No. 05-1382

In The Supreme Court of the United States

ALBERTO R. GONZALES,
Attorney General,

Petitioner,

v.

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC., *et al*.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF *AMICI CURIAE* AMERICAN ASSOCIATION OF PRO LIFE OBSTETRICIANS AND GYNECOLOGISTS (AAPLOG), SENATOR TOM COBURN, M.D., CONGRESSMAN MICHAEL BURGESS, M.D., CONGRESSMAN PHIL GINGREY, M.D., CONGRESSMAN DAVE WELDON, M.D., C. EVERETT KOOP, M.D., ScD., EDMUND D. PELLEGRINO, M.D., IN SUPPORT OF PETITIONER

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INTEREST OF *AMICI*[1]

Amicus American Association of Pro Life Obstetricians and Gynecologists (AAPLOG) is a non-profit medical organization currently consisting of over 2,000 obstetrician and gynecologist members and associates. The American College of Obstetricians and Gynecologists (ACOG) recognizes AAPLOG as one of the largest special interest groups within ACOG.[2] AAPLOG affirms that the physician has two patients and is caregiver to both mother and unborn child.

Amici Senator Tom Coburn, M.D., Congressman Michael Burgess, M.D., Congressman Phil Gingrey, M.D., and Congressman Dave Weldon, M.D., are physicians and members of Congress who voted for or support the Partial-Birth Abortion Ban Act of 2003.[3]

Amicus C. Everett Koop, M.D., ScD., the former Surgeon General of the United States (1981-1989), is Senior Scholar of the C. Everett Koop Institute and the Elizabeth DeCamp McInerny Professor of Surgery at Dartmouth Medical School. *Amicus* Edmund D. Pellegrino, M.D., is Professor Emeritus of Medicine and Medical Ethics and Adjunct Professor of Philosophy at Georgetown

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[1] This brief is filed with the written consent of the parties. Letters of consent have been filed with the Clerk of this Court. No counsel for a party authored this brief in whole or in part. No entities other than the *Amici* or their counsel have made a monetary contribution to the preparation or submission of this Brief.

[2] Elizabeth Shadigian, M.D., the current President of AAPLOG, Watson Bowes, M.D., Curtis Cook, M.D., and Leroy Sprang, M.D., are or have been members of AAPLOG and testified for the Petitioner in this case.

[3] Pub. L. No. 108-105, 117 Stat. 1201, 18 U.S.C. § 1531 (2006).

University. He has served as Director of the Center for Clinical Bioethics at Georgetown University, head of the Kennedy Institute of Ethics, and Director of the Center for the Advanced Study of Ethics at Georgetown.

SUMMARY OF ARGUMENT

This brief critically examines the medical testimony presented to the Northern District of California in *Planned Parenthood v. Ashcroft*, 320 F.Supp.2d 957 (N.D. Cal. 2004), and referenced by the Ninth Circuit in *Planned Parenthood v. Gonzales*, 435 F.3d 1163 (9th Cir. 2006). As demonstrated below, the evidence presented to the district court revealed that D&X is not the "safest medical option" and that D&X is never "medically necessary"[4] for maternal medical conditions or fetal anomalies. Hence, there is no reliable evidence that a prohibition on D&X will increase medical risk to any woman. Accordingly, the Partial-Birth Abortion Ban Act's prohibition of D&X creates no "substantial obstacle" and thus no undue burden under *Planned Parenthood v. Casey*, 505 U.S. 833 (1992).[5]

[4] *See infra* n.42 for a discussion of the phrase "medically necessary."

[5] The record in these cases demonstrates that D&X has been adopted because of the intuition of certain practitioners, without any support from evidence-based medicine. The judgment that medical procedures supported by evidence-based medicine are superior to innovations unsupported by empirical evidence is one traditionally left to the people through the legislative process.

ARGUMENT

As in both the Second and Eighth Circuits,[6] there was strong medical testimony in the Ninth Circuit supporting the Partial-Birth Abortion Ban Act of 2003. Yet despite the strong evidence indicating that D&X[7] is never "medically necessary," the Ninth Circuit Court of Appeals erroneously concluded the following in an opinion written by Judge Reinhardt:

> [A]s the district court found, [D&X] is *in fact the safest medical option* for some women in some circumstances. For example, *women with specific health conditions* and women who are carrying *fetuses with certain abnormalities* benefit particularly from the availability of the [D&X] procedure.

Planned Parenthood v. Gonzales, 435 F.3d at 1168 (emphasis added). In making this conclusion, the Ninth Circuit completely ignored the following evidence, which demonstrates that D&X is not the "safest medical option" and that it is not "medically necessary" for any woman, and

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[6] *See generally* American Association of Pro Life Obstetricians and Gynecologists (AAPLOG), et al., Brief of *Amici Curiae* in Support of Petitioner, *Gonzales v. Carhart*, No. 05-380 (2006) (examining the evidence presented in the Second and Eighth Circuits); *Nat'l Abortion Fed'n v. Gonzales*, 437 F.3d 278 (2nd Cir. 2006); *Carhart v. Gonzales*, 413 F.3d 791 (8th Cir. 2005); *Nat'l Abortion Fed'n v. Ashcroft*, 330 F.Supp.2d 436 (S.D.N.Y. 2004); *Carhart v. Ashcroft*, 331 F.Supp.2d 805 (D. Neb. 2004).

[7] For ease of reference *Amici* refer to partial-birth abortion as D&X, as used by this Court in *Stenberg v. Carhart*, 530 U.S. 914 (2000). D&E refers solely to the dismemberment method.

particularly not for women with certain medical conditions or carrying fetuses with certain anomalies.[8]

I. THE EVIDENCE PRESENTED IN THE LOWER COURT REVEALED THAT D&X IS NOT "THE SAFEST MEDICAL OPTION"

The Ninth Circuit's conclusion that D&X is "*in fact* the safest medical option" is an even stronger conclusion than that of the American College of Obstetricians and Gynecologists (ACOG). *Id*. at 1168. Even in ACOG's problematic[9] *Statement of Policy* on D&X, the organization merely states that D&X "*may be* the best or most appropriate procedure in a particular circumstance."[10] Yet the Circuit made its conclusion in spite of the fact that no empirical data supports its determination. In addition, the Circuit erroneously disregarded reliable evidence concerning the risks of D&X and the fact that adequate medical alternatives exist.

A. No empirical data supports the Ninth Circuit's conclusion that D&X is safer than any other abortion method.

At the time they testified, Respondents' witnesses admitted that there were no published, randomized, peer-reviewed studies, prospective or retrospective, analyzing

[8] The transcript from the district court in San Francisco is referenced as SF TR [page].

[9] *See* AAPLOG Brief, *supra*, at 16 (examining various problems with ACOG's *Statement*).

[10] American College of Obstetricians and Gynecologists, *ACOG Statement of Policy: As Issued by the ACOG Executive Board* 1061 (Reaffirmed 2004) (emphasis added).

or comparing the safety of D&X to other methods of abortion, including D&E. SF TR 88-89, 101-02, 252, 438, 443, 593-94, 611-13 (Paul, Sheehan, Doe, Broekhuizen). In the absence of such studies, the Circuit could not have made its conclusion that D&X is safer than any other abortion method.[11] Indeed, as Dr. Elizabeth Shadigian testified, because D&X had never been studied in a systematic way, there was *no sound basis* to say it is safer than other methods.[12] *Id*. at 1221, 1232 (Shadigian).

While the district court did hear testimony about a forthcoming peer-reviewed article by Dr. Stephen Chasen comparing D&E and D&X,[13] that study's results do not support the Circuit's conclusion, and the study was severely flawed. As Dr. Chasen himself testified, there "was no significant difference in the complication rate between those women undergoing [D&X] compared to those women undergoing D&E with disarticulation." *Id*. at 1745 (Chasen). From the data, Dr. Chasen concluded that both D&E

[11] Witnesses from both parties repeatedly testified that randomized studies on D&X are feasible and reliable safety data could be obtained. *See* SF TR 778-79, 922-31, 939-40, 961, 1239-41, 1457 (Creinin, Bowes, Shadigian, Cook).

[12] Dr. Shadigian did a systematic review of all medical literature published nationally and internationally on D&X, and she found that D&X is completely unstudied. *Id*. at 1221, 1229-30, 1244-45, 1297-98 (Shadigian). *See also id*. at 905-06, 987 (Bowes, testifying that there are no published, peer-reviewed prospective or retrospective studies or other valid scientific evidence comparing the safety of D&X and D&E); *id*. at 1093-94, 1125 (Sprang, testifying that he is not aware of any published data regarding the safety or risks of D&X or randomized trials comparing D&E and induction using misopristol).

[13] The study compared 263 D&E procedures with 120 D&X procedures. ST Chasen et al., *Dilation and evacuation at > or = 20 weeks: Comparison of operative techniques*, 190 AM. J. OB. GYN. 1180 (2004).

and D&X are safe procedures; he did not conclude that one method is safer than the other. *Id*. at 1751-52 (Chasen); *id*. at 808, 855-56 (Westhoff, relating that the complication rates in the Chasen study were the same for both D&E and D&X); *id*. at 911 (Bowes, explaining that the complication rates for both D&E and D&X were similar). There were simply no statistically significant differences between the two procedures. *Id*. at 1807 (Chasen).[14]

For example, there was no difference in the median blood loss between the two groups. *Id*. at 855-56, 862-63, 915, 1102-03, 1749, 1807 (Westhoff, Bowes, Sprang, Chasen).[15] There was also no difference in the median operative times. *Id*. at 855, 862-63, 913, 1749, 1807 (Westhoff, Bowes, Chasen).[16] As far as lacerations were concerned, there were 4 genital tract lacerations in each group, and those lacerations comprised 3.3 percent of the D&X procedures, but only 1.5 percent of the D&E procedures. *Id*. at 1103-04 (Sprang). While Dr. Chasen claims that the study revealed no difference in the obstetric outcomes of subsequent pregnancies between the two groups, witnesses from both parties claimed that the study revealed that D&X produced a higher rate of subsequent preterm births than did D&E. *Id*. at 863, 1106-07, 1139-40, 1749-50 (Westhoff, Sprang, Chasen).[17]

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[14] Out of 383 total patients, only 19 had complications resulting from either D&X or D&E procedures. SF TR 1807 (Chasen).

[15] Dr. Chasen admitted that the blood loss between the groups was identical. *Id*. at 1807 (Chasen).

[16] Dr. Chasen admitted that the median operating times were identical. *Id*. at 1749 (Chasen).

[17] A follow-up study by Chasen et al., examining obstetric outcomes after D&E or D&X at greater than or equal to 20 weeks gestation, was

(Continued on following page)

The only three serious complications that occurred took place in the D&E group, but Dr. Chasen admitted that those complications could not have been avoided with D&X. *Id*. at 1808-09 (Chasen). Indeed, Dr. Chasen "readily acknowledge[d]" that, because he performs D&X when possible, the fact that a D&E was performed in those situations indicates that it was not even possible to perform D&X. *Id*. When the one and only study comparing D&X and D&E reveals that, *at the very least*, there is no statistical difference in the safety of D&X and D&E, the Ninth Circuit erred in concluding that D&X is safer than other abortion methods.

Moreover, Dr. Chasen's study was so severely flawed that it is unreliable. First, there was an inadequate number of subjects in the study. In fact, there were so few patients that no conclusions could be reached with any statistical validity.[18] Dr. Chasen admitted that because the number of complications between the D&X and D&E groups was virtually identical, the study did not have sufficient power. *Id*. at 1812 (Chasen); *see also id*. at 1105 (Sprang, stating that a study would require thousands of

published in 2005, after the lower court's record was closed. *See* ST Chasen et al., *Obstetric outcomes after surgical abortion at > or = 20 weeks' gestation*, 193 AM. J. OB. GYN. 1161 (2005). The study used the previous dataset but somehow found twice as many prenatal patients. No valid safety or preterm birth conclusions can be drawn from this study, because the D&X data were excluded when D&X was performed in the presence of premature preterm ruptured membranes and/or advanced cervical dilation.

[18] Dr. Sprang testified that the study acknowledged its lack of power and that most of the information was not statistically significant, which was "unusual for a study." SF TR 1101-02 (Sprang). Dr. Bowes also testified to the insufficient number of patients in the study. *Id*. at 916, 969 (Bowes).

patients to determine any statistical differences). Additionally, the number of patients in each group was drastically different: almost a two to one ratio of D&E patients to D&X patients. *Id*. at 857 (Westhoff).

Furthermore, there was a substantial difference between the gestational ages between the two groups. *Id*. at 916-17 (Bowes). The median gestational age in the D&E group was 21 weeks, while the median gestational age in the D&X group was 23 weeks. Respondents' witness Dr. Westhoff termed this a "clinically important difference." *Id*. at 808-09 (Westhoff).

Perhaps the most glaring flaw in Dr. Chasen's study was the inadequate follow-up on patients. Because Dr. Chasen did not follow up with patients who returned to other obstetricians, he was not able to assess the subsequent outcomes for 321 of the 383 patients in the study. *Id*. at 1812 (Chasen).[19]

Finally, the Chasen study was not a randomized, prospective study, but was a retrospective review. *See id*. at 851-52 (Westhoff, stating that a randomized study is preferred over a retrospective study). This lack of randomization reduces the reliability of its results. *Id*.[20] Dr. Chasen admitted that because of the study's retrospective

[19] *See also id.* at 810 (Westhoff); *id*. at 919 (Bowes, stating that the study admitted that not all patients came back to their facility for care and that they only used their own medical records).

[20] In a randomized study, patients are assigned a form of treatment at random. When a study is not randomized, each patient receives treatment based upon the physician's judgment. This leads to selection bias. *See, e.g*., *id*. at 851 (Westhoff). *See also id*. at 920 (Bowes, stating that the study cannot be reproduced); *id*. at 1101 (Sprang, citing concerns regarding the inclusion criteria).

nature, it does not support a statement that one technique is safer than or superior to another. *Id*. at 1810 (Chasen).[21]

Because there are no studies supporting their claims, the Respondents are left with intuitive, anecdotal "evidence."[22] For example, Respondents claim that D&X is safer because it involves fewer instrument passes. Yet Respondents' witnesses admitted that such claims are unsupported in medical literature and based entirely on intuition.[23] Not only is intuition unreliable, but so are Respondents claims that D&X requires more passes than D&E. One of Respondents' witnesses admitted that the number of passes used is not indicated on medical charts. *Id*. at 762-65 (Creinin). Others admitted that the use of ultrasound technology reduces the number of passes and the risk of injury from instrument passes, and one testified that with ultrasound guidance, her personal experience in injuring a patient with an instrument is less than

[21] *See also id*. at 252-53 (Sheehan, stating it is difficult to do a retrospective study because statistics are not kept adequately, and that prospective studies are more authoritative).

[22] In the past, physicians have claimed that other procedures are safe and effective based upon their intuition alone, only to be proven wrong at a later date. For example, physicians once believed that electric fetal heart rate monitoring and episiotomies were safe based upon intuition. Studies later revealed physicians' intuition dangerously wrong. *Id*. at 103-05, 109, 439-40, 897, 972-73 (Paul, Doe, Bowes).

[23] *See id*. at 438 (Doe, stating that there have been no peer-reviewed studies evaluating whether multiple instrument passes pose greater risks and admitting that it is an intuitive assessment); *id*. at 593-94 (Broekhuizen, stating that he knows of no peer-reviewed studies, randomized clinical trials, or retrospective trials evaluating whether D&X reduces the risk of injury because of fewer instrument passes and admitting that the belief is based on intuition); *id*. at 682 (Creinin, stating he "feels" D&X is safer with fewer passes).

0.1 percent. *Id*. at 236, 577 (Sheehan, Broekhuizen).[24] The fact of the matter is that regardless of whether a physician uses D&E or D&X, there will always be multiple instrument passes.[25] *Id*. at 763, 777 (Creinin). An alleged number of passes is simply not a sound basis to conclude that D&X is safer than any other abortion method. *Id*. at 1330-31 (Shadigian).

Another claim based on intuition is that D&X is safer because there are fewer bony fragments involved, but there are no published studies specifically analyzing injury to patients from fetal fragments. *Id*. at 224 (Sheehan). And, once again, the use of ultrasound reduces the risk of leaving fetal parts. *Id*. at 236 (Sheehan). Respondents' witness Dr. Broekhuizen testified that a physician should be able to avoid leaving fetal parts by doing a careful procedure and inspection. *Id*. at 573-74 (Broekhuizen). In fact, one of Respondents' witnesses conceded that it is sometimes the safest procedure to remove the fetus in pieces in order to minimize the cervical opening. *Id*. at 740 (Creinin). Additional methods of ensuring the removal of all fetal parts include reconstructing the fetus outside of the mother, using a curette, and feeling inside the uterus for any remaining parts. *Id*. at 1063 (Sprang).[26] As such, Respondents' claim of retained fetal parts or

[24] *See also id*. at 1127-28 (Sprang, testifying that when ultrasound is used, focusing on the number of passes is too simplistic and that using instruments is safe when a physician can see what he is doing).

[25] Respondents' witness Dr. Westhoff claimed that she can sometimes remove fetal parts with her fingers. *Id*. at 815 (Westhoff). This claim further demonstrates that D&E does not necessarily require more instrument passes than D&X.

[26] "By feel, by ultrasound, and then reconstructing you can know that you have all the material." *Id*. at 1063 (Sprang).

boney fragments is not a sound basis to conclude that D&X is safer than other abortion methods. *Id*. at 1330-31 (Shadigian).[27]

The Ninth Circuit's reliance on Respondents' intuition arguments is unsound. As Dr. Paul, one of Respondents' witnesses, testified, intuition is not a valid research method in the field of epidemiology. *Id*. at 96 (Paul).[28] Another of Respondents' witnesses, Dr. Westhoff, stated that intuition is not a valid analytical method. *Id*. at 846 (Westhoff). Respondents' witness Dr. Drey stated that the "gold standard" for studies is a blind, randomized trial. *Id*. at 347 (Drey). Neither Dr. Chasen's study nor the Respondents' intuitive arguments fulfill this gold standard. In the absence of valid epidemiological studies, the Respondents' arguments and the Circuit's conclusion are merely anecdotal and, as such, unreliable. *Id*. at 1298-99 (Shadigian).[29]

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[27] Respondents' other intuitive claims are that D&X involves a shorter procedure time and less blood loss, but even the flawed Chasen study reveals that these claims are fallacious. Furthermore, blood loss is never measured by physicians performing abortions, and thus any claims that D&X involves less blood loss cannot be substantiated. *Id*. at 237-38 (Sheehan). In fact, Dr. Sheehan testified that a comparison of blood loss cannot be performed. *Id*. at 238 (Sheehan). Respondents' claims in this regard are just "assertions" and are "not based on any kind of study." *Id*. at 1331 (Shadigian).

[28] Dr. Paul also testified that a randomized control trial is the best form of study, and peer review ensures that the research methodology used is appropriate. *Id*. at 97-98 (Paul).

[29] Dr. Bowes ranked different studies according to reliability, and case reports, such as those of Doctors Haskell and McMahon, fell on the "lowest rung of the ladder." *Id*. at 891 (Bowes). The "ultimate in evidence-based medicine" is the randomized control trial, which eliminates much of the bias involved in retrospective studies. *Id*. at 892-93 (Bowes). No randomized control trials have been performed examining the effects of D&X or comparing it to other methods of

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B. The Ninth Circuit disregarded reliable testimony about the short-term and long-term risks of D&X.

While giving undue weight to the anecdotal evidence and opinions of the Respondents' witnesses, the Court disregarded reliable testimony about the inherent risks and complications of D&X. Yet D&X presents serious safety risks to the mother. *Id*. at 1079 (Sprang); *id*. at 1497 (Cook, stating his immediate concerns are bleeding, infection, uterine perforation, and triple lacerations).

One substantial short term risk is perforation of the uterus. Respondents' witness Dr. Broekhuizen testified that when the fetus's head is lodged in the cervix, puncturing it with a sharp instrument could accidentally perforate the uterus, causing significant bleeding. *Id*. at 631-33 (Broekhuizen). *See also id*. at 1079, 1090-91 (Sprang, testifying that there is a risk of trauma from using a sharp instrument, as D&X is a fairly blind procedure and the scissors can go to the right or left of the fetus's skull). There is potential to puncture the uterine artery, because the physician is forcibly pushing scissors through the skull within close proximity to the artery. *Id*. at 1090-91 (Sprang); *id*. at 1412-13 (Cook, testifying that exposing the cervix to the boney skull increases the risk of bleeding and lacerations). In fact, Dr. Sprang testified that piercing the uterine artery could be "easy." *Id*. at 1091 (Sprang).

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abortion. Without such an unbiased study, the Circuit's conclusion that D&X is safer than other methods of abortion is not based on the trial testimony from either side, but is yet another unreliable "intuitive" judgment.

Performing an internal podalic version,[30] or maneuvering the fetus within the mother, can also cause trauma to the patient's uterus and is the most common cause of traumatic uterine rupture. *Id*. at 1079, 1086 (Sprang). Internal podalic version can also cause internal hemorrhage. *Id*. at 1087 (Sprang). In addition, when the placenta is disrupted, some of that material can get into the maternal circulation and cause amniotic fluid embolism in the mother. *Id*. at 1086 (Sprang).

Another short term risk is the harm caused by serial dilation.[31] Respondents' witness Dr. Creinin admitted that D&E is actually safer to perform than D&X because D&X involves more dilators, causing more pain and potential injury to the cervix. *Id*. at 744 (Creinin). In addition to pain, the use of laminaria to dilate the cervix increases the risk of infection and bleeding. *Id*. at 1079 (Sprang). When laminaria are inserted, there is trauma to the woman's tissue, which enhances bacterial growth. *Id*. at 1083-84 (Sprang). Very large numbers[32] of bacteria are present in the vagina, and that bacteria works its way up the laminaria from the vagina to the internal os, next to the amniotic sac. *Id*.; *see also id*. at 1412, 1423, 1450 (Cook, testifying that the excessive cervical manipulation and

[30] ACOG's definition of D&X includes "instrumental conversion of the fetus to a footling breech." *ACOG Statement of Policy*, *supra*, at 1060.

[31] ACOG's definition of D&X includes "deliberate dilation of the cervix, usually over *a sequence of days*." *Id.* (emphasis added).

[32] Dr. Sprang testified that the actual number of bacteria present is 10 to the ninth – or 10 with nine zeros added. SF TR 1085 (Sprang).

dilation increase the risk for bleeding, laceration, and infection).

Dilation for D&X can take days, and the longer the amount of time the laminaria are inserted, the greater the risk of bringing bacteria from the vagina to the cervix. *Id*. at 1084 (Sprang). Furthermore, the sticks of laminaria can break the amniotic sac, which significantly increases the risk of infection by bringing bacteria directly into the uterine cavity. *Id*. at 1084. Because laminaria may be inserted on day two, if a physician waits until day three to do the procedure, foreign bodies may sit in the cervix for 24 hours. *Id*. at 1085 (Sprang).[33]

In addition to the risk of perforation, dilation, bleeding, and infection, D&X poses significant long term risks. During D&X, the cervix is dilated more than in any other abortion method. *Id*. at 1386, 1413 (Cook). This massive amount of dilation threatens the integrity of the cervix and can lead to cervical incompetence, which in turn can lead to preterm birth.[34] *Id*. at 1413 (Cook). Despite the

[33] Dilation with laminaria for D&E does not pose the same risks as it does with D&X – D&X uses more laminaria over an extended period of time. *Id*. at 1307 (Shadigian).

[34] Preterm birth occurs when a baby is born before the 37th week of gestation. It is the leading cause of infant morbidity and mortality. *Id*. at 1254-56 (Shadigian). Dr. Cook testified that there is strong data that subsequent preterm birth and low birth weight occur after first trimester abortions, which indicates the risk would be even greater later in gestation. *Id*. at 1487, 1495-96 (Cook); *see also id*. at 1081-82, 1137 (Sprang, testifying that cervical incompetence is more prevalent at and after the midtrimester); *id*. at 1414 (Cook, testifying that an increasing body of evidence demonstrates that women who have first trimester abortions suffer an increased risk of premature deliveries due to cervical incompetence-related issues). The more abortions a woman has, the higher the chance that she will have a preterm birth. *Id*. at 1256 (Shadigian).

flawed follow-up procedures, the Chasen study revealed that the number of preterm births following D&X procedures tripled the number of preterm births following D&E procedures. *Id*. at 1814-15 (Chasen); *id*. at 863 (Westhoff). In fact, Dr. Chasen admitted that D&X is a possible cause of preterm birth. *Id*. at 1815 (Chasen).[35]

C. The Ninth Circuit ignored evidence that well-established alternatives exist.

In erroneously concluding that D&X is the safest method of abortion for some women, the Ninth Circuit ignored evidence that medical induction and D&E have been the subject of many peer-reviewed studies over the past 20 years and are widely considered "safe."[36] Respondents' witnesses testified that either induction or D&E are safe. *Id*. at 103, 194, 430, 580, 718-19, 748-49, 846, 1819 (Paul, Sheehan, Doe, Broekhuizen, Creinin, Westhoff, Chasen). The "prevailing thought" is that there are other, well-established, safer methods than D&X available. *Id*. at 1390 (Cook); *see also id*. at 1227 (Shadigian).[37]

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[35] Respondents' witness Dr. Westhoff testified that the belief that D&X does not lead to cervical incompetence is simply a belief, and a mere belief is not given much weight in epidemiology. *Id*. at 845 (Westhoff). Dr. Creinin testified that cervical incompetence can result from surgical abortion. *Id*. at 751 (Creinin).

[36] While AAPLOG's position is that medical induction and D&E are *safer* than D&X, no abortion is completely "*safe*," as short-term and long-term complications are well documented in the medical literature.

[37] *See also id*. at 1415, 1423 (Cook, stating that the risks of dilation and preterm birth with D&X "go above and beyond other abortion techniques" and that D&X "poses an increased risk for bleeding or infection"). Indeed, with D&X, the cervix is dilated more than in any other method. *Id*. at 1386 (Cook).

No empirical evidence exists that induction or D&E are less safe than D&X. Respondents' witness Dr. Broekhuizen testified that D&E is a safe procedure, and that ultrasound makes D&E safer and easier. *Id*. at 575-78 (Broekhuizen). Dr. Creinin, also testifying for Respondents, admitted that it is sometimes safest to minimize the cervical opening and remove the fetus in pieces with D&E. *Id*. at 740 (Creinin).

Of the available abortion procedures, medical induction is the most physiological, natural process, and it does not necessarily require any instrument passes. *Id*. at 1093, 1127, 1392 (Sprang, Cook). Surgical methods, such as D&X and D&E, are "decidedly nonphysiologic[al] phenomena." *Id*. at 1478 (Cook). In fact, Dr. Cook testified that medical induction is more natural than a shorter D&E process. *Id*. at 1481 (Cook). Not only is induction the least traumatic of the procedures, but it also involves constant monitoring by trained medical professionals in a controlled setting. *Id*. at 1331, 1392, 1400-01, 1476-77 (Shadigian, Cook). Induction is also the best way to treat women with underlying conditions or complicated pregnancies. *Id*. at 1480-81, 1499 (Cook). Dr. Cook testified that it also renders an intact fetus with an intact nervous system for pathological examination. *Id*. at 1358-59, 1392 (Cook).

The district court also heard testimony from both parties that induction is safer than D&E or D&X. Respondents' witness Dr. Broekhuizen testified that induction has less risk of injury from instrumentation and trauma to the uterus than D&E, and Dr. Sprang testified that induction

is safer for the cervix than either D&E or D&X.[38] *Id*. at 579, 1136 (Broekhuizen, Sprang).[39]

In fact, at 20 weeks gestation and later, medical data demonstrates that induction is safer than D&E. *Id*. at 578-79, 1122-23, 1202, 1225, 1229, 1303, 1499-1500, 1516 (Broekhuizen, Sprang, Shadigian, Cook). Thus, even when D&X is included in D&E data and the D&E data is used, induction is safer than D&X after 20 weeks. *Id*. at 1263, 1303 (Shadigian). Even without the use of misopristol during inductions, studies reveal that induction is the safer procedure at 21 weeks gestation and later. *Id*. at 1269-70 (Shadigian). The use of misopristol renders even better safety data. *Id*. at 1226 (Shadigian). There is simply no sound basis to claim that D&X is safer than induction. *Id*. at 1302 (Shadigian).

To the contrary, abundant testimony in the record confirms that D&X is never "medically necessary" because there are safer, readily available, and well-established alternatives.[40]

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[38] Dilation during induction is different than dilation during D&E (or D&X), as dilation during D&E requires the use of dilators, which is not physiological. *Id*. at 1259 (Shadigian). Induction causes the woman's uterus to contract, which slowly dilates the cervix in a physiological manner. *Id*. at 1259-60 (Shadigian).

[39] Dr. Broekhuizen also testified that if an infection were to arise during an induction, the patient could be treated with an antibiotic immediately and given adequate pain relief. *Id*. at 580 (Broekhuizen).

[40] *Id*. at 1453 (Cook, testifying that D&X is not necessary because there are other procedures readily available); *id*. at 1454 (Cook, stating that D&X is not necessary because there are preexisting, well-established options readily available that have been demonstrated to be safe); *id*. at 1509-10 (Cook, testifying that if a woman is unstable and the fetal head is not yet delivered, options include hand manipulation, forceps, or Duhrssen's incision); *id*. at 1779-80 (Chasen, stating that if

(Continued on following page)

II. THE EVIDENCE PRESENTED IN THE LOWER COURT REVEALED THAT D&X IS NEVER "MEDICALLY NECESSARY" FOR MATERNAL MEDICAL CONDITIONS OR FETAL ANOMALIES

A. The record demonstrates that D&X is never "medically necessary" for maternal medical conditions.

The claim that D&X is "medically necessary" is entirely theoretical.[41] Witnesses from neither side identified or recalled real-life conditions, in their own practice or otherwise, where D&X was necessary for maternal medical conditions.[42] For example, Dr. Shadigian stated that she has never had to use D&X to treat "even sick women with medical conditions," and she has never seen any of

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the calvarium is trapped, there are multiple options). *See also id*. at 1822 (Chasen, affirming that D&X "is never the only available procedure to terminate a second-trimester pregnancy"); *id*. at 1412, 1455 (Cook, stating that "there are safer and readily available alternatives [to D&X] to emptying a uterus . . . this procedure [D&X] doesn't offer anything new to what we have available").

[41] The lower courts erred by applying a vague and subjective standard ("medically necessary to preserve women's health"). The terms "medically necessary" and "health" have become terms of art with broad definitions unique to abortion law. A "medically necessary" abortion is whatever an abortion provider, in his or her subjective judgment, determines it to be. "Health risk," in abortion law, has come to mean the potential for exposure to the chance of a loss of "well-being" under *Doe v. Bolton*, 410 U.S. 179 (1973). *See* AAPLOG Brief, *supra*, at 3-6. Because this standard contradicts *Casey*, this Court should reject it and ask more precisely ***whether there is substantial, reliable evidence that the D&X procedure is necessary to successfully treat any maternal or fetal condition or is significantly safer than existing procedures. Herein, the phrase "medically necessary" refers to such a standard.*** *See id*.

[42] *See*, *e.g.*, SF TR 1108-09, 1226, 1292, 1390, 1394, 1411, 1415-16, 1419, 1431, 1453, 1524 (Sprang, Shadigian, Cook). The testimony of Respondents' witnesses is void of any examples.

her colleagues use it "to take care of even the sickest women." *Id*. at 1220 (Shadigian). Dr. Sprang asserted that he has "never seen a situation where an intact D&X method was necessary. . . ." *Id*. at 1111 (Sprang).

Respondents' witness Dr. Creinin admitted that the only medical condition he could imagine was "a theoretical example" – and in practice, he himself used hysterotomy for that situation. *Id*. at 686-89, 769-70 (Creinin). Similarly, Dr. Broekhuizen indicated only one situation where D&X might be used, but in his practice he used induction in that situation. *Id*. at 591-97 (Broekhuizen).

In addition, there are no valid medical studies supporting the claim that D&X is ever "medically necessary" for maternal medical conditions. Neither the AMA Task Force nor the ACOG select panel could "find any medical conditions" or "come up with any situations that would require an intact D&X." *Id*. at 1110 (Sprang).

Thus, contrary to the Ninth Circuit's conclusions, D&X is not "medically necessary" for any of the following conditions:

Blood Loss

D&X is not "medically necessary" for women who suffer from bleeding-related disorders. Instead, induction under the controlled and monitored setting of a hospital is preferred because of the double safety net it provides: first, it is the more natural, physiological procedure, and second, when done in a hospital setting, sophisticated monitoring and highly-trained specialists are available to treat the mother. *Id*. at 1473-81 (Cook). This double safety feature makes induction under a hospital setting "the safest way

to deliver patients with underlying medical complications." *Id*. at 1480-81 (Cook).

When a woman is diagnosed with preeclampsia or HELLP syndrome, D&X is never necessary because there are "safer techniques available." *Id*. at 1420 (Cook). A physician must "avoid[ ] operative procedures, if at all possible." *Id*. at 1392, 1420-21 (Cook).[43] Induction would be the "most appropriate procedure,"[44] as it avoids risk of perforation, uterine trauma, cervical laceration, and potentially uncontrolled bleeding.[45] Safety data demonstrate that in cases of preeclampsia, induction is healthier and faster than D&X or D&E. *Id*. at 1265 (Shadigian). In addition, D&X is not necessary in cases of preeclampsia because, according to Respondents' witness Dr. Chasen, the pregnancy doesn't need to end in minutes or hours, but in a day or two. *Id*. at 1764 (Chasen).

For women with anemia, low platelet counts, or on blood-thinning medication, D&X "poses an increased risk for bleeding or infection because of the amount of dilation in the intrauterine manipulation." *Id*. at 1423 (Cook). Again, the patient should deliver "in as natural and controlled and as monitored a situation as possible," which

[43] *See also id*. at 1392 (Cook, testifying that physicians should utilize the most natural process and controlled setting as possible).

[44] *Id*. at 1391 (Cook); *see also id*. at 1223, 1265 (Shadigian, stating that she generally uses induction, or if a fetus is viable, cesarean section); *id*. at 1421 (Cook, testifying that induction is safest and most natural).

[45] *Id*. at 1391, 1466 (Cook).

would mean "induction in a hospital" under "close monitoring of her fluid status. . . ." *Id*. at 1400, 1423 (Cook).[46]

In the case of inherent renal conditions, such as glomerulonephritis, and secondary renal conditions, such as diabetes, D&X is never necessary. *Id*. at 1421-22 (Cook). Induction is always preferred so as not to put the mother "at risk of perforation." *Id*. at 1466 (Cook).

D&X is also not "medically necessary" for women with cardiac or pulmonary diseases such as peripartum cardiomyopathy, Eisenmenger's syndrome or left-to-right shunting disorder, marfan syndrome, severe aortic stenosis, dilated aortic route, and pulmonary hypertension. *Id*. at 1424-27 (Cook). Induction under intense monitoring and critical care support in a supervised hospital setting is always the first option and is preferred as the safer, more superior, least invasive, and most natural physiologic process. *Id*. at 1400, 1427-28, 1467-69, 1471 (Cook).

Placenta Previa

D&X is never "medically necessary" for women with placenta previa.[47] Placenta previa is a contraindication of vaginal delivery, by surgery or by induction, and in some circumstances it is "a contraindication to even doing a vaginal exam." *Id*. at 1429-30 (Cook). Vaginal delivery by surgery or induction in this case would place the mother at significant risk of severe bleeding complications. *Id*. at 1429 (Cook). Respondents' witness Dr. Chasen admitted

[46] *See also id*. at 1423 (Cook, recommending medical induction for women with anemia and low platelets).

[47] Placenta previa is not in itself an indication for termination of pregnancy. *Id*. at 1428 (Cook).

that in the case of placenta previa, "my choice . . . would be hysterotomy." *Id*. at 1768 (Chasen).[48]

Uterine Infection

D&X is never medically necessary for women with uterine infection such as sepsis. *Id*. at 1429 (Cook). Dr. Shadigian and Dr. Cook emphasized that surgery must be avoided when uterine infection develops in order to prevent exposing other areas of the mother's body to infection. *Id*. at 1267, 1430 (Shadigian, Cook). Indeed, surgical termination or any other procedure that would increase the risk for uterine trauma would be contraindicated in the case of uterine infection. *Id*. at 1430 (Cook). Medical induction under careful monitoring, antibiotics, and fluid administration is the procedure utilized because it would limit infection. *Id*. at 1268, 1430 (Shadigian, Cook). Induction may also be more expedient, especially when using misopristol, thereby ensuring that the infection does not continue for longer periods of time. *Id*. at 1268 (Shadigian).

In addition, D&X is never medically necessary for women with chorioamnionitis. In a situation where the mother has chorioamnionitis and is already dilated and presenting with fetal parts, it is the infection itself that causes labor, and the delivery will occur rapidly. *Id*. at 1474-75 (Cook). Under this circumstance, the doctor should do everything to avoid intrauterine manipulations.

[48] *See also id*. at 1439 (Cook, stating that no one he knows would ever "recommend a vaginal procedure, let alone a surgical vaginal procedure in a patient with placenta previa," as D&X would potentially compromise the mother's health and life); *id*. at 1440-41 (Cook, testifying that D&X is "decidedly inappropriate" for a woman with placenta previa).

Id. at 1474 (Cook). Continuation of labor in this situation is recommended as being "the safest, most natural, least risky procedure." *Id*. at 1474-75 (Cook).[49]

Uterine Scarring

D&X is never "medically necessary" for women with uterine scarring from a prior cesarean section or other uterine surgery. *Id*. at 1436 (Cook). Valid medical study revealed that induction using an E2 type of prostaglandin is safe for women with uterine scarring. *Id*. at 1432 (Cook). There was no data showing an increased risk of maternal morbidity. *Id*. at 1432-34 (Cook). Dr. Cook stated that for women with uterine scars, studies found that physicians should proceed with induction using E2 prostaglandins. *Id*. at 1432 (Cook). The risk of rupturing a uterine scar during an induction is negligible with the correct timing of prostaglandin administration and monitoring. *Id*. at 1435 (Cook). In cases where there has been a prior rupture of a uterine scar, a hysterotomy is the established and recommended choice. *Id*. at 1434-36 (Cook).

Emergency Situations

Medical testimony demonstrated that D&X is never "medically necessary" in emergency situations that require immediate uterine evacuation. Dr. Shadigian testified that D&X is never an appropriate procedure in an emergency situation because dilation requires two days, and some sick women may "be near death" and "don't have two or three days." *Id*. at 1227 (Shadigian). Dr. Sprang asserted that when the fetus must be removed as quickly as

[49] *See also id*. at 1224 (Shadigian, testifying that in cases of chorioamnionitis, induction is most often used).

possible, D&X "would never be the only choice and never be the best choice," and "could not be used" because it takes too long. *Id*. at 1112 (Sprang). Dr. Chasen reiterated Dr. Sprang's conclusion, asserting that in a real emergency situation where the woman "needs to be delivered that minute," he would choose to use a hysterotomy, not D&X. *Id*. at 1768 (Chasen). Furthermore, Dr. Cook testified that in emergency situations involving significant bleeding or infection, D&X is unnecessary and inappropriate because it would "worsen or exacerbate that situation" and "because we have other safer and readily available alternatives at our disposal." *Id*. at 1436-37 (Cook).

Furthermore, Respondents' witnesses testified most emphatically that they do not distinguish between D&E and D&X before beginning a procedure, and that when an abortion procedure ultimately results in the performance of a D&X, it occurs unpredictably.[50] Witnesses testified that they "never know,"[51] "can't predict,"[52] and "have no control over"[53] the amount of dilation that will be achieved, and consequently over whether or not a D&X will be performed. Dr. Paul, testifying for the Respondents, stated that, when the abortion procedure is already underway, she decides to attempt a D&X "[i]f . . . I think I can accomplish it." *Id*. at 70 (Paul). *See also id*. at 205 (Sheehan, testifying that she simply sets out to terminate a pregnancy).

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[50] *Id*. at 44-45, 188-89, 205, 458, 521 (Paul, Sheehan, Doe, Broekhuizen).

[51] *Id*. at 436, 462 (Doe).

[52] *Id*. at 71, 89, 402, 407, 420, 458, 511-12, 522, 681 (Paul, Doe, Broekhuizen, Creinin).

[53] *Id*. at 206 (Sheehan).

Respondents' witnesses also testified that factors unrelated to maternal health determine which procedure they will use. These factors include "the availability of a trained provider" and the "training, experience, and skill" of the physician. *Id*. at 43, 944 (Paul, Bowes). Dr. Broekhuizen emphasized that the most important factor is the choice and request of the patient. *Id*. at 536 (Broekhuizen). None of these factors – availability and skill of the physician, opinion, and the personal request of the patient – are in any way related to "medical necessity."

B. The record demonstrates that D&X is never "medically necessary" for fetal abnormalities.

D&X is never "medically necessary" for women carrying fetuses with abnormalities. Not a single witness could identify a fetal anomaly that required D&X.[54] Dr. Broekhuizen could identify only two fetal anomalies where he believed D&X might be indicated, and in the first case, he actually used induction. *Id*. at 539-40, 599-602 (Broekhuizen). The second situation was a case of hydrocephaly, or excess fluid in the skull. However, "in reality," Dr. Broekhuizen performed D&X not out of "medical necessity," but just "to avoid the cesarean section," and he conceded that a cephalocentesis through the uterine wall could have been performed. *Id*. at 605-06 (Broekhuizen).

[54] *Id*. at 1229 (Shadigian, testifying that D&X is never necessary to terminate a pregnancy in which there is a fetal anomaly); *id*. at 1230 (Shadigian, stating she has never seen anything unique about fetal anomalies that would require D&X); *id*. at 1441 (Cook, testifying that no fetal anomalies necessitate D&X); *id*. at 1113 (Sprang, stating that he is not aware of any anomalies requiring D&X).

Dr. Shadigian pointed out that D&X is never necessary for fetal anomalies because, as demonstrated by safety data "from many different sources, from many different institutions, both nationally [and] internationally," there are simply better methods. *Id*. at 1229-30 (Shadigian).

In fact, D&X is never "medically necessary" for cases of hydrocephaly, ascites, or hydrops.[55] Established alternatives include a "shunting procedure to bypass the obstruction," "placement of a reservoir into the ventricular system in order to decompress the system," and cephalocentesis. *Id*. at 1447 (Cook). Dr. Chasen also testified that cephalocentesis could be used in cases of hydrocephaly and hydrops. *Id*. at 1761 (Chasen).[56] *See also id*. at 1444 (Sprang, testifying that medical induction is the general procedure for hydrops).

When an intact fetus is desired for a pathological diagnosis, Dr. Chasen admitted that in most cases induction would offer an intact fetus. *Id*. at 1820 (Chasen). Dr. Cook concurred, stating that induction would result in an "intact fetus and an intact central nervous system." *Id*. at 1392 (Cook). In addition, Dr. Chasen and Dr. Doe recommend induction for neurological fetal anomalies because D&X destroys the contents of the brain, rendering the fetal body utterly useless for autopsy purposes. *Id*. at 432-34, 1820-21 (Doe, Chasen).

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[55] In addition, D&X is never "medically necessary" for molar gestation, triploidy, trisomy, cleft lip, ventricular septal defect, and conjoined twins. *Id*. at 1230-31, 1442-45 (Shadigian, Cook).

[56] *See also id*. at 1113-14 (Sprang, testifying that physicians can inject a needle through the uterine or vaginal wall to drain fluid).

Because D&X is not safer than any other method of abortion, and because there are well-established alternatives to D&X, the Act imposes no "substantial obstacle" and no "significant threat to the life or health of a woman." *Casey*, 505 U.S. at 877, 880. The Act "in no real sense deprives women of the ultimate decision." *Id*. at 875. The Act therefore imposes no undue burden in violation of *Casey*.

CONCLUSION

The judgment of the court below should be reversed.

Respectfully submitted,

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