and the drug manufacturer (Danco Laboratories) issued "Dear Health Care Professional" and "Dear Emergency Room Director" letters to inform of updated prescribing information which includes the Medication Guide and the Patient Agreement. A summary of updated warnings included: (a) infection and sepsis; (b) vaginal bleeding; and (c) ectopic pregnancy.
- 47. On November 15, 2004, more than a year after Holly's death and three years after the Canadian death, the FDA announced important labeling changes made by the manufacturer for mifepristone (trade name Mifeprex, RU-486). The new warnings to health care providers and patients included changes to the existing black box on the product to add new information on the risk of serious bacterial infections, sepsis, and bleeding and death that may occur following any termination of pregnancy, including use of Mifeprex.
- 48. On July 19, 2005 the FDA issued a "Public Health Advisory for Mifepristone" highlighting the risk of sepsis or blood infection when undergoing medical abortion using Mifeprex and misoprostol in a manner (off-label) that is not consistent with the approved labeling.

49. On November 4, 2005 the FDA updated their "Public Health Advisory: Sepsis and Medical Abortion" confirming four cases of fatal infection tested positive for Clostridium sordelli and all providers of medical abortion and their patients need to be aware of the risks of sepsis.

DEATHS FROM INFECTION AFTER MIFE-PRISTONE OFF-LABEL USE

- 50. Subsequently, there were other clostridium sordelli deaths only months after Holly died.
- 51. On December 29, 2003, 21 year-old Vivian Tran died in Las Vegas six days after taking an off-label Mifeprex (mifepristone) regimen. The circumstances surrounding her death are almost identical to those of Holly Patterson and the Canadian clinical trial patient. Vivian Tran's death remained unreported until April 2005 until a family lawyer reported the case to the FDA.
- 52. On January 14, 2004, 22 year-old Chanelle Bryant died in Pasadena six days after taking an off-label Mifeprex regimen. Her case, too, was similar to those of Holly Patterson, Vivian Tran and the Canadian patient. Despite the seriousness of the fatal event, Ms. Bryant's death was not reported to the FDA until August 2004.
- 53. On May 24, 2005, 34 year-old Oriane Shevin died in Southern California five days after taking an off-label Mifeprex regimen. Once again, her case was similar to Holly Patterson, Vivian Tran, Chanelle Bryant, and the Canadian patient.

- 54. Since 2001, there have been 11 reported deaths from sepsis (serious infection involving the blood) and 9 of these were from Clostridium sordellii.
- 55. Leading scientists and physicians have been examining mifepristone's role in medical abortion where its use may impair a woman's immune response and predispose her to lethal infection caused by Clostridium sordelli and other pathogens.
- 56. Of these 11 reported deaths from sepsis, 10 women were confirmed to have been administered a medical abortion drug regimen that was non-registered, off-label, not approved or recognized by the FDA.
- 57. The First European Death from Clostridium sordelli Following Medical Abortion: On May 6, 2011, I informed and reported to the FDA the first known European sepsis death of a 16 year old adolescent girl to be associated with Clostridium sordellii fatal toxic shock syndrome postmedical-abortion in Portugal. This international case is being investigated as part of the ongoing review of C. sordellii medical abortion deaths that includes my daughter, Holly Patterson and other women in the United States and Canada. The relevance of this information suggests that C. sordellii fatal toxic shock after medical abortion must be recognized as a global concern.

PLANNED PARENTHOOD CHANGES TO ANOTHER ALTERNATIVE TREATMENT

- 58. Planned Parenthood continues to violate the FDA approved protocol through its off-label use of miferistone and misoprostol for medical abortion.
- 59. From 2001 through March 2006, Planned Parenthood provided medical abortion principally by a regimen of oral mifepristone followed 24 to 48 hours later by vaginal misoprostol.
- 60. Prompted by deaths and rates of serious infections from medical abortion, in early 2006 Planned Parenthood changed the route of misoprostol administration from vaginal to buccal (between cheek and gum) in an effort to fix the problem.
- 61. After abortion providers had switched to the so called "new and improved" off-label medical abortion regimen, on July 4, 2007, an 18 year old previously healthy woman died from a Clostridium sordelli infection, 8 days after being prescribed the unapproved/off-label regimen of oral mifepristone/buccal misoprostol to terminate her early 6.5 week pregnancy.

ADVERSE EVENTS & ALTERNATIVE OFF-LABEL TREATMENTS

62. Prior to Holly Patterson's death on September 17, 2003, there were hundreds of adverse events reported to the drug manufacturer and the FDA concerning the use of Mifeprex (mifepristone).

- 63. As of April 2011, the FDA Adverse Event Summary report states 2207 women have been hospitalized or have experienced serious complications including hemorrhage, toxic shock, sepsis, organ failure, and ruptured ectopic pregnancy following early medical abortion with mifepristone and misoprostol.
- 64. Since it has been reported that only 4% of providers are using the FDA approved protocol, the majority of women who have been reported to have experienced adverse events were administered off-label Alternative Treatment Plans that were not recognized by the FDA.
- 65. It is noteworthy, that the FDA estimates 1 to 10 percent of all adverse events associated with the use of prescription drugs are reported to the agency.
- 66. There is no question, with regards to Mifeprex medical abortion, there is under-reporting and the extent is truly unknown. With the current voluntary system of adverse event reporting there appears to be a strong indication that potentially hundreds if not thousands of women have had serious infections, complications, or possibly have died after medical abortion with mifepristone and misoprostol than previously reported.

SUMMARY

67. My extensive work and research on mifepristone and medical abortion has been instrumental in bringing health and safety problems to the

forefront of regulatory authorities, the press, and the scientific and medical community. This work has helped raised awareness instrumental in changes that were made to the Mifeprex label in November 2004 adding the black box warning, having the November 2004 "Dear Doctor" letters sent to emergency room directors and medical abortion providers, and in the organization of the May 11, 2006 Clostridium sordelli Workshop in Atlanta.

- 68. Litigators for abortion providers have made inaccurate and misleading statements to the media about the women who have died from mifepristone medical abortions by stating "Those cases were investigated by both the FDA and the CDC and there was absolutely no causal relationship found between those unfortunate deaths and the medications that had been used." However, it is important to note, the 2004 and 2005 mifepristone black box warnings and labeling changes were revised to include: warning about a clinically significant hazard as soon as there was reasonable evidence of a causal association with a drug; a causal relationship need not to have been definitely established.
- 69. Planned Parenthood and other medical abortion providers have continued to practice the promotion of alternative treatment plans or off-label use of Mifeprex, which has not been recognized by the FDA, resulting in serious health complications, injuries and deaths in women.
- 70. The drug manufacturer, abortion providers and their affiliates each owes a duty to the patient to

ensure that medical abortion is safe and effective. It is critical that the safety of all medical abortion procedures are unbiased and have been properly researched, investigated, and monitored. All risks and knowable dangers must be properly communicated to doctors and patients.

- 71. Planned Parenthood had a duty of care to their patient, Holly Patterson, with an obligation to act solely in her interests, and specifically disclose information, in an easy to understand manner, all known risks and health problems associated with the medical abortion.
- 72. Based on Holly's experience, I believe Planned Parenthood performed their professional duties below the standard of care practiced by physicians and healthcare professionals in the community by: (a) failing to fully inform her regarding all potential risks of severe and life threatening side effects; (b) failing to inform her the safety of Alternative Treatments Plans had not been established by the FDA; (c) failing to get her signature on an important informed consent form; (d) failing to properly monitor, diagnose/ and or treat her after the treatment began; and (e) failing to report Holly's death to the State of California Department of Health because they did not consider it their responsibility because she had died in a hospital and not at one of their clinics.
- 73. Women are relying upon what they believe is factual information along with a supportive network of providers assuring them of the drug's safety and effectiveness. That wasn't the case for

my daughter, Holly Patterson, as well as thousands of other women who have participated in their own "at home" off-label medical abortion procedure.

- 74. No woman should risk her life or her health because she lacks factual and accurate medical abortion information to make a well-informed decision when terminating an early pregnancy with mifepristone (RU-486) and misoprostol.
- 75. I built the website, Abortionpillrisks.org Just the Facts, is a way for women, families, and the public to learn about the factual risks of RU-486 medical abortion.
- 76. It is also my belief that mifepristone (RU-486)/misoprostol for medically induced abortions should be removed from the market because it is can be dangerous to the health, safety and welfare of women.
- 77. Had Holly Patterson known of the full extent of the risks and dangers associated with mifepristone and misoprostol, she would not have taken the medical abortion drug regimen or would have obtained the help or care necessary to save her life.

Further Affiant sayeth not."

/s/ Monty L. Patterson Monty L. Patterson SWORN TO AND SUBSCRIBED BEFORE ME, the undersigned authority, on this <u>28th</u> day of <u>March</u> 2013.

/s/ Jaspreet K. DHillon NOTARY PUBLIC IN AND FOR THE STATE OF CALIFORNIA

Notary Public, <u>Alameda</u> County, California

My Commission Expires: June 28, 2016

Affidavit of Dr. Priscilla K. Coleman, Ph.D

STATE OF OHIO

COUNTY OF WOOD

STATE OF OHIO

NOTE: STATE OF OHIO

NOTE:

BEFORE ME, the undersigned authority, on this day personally appeared Priscilla K. Coleman, Ph.D. who is known to me, and after being by me first duly sworn according to law on her oath did depose and say that:

- 1. "My name is PRISCILLA K. COLEMAN. I am over the age of eighteen (18) years of age, and I am fully competent to make this Affidavit. I reside in Bowling Green, Ohio. I have personal knowledge of the facts stated herein and the following is true and correct.
- 2. I am a developmental psychologist and a Professor of Human Development and Family Studies at Bowling Green State University in Ohio, where I have been employed full-time for the past 11 years. I have published over 50 peer-reviewed scientific articles, of which 37 are on the psychology of abortion. Based on my expertise and the fact that I have published more peer-reviewed studies on abortion and mental health than any other researcher in the world, I am often called upon to serve as a content expert in state and civil cases involving abortion. I have given presentations in parliament houses in Great Britain, Northern Ireland, New South Wales,

and Queensland. Finally, I am on the editorial boards for five international medical journals.

3. The opinions expressed in the Affidavit are based upon my education, professional experience, the psychological research I have conducted, and my extensive and ongoing review of the abortion and mental health literature. The references in Exhibit A and Tables 1-4 in Exhibit B list publications that have been formative in shaping my opinions on the issues identified in this Affidavit, as well as other publications too numerous to mention in my ongoing review of the scientific literature.

Overview and Synopsis of Opinions

- 4. Over the course of my professional career, I have spent approximately twenty years conducting research, publishing the results of studies, analyzing the research of others, and performing systematic reviews of the literature for publication in peer-reviewed journals. Based on the research I have done, it is my opinion and I can say with a reasonable degree of scientific and medical certainty that abortion is a substantial contributing factor in women's mental health problems.
- 5. Scientific evidence accrued over the last two decades and published in leading peer-reviewed journals in psychology and medicine indicates that abortion places women at an increased risk for anxiety, depression, substance abuse, suicidal ideation, and suicide.

- 6. Women undergoing this procedure often report additional adverse consequences including unrelenting feelings of regret, shame, guilt, bereavement/loss, and lowered self-esteem. Many women withdraw from family and friends, become preoccupied with the abortion, and develop a sense that their lives will never feel right again.
- 7. There are several reasons women taking the RU-486 regimen are likely to be at an even greater risk for psychological problems than women who choose surgical abortion. Specific reasons are outlined below.
- 8. Pre-abortion counseling and informed consent are key factors in post-abortion difficulties. It is my opinion and research supports that when a woman feels she was misinformed or denied relevant information, this often precipitates post-abortion difficulties.
- 9. Avoiding discussion of fetal development or using terms like "tissue," "blood," "content of the uterus," or "a clump of cells" to refer to the fetus often encourages consent that would not have been made if she were told the truth. This dishonest practice denies a woman the information a reasonably prudent person would expect in considering whether or not to pursue an abortion. Subsequently, if a woman obtains truthful information concerning fetal development, adverse psychological consequences become more probable.

RU-486 - Chemical Abortions

- 10. Women choose chemical over surgical abortion for several reasons: a) they believe that it is safer and more natural, being akin to menstruation; b) no surgery or anesthesia is needed; c) one or both drugs may be taken at home; d) it is perceived to be easier; e) they feel they are more in control; and f) they are attracted to having greater privacy.
- 11. Lowenstein and colleagues (2006) found that compared to women choosing surgical abortion, those choosing chemical abortion were more fragile psychologically. In particular, there were higher obsessive-compulsive symptoms, higher levels of guilt, higher interpersonal sensitivity scores, more paranoid ideation, and more general psychiatric symptoms.
- 12. In studies of chemical abortion, expressed preabortion concerns voiced by women included wondering whether the procedure would really work, the level of pain that would be involved, and the longterm detrimental health effects. Women need accurate and truthful information about these medical issues prior to making a decision.
- 13. There are at least five major reasons why there is likely to be more psychological trauma with chemical abortion, compared to surgical abortion. First, the participatory role of the woman may cause greater psychological trauma. Specifically, the woman is directly responsible for the abortion and this may exacerbate guilt and other negative self-directed thoughts and feelings. Researchers Slade

and colleagues (1998) noted: "One of the main differences between these two methods of termination is the consciousness and participation of the patient in the medical procedure in a process that involves blood, pain, and death."

- 14. Second, medical abortion requires the woman to be more alert and involved during the process. This makes it impossible for her to distance herself psychologically from what is happening.
- 15. Third, the woman may see the expelled fetus. As a participant in a study by Hallden and colleagues (2008) explained: "You really take your child's life. I think if you see it then you see that you really do take the life of your child."
- 16. Fourth, the woman is more likely at home and alone, and therefore, she is likely to be without emotional support at the time of the abortion.
- 17. Fifth, the home generally, or the bathroom specifically, may become associated with the abortion. Therefore, the woman's home may become a trigger for negative emotions instead of being a place of refuge.
- 18. Studies indicate that there is more psychological distress among women having a chemical abortion as opposed to a surgical abortion. Slade and colleagues (1998) found that those who had a medical abortion rated it as more stressful and experienced more disruption in their lives. Ashok and colleagues (2005) reported 46.8% of women undergoing a medical

abortion experienced a significant decline in selfesteem 2-3 weeks following the abortion. This was a higher percentage than among those who had a surgical abortion (39.5%). Kelly and colleagues (2010) reported women who had chemical abortions had higher PTSD intrusion scores, such as nightmares, than women who had surgical abortions.

Abortion and Women's Mental Health in General

- 19. I can say with a reasonable degree of scientific and medical certainty that abortion is a substantial contributing factor in women's mental health problems. Abortion is a particularly risky choice for women with pre-existing mental illness. There is no empirical evidence documenting mental-health benefits to women with or without pre-existing mental illness, and there is an abundance of literature documenting the association between abortion(s) and declining mental health status.
- 20. The formal study of the psychology of induced abortion has garnered considerable momentum over the past several decades and the scientific rigor of the published studies has increased dramatically. Potential negative psychological and relational consequences of induced abortion and risk factors for such consequences have been the two primary focal areas in the literature. Paralleling the expansion of research, both in terms of the quantity and quality of studies published, there has been growing awareness in the medical community of the need for evidence-based practice.

- 21. The overwhelming preponderance of scientific evidence published world-wide indicates that abortion is a substantial contributing factor in women's mental health problems, including depression and death from suicide. Other well-established psychological difficulties associated with abortion include anxiety, substance use disorders, and relationship problems.
- 22. The scientific evidence is published in leading peer-reviewed journals in psychology and Medicine; and there are now dozens of large scale, prospective studies incorporating different types of comparison groups (unintended pregnancy delivered, other forms of perinatal loss, etc.) and other control techniques, effectively fortifying the level of confidence in the results derived. Exhibit A provides a list of the most methodologically sophisticated studies on abortion and mental health published over the last several decades; whereas Exhibit B provides an assessment of the casual evidence linking abortion to various mental health problems.
- 23. Exhibit C contains a report of a meta-analysis I conducted titled "Abortion and Mental Health: A Quantitative Synthesis and Analysis of Research Published from 1995-2009". This paper was published in the British Journal of Psychiatry on September 1, 2011. A meta-analysis is a specific form of systematic literature review wherein quantitative data from multiple published studies are converted to a common metric and combined statistically to derive an overall measure of the effect of an exposure such as abortion. This methodology gives the results more statistical

power (due to the increased sample size) and much more credibility than the results of any individual empirical study or narrative review, such as the one conducted by the American Psychological Association in 2008. In a meta-analysis, the contribution or weighting of any particular study to the final result is based on objective scientific criteria (sample size and strength of effect), as opposed to an individual's opinion of what constitutes a strong study.

- 24. After applying methodologically-based selection criteria and extraction rules to minimize bias, the sample consisted of 22 studies, 36 measures of effect, and 877,297 participants (163,880 experienced an abortion). Results revealed that women who aborted experienced an 81% increased risk for mental health problems. When compared specifically to unintended pregnancy delivered, women were found to have a 55% increased risk of experiencing mental health problem.
- 25. Separate effects were calculated based on the type of mental health outcome with the results revealing the following: the increased risk for anxiety disorders was 34%; for depression it was 37%; for alcohol use/abuse it was 110%; for marijuana use/abuse it was 220%; and for suicide behaviors it was 155%. Calculation of a composite Population Attributable Risk (PAR) statistic revealed that 10% of the incidence of mental health problems was directly attributable to abortion.

- 26. Very stringent inclusion criteria were used to avoid bias. Every strong study was included and weaker studies were excluded based on the criteria. Specifically, among the rules for inclusion were sample size of 100 or more participants, use of a comparison group, and employment of controls for variables that may confound the effects such as demographics, exposure to violence, prior history of mental health problems, etc.
- 27. The British Journal of Psychiatry is considered one of the top psychiatry journals in the world. Specifically, it has a very high Impact Factor (5.947) and it is currently the 3rd most-cited general psychiatry journal in the world (based on ISI rankings). Submitted papers are extensively scrutinized by well-respected scientists and the results of studies published are trusted by practitioners around the globe. This review offers the largest quantitative estimate of mental health risks associated with abortion available in the world.
- 28. The literature on risk-factors for adverse postabortion psychological consequences is well-developed. There is undisputed opinion among researchers and even among many abortion providers that risk factors for poor adjustment include the following: prior mental health problems, difficulty with the decision, emotional investment in the pregnancy, timing during adolescence or being unmarried, involvement in unstable or violent relationships, conservative views of abortion and/or religious affiliation, second trimester abortions, and feelings of being forced into abortion

by one's partner, others, or by life circumstances (Allanson, & Astbury, 2001; Bracken, 1978; Bracken et al., 1974; Campbell et al., 1988; Cozzarelli et al., 1994; Kero et al., 2004; Lewis, 1997; Lyndon et al., 1996; Osofsky & Osofsky, 1972; Osofsky et al., 1973; Remennick & Segal, 2001; Russo & Denious, 2001). Internalized beliefs regarding the humanity of the fetus, moral, religious, and ethical objections to abortion, and feelings of bereavement/loss also frequently distinguish those who suffer profoundly (see Coleman et al., 2005 for a review).

- 29. Hern (1990), a well-known abortion provider, emphasized the central role of pre-abortion counseling in evaluating women's mental status, circumstances, and abortion readiness while stressing the importance of developing a supportive relationship between the counselor and patient to prevent complications.
- 30. For the purpose of litigation in South Dakota (HB 1217), I completed a search of the professional literature for studies published between 1972 and 2011, documenting personal, demographic, situational, and relational factors that increase the likelihood of women experiencing post-abortion psychological problems. Over 400 abstracts of articles were read to assess relevance, 258 articles were ordered and examined closely, and a final list of 119 articles on risk factors for psychological difficulties was developed. I identified 12 risk factors documented in a minimum of 10 peer-reviewed journal articles. The risk factors are listed below.

- 1) Character traits indicative of emotional immaturity, emotional instability, or difficulties coping including low self-esteem, low self-efficacy, problems describing feelings, being withdrawn, avoidant coping, blaming oneself for difficulties etc. (42 studies)
- 2) Pre-abortion mental health/psychiatric problems (35 studies)
- 3) Decision ambivalence or difficulty, doubt once decision was made, or high degree of decisional distress (29 studies)
- 4) Conflicted, unsupportive relationships with others (28 studies)
- 5) Conflicted, unsupportive relationship with father of child (24 studies)
- 6) Desire for the pregnancy, psychological investment in the pregnancy, belief in the humanity of the fetus and/or attachment to fetus (21 studies)
- 7) Repeat or second trimester abortion (19 studies)
- 8) Timing during adolescence or younger age (18 studies)
- 9) Religious, frequent church attendance, personal values conflict with abortion (18 studies)
- 10) Negative feelings and attitudes related to the abortion (16 studies)
- 11) **Pressure or coercion to abort** (10 studies)

12) *Indicators of poor quality abortion care* (feeling misinformed/inadequate counseling, negative perceptions of staff, etc.) (10 studies)

Pre-Abortion Counseling

- 31. The importance of pre-abortion counseling and informed consent for women considering abortion has been well-documented in the scientific literature. The overwhelming preponderance of objective scientific evidence published in prestigious academic journals world-wide indicates that abortion does indeed pose serious mental health risks and significantly increases a woman's chance of dying, particularly by her own hand (see Exhibits A and B). All women who seek an abortion have a right to be informed of these risks. Affirmative statements that minimize the risks of mental health problems are incorrect and should never be made when the scientific/medical evidence is to the contrary.
- 32. Criticism leveled against pre-abortion counseling has focused on insufficient assistance with the decision-process (Butlet, 1996; Stites, 1982). Professionals will more effectively serve women by helping them to avert a decision that can cause later suffering through dissemination of accurate and objective scientific information regarding the risk factors for emotional problems, listening sensitively for any feelings of ambiguity, and offering assistance that facilitates the woman's autonomous decision-making. This idea was emphasized by Miller (1992, p. 91) who

stated that "a woman considering abortion who expresses enjoyment in being pregnant or the desire to have a child to take care of deserves some preabortion, exploratory counseling regarding these feelings." A related opinion was expressed by, Lemkau (1991, p. 100) who noted "in a political environment in which a woman's right to choose abortion is constantly challenged, it is easy to forget the importance of the right to choose not to abort." Furthermore, professionals working with women contemplating an abortion need to be encouraged not to interject their own opinions regarding what they perceive to be the best decision for an individual and should help instill confidence in women to not yield to pressures from others as they weigh their options.

33. Insufficient information dissemination and inappropriate counseling by professionals is likely to lead to decisions to abort that are inconsistent with women's value systems, initiate negative psychological reactions, lead to a lifetime of suffering, or factor into a premature death. Women should be given sufficient time to make a comfortable decision, and they should have opportunity to ask questions in a private, individualized context.

Informed Consent and the Consequences of Not Having Full and Accurate Information

34. Unfortunately, many women who make the decision to abort do so without a thorough understanding of the procedure. Research suggests that

feeling misinformed or being denied relevant information often precipitates post-abortion difficulties (Congleton & Calhoun, 1993; Franz & Reardon, 1992). Employment of ambiguous, misleading language violates a woman's right to make a fully informed decision and leaves her vulnerable to adverse outcomes, unanticipated at the time of the decision. If a woman obtains subsequent information, contradicting that provided by the abortion facility and used as the basis of her earlier abortion decision, adverse psychological consequences become more probable.

Provision of accurate information pertaining to fetal development should help to insure that women are making decisions that are consistent with their beliefs and value systems. Avoiding discussion of fetal development or using vague terms like "tissue," "blood," "content of the uterus," or "a clump of cells" to refer to an embryo or fetus may seem to make the women's decision easier, but it can often encourage a consent that would not have been made if she were told the scientific truth. This practice denies women the information a reasonably prudent person would expect in considering whether or not to pursue the medical procedure. Moreover, employment of ambiguous, misleading language violates a woman's right to make a fully informed decision and leaves her vulnerable to adverse outcomes, unanticipated at the time of the decision.

36. In a paper published in the top-rated medical ethics journal, *The Journal of Medical Ethics*, Reardon, Lee, and I found that 95% of a socio-demographically

diverse group of women wished to be informed of all possible complications associated with drugs, surgery, and/or other forms of elective treatments, including abortion (Coleman et al., 2006). In addition, a frequency of complications rate of 1:100 or higher would factor into most women's elective treatment decisions. As indicated by Gissler and colleagues as a key point in their 2005 article "Elevated mortality risk after a terminated pregnancy has to be recognized in the provision of health care and social services" (p. 462).

- 37. If a woman obtains subsequent information, contradicting that provided by the abortion facility and used as the basis of her earlier abortion decision, devastating psychological consequences become more probable. This fact is one that has been known in the medical profession for decades. In a 1980 letter published by the *New England Journal of Medicine*, this position is expressed by Riggs: "Women deserve to know exactly what would be removed before they make a decision. The doctor who protects them from the facts to preserve them from anxiety and guilt has made a moral decision on their behalf . . . and to deprive a woman contemplating abortion of a description of the fetus whether or not she requests it, is to deprive her of truly informed consent" (p. 350).
- 38. Research firmly indicates that when women feel they have been misinformed regarding the specifics of an abortion procedure, they are more inclined to suffer in the aftermath as they acquire factual information (Congleton & Calhoun, 1993; Franz & Reardon, 1992).

Further. Affiant sayeth not."

Dr. Priscilla K. Coleman, Ph.D

SWORN TO AND SUBSCRIBED BEFORE ME, the undersigned authority, on this ____ day of _____ 2013.

NOTARY PUBLIC IN AND FOR THE STATE OF OHIO

My commission expires:
Notary Public, ____ County, Ohio
My Commission Expires:

EXHIBIT A

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EXHIBIT B

Evidence for a Causal Association between Abortion and Mental Health Problems

I. Background for understanding causality when studying human behavior Due to the inherent complexity of human psychological health outcomes, such as depression and suicidal behavior, identification of a single, precise causal agent applicable to all cases is not possible. Every mental health problem is determined by numerous physical and psychological characteristics, background, and current situational factors subject to individual variation. Further, any one cause (e.g. abortion) is likely to have a variety of effects (e.g., anxiety, depression, suicidal behavior) based on the variables involved.

A *risk factor* refers to any variable that has been established to increase the likelihood of an individual experiencing an adverse outcome. Risk factor data are used in medicine and psychology for the explicit purposes of understanding etiology, warning patients of risks associated with various medical interventions, and development of effective prevention and intervention protocols to maximize health.

Assessment of degree of risk is often expressed in terms of *absolute risk*, which relates to the chance of developing a disease over a time-period (e.g., a 10% lifetime risk of suicide) or in terms of *relative risk*, which is a comparison of the probability of an adverse outcome in two groups. For example, abortion would be considered an increased risk for suicide if the

relative risk is significantly higher for women who abort compared to women who give birth or never have children.

Determination of causality technically requires an experimental design in which there is random assignment of large groups to expected cause conditions (e.g., abortion, no abortion/delivery, no abortion/no pregnancy). However, as is true with numerous variables of interest in psychology and medicine, it is not ethical nor is it practically feasible to implement such a study. When scientists are not able to control or manipulate the variable of interest, risk factors for negative outcomes are established over time through the two primary scientific steps described below.

- 1. Analysis of each individual study. Each individual study published in a peer-reviewed journal is examined to assess the quality of evidence suggestive of a causal link between abortion and negative outcomes. The following three criteria are applied when the variable of interest such as abortion can not be manipulated.
 - a. Abortion must be shown to precede the mental health problem (referred to as *time precedence*). This is typically accomplished with longitudinal or prospective data collection in which testing occurs over an extended period of time following the abortion.
 - b. Differences in abortion history (abortion, no abortion) must be systematically associated with differences in mental health status (*covariation*).

- Finally, all plausible alternative explanations for associations between abortion and mental health must be ruled out using a method of control. Typically third variables predictive of both the choice to abort and mental health (e.g. income, previous psychological problems, exposure to domestic violence etc.) are statistically removed from the analyses. Identifying, measuring, and statistically controlling for known predictors of abortion would go a long way to help establish causality; however there are many other means for achieving the same goal of infusing control. Additional control techniques include: (1) matching groups on all variables known to be related to abortion and the outcome measures; (2) measuring potential confounding variables and introducing them as additional variables to assess their independent effects; (3) identifying and selecting homogeneous populations to draw the pregnancy outcome groups.
- 2. Integrative analysis. After evaluating individual studies for causal evidence linking abortion to decrements in mental health, scientists assess the consistency and magnitude of associations between abortion and particular mental health problems across all available studies. This integrative process represents the second step for determining whether or not abortion is a substantial contributing factor for severe depression and other mental health problems.
 - **a.** *Consistency* refers to repeated observation of an association between abortion and

mental health across several studies using different people, places, and circumstances tested at distinct points in time. When results become generalized in this manner, the probability that an association would be due to chance is dramatically reduced.

- **b.** *Magnitude* (or strength of effect) refers to whether the associations between abortion and various mental health problems are slight, moderate, or strong. Strong associations across various studies are more likely causal than slight or modest associations. This point has been illustrated with the high risk ratios for the association between exposure levels of smoking and incidence of lung cancer.
- II. Causal Evidence from Research on the Mental Health Risks of Abortion The tables below provide an overview of the studies related to abortion and suicide ideation and suicide, abortion and substance use/abuse, abortion and depression, and abortion and anxiety. The arrangement of the data in the tables offers guidance regarding the extent to which the conditions for causality have been met.

Table 1: Scientific Studies Identifying Abortion as a Risk Factor in Suicidal Behavior.

Study	Time sequence	Co- variation	Controls and Other Strengths	Results/ Magnitude of effect
1. Fergusson, D. M. et al. (2006). Abortion in young women and subsequent mental health. Journal of Child Psychology and Psychiatry, 47, 16-24.	*	√	Pregnancy delivered and never pregnant used as comparison groups. Controlled for demographic, family of origin, history of abuse, partner, personality, and mental health history variables. National sample, high retention, low concealment, thorough assessments of outcomes.	27% of women who aborted reported suicidal ideation. The risk was 4X greater for women who aborted compared to never pregnant women and more than 3X greater for women who delivered.
2. Fergusson, D.M. et al. (2008). Abortion and mental health disorders: Evidence from a 30-year longitudinal study, <i>The British Journal of Psychiatry</i> , 193, 444-451.	•	•	Pregnancy delivered and never pregnant used as comparison groups. Controlled for demographic, family of origin, history of abuse, partner, personality, mental health history, exposure to adverse events variables and pregnancy intendedness. National sample, high retention, low concealment, thorough assessments of outcomes.	61% increased risk of suicide ideation associated with abortion.
3. Gilchrist, A. C. et al. (1995). Termination of pregnancy and psychiatric morbidity. <i>British Journal of Psychiatry</i> 167, 243.	√	✓	Compared women who were refused abortion and women who chose abortion but changed their minds. Pregnancy intendedness controlled.	Among women with no history of psychi- atric illness, the rate of deliberate self- harm was significant- ly higher (70%) after abortion than child- birth.
4. Gissler, M. et al. (1996). Suicides after pregnancy in Finland, 1987-94: Register linkage study. <i>British Medical Journal</i> , 313, 1431 4.	√	✓	Compared women who aborted to those who delivered, miscarried, and the general population. Large study population Use of medical claims data: ICD-8 codes.	Suicide rate was nearly 6X greater among women who aborted compared to women who deliv- ered.
5. Gissler, M. et al. (2005). Injury deaths, suicides and homicides associated with pregnancy, Finland 1987-2000. European Journal of Public Health, 15, 459-463.	√	✓	Compared women who aborted, delivered, miscarried, and were not pregnant. Large study population Use of medical claims data: ICD-8 codes. Distinguished level of risk associated with suicide and other forms of death.	Abortion was associated with a 6X higher risk for suicide compared to birth.
6. Reardon, D.C. et al. (2002). Deaths associated with delivery and abortion among California Medicaid patients: A record linkage study. Southern Medical Journal, 95,834-41.	√	√	Use of homogenous population. Controlled for prior psychiatric history, age, and eligibility for state medical coverage. Large sample.	Suicide risk was 154% higher among women who aborted compared to those who delivered.

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7. Rue, V.M. et al. (2004). Induced abortion and traumatic stress: A preliminary comparison of American and Russian women. <i>Medical Science Monitor</i> 10, SR 5-16.	✓	✓	Controlled for stressors pre-and post-abortion, demographic and psychosocial variables (including abuse and parental divorce, etc.). Women specifically asked if they believed the abortion was the cause.	36.4% of the American women and 2.8% of the Russian women respectively reported suicidal ideation.	
8. Mota, N.P. et al (2010). Associations between abortion, mental disorders, and suicidal behaviors in a nationally representative sample. <i>The Canadian Journal of Psychiatry</i> , 55 (4), 239-246.		√	Nationally representative sample. Controlled for the experience of interpersonal	women without a history of abortion, those who had an	**

Table 2: Scientific Studies Identifying Abortion as a Risk Factor in Depression.

Study	Time sequence	Co- variation	Controls and Other Strengths	Results/ Magnitude of effect
1. Coleman, P. K. et al. (2002). State-funded abortions vs. deliveries: A comparison of outpatient mental health claims over four years. American Journal of Orthopsychiatry, 72, 141-152.	•	*	Homogeneous population. Controls for pre- pregnancy psychological difficulties, age, and months of eligibility. Large sample. Used actual claims data, eliminating the conceal- ment problem. Avoids recruitment, retention problems, and simplistic forms of as- sessment.	Across the 4-yrs, the abortion group had 40% more claims for neurotic depression than the delivery group.
2. Coleman, P. K. (2006). Resolution of unwanted pregnancy during adolescence through abortion versus childbirth: Individual and family predictors and psychological consequences. The Journal of Youth and Adolescence, 35, 903-911.	√	√	Nationally representative, diverse sample. Exclusive focus on unwanted pregnancies aborted and delivered. Implemented controls for several demographic, psychological, and familial variables.	After implementing controls, adolescents with an abortion history, when compared to those with a birth history, were: 5X more likely to seek counseling for psychological or emotional problems and 4X more likely to report frequent sleep problems, a common symptom of depression.
3. Coleman, P. K. et al. (2009), Induced Abortion and Anxiety, Mood, and Substance Abuse Disorders: Isolating the Effects of Abortion in the National Comorbidity Survey. <i>Journal of Psychiatric Research</i> , 43, 770-776.		•	Controlled 22 different demographic, history, and personal/situational variables mostly related to adverse life events. Nationally representative sample. Thorough assessments of psych outcomes by trained professionals. PAR statistic calculated.	After implementing controls, an abortion increased the risk of developing Major Depression with Hierarchy by 42.5%. Abortion was linked to 4.3% of the incidence of Major Depression with Hierarchy.
4. Cougle, J., et al. (2003). Depression associated with abortion and childbirth: A long-term analysis of the NLSY cohort. Medical Science Monitor, 9, CR105-112	✓	✓	Controlled for prior psychological state, age, race, marital status, divorce history, education, and income (stratification by ethnicity, current marital status, and history of divorce). Nationally representative, racially-diverse sample. Extended time frame.	Women whose 1st pregnancies ended in abortion were 65% more likely to score in the "high-risk" range for clinical depression. (White: 79% higher risk; married: 116% higher risk; 1st marriage didn't end in divorce: 119% higher risk).
5. Dingle, K., et al. (2008). Pregnancy loss and psychiatric disorders in young women: An Australian birth cohort study. <i>The British Journal of Psychiatry</i> , 193, 455-460.	~	•	Controlled for maternal and familial factors, pre- existing behavior prob- lems and substance misuse, and demographic factors.	Young women reporting an abortion history had almost twice the risk for 12 month depression compared to women who did not report an abortion.

6. Fergusson, D. M. et al. (2006). Abortion in young women and subsequent mental health. Journal of Child Psychology and Psychiatry, 47, 16-24.		√	Pregnancy delivered and never pregnant used as comparison groups. Controlled for demographic, family of origin, history of abuse, partner, personality, and mental health history variables. National sample, high retention, low concealment, thorough assessments of outcomes.	42% of the women who had aborted reported major depression by age 25.	App. 90
7. Fergusson, et al. (2008). Abortion and mental health disorders: Evidence from a 30-year longitudinal study, <i>The British Journal of Psychiatry</i> , 193, 444-451.		•	Pregnancy delivered and never pregnant used as comparison groups. Controlled for demographic, family of origin, history of abuse, partner, personality, pregnancy intendedness, and mental health history variables. National sample, high retention, low concealment, thorough assessments of outcomes.	Major depression: 31% increased risk associated with abortion.	
8. Harlow, B. L. et al. (2004). Early life menstrual characteristics and pregnancy experiences among women with and without major depression: the Harvard Study of Mood and Cycles. <i>Journal of Affective Disorders</i> , 79, 167-176.	√	✓	Employed demographic controls (age, age at menarche, educational attainment, and history of marital disruption). Population-based sample. 73.5% response rate.	Compared to women with no history of induced abortion, those with two or more were 2-3X more likely to have a lifetime history of major depression.	
9. Major, B. et al. (2000). Psychological responses of women after first trimester abortion. Archives of General Psychiatry, 57, 777-84.	√	✓	Controlled for demographic characteristics, medical complications, and prior mental health.	Two years post- abortion, 20% were depressed. Younger age and having more children pre-abortion predicted more negative post- abortion outcomes.	
10. Pedersen W. (2008). Abortion and depression: A population-based longitudinal study of young women. Scandinavian Journal of Public Health, 36 (4):424-8.	√	√	Controlled for parental education level, parental smoking habits, parental support, and prior history of depression. Large national sample	Women with an abortion history were nearly 3X as likely as their peers without an abortion experience to report significant depression.	
11. Pope, L. M. et al. (2001). Post-abortion psychological adjustment: Are minors at increased risk? <i>Journal of Adolescent Health</i> , 29, 2-11.	✓	√	Compared current sample results with those reported in other studies using similar samples.	19% experienced moderate to severe levels of depression 4 weeks post-abortion.	

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12. Reardon, D. C., & Cougle, J. (2002). Depression and Unintended Pregnancy in the National Longitudinal Survey of Youth: A cohort Study. <i>British Medical Journal</i> , 324, 151-152.		•	Confined analyses to unintended pregnancy aborted or delivered. Nationally representative sample. Controlled for the following: prior psychiatric state, family income. Education, race, age at first pregnancy. Stratified by marital status.	range for depression was 22.7% compared to 27.3% of women who aborted (OR=1.54). Among married women, the percentage of women who carried to term considered to be in the high-risk range for depression was 17.3% compared to 26.2% of women who
13. Reardon, D. C. et al. (2003). Psychiatric admissions of lowincome women following abortion and child-birth. Canadian Medical Association Journal, 168, 1253-1256.	•	√	Homogeneous population. Controls for pre- pregnancy psychological difficulties, age, and mos. of eligibility. Large sample. Used actual claims data, eliminating the conceal- ment problem. Avoids recruitment and retention problems, and simplistic forms of assessment.	abortion group more claims for depressive disorders compared to the birth group, with the percentages equaling 90%, 110%, and 200% for depressive psychosis, single and recurrent episode, and bipolar disorder respectively.
14. Rees, D. I. & Sabia, J. J. (2007) The relationship between abortion and depression: New evidence from the Fragile Families and Child Wellbeing Study. <i>Medical Science Monitor</i> , 13(10), 430-36.			A number of controls were incorporated: race, ethnicity, age, education, household income, number of children, prior depression.	Women who had an abortion were at a significantly higher risk for reporting symptoms of Major Depression compared to women who had not become pregnant. After adjusting for controls, abortion was associated with more than a two-fold increase in the likelihood of having depressive symptoms at second follow-up.
15. Schmiege, S., & Russo, N. F. (2005). Depression and unwanted first pregnancy: Longitudinal cohort study. British Medical Journal.	•	•	Employed controls to only some analyses with no explanation. The analyses in Table 3 of the article do not incorporate controls for variables identified as significant predictors of abortion (higher education and income and smaller family size). This is highly problematic since lower education and income and larger family size predicted depression. Without the controls, the delivery group will have	Percent of women exceeding the depres-

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16. Söderberg et al. (1998). Emotional distress following induced abortion. A study of its incidence and determinants among abortees in Malmö, Sweden. European Journal of Obstetrics and Gynecology and Reproductive Biology 79, 173-8.	✓	✓	more depression variance erroneously attributed to pregnancy resolution. Utilized a case control data analysis strategy. Extensive semistructured interview methodology.	group. Statistical significance is likely to have been achieved with the controls instituted. 50-60% of the women experienced emotional distress of some form (e.g., mild depression, remorse or guilt feelings, a tendency to cry without cause, discomfort upon meeting children), classified as severe in 30% of cases.
17. Mota, N.P. et al (2010). Associations between abortion, mental disorders, and suicidal behaviors in a nationally representative sample. <i>The Canadian Journal of Psychiatry</i> , 55 (4), 239-246.		*	Nationally representative sample. Controlled for the experience of interpersonal violence and demographic variables.	When compared to women without a history of abortion, those who had an abortion had a 61% increased risk for Mood Disorders

Table 3: Scientific Studies Identifying Abortion as a Risk Factor in Anxiety.

Study	Time sequence	Co- variation	Controls and Other Strengths	Results/ Magnitude of effect
1. Broen, A.N., Moum, T., Bodtker, A. S., & Ekeberg, O. (2004). Psychological impact on women of miscarriage versus induced abortion: A 2 year follow-up study. Psychosomatic Medicine, 66, 265-271.		→	Number of children Marital status Vocational status	10 days after the pregnancy ended, 30% of those who had an abortion scored high on measures of avoidance or intrusion, which includes symptoms such as flashbacks and bad dreams. 2 years after the pregnancy ended, nearly 17% of 80 women who had an abortion scored highly on a scale measuring avoidance symptoms, compared with about 3% of
2. Broen, A.N., Moum, T., Bodtker, A. S., & Ekeberg, O. (2005). Reasons for induced abortion and their relation to women's emotional distress: a prospective, two-year follow-up study. General Hospital Psychiatry, 27, 36-43.			Marital status Psychiatric history	Male pressure on women to abort was significantly associated with negative abortion-related emotions in the two years following an abortion. Pre-abortion psychiatric history was not significantly related to immediate negative abortion related emotion or with negative emotional responses measured at 2 years out. 23.8% of the sample scored high on The Impact of Events Scale (a measure of stress reactions after a traumatic event) 10 days after the abortion, 13.3% at 6 months, and 1.4% after 2 years.
3. Coleman, P.K., Coyle, C.T., Shuping, M., & Rue, V. (2009), Induced Abortion and Anxiety, Mood, and Substance Abuse Disorders: Isolating the Effects of Abortion in the National Comorbid- ity Survey. Journal of Psychiatric Research. 43, 770-776.		√	Twenty two different demographic, history, and personal/situational variables mostly related to adverse life events.	For PTSD, Agoraphobia with or without Panic Disorder, Agoraphobia without Panic Disorder, a history of abortion when compared to no history was associated with an 81.6%, 1.24.6%, and a 1.32% increased risk respectively after implementing statistical

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				controls. Calculation of population attributable risks indicated that abortion was implicated in 8.3% of the incidence of PTSD, 12.3% of the incidence of Agoraphobia with/or without Panic, and 13.0% of Agoraphobia without Panic.
4. Coleman, P.K., & Nelson, E.S. (1998). The quality of abortion decisions and college students' reports of post-abortion emotional sequelae and abortion attitudes. <i>Journal of Social and Clinical Psychology</i> , 17, 425-442.	✓	√	Gender: Compared men and women with abortion experience. Time elapsed since abor- tion	Anxiety increased after the abortion: female: 13.3%; male: 9.7%
5. Cougle, J., Reardon, D. C., Coleman, P. K., & Rue, V. M. (2005).Generalized anxiety associated with unintended pregnancy: A cohort study of the 1995 National Survey of Family Growth. Journal of Anxiety Disorders, 19, 137-142	✓	•	All women were experiencing an unintended pregnancy Stratification by ethnicity, current marital status, and age.	The odds of experiencing subsequent Generalized Anxiety were 34% higher among women who aborted compared vs. delivered. Greatest differences among the following demographic groups: Hispanic: 86% higher risk, Unmarried at time of pregnancy: 42% higher risk; under age 20: 46% higher risk.
6. Fayote, F.O., Adeyemi, A.B., Oladimeji, B.Y. (2004). Emotional distress and its correlates. <i>Journal</i> of Obstetrics and Gyne- cology, 5, 504-509.	✓	√	Used a matched control group	Previous abortion was significantly associated with anxiety among the pregnant women
7. Fergusson, D. M., Horwood, J., & Ridder, E. M. (2006). Abortion in young women and subsequent mental health. Journal of Child Psychology and Psychiatry, 47, 16-24.	✓	✓	Those who delivered and were never pregnant used as comparison groups. Controlled for maternal education, childhood sexual abuse, physical abuse, child neuroticism, self-esteem, grade point average, smoking, prior history of depression, anxiety, prior history of suicide ideation, living with parents, living with partner	39% of post-abortive women suffered from anxiety disorders by age 25.
8 Fergusson, D.M., Horwood, J. H., & Boden, J. M. (2008). Abortion and mental health disorders: Evi- dence from a 30-year	√	✓	Controls: childhood socio- economic circumstances, childhood family func- tioning, parental adjust- ment, abuse in childhood, individual characteristics,	Anxiety Disorder: 113% increased risk associated with abortion.

longitudinal study, The British Journal of Psychiatry, 193, 444- 451. 9. Lauzon, P., Roger- Achim, D., Achim, A.,	√	√	educational achievement, adolescent adjustment, lifestyle and related factors such as exposure to adverse events, and pre-abortion mental health. Random sample of the general population of	Before the abortion, 56.9% of women and
& Boyer, R. (2000). Emotional distress among couples. involved in first trimester abortions. Canadian Family Physician, 46, 2033-2040.			reproductive age used as the control group	39.6% of men were much more distressed than their respective controls. Three weeks after the abortion, 41.7% of women and 30.9% of men were still highly distressed.
10. Major,B.,& Gramzow, R. H. (1999).Abortion As stigma: Cognitive and emotional implications of concealment. Journal of Personality and Social Psychology,77, 735-745.	√	√		Two years after abortion: Intrusive thoughts – quite a bit: 3% – some intrusive thoughts: 62%
11. Mota, N.P. et al (2010). Associations between abortion, mental disorders, and suicidal behaviors in a nationally representative sample. <i>The Canadian Journal of Psychiatry</i> , 55 (4), 239-246.		√	Nationally representative sample. Controlled for the experience of interpersonal violence and demographic variables.	When compared to women without a history of abortion, those who had an abortion had a 61% increased risk for social phobia.
12. Pope, L. M., Adler, N. E., & Tschann, J. M. (2001). Post-abortion psychological adjustment: Are minors at increased risk? Journal of Adolescent Health, 29, 2-11.	√	√	Compared current results with those in other studies using similar samples.	Scale – Intrusion
13. Rue, V. M., Coleman, P. K., Rue, J. J., & Reardon, D. C. (2004). Induced abortion and traumatic stress: A preliminary comparison of American and Russian women. Medical Science Monitor 10, SR 5-16.	•	√	Controls for severe stress symptoms prior to the abortion, other stressors pre-and post-abortion, several demographic variables, psycho-social variables (harsh discipline, abuse, parental divorce, etc).	The percentages of Russian and U.S. women who experienced 2 or more symptoms of arousal, 1 or more symptom of re-experiencing the trauma, and 1 or more experience of avoidance (consistent with DSM-IV diagnostic criteria for PTSD) were equal to 13.1% and 65% respectively.
14. Sivuha, S. Predictors of Posttraumatic Stress Disorder Following Abortion in a Former Soviet Union		√		35% of women had some posttraumatic consequences of abortion (elevated avoidance, intrusion,

Country. Journal of Prenatal & Perinatal Psych & Health,17, 41- 61 (2002).	✓	√		or hyper-arousal scores) 46% of women had evidence of PTSD, exceeding the cut-offs for intrusion and avoidance subscales. 22% of women experienced PTSD, exceeding the cut-offs on all 3 subscales.
15. Slade, P., Heke, S., Fletcher, J., & Stewart, P. (1998). A comparison of medical and surgical methods of termination of pregnancy: Choice, psychological consequences, and satisfaction with care. British Journal of Obstetrics and Gynecology, 105, 1288-95.		•		1 month post- abortion: Cases of anxiety: 27%
16. Suliman et al. (2007) Comparison of pain, cortisol levels, and psychological distress in women undergoing surgical termination of pregnancy under local anaesthesia vs. intravenous sedation. BMC Psychiatry, 7 (24), p.1-9.	✓	√	Baseline levels of depression, state anxiety, selfesteem, and functional disability.	The percentages of women experiencing PTSD symptoms after abortion were 17.5% and 18.2% at one and three months respectively.
17. Williams, G. B. (2001). Short-term grief after an elective abortion. Journal of Obstetrics, Gynecologic, and Neonatal Nursing, 30, 174-183.	√	√	Controlled for other forms of loss and psychiatric history. Control group with no abortion history.	abortion associated with more grief in terms of loss of control, death anxiety, and dependency than controls.
18. Urquhart D.R., & Templeton, A. A. (1991). Psychiatric morbidity and acceptability following medical and surgical methods of induced abortion. British Journal of Obstetrics and Gynecology, 98, 396-399.	√	√		Clinically significant feelings of anxiety at 1 month postabortion by 10% of the sample.

Table 4: Scientific Studies Identifying Abortion as a Risk Factor in Substance Use/Abuse.

Study	Time sequence	Co- variation	Controls and Other Strengths	Results/ Magnitude of effect
1. Amaro H., Zuckerman B, & Cabral H. (1989). Drug use among adolescent mothers: profile of risk. <i>Pediatrics</i> , 84, 144-151.	√	√	Other forms of perinatal loss as comparison groups	Adolescent drug users when compared to nonusers were significantly more likely to report a history of elective abortion (33% vs. 16.3%). No associations were identified between drug use and parity
2. Coleman, P. K. (2006). Resolution of Unwanted Pregnancy During Adolescence Through Abortion versus Childbirth: Individual and Family Predictors and Consequences. Journal of Youth and Adolescence.	✓	√	Demographic, educational, psychological, and family variables found to predict the choice to abort Exclusive focus on unwanted pregnancies	or other forms of perinatal loss (miscarriage /stillbirth). After implementing controls, adolescents with an abortion history, when compared to adolescents who had give [sic] birth were 6 times more likely to use marijuana.
3. Coleman., P.K., Coyle, C.T., Shuping, M., & Rue, V. (2009), Induced Abortion and Anxiety, Mood, and Substance Abuse Disorders: Isolating the Effects of Abortion in the National Comorbid- ity Survey. Journal of Psychiatric Research. 43, 770-776.			Controlled for twenty two different demographic, history, and personal/situational variables mostly related to adverse life events.	Abortion was related to an increased risk for substance abuse disorders after statistical controls were instituted. An induced abortion was specifically associated with a 105%, 134%, 70.9%, 104% increased risk for Alcohol Abuse with or without Dependence, Drug Abuse with or without Dependence respectively. Calculation of population attributable risks indicated that abortion was implicated in 9% of the incidence of Alcohol Abuse with/or without Dependence, 12.5% of the incidence of Alcohol Dependence, 7.1% of the incidence of Drug Abuse with/or without Dependence, and 10.4% of the incidence of Drug Abuse with/or without Dependence, and 10.4% of the incidence of Drug Dependence.

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4. Coleman, P. K., & Maxey, D. C., Spence, M. Nixon, C. (2009). The choice to abort among mothers living under ecologically deprived conditions: Predictors and consequences. International Journal of Mental Health and Addiction7, 405-422.	~	√	Controls for the following variables: mother and father married at baseline, mother considered an abortion during first pregnancy, and relationship with father got worse or remained the same after first pregnancy confirmed, and 11 variables related to paternal involvement in the care of the child born at baseline.	Women who chose abortion when compared to women who delivered a second child were more likely to report recent heavy use of alcohol (239% increased risk) and cigarette smoking (99% increased risk).
5. Coleman, P. K., Reardon, D. C., Rue, V., & Cougle, J. (2002). History of induced abortion in relation to substance use during subsequent pregnancies carried to term. American Journal of Obstetrics and Gynecology, 187, 1673-1678.		✓	Results were stratified by potentially confounding factors (marital status, income, ethnicity, and time elapsed since a prior abortion or birth)	Compared with women who had previously given birth, women who aborted were significantly more likely to use marijuana (929%), various elicit drugs (460%), and alcohol (122%) during their next pregnancy. Differences relative to marijuana and use of any elicit drug were more pronounced among married and higher income women and when more time had elapsed since the prior pregnancy. Differences relative to alcohol use were most pronounced among the white women and when more time had elapsed since the
6. Coleman, P. K., Reardon, D. C., & Cougle, J. (2005) Substance use among pregnant women in the context of previous reproductive loss and desire for current pregnancy. British Journal of Health Psychology, 10, 255- 268.		✓	Other forms of loss Age Marital status Trimester in which prenatal care was sought Education Number in household	prior pregnancy. No differences were observed in the risk of using any of the substances measured during pregnancy relative to a prior history of miscarriage or stillbirth. A prior history of abortion was associated with a significantly higher risk of using marijuana (201%), cocaine-crack (198%), cocaine-other than crack (406%), any illicit drugs (180%), and cigarettes (100%).
7. Dingle, K., Alta, R., Clavarino, A. et al. (2008). Pregnancy loss and psychiatric	√	✓	Controlled for maternal and familial factors, pre- existing behavior prob- lems and substance	Young women reporting an abortion history had almost 3 times a greater risk

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disorders in young women: An Australian birth cohort study. The British Journal of Psychiatry, 193, 455-460.			misuse, and demographic factors.	of experiencing a lifetime illicit drug use disorder (not including marijuana) and twice the risk for an alcohol use disor- der compared to women who did not report an abortion.
8. Fergusson, D. M., Horwood, J., & Ridder, E. M. (2006). Abortion in young women and subsequent mental health. <i>Journal of Child Psychology and Psychiatry</i> , 47, 16-24.	√	✓	Those who delivered and were never pregnant used as comparison groups. Controlled for maternal education, childhood sexual abuse, physical abuse, neuroticism, selfesteem, grade point average, smoking, prior history of depression, anxiety, suicide ideation, living with parents, living with partner	6.8% indicated alcohol dependence, and 12.2% were abusing drugs. By age 25.
9. Fergusson, D.M., Horwood, J. H., & Boden, J. M. (2008). Abortion and mental health disorders: Evidence from a 30-year longitudinal study, The British Journal of Psychiatry, 193, 444- 451.	✓	✓	Controls: Measures of childhood socio-economic circumstances, childhood family functioning, parental adjustment, exposure to abuse in childhood, individual characteristics, educational achievement, adolescent adjustment, lifestyle and related factors which included exposure to adverse events, and pre-abortion mental health.	Alcohol dependence: 188% increased risk associated with abortion Illicit drug dependence: 185% increased risk associated with abortion.
10. Hope, T. L., Wilder, E. I., & Watt, T. T. (2003). The relationships among adolescent pregnancy, pregnancy resolution, and juvenile delinquency, <i>Sociological Quarterly</i> , 44, 555-76.	✓	√	Controls for a wide range of socioeconomic and demographic variables likely to influence juve- nile delinquency.	Compared to adolescents who ended their pregnancies through abortion, those who keep their babies experienced a dramatic reduction in smoking and marijuana use
11. Pedersen, W. (2007). Addiction. Childbirth, abortion and subsequent substance use in young women: a population-based longitudinal study, 102 (12), 1971-78.	✓	√	Controls for social back- ground, parental and family history, smoking, alcohol and drug use, conduct problems, de- pression, schooling, and career variables. Comparison groups included those who had never been pregnant and those who delivered.	Elevated rates of substance use (nicotine dependence: 400% increased risk; alcohol problems: 180% increased risk; Cannabis use: 360% increased risk: and other illegal drugs: 670% increased risk) compared to other women
12. Reardon, D. C., Coleman, P. K., & Cougle, J. (2004) Substance use associat- ed with prior history of abortion and unintend- ed birth: A national cross sectional cohort study.	√	√	Age Ethnicity Marital status Income Education Pre-pregnancy self- esteem and locus of control	Compared to women who carried an unintended first pregnancy to term, those who aborted were 100% more likely to report use of marijuana in the past 30 days and

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Am. Journal of Drug and Alcohol Abuse, 26, 369-383.				149% more likely to use cocaine in the past 30 days (only approached significance). Women with a history of abortion also engaged in more frequent drinking than those who carried an unintended pregnancy to term. Except for less frequent drinking, the delivery group was not significantly
13. Reardon D.C., Ney, P.G. (2002) Abortion	√	√	Controlled for substance use prior to the abortion	different from the no pregnancy group. Women who aborted a first pregnancy
and subsequent substance abuse. American Journal of Drug and Alcohol Abuse, 26, 61-75.			and age	were 5 times more likely to report subsequent substance abuse than women who carried to term and 4 times more likely to report substance abuse compared to those who had a nonvoluntary pregnancy loss
14. Yamaguchi D, & Kandel D. (1987). Drug use and other determinants of premarital pregnancy and its outcome: A dynamic analysis of competing life events. Journal of Marriage and the Family, 49, 257-270.	√	•		The use of illicit drugs other than marijuana was 6.1 times higher among women with a history of abortion when compared to women without a history.
15. Mota, N.P. et al (2010). Associations between abortion, mental disorders, and suicidal behaviors in a nationally representative sample. <i>The Canadian Journal of Psychiatry</i> , 55 (4), 239-246.		√	Nationally representative sample. Controlled for the experience of interpersonal violence and demographic variables.	The increased risk for alcohol abuse, alcohol dependence, drug abuse, drug dependence, and any substance use disorder were equal to 261%, 142%, 313%, 287%, and 280% respectively.

EXHIBIT C

Coleman, P.K. (Sept 1, 2011). Abortion and Mental Health: A Quantitative Synthesis and Analysis of Research Published from 1995-2009. *British Journal of Psychiatry*.

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The British Journal of Psychiatry

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Review article

Abortion and mental health: quantitative synthesis and analysis of research published 1995-2009

Priscilla K. Coleman

Background

Given the methodological limitations of recently published qualitative reviews of abortion and mental health, a quantitative synthesis was deemed necessary to represent more accurately the published literature and to provide clarity to clinicians.

Aims

To measure the association between abortion and indicators of adverse mental health, with subgroup effects calculated based on comparison groups (no abortion, unintended pregnancy delivered, pregnancy delivered) and particular outcomes. A secondary objective was to calculate population-attributable risk (PAR) statistics for each outcome.

Method

After the application of methodologically based selection criteria and extraction rules to minimise bias, the sample comprised 22 studies, 36 measures of effect and 877 181 participants (163 831 experienced an abortion). Random effects pooled odds ratios were computed using adjusted odds ratios from the original studies and PAR statistics were derived from the pooled odds ratios.

Results

Women who had undergone an abortion experienced an 81% increased risk of mental health problems, and nearly 10% of the incidence of mental health problems was shown to be attributable to abortion. The strongest subgroup estimates of increased risk occurred when abortion was compared with term pregnancy and when the outcomes pertained to substance use and suicidal behaviour.

Conclusions

This review offers the largest quantitative estimate of mental health risks associated with abortion available in the world literature. Calling into question the conclusions from traditional reviews, the results revealed a moderate to highly increased risk of mental health problems after abortion. Consistent with the tenets of evidence-based medicine, this information should inform the delivery of abortion services.

Declaration of interest

None.

Despite federal legalisation of abortion in the USA in 1973, women's right to choose abortion has been hotly debated, factoring heavily into the broader political landscape. Paralleling political division at the societal level, there has been considerable debate among academics regarding the extent to which abortion poses serious mental health risks to women. Over the past

several decades, hundreds of studies have been published indicating statistically significant associations between induced abortion and adverse psychological outcomes of various forms. ¹⁻⁴ However, the authors of the three most recent qualitative literature reviews arrived at the conclusion that abortion does not pose serious risks above those associated with unintended pregnancy carried to term. ⁵⁻⁷ This conclusion is problematic for several reasons, the most salient of which are described briefly below.

First, only a handful of studies have actually included unintended pregnancy carried to term as a control group. Pregnancy intendedness is not well defined in the literature and basic conceptualisation and measurement issues challenge the validity of the intendedness variable as used in the available studies. Specifically, pregnancies that are terminated are sometimes initially intended by one or both partners and pregnancies that are initially unintended may become wanted as the pregnancy progresses, rendering assessment of intendedness subject to considerable change over time. In addition, pregnancy intendedness is typically measured dichotomously (intended/unintended) when true responses may actually fall on a continuum from fully intended and planned for years to entirely unintended, with a great deal of variation likely between these two extremes. At least half of all pregnancies in the USA are classified as unintended and among adolescents and women over 40 years old the percentage is over 75%, 8,9 meaning the majority of women in the control groups

in studies comparing abortion with term pregnancy actually delivered unintended pregnancies even if the variable was not directly assessed.

Second, many recently published studies with extensive controls for third variables were not reflected in the three recent reviews, with no explanation given as to why large segments of the peer-reviewed literature were missing. For instance, in the 2008 review by Charles *et al*, 6 several of the studies that were overlooked actually met the inclusion criteria. Similarly, studies examining substance misuse were not included in two of the three reviews, 6,7 with no rationale for excluding them. Numerous studies have demonstrated statistically significant associations between abortion and subsequent substance misuse, a widely recognised and prevalent mental health problem. 2,10,20-24

Third, in all three literature reviews the choice of studies lacked sufficient methodologically based selection criteria. As a result the sample of studies included was either too broad, resulting in incorporation of results from numerous weaker studies, or too narrow, resulting in unjustified elimination of sound studies. Ironically, the largest review, by the American Psychological Association Task Force, exemplifies both problems as the selection criteria for one type of study (those with a comparison group) were simply publication of empirical data on induced abortion with at least one mental health measure in peerreviewed journals in English on US and non-US samples; however, non-US samples were avoided

entirely for a second type of study (no comparison group) examined in this review without an appropriate rationale, resulting in elimination of dozens of methodologically sophisticated international studies. In the review conducted by Robinson *et al* the authors mention having identified 216 peer-reviewed papers on the topic of abortion and mental health and then note selection of a sample of studies that 'exemplify common errors in research methodology' as well as 'major articles that attempt to correct the flaws'.⁷ No details were offered regarding how studies were chosen to fit into these two categories.

The fourth troubling issue is the fact that quantification of effects was not attempted by any of the three research teams. Given the expansive literature on abortion and mental health, there is no reasonable justification for not quantifying effects. In the only truly systematic review available, published in 2003 by Thorp *et al*, stringent selection criteria were employed and their analysis of the largest and strongest studies available resulted in the conclusion that abortion is associated with an increased risk of depression that may lead to self-harm.⁴ Owing to the broad objective of this review, which addressed physical complications as well, a wide range of mental health effects were not examined.

In this highly politicised area of research it is imperative for researchers to apply scientifically based evaluation standards in a systematic, unbiased manner when synthesising and critiquing research findings. If not, authors open themselves up to accusations

of shifting standards based on conclusions aligned with a particular political viewpoint. Moreover, the results may be dangerously misleading and result in misinformation guiding the practice of abortion. Through a process of systematically combining the quantitative results from numerous studies addressing the same basic question (e.g. 'is there an association between abortion and mental health?") far more reliable results are produced than from particular studies that are limited in size and scope. Moreover, as a methodology wherein studies are weighted based on objective scientific criteria, meta-analysis offers a logical, more objective alternative to qualitative reviews when the area of study is embedded in political controversy. Therefore, in an effort to provide a long overdue, dispassionate analysis of the literature on abortion and mental health, the primary objective of this review was to conduct meta-analyses of associations between induced abortion and adverse mental health outcomes (depression, anxiety, substance use and suicidal behaviour) with sensitivity to the use of distinct control groups employed in the various studies (no abortion, unintended pregnancy delivered, pregnancy delivered). The focus was on studies published between 1995 and 2009 because of the considerable improvement in research designs on the topic of post-abortion mental health in recent years. Contemporary research on abortion and mental health has addressed a number of shortcomings of the earlier work by employing comparison groups with controls for third variables. However, there has also been increased emphasis on incorporating nationally

representative samples, prospective designs, controls for prior psychiatric history and comprehensive assessments of mental health outcome measures which in some cases included actual medical records. A secondary objective of this review was to calculate population-attributable risk (PAR) percentages using pooled odds ratios derived from the meta-analysis subdivided by outcome measures. These statistics reflect the incidence of a disorder in the exposed sample (e.g. women who have undergone abortion) that is directly due to the exposure (the abortion procedure). Both the pooled odds ratios and the PAR percentages vielded herein provide readily interpretable indices of the mental health consequences of abortion and should offer new clarity to the academic debate and to clinicians seeking information to guide effective practice.

Method

Inclusion criteria

Studies identified using the Medline and PsycINFO databases were included in this review if they met the following criteria: a sample size of 100 or more participants; use of a comparison group (no abortion, pregnancy delivered or unintended pregnancy delivered); one or more mental health outcome variables (depression, anxiety, alcohol use, marijuana use or suicidal behaviour); controls for third variables; use of odds ratios to express effects observed to facilitate calculation of readily interpretable pooled odds ratios

and PAR statistics; publication in English in peer-reviewed journals between 1995 and 2009.

Rules for extraction and synthesis of effects

In addition to the above criteria, rules for extracting and synthesising data derived from the studies selected were developed based on the recommendations outlined by Lipsey,²⁵ to avoid overrepresentation of particular samples and statistical dependences among effects, and generally to ensure the most conservative and unbiased assemblage of results from the individual studies exhibiting considerable variability in reporting.

- (a) Relevant studies contributed a maximum of one effect per outcome. When authors reported more than one effect per variable based on separate analyses conducted for distinct demographic groups, or when different diagnoses were reported on within a general class such as anxiety or depression, a composite odds ratio was derived to avoid overweighting in favour of particular studies.
- (b) When studies had more than one comparison group, selection rules were employed to provide more weight to comparisons wherein the control group was most closely matched to the abortion group. Specifically, if 'unintended pregnancy delivered' was used the results relative to this group were selected, and when only 'pregnancy delivered' and 'no abortion' comparison groups were used, the effects pertaining to the 'pregnancy delivered' group were selected.

- (c) In situations wherein separate results were reported based on one *v*. two or more abortions, the results specific to one abortion were selected to enable sampling of a more homogeneous population. There are studies suggesting differential effects based on the number of abortions.^{26,27}
- (d) When particular authors used the same sample and variables in more than one publication, only the most recent publication was selected. When the same data-set was used by different groups, both sets of results were included when distinct samples were defined.

Statistical analysis

Meta-analyses were conducted using Comprehensive Meta-Analysis version 2.0 for Windows (Biostat, www. meta-analysis.com). Random effects meta-analyses were computed based on the sociodemographic heterogeneity of the study samples. 43 The random effects model takes into account two sources of variance (within-study error and variation in the true effects across studies) with the study weights designed to minimise both sources of variance. 43 A pooled odds ratio was computed using the full 36 effects extracted. In addition, two sets of subgroup pooled odds ratios were calculated based on the type of comparison group used and on specific forms of mental health problems. Adjusted odds ratios with controls for third variables were used in all the random effects metaanalyses. Finally, PAR percentages were computed using the pooled odds ratios (OR) derived from the random effects model subdivided by outcome measures. The PAR percentages were calculated using the formula $100 \times (Px(\mathrm{OR}-1))/(1+Px(\mathrm{OR}-1))$, where Px is the estimate of population exposure; Px is calculated as c/(c+d), where c is the number of women in the abortion group who did not experience the mental illness in question and d is the number of women in the 'no abortion' group who were identified as not having the mental illness examined.

Results

After applying the inclusion criteria and rules detailed above, the sample consisted of 22 peer-reviewed studies (15 from the USA and 7 from other countries); 3,20-22,24,26-42 these comprised 36 measures of effect (9 alcohol use/misuse, 5 marijuana, 7 anxiety, 11 depression, 4 suicidal behaviour) and a total of 877 181 participants, of whom 163 831 had experienced an abortion (see online Table DS1).

The first random effects meta-analysis, which included 36 adjusted odds ratios from the 22 studies identified, resulted in a pooled odds ratio of 1.81 (95% CI 1.57-2.09, P<0.0001). The results of this analysis indicated that women who have had an abortion experienced an 81% higher risk of mental health problems of various forms when compared with women who had not had an abortion (Fig. 1). Results of a second random effects meta-analysis, wherein separate effects were produced based on the type of outcome measure, are provided in Fig. 2. All effects

were statistically significant, with the largest pooled odds ratio derived for marijuana use (OR = 3.30, 95% CI 1.64- 7.44, P=0.001), followed by suicide behaviours (OR= 2.55, 95% CI 1.31-496, P=0.006), alcohol use/misuse (OR= 2.10, 95% CI 1.77-2.49, P<0.0001), depression (OR= 1.37, 95% CI 1.22-1.53, P<0.0001) and anxiety (OR =1.34, 95% CI 1.12-1.59, P<0.0001). These results indicate that the level of increased risk associated with abortion varies from 34% to 230% depending on the nature of the outcome.

In the third random effects meta-analysis (Fig. 3) three separate pooled odds ratios were produced based on the type of comparison group employed in the respective studies. When women who had terminated a pregnancy were compared with women who had not done so relative to all mental health problems, the result was statistically significant (OR = 1.59, 95% CI 1.36-1.85, P < 0.0001). When women who terminated a pregnancy were compared with women who carried to term, using the full set of mental health variables, the result was considerably stronger (OR = 2.38, 95% CI 1.62-3.50, P < 0.0001). Finally, when 'unintended pregnancy carried to term' operated as the comparison group, the result was likewise statistically significant and closer to the result relative to the 'no abortion' comparison group (OR = 1.55, 95% CI 1.30-1.83, P < 0.0001). These data indicate that regardless of the type of comparison group used, abortion is associated with an enhanced risk of experiencing mental health problems, with the magnitude of this risk ranging from 55% to 138%.

The last set of analyses involved calculation of PAR percentages based on pooled odds ratio estimates. The overall PAR percentage was nearly 10%, with the range for particular mental health problems extending from 8.3% for anxiety to 26.5% for marijuana use (Table 1). In addition, a pooled odds ratio for the two large-scale studies in which actual suicide was measured yielded a significant result (OR = 4.11, 95% CI 1.82-9.31) and a PAR percentage of 34.9% was derived using this pooled odds ratio.

App. 114

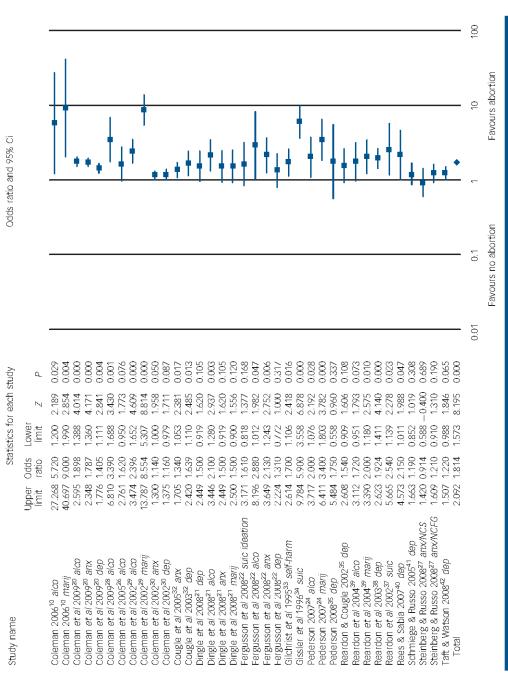


Fig. 1 Abortion and subsequent mental health outcomes. *alco*, alcohol misuse, *anx*, anxiety, dep, depression; *marij*, marijuana use; NCS, National Comorbidity Survey; NCFG, National Survey of Family Growth; *suic*, suicide.

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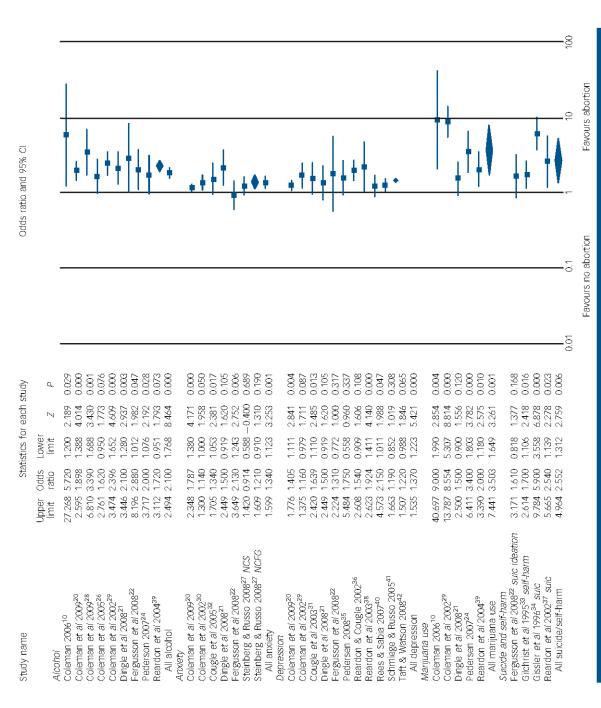
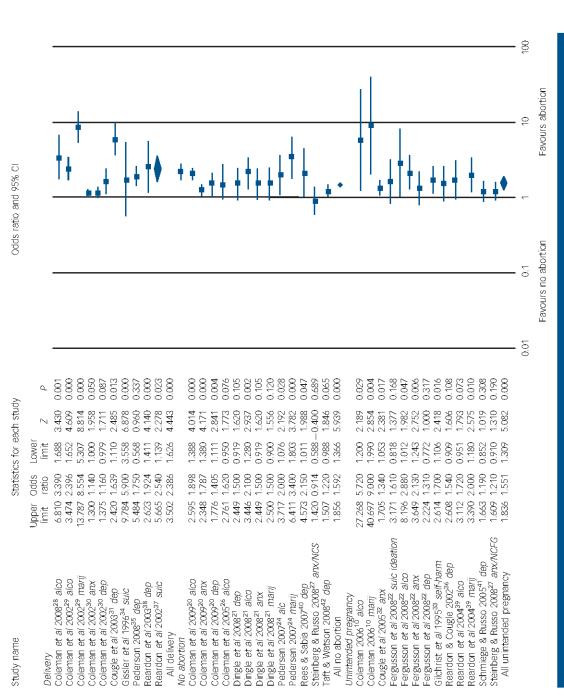


Fig. 2 Abortion and subsequent mental health outcomes, organised by dependent measures. NCS, National Comborbidity Survey, NCFG, National Survey of Family Growth; suic, suicide.



dep, depression; marij, marijuana use; NCS, National Comorbidity Survey; NCFG, National Survey of Family Growth; suic, suicide. Fig. 3 Abortion and subsequent mental health outcomes, organised by comparison group. alco, alcohol misuse; anx, anxiety;

Discussion

Based on data extracted from 22 studies, the results of this meta-analytic review of the abortion and mental health literature indicate quite consistently that abortion is associated with moderate to highly increased risks of psychological problems subsequent to the procedure. The magnitude of effects derived varied based on the comparison group (no abortion, pregnancy delivered, unintended pregnancy delivered) and the type of problem examined (alcohol use/ misuse, marijuana use, anxiety, depression, suicidal behaviours). Overall, the results revealed that women who had undergone an abortion experienced an 81% increased risk of mental health problems, and nearly 10% of the incidence of mental health problems was shown to be directly attributable to abortion. The strongest effects were observed when women who had had an abortion were compared with women who had carried to term and when the outcomes measured

Table 1 Population-attributages based on outcome meas	_
Outcome	PAR %
Anxiety	8.1
Depression	8.5
Alcohol use	10.7
Marijuana use	26.5
All suicidal behaviours	20.9
Suicide	34.9
All	9.9

related to substance use and suicidal behaviour. Great care was taken to assess accurately the risks from the most methodologically sophisticated studies, and the quantitatively based conclusions reflect data gathered on over three-quarters of a million women. Of particular significance is the fact that all effects entered into the analyses were adjusted odds ratios with controls for numerous third variables.

The finding that abortion is associated with significantly higher risks of mental health problems compared with carrying a pregnancy to term is consistent with literature demonstrating protective effects of pregnancy delivered relative to particular mental health outcomes. For example, with regard to suicide, Gissler et al reported the annual suicide rate for women of reproductive age to be 11.3 per 100 000, whereas the rate was only 5.9 per 100 000 in association with birth.³⁴ Several other studies conducted in different countries have revealed even lower rates of suicide following birth when compared with women in the general population. 44-47 More research is needed to examine systematically the specific nature of this protective effect against suicide, to determine the extent to which the protective effect holds for unintended pregnancies delivered, and to examine possible protective effects of childbirth relative to other mental health variables.

When the abortion group was compared with the no pregnancy group and with the unintended pregnancy delivered group, the magnitude of the effects was very close. This finding challenges the generally accepted belief that unintended pregnancy delivered represents the only or most appropriate control group for studies designed to explore the impact of abortion on mental health. Use of a no pregnancy delivered group may be a cleaner control group, since many women experience postpartum depression and/or anxiety following childbirth. From a practical standpoint, a no pregnancy comparison group should be considerably easier to secure than a group of women who deliver an unintended pregnancy.

Future research

Future studies should explore possible process mechanisms linking abortion to substance misuse and suicidal behaviour, since the strongest effects were detected for these variables. For example, substance misuse and suicidal behaviour may result from efforts to block or avoid any psychological pain associated with the procedure and may be construed as faster, easier remedies for personal suffering than seeking professional help. Women could find it particularly difficult to reach out to others if they experience shame or guilt associated with the abortion. Consistent with the contemporary ethos of evidencebased medicine wherein effective use is made of the best available data from systematic research, firm standards should be articulated for accessing and synthesising information from the published literature for the purpose of training healthcare personnel. The results of this systematic, quantitative review cast serious doubt on the conclusions derived from the

recently published traditional reviews described earlier,⁵⁻⁷ and suggest that there are in fact some real risks associated with abortion that should be shared with women as they are counselled prior to an abortion decision.

Healthcare professionals are responsible for educating patients in a manner that reflects the current scientific literature; however, the average practitioner does not generally have the time and expertise to study and attempt to resolve conflicting interpretations of the published research in order to extract the most reliable information. The responsibility therefore rests initially within the research community to set aside personal ideological commitments, objectively examine all high-quality published data, and conduct analyses of the literature that are based on state-of-the-art data analysis procedures, yielding readily interpretable synopses as has been attempted here. Once this goal is satisfactorily realised, professional organisations will face the challenge of developing efficient protocols for informing practitioners and for streamlining the dissemination of information to the public.

The US Preventive Services Task Force (USPSTF) within the Agency for Healthcare Research and Quality, which is a division of the US Department of Health and Human Services (www. ahrq.gov/clinic/3rduspstf/ratings.htm), has identified basic guidelines for how scientific evidence should be used to inform practice. These are summarised below and are

based on an analysis of risks and benefits as established in the scientific literature.

- Level A: Good scientific evidence indicates the benefits of the service substantially outweigh the risks with clinicians advised to discuss the service with eligible patients.
- Level B: Fair scientific evidence indicates the benefits of the service outweigh the risks with clinicians encouraged to discuss the service with eligible patients.
- Level C: At least fair scientific evidence indicating benefits are provided by the service, but the balance between benefits and risks precludes general recommendations. Clinicians are advised to only offer the service if there are special considerations.
- Level D: At least fair scientific evidence indicates the risks of the service outweigh benefits with clinicians advised not to routinely offer the service.
- Level I: Scientific evidence is deficient, poorly done, or conflicting precluding assessment of the risk benefit ratio. Clinicians are advised to convey the uncertainty of evidence surrounding the service to patients.

Putative benefits of abortion

Procedure benefits of abortion have not been empirically established and the results of the substantial review by Thorp *et al* described earlier in conjunction

with the results of the present quantitative synthesis indicate considerable evidence documenting mental health risks.4 Without more research pertaining to possible benefits, the above guidelines are difficult to apply. In one study by Major et al,14 the average response of the study respondents reflecting their positive post-abortion emotional reactions (defined as 'happy', 'pleased' or 'satisfied') was 2.24 on a scale of 1 to 5, with 1 corresponding to 'not at all' and a 5 representing 'a great deal'. The passage of time apparently did not result in more positive emotions, because 2 years after abortion the average rating dropped by a statistically significantly [sic] amount to 2.06. A few additional studies have addressed associations between abortion and educational attainment, income and other outcomes of this nature, which may be construed as indirect indicators of mental health; 48,49 however, mental health benefits have received scant direct attention in the literature.

Concerns regarding the deficient positive effects literature were echoed in an editorial published in the *Psychiatric Bulletin*,⁵⁰ in which Fergusson questioned the legitimacy of justifying over 90% of UK abortions based on the presumption that abortion offers the benefit of reducing mental health risks associated with continuing the pregnancy. Fergusson specifically stated:

Although decisions on whether to proceed with induced abortion are made on the basis of clinical assessments of the extent to which abortion poses a risk to maternal mental health, these clinical

assessments are not currently supported by population-level evidence showing the provision of abortion reduces mental health risks for women having unwanted pregnancy.⁵⁰

Until sound evidence documenting mental health benefits of abortion is available, clinicians should convey the current state of uncertainty related to benefits of abortion in addition to sharing the most accurate information pertaining to statistically validated risks.

Strengths and limitations of this review

Motivated by the shortcomings of previous nonquantitative efforts to synthesise and analyse a complex literature prone to biased interpretations, I have attempted in this study to evaluate systematically a wealth of data on the topic of abortion and mental health. The use of inclusion criteria that resulted in incorporation of the largest and strongest studies published in recent years is an obvious strength. However, the review is clearly not exhaustive as only a 15-year publication window was examined and studies that did not incorporate a comparison group were not analysed. There is a strong need for a quantitative review of literature examining the hundreds of studies that have been conducted on samples of women who obtained abortions without inclusion of a comparison group. As noted previously, the review of literature conducted by the American Psychological Association Task Force confined their examination of this study form to US samples.⁵ Another limitation of my study relates to the lack of uniformity in control variables, demographic characteristics of the samples, length of time between the procedure and the follow-up assessments, and considerable variation in how the outcomes were measured.

It is encouraging to note that methodologically sophisticated studies on the topic of abortion and mental health are being published at a significantly higher rate than ever before. Researchers throughout the world are seeking to understand the experience of induced abortion more fully and are increasingly willing to take on a subject that has been shrouded in political controversy and has not received the scholarly attention it deserves. The latest example is a study based on National Comorbidity Survey - Replication data by Canadian researchers Mota et al.⁵¹ This 2010 study was published after the analyses reported herein were conducted; however, its results are startlingly similar. Statistically significant associations were observed between abortion history and a wide range of mental health problems after controlling for the experience of interpersonal violence and demographic variables. When compared with women without an abortion history, women with a prior abortion experienced a 61% increased risk of mood disorders. Abortion was further linked with a 61% increased risk of social phobia, and increased the risk of suicide ideation by 59%. In the realm of substance misuse, the abortion-related increased risks for alcohol misuse, alcohol dependence, drug misuse, drug

dependence and any substance use disorder were 261%, 142%, 313%, 287% and 280% respectively. Population-attributable risk percentages were likewise similar, ranging from 5.8% to 24.7%. 51

Concluding remarks

This review was undertaken in an effort to produce an unbiased, quantitative analysis of the best available evidence addressing abortion as one risk factor among many others that may increase the likelihood of mental health problems. The composite results reported herein indicate that abortion is a statistically validated risk factor for the development of various psychological disorders. However, when the independent variable cannot be ethically manipulated, as is the case with abortion history, definitive causal conclusions are precluded from both individual studies and from a quantitative synthesis such as this one. Although an answer to the causal question is not readily discerned based on the data available, as more prospective studies with numerous controls are being published, indirect evidence for a causal connection is beginning to emerge.

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Data supplement

Table DSI OV	Semale	Course Companies Aboution True of from	A bention	eta-analyses Tring of som		
Study	location group n	group n		parison group	Dependant variables	Control variables
Coleman 2006 ¹⁰ USA	· USA		65	Unintended pregnancy delivered	Unintended Problems with parents because pregnancy of alcohol use delivered Marijuana use	Risk-taking and desire to leave home
Coleman <i>et al</i> 2009 ²⁰	USA	2583	350	No abortion	with or without an without hierarchy anic disorder, TSD, agoraphobia t panic	22 different demographic, history and personal/ situational variables mostly related to adverse life events
Coleman et al 2009²8	$\overline{ ext{USA}}$	130	112	Pregnancy delivered		11 paternal variables, having considered a prior abortion, marital status and quality of relationship with father
Coleman $et~al$ 2005^{26}	USA	594	426	No abortion	Alcohol use during pregnancy	Number of prior births, miscarriages, stillbirths, age, education, number of people the respondents live with, first trimester sought prenatal care
Coleman $et~al$ 2002^{29}	USA	(a) 531 (b) 738	74	Pregnancy delivered	(a) alcohol use during pregnancy Previous reproductive out.(b) Marijuana use during preg- come, income, marital stationancycy, ethnicity	Previous reproductive outcome, income, marital status, time since previous pregnancy, ethnicity
Coleman et al 2002³º	USA	40 122	14 297	Pregnancy delivered	Out-patient anxiety states Composite of out-patient depressive psychosis single episode, recurrent episode, neurotic depression and depression not elsewhere classified	Pre-pregnancy psychological difficulties, age and months of Medi-Cal eligibility
Cougle <i>et al</i>	USA	1591	293	Pregnancy	General measure of depression	Controlled for prior psycho-

9009 ³¹				المستنابالم		Lowins atoto and otherinity
0001				aciiveica		nogical states, age, comments, marital status, divorce histo-
						ry, education and income
						(stratification by ethnicity,
						current marital status and
					;	nistory of divorce)
Cougle <i>et al</i>	$\overline{ ext{USA}}$	1813	1033	Unintended	Generalized anxiety	Age, ethnicity, pregnancy
2005^{32}				pregnancy delivered		intendedness, prior anxiety
$\overline{\mathrm{Dingle}}$ et al	Australia 943	943	101	No abortion	Alcohol misuse and dependence	Demographic factors at 21,
$2008^{^{21}}$					Marijuana misuse and depend-	age, education level, living
					ence	arrangements, marital status
					Affective disorders Anxiety	and age left home
Fergusson et al	New	52	153	Unintended	Major depression	Controlled for demographic,
$2008^{^{22}}$	Zealand			pregnancy	Anxiety disorder	family of origin, history of
				$\operatorname{delivered}$	Alcohol dependence	abuse, partner, personality,
						mental health history, expo-
						sure to adverse events varia-
						bles and pregnancy
						intendedness
Gilchrist et al	UK	3000	2122	Unintended	Self-harm	Planning of pregnancy, psy-
1995^{33}				pregnancy		chiatric history, age, marital
				delivered		history, smoking habits,
						gravidity and previous abortion
Gissler $et\ al$ 1996 34	Finland	519 139	938 07	Pregnancy delivered	Suicide	Age and marital status
Pedersen 2007^{24} Norway	⁴ Norway	461	92	No abortion	Alcohol problems	Parental education, parental
					Marijuana use	break-up, parental smoking
						habits, perceived parental
						support and monitoring,
						school marks, level of depres-
						sion, conduct problems,
						smoking patterns, alcohol
						intoxication, cannabis use,
						carry mocreoarse aceas, and

						number of sexual partners measured at age 15 years
Pedersen 2008^{35} Norway	35 Norway	440	169	No abortion	General measure of depression	Parental education, parental smoking habits, parental support and prior depression
${\rm Reardon}\ et\ al \\ 2004^{^{39}}$	$_{ m NSA}$	535	213	Unintended pregnancy delivered	Alcohol use Marijuana use	Self-esteem, locus of control, age, income, education, marital status, ethnicity
Reardon & Cougle 2002^{36}	$_{ m NSA}$	128	293	Unintended pregnancy delivered	Symptoms of major depression	Family income, education, ethnicity, age at first pregnancy and locus of control
${\rm Reardon}~et~al\\2003^{^{38}}$	USA	41 442	15 299	Pregnancy delivered	Composite of in-patient depressive psychosis single episode, recurrent episode, neurotic depression, and depression not elsewhere classified	Pre-pregnancy psychological difficulties, age and months of Medi-Cal eligibility
${\rm Reardon}\ et\ al \\ 2002^{^{37}}$	$\overline{ ext{USA}}$	844 20	$318\ 54$	Pregnancy delivered	Suicide deaths	Pre-pregnancy psychological difficulties, age and months of Medi-Cal eligibility
Rees & Sabia 2007 ⁴⁰	$\overline{ ext{USA}}$	1734	66	No abortion	Symptoms of major depression	Ethnicity, age, education, household income, number of children, prior depression
$\begin{array}{c} \text{Schmiege \&} \\ \text{Russo } 2005^{41} \end{array}$	$_{ m USA}$	768	479	Unintended pregnancy delivered	General measure of depression	Ethnicity, age at first pregnancy, marital status, education and family income
Steinberg & Russo 2008^{27}	USA Study 1 (NSFG)	2315	1167	Unintended pregnancy delivered	Experience of anxiety symptoms Ethnicity, age at first pregnancy, number of subsequent births, rape history, marital status, poverty status, eductional level, pregnancy intendedness	Ethnicity, age at first pregnancy, number of subsequent births, rape history, marital status, poverty status, educational level, pregnancy intendedness

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