No. 05-380

In The Supreme Court of the United States

ALBERTO R. GONZALES, Attorney General,

Petitioner,

v.

LEROY CARHART, *et al*.,

Respondents.

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

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

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INTEREST OF *AMICI CURIAE*

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.[1] The American College of Obstetricians and Gynecologists (ACOG) recognizes AAPLOG as one of the largest special interest groups within ACOG, as 2,200 Fellows of ACOG have joined AAPLOG.[2] AAPLOG affirms that the physician has two patients and is caregiver to both mother and unborn child.

Senator Tom Coburn, M.D., Congressman Charles Boustany, Jr., 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.

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. Edmund D. Pellegrino, M.D. is Professor Emeritus of Medicine and Medical Ethics and Adjunct Professor of Philosophy at Georgetown University. He has served as Director of the Center for Clinical Bioethics at

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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 its 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 Government in this case.

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 summarizes the record testimony in the Nebraska, New York, and San Francisco cases challenging the Partial Birth Abortion Ban Act of 2003 and demonstrates that "partial-birth abortion" as defined by the Act (hereinafter D&X) is not necessary for any maternal or fetal condition. There is no reliable evidence that any maternal or fetal medical condition requires the use of D&X or that D&X is safer than existing procedures. In contrast, there is substantial and reliable evidence that there are well-established alternatives to D&X (namely, dilation & evacuation (D&E) and medical induction). Hence, there is no reliable evidence that a prohibition on D&X will increase medical risk to any woman. Accordingly, the 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).

ARGUMENT

I. THE ACT IMPOSES NO UNDUE BURDEN UNDER *PLANNED PARENTHOOD V. CASEY* BECAUSE THERE IS NO SUBSTANTIAL, RELIABLE EVIDENCE THAT THE ACT WILL INCREASE MEDICAL RISKS FOR ANY WOMAN.

The Partial-Birth Abortion Ban Act of 2003, Pub. L. No. 108-105, 117 Stat. 1201, 18 U.S.C.S. §1531 (2006) (hereinafter "the Act") imposes no undue burden under *Planned Parenthood v. Casey*, 505 U.S. 833 (1992), on a woman's ability to choose abortion because the Act will not be a "substantial obstacle to the woman's exercise of the right to choose." *Id.* at 877.[3] Contrary to *Casey*, the lower courts erred by applying a vague and subjective standard ("medically necessary to preserve women's health") in evaluating the evidence.[4] 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/her

[3] The Act contains an express exception "to save the life of a mother whose life is endangered by a physical disorder, physical illness, or physical injury, including a life-endangering physical condition caused by or arising from the pregnancy itself," which is sufficient to cover a true life-threatening medical emergency. 18 U.S.C.S. §1531(a) (2006).

[4] See e.g., *Carhart v. Ashcroft*, 331 F.Supp.2d 805, 1012 (D. Neb. 2004) ("there are times when the banned procedure is medically necessary to preserve the health of a woman"); *Carhart v. Gonzales*, 413 F.3d 791, 795 (8th Cir. 2005) ("necessary, in appropriate medical judgment, for the preservation of the health of the mother"); *National Abortion Federation v. Gonzales*, 437 F.3d 278, 287 (2d Cir. 2006) ("the procedure might sometimes be necessary to avoid risk to a woman's health"); *Planned Parenthood v. Gonzales*, 435 F.3d 1163, 1171, 1172 (9th Cir. 2006) ("necessary, in appropriate medical judgment for the preservation of the life or health of the mother.").

subjective judgment, determines it to be.[5] Any use of the term "health" in abortion law automatically incorporates the definition of "health" in *Doe v. Bolton*, 410 U.S. 179, 192 (1973) ("all factors – physical, emotional, psychological, familial, and the woman's age – relevant to the well-being of the patient. All these factors may relate to health").[6] When these two terms are combined – "medically necessary to preserve the health of the woman" – a "medically necessary" abortion means any abortion a provider agrees to perform for any reason.[7] The subjective

[5] See e.g., *Women's Medical Professional Corp. v. Voinovich*, 130 F.3d 187, 209-10 (6th Cir. 1997) ("importance of giving the physician discretion to decide whether an abortion is necessary"; finding health exception unconstitutionally limited "the physician's discretion to determine whether an abortion is necessary to preserve the woman's health . . . "), *cert. denied*, 523 U.S. 1036 (1998).

[6] See e.g., *American College of Obstetricians & Gynecologists v. Thornburgh*, 737 F.2d 283, 299 (3d Cir. 1984) ("It is clear from the Supreme Court cases that "health" is to be broadly defined," (citing *Doe v. Bolton*)), *aff'd*, 476 U.S. 747 (1986). There is no indication in the record in any of the cases challenging the Act that the doctors who testified understood this unique definition of "health" in abortion law. See Appendix A to this Brief for an Index of the testimony in the three trials.

[7] See e.g., *Colautti v. Franklin*, 439 U.S. 379, 394 (1979) ("The contested provisions in those cases [*United States v. Vuitch* and *Doe v. Bolton*] had been interpreted to allow the physician to make his determination in the light of all attendant circumstances – psychological and emotional as well as physical – that might be relevant to the well-being of the patient. The present statute does not afford broad discretion to the physician."); *Women's Medical Professional Corp v. Taft*, 353 F.3d 436, 462 (6th Cir. 2003) (Tarnow, J., dissenting) ("To determine whether an abortion is medically "necessary," . . . that "medical judgment may be exercised in the light of all factors – physical, *emotional, psychological*, familial, and the woman's age – relevant to the well-being of the patient. *All these factors may relate to health."* [citing *Doe*] . . . "a woman's *mental* health, in addition to her physical health, must be considered in assessing whether an exception to an

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elasticity of the lower courts' standard is compounded by the courts' loose reference to "risk." Risk is simply "exposure to the chance of injury or loss." *Random House Webster's Unabridged Dictionary* 1660 (2d ed. 1998). "Health risk" in abortion law, therefore, means *the potential for exposure to the chance of a loss of "well-being"* under *Doe v. Bolton*. 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*. *Casey*, 505 U.S. at 880.

The extreme subjectivity of the lower courts' standard of review ("medically necessary to preserve women's health") is magnified by the fact that the Respondents' case against the Act is based entirely on intuition and personal observation, not empirical evidence. There was substantial testimony, from witnesses on both sides, that intuition is fallible and inferior to empirical evidence.[8] Intuition and personal observation alone are not "substantial

abortion regulation actually preserves the health of the pregnant woman.") (emphasis in original).

[8] The Nebraska trial transcript will be referenced as NE TR (page number); the New York transcript as NY TR, and the San Francisco transcript as SF TR. See NE TR 1353 (Cook) (intuition not enough); NE TR 475 (Howell) (intuition often fallible); NE TR 1524 (Shadigian) (assertions that D&X is intuitively safe is "just anecdotal evidence they have that they think it's safe"); NY TR 1882 (Lockwood) (contrasted intuition with empirical evidence); NY TR 2389-91 (Clark) (medical decisions based on intuition can often be wrong); NE TR 912-13 (Bowes) (citing examples where intuition was wrong, including episiotomy); NY TR 108 (Nuland); NY TR 1751 (Lockwood) (citing the use of DES, a form of synthetic estrogen, to treat threatened miscarriage).

evidence."[9] The lower courts' total reliance on intuition in the absence of empirical evidence conflicts with objective standards for evidence-based medicine adopted by the American College of Obstetricians and Gynecologists (ACOG) and contained in the U.S. Preventive Services Task Force (USPSTF) standards (Appendix 2 to this Brief).[10] The USPSTF standards rank intuition as "poor" evidence (Level C) of the acceptability of clinical practices and innovations.[11] Consequently, there is no reliable evidence that the Act will deny any woman a safe procedure.[12]

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[9] Under federal law, "substantial evidence" of safety and effectiveness is "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved. . . . " 21 U.S.C.S. §355(d) (2006). "The usual requirement for more than one adequate and well-controlled investigation reflects the need for *independent substantiation* of experimental results." US HHS, FDA, *Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products* 4 (May 1998) (emphasis in original).

[10] Evidence-based medicine has become "increasingly adopted" in "all specialities and areas of medicine." NY TR 1464-65 (Paul); NY TR 107 (Nuland). ACOG has adopted the USPSTF standards (Appendix B). Since 1997, the National Abortion Federation (NAF) purports to adhere to evidence-based medicine in its abortion standards. NY TR Exh. K-4 at 1NAF 019321.

[11] Innovations in medicine should be subjected to rigorous study. First with retrospective study and then with randomized clinical trials. NY TR 1750-51 (Lockwood). Respondents' expert Maureen Paul agreed that ideally, a procedure should be subject to controlled studies. NY TR 1464 ("I would never argue against evidence-based medicine.") Respondents' expert Carolyn Westhoff favored the use of clinical trials with external monitoring as a way to assess medical procedures. NY TR 968.

[12] Safety is inherently a relative term in medicine. *Amici* do not concede that elective abortion is safe. Current collection and analysis of data in the U.S. is inadequate, and the focus on immediate complications ignores long-term complications. See John Thorp, Katherine Hartmann and Elizabeth Shadigian, *Long-Term Physical*

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II. THERE IS NO SUBSTANTIAL, RELIABLE EVIDENCE THAT ANY MATERNAL OR FETAL CONDITION REQUIRES THE USE OF D&X.

A. The record demonstrates that D&X is not necessary for any maternal medical condition.

Several experts on both sides testified that D&X is not necessary for any maternal medical condition, because well-established alternative procedures exist.[13] A maternal-fetal medicine specialist, Dr. Steven Clark, testified that "[u]nder no circumstance would the abolition of this procedure in any way jeopardize the life or health of any mother regardless of what medical condition she may have." *Carhart v. Ashcroft*, 331 F.Supp.2d 805, 931 (D.

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and Psychological Health Consequences of Induced Abortion: Review of the Evidence, 58 Obstetrical & Gynecological Survey 67 (2003) (NE TR Defendants' Exhibit).

[13] See NE TR 897-98, 920 (Bowes) (never seen a situation where D&X is necessary or advantageous); NE TR 1098, 1102, 1162 (Sprang) ("never seen a situation where a D&X would be the safest, the best, or the only procedure to use to protect the health of the mother"); SF TR 1112 (Sprang) ("never seen a situation where an intact D&X method was necessary; AMA "task force . . . could not find any medical conditions that would require an intact D&X"). NE TR 1255, 1299, 1327; NY TR 2532 (Cook) (D&X is never medically necessary); NE TR 1513, 1517, 1572, 1597-98 (Shadigian) (knows of no circumstance where D&X is medically necessary); NY TR 491 (Johnson) (no maternal complication that would require D&X or make it only procedure that could be performed); NY TR 261 (Grunebaum) (D&X "absolutely not" the only method of abortion in any given circumstance); NY TR 1369 (Weiss) (could not think of circumstance where D&X required for maternal health condition); NY TR 1683 (Chasen) (agreeing that his study showed that D&X "is rarely used in cases of a maternal medical problem").

Neb. 2004).[14] Dr. Charles Lockwood, Chairman of the Yale Department of Obstetrics and Gynecology and a maternal-fetal medicine specialist, testified that he could not "envision a circumstance in which the D&X procedure would be required. . . . " NE TR 895, 940. Respondents' witness Dr. Doe could not "identify a specific maternal physical health indication for which an intact D&E [D&X] would be necessary because of that physical health condition," as the district court noted. *Carhart*, 331 F.Supp.2d at 935.

Furthermore, there are no medical studies supporting the claim that D&X is medically necessary. *Carhart*, 331 F.Supp.2d at 894, 931 (Clark). After doing a systematic review of the medical literature on D&X, Dr. Shadigian concluded that there is no substantial body of medical opinion that D&X is the safest and most appropriate procedure for some women in some circumstances. NE TR 1510, 1582. The district courts erred by dismissing the testimony of certain experts simply because they do not do abortions on live fetuses.[15]

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[14] Clark testified that it is "very rare" that it would be necessary to terminate a pregnancy to treat a woman's medical condition. And, in those rare cases, D&X is never necessary to effectively treat the woman's condition, because maternal fetal medicine has established alternative procedures to treat all conditions that are as safe or safer than D&X. NY TR 2315 (Clark) (no cases where D&X is preferable to D&E or induction).

[15] Two district courts dismissed the testimony of some of the Government's experts for the sole reason that they did not do "abortions" on *live* fetuses. *Planned Parenthood v. Ashcroft*, 320 F.Supp.2d 957, 980 (N.D. Cal. 2004); *Carhart v. Ashcroft*, 331 F.Supp.2d at 1011. In addition to compounding the misunderstanding that personal experience is decisive, the courts overlooked the fact that maternal-fetal medicine and ob-gyn experts have experience doing comparable techniques (D&E, labor induction, and variations thereof) involving live and dead fetuses to treat women with high risk pregnancies, or

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In addition, experts on both sides testified that D&X is not necessary for specific maternal conditions: diabetes,[16] renal conditions,[17] breast cancer,[18] infection or sepsis,[19] leukemia,[20] chorioamnionitis (uterine infection),[21] hyperthyroidism,[22] uncontrolled blood pressure,[23] acute fatty liver,[24]

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pregnancies in which it is necessary to deliver a fetus early (such as pre-eclampsia). NE TR 904, 920-21 (Bowes) (describing comparable procedures to D&E and D&X where the fetus is already dead and the procedure is used to complete or terminate the pregnancy).

[16] NE TR 286 (Fitzhugh) (D&E safe); *Carhart*, 331 F.Supp.2d at 901 (Knorr) (refers patients to hospital if uncontrolled).

[17] NE TR 287 (Fitzhugh) (D&E safe); NE TR 1311 (Cook) (D&X not necessary); *Carhart*, 331 F.Supp.2d at 901-02 (Frederiksen) (induction and D&E both safe); NY TR 2368-69 (Clark) (not a medical indication for abortion and D&E or induction appropriate); NY TR 1229-30 (Frederiksen) (can be managed to term and D&E or induction appropriate).

[18] NE TR 287 (Frederiksen) (D&E safe); NE TR 1322-23, 1408-09 (Cook) (D&X never necessary).

[19] NE TR 287 (Fitzhugh) (D&E safe); *id*. at 1320 (Cook) (D&X never necessary).

[20] NE TR 1319 (Cook) (D&X never medically necessary in case of leukemia, other safer alternatives available).

[21] *Carhart*, 331 F.Supp.2d at 893 (Shadigian) (uses induction); *id*. at 901 (Frederiksen) (induction or D&E appropriate); NY TR 2347 (Clark) (women with this condition easily induced because the infection starts the process, and either D&E or induction safe and acceptable); *id*. at 2347-48 (Clark) (if infection is severe, a physician would not do surgical procedure); *id*. at 1227-28 (Frederiksen) (no particular method of abortion required).

[22] NE TR 901 (Knorr) (hospitalization preferable).

[23] *Id.* (Clark) (D&E appropriate).

[24] NY TR 2342-44 (Clark) (acute fatty liver occurs in the third trimester, at which time he uses induction to live birth); NY TR 2344-45 (Clark) (in an extreme situation where the liver is failing, surgical procedures such as D&X are contraindicated and induction is preferable); *id*. at 1226 (Frederiksen) (D&E appropriate).

autoimmune disorders,[25] cancer,[26] cardiac disease,[27] including cardiomyopathy,[28] fluid shifts,[29] pulmonary hypertension,[30] a history of classical caesarean section,[31] HELLP syndrome,[32] hypertension or severe pre-eclampsia,[33] lung

[25] NY TR 2348-49 (Clark) (generally not indications for abortion and D&E or induction appropriate).

[26] NY TR 2372 (Clark) (not a medical indication for abortion, most forms do not require chemotherapy that is harmful to the fetus, and either D&E or induction appropriate).

[27] NY TR 2328-29 (Clark) (inductions are safe and "under most circumstances preferable," and it would be "irresponsible" in such situations to perform D&X); NY TR 2540, 2542 (Cook) (no circumstances where D&X necessary to preserve the health of a cardiac patient, and the controlled approach of induction is better than the uncontrolled surgical approach); NE TR 1311-12 (Cook); NE TR 1313-16 (Cook) (D&X not necessary); *Carhart*, 331 F.Supp.2d at 901 (Knorr) (refers heart conditions to hospital); *id*. at 953 (Clark) (D&X offers no benefit; D&E or induction appropriate).

[28] NY TR 2331-34 (Clark) (D&E or induction appropriate).

[29] NY TR 2324-25 (Clark) (occurs after birth and is irrelevant to the selection of abortion method).

[30] NY TR 1229 (Frederiksen) (D&E appropriate); *id*. at 2326 (Clark) (dramatic increased risk of death when a mother with this condition is delivered surgically instead of medically).

[31] *Id*. at 1230 (Frederiksen) (D&E appropriate); *id*. at 436 (Johnson) (recommends D&E); *id*. at 2357-58 (Clark) (not medical indications for abortion).

[32] NY TR 2341-42 (Clark) (D&E and inductions appropriate, and if a woman's platelets are really low, induction vastly preferable to surgical manipulation); NE TR 1317 (Cook) (D&X not necessary).

[33] NY TR 2370-71 (Clark) (the majority occur near term and D&E or induction is appropriate); NY TR 2537-39 (Cook) (physicians want to avoid surgical procedures when a woman has low platelets or other clotting abnormalities); *id*. at 1228 (Frederiksen) (no particular abortion method needed); NE TR 287 (Fitzhugh) (D&E safe); *id*. at 327 (Vibhakar) (performs D&E); *id*. at 1308 (Cook) (D&X not necessary); *Carhart*, 331 F.Supp.2d at 893 (Shadigian).

disease,[34] organ transplants,[35] placenta previa,[36] thromboembolic disease,[37] or hemophilia.[38] D&X is medically contraindicated for: a bleeding brain, vaginal hemorrhaging,[39] or other bleeding.[40] Other conditions, such as placental insufficiency,[41] lung disease,[42] and prior organ transplantation[43] do not require termination of pregnancy. Moreover, D&X is contraindicated in true emergency situations because the dilation of the cervix takes too long.[44] *Carhart*, 331 F.Supp.2d at 934-35.

Coupled with the lack of necessity for D&X is the fact that Respondents' witnesses admitted that they generally do not know what abortion procedure they will use and that a number of factors, other than the woman's health,

[34] NY TR 2337-38 (Clark) (D&E and induction safe and accepted).

[35] NY TR 2374-75 (Clark) (not an indication for abortion and D&E or induction appropriate).

[36] NY TR 2352, 2354 (Clark) (never a medical indication for abortion and D&E appropriate).

[37] NY TR 2362-63, 2367-68 (Clark) (not an indication for abortion because it can be successfully treated and, if a woman is on blood thinners, induction and not surgical abortion is preferable).

[38] NY TR 2349-50 (Clark) (not indications for abortion and D&E or induction appropriate); *id*. at 2350 (Clark) (if condition is severe and the woman has bad bleeding tendency, induction is preferable).

[39] *Id*. at 1405 (Cook).

[40] *Carhart*, 331 F.Supp.2d at 923 (Cook).

[41] NE TR 1341 (Cook).

[42] *Carhart*, 331 F.Supp.2d at 900 (Clark).

[43] *Id*. (Clark).

[44] NE TR 1327-2 (Cook); *id*. at 1517-18 (Shadigian); *Carhart*, 331 F.Supp.2d at 934 (Cook); *id*. at 936 (Shadigian); *see also id*. at 892-93.

determine which procedure is ultimately used.[45] Dr. Chasen testified that the method chosen is "*not dependent upon the medical condition . . .* " *Carhart*, 331 F.Supp.2d at 869. The presence of maternal medical conditions does not affect his choice of abortion method. NY TR 1683. Instead, several of Respondents' experts testified that they perform D&X procedures *when possible – not* because it is ever "medically necessary."[46]

The court in *National Abortion Federation v. Ashcroft* (hereinafter *NAF*) concluded that some of the alleged reasons necessitating D&X were "incoherent" or "merely theoretical." 330 F.Supp.2d 436, 479-80 (S.D.N.Y. 2004). The court concluded: "the Court does not believe that many of Plaintiffs' purported reasons for why D&X is medically necessary are credible; rather they are theoretical or false." *Id*. at 480.

This was supported by abundant testimony in the record. Dr. Clark testified that "under no circumstance is D&X abortion necessary to preserve the life or health of the mother" and that banning D&X would not jeopardize the life of any woman. NY TR 2311. The Government's witnesses, Dr. Lockwood[47] and Dr. Cook,[48] concurred.

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[45] *See*, *e.g*., NE TR 346 (Vibhakar); NE TR 517, 557 (Knorr); NE TR 211-12, 246, 250-51, 256 (Fitzhugh) (stating his *amount of sleep* impacts which procedure he uses).

[46] *Id*. at 1683-84 (Chasen); *id*. at 675 (Hammond); *id*. at 1438-39 (Paul).

[47] NY TR 1760 (Lockwood) (could think of no circumstance where D&X would be necessary).

[48] NY TR 2532-33 (Cook) (could think of no maternal medical condition where D&X medically necessary).

The testimony of Respondents' seven doctors who have actually used D&X echoed this testimony. Doctors Chasen, Westhoff, Grunebaum, Frederiksen, Weiss, Paul, and Hammond could not recall or identify even one case in which they used D&X for a maternal health condition. NY TR 1684-85 (Chasen); NY TR 1007-11 (Westhoff); NY TR 691-92, 695-96, 707-11 (Hammond); NY TR 261, 345 (Grunebaum);[49] NY TR 1037, 1082, 1138, 1237 (Frederiksen); NY TR 1305-1426, 1369 (Weiss),[50] NY TR 1448-49, 1463 (Paul). Neither Creinin (NY TR 1512-1513) nor Johnson (NY TR 476) perform D&X abortions.[51] None of the nine physicians presented by Respondents could identify a single case in which D&X was needed for a maternal medical condition.

All of this testimony led the court to conclude:

> In no case involving these or other maternal health conditions could Plaintiffs point to a specific patient or actual circumstance in which D&X was necessary to protect a woman's health.

NAF, 330 F.Supp.2d at 480.[52]

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[49] NY TR 261 (Grunebaum) (D&X "absolutely not" the only method for abortion in any given circumstance).

[50] NY TR 1369 (Weiss) (could think of no circumstance where D&X required).

[51] NY TR 491 (Johnson) (no maternal complication requires D&X or makes it the only procedure performable).

[52] *See also id*. at 2315 (Clark); *id*. at 352 (Grunebaum); *id*. at 1743 (Lockwood); *id*. at 487-90 (Johnson).

B. The record demonstrates that D&X is not necessary for any fetal anomaly.

Several witnesses on both sides confirmed that abortions for fetal anomalies are elective, not necessitated by maternal health reasons, and that no fetal anomaly requires the use of D&X. *Carhart*, 331 F.Supp.2d at 906 (citing Dr. Doe's testimony).[53] D&X is never necessary for hydrocephaly, one of the most often-cited fetal anomalies. *See Carhart*, 331 F.Supp.2d at 936 (citing Cook). Respondents' witnesses testified that D&E can be safely used for hydrocephaly and that the procedure need not be modified. NE TR 288 (Fitzhugh); NE TR 385 (Vibhakar); NE TR 554-55 (Knorr).[54] For example, while the occurrence of hydrocephalus is "very rare," a procedure can be performed to take abnormal fluid off of the head, and induction or D&E is "appropriate." NY TR 2379-80 (Clark); NY TR 1687-88 (Chasen). See also NE TR 1335 (Cook); NE TR 1522 (Shadigian). D&X is never necessary. *Id*. at 2512 (Cook); *see also id*. at 1461-62 (Paul) (stating that most of her abortions for anomalies are by induction).[55] D&E can

[53] See NE TR 386 (Vibhakar); *id*. at 1330, 1334 (Cook); *id*. at 1521 (Shadigian).

[54] NY TR 821 (Westhoff) (prefers D&E for large abnormalities); *id*. at 2378-80 (Clark) (induction and D&E acceptable); *id*. at 440 (Johnson) (D&E beneficial).

[55] Evidence was presented that for pathological diagnoses, induction – and not D&X – is preferred. NY TR 438, 485, 487 (Johnson); *id*. at 951 (Westhoff) (stating that an induction is advantageous); *id*. at 1462 (Paul) (stating that an intact fetus is an advantage of induction). To obtain a "truly intact fetus," induction is necessary. *Id*. at 1220 (Frederiksen). Brain defects cannot be confirmed after D&X. *Id*. at 1221 (Frederiksen). While an intact fetal brain, face, and back of head and base of skull are advantageous, such features are destroyed by D&X. *Id*. at 1123-29 (Baergen).

also be used for genetic defects,[56] Trisomy 21,[57] Trisomy 13 or Trisomy 18 or spina bifida,[58] neural tube defects,[59] chromosomal defects,[60] organ malformations,[61] and anencephaly.[62] Medical induction has been used safely after 20 weeks to remove conjoined twins. NE TR 1522 (Shadigian).

Likewise, D&X is not necessary for pathological diagnoses of fetal anomalies. *Carhart*, 331 F.Supp.2d at 906 (recounting Chasen's testimony); *Id.* at 937 (restating Clark testimony). Respondents' witnesses testified that "[t]he intact D&E procedure makes it more difficult to diagnose brain abnormalities." *Id*. at 905 (citing testimony of Baergen, Broekhuizen, Frederiksen). A medical induction usually results in a completely intact fetus. *Id*. at 905, 906 (citing Frederiksen and Baergen testimony). Finally, '[t]here are no studies or literature comparing the method of abortion with the ability to diagnose fetal anomalies. . . . " *Id.* at 906. Respondents could not identify a single situation where D&X was necessary to preserve maternal health in the case of a fetal anomaly.

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[56] NE TR 287 (Fitzhugh).

[57] *Id*. (Frederiksen); *Carhart*, 331 F.Supp.2d at 903 n.65 (citing Clark testimony).

[58] NE TR 288 (Fitzhugh); NY TR 714-15 (Hammond) (no complications with other methods).

[59] *Id*. at 384 (Vibhakar).

[60] *Id*. (Vibhakar).

[61] *Id*. (Vibhakar).

[62] NE TR 355 (Knorr); NY TR 713-14 (Hammond) (no complications with other methods).

C. The ACOG Policy Statement has no basis in empirical evidence and is not reliable.

The ACOG "select panel" met for only two days to draft the organization's 1997 policy statement on D&X. NY TR 2235.[63] The panel did not identify or examine any studies regarding the safety of D&X and other abortion methods. NY TR 153-54, 2457. Any written materials were reviewed only for "issue spotting," and the panel failed to discuss D&X with any other physicians. NY TR 2438-42. The panel then sent a draft statement to the ACOG executive board with the following conclusion: *it could identify no circumstances under which [D&X] would be the only option to save the life or preserve the health of the woman*. NY TR 153-54, 2461 (emphasis added).[64]

Without consulting the panel, the ACOG executive board unilaterally added the statement that D&X "*may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman*. . . . " NY TR 2460-62. The statement was never discussed or voted upon by ACOG's fellows or membership. NY TR 2221-22, 2229. Due to the executive board's unilateral addition of a statement unsupported by empirical evidence, the ACOG statement cannot be relied upon for the proposition that D&X is necessary for any maternal or fetal condition.

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[63] Dr. Joanna Cain, who was deposed, was ACOG's president and a select panel member.

[64] See also NE TR 1098-1102 (Sprang) (ACOG "couldn't come up with a single example where it would be . . . the best, most appropriate alternative to save the health of the mother").

III. THERE IS NO SUBSTANTIAL, RELIABLE EVIDENCE THAT D&X IS SAFER THAN EXISTING PROCEDURES.

A. Intuition and personal observation are not reliable or substantial evidence of safety.

In addition to relying on intuition alone, Respondents' witnesses consistently used general and vague assertions about the utility or safety of D&X.[65] The claims of intuition were made to support the vague standard that D&X may be "medically necessary to preserve a woman's health under some circumstances." When tested against a clear, definite standard, however, Respondents' experts conceded that D&X was not the "only method available for performing abortions in any given circumstance."[66]

For example, Respondents' first intuition claim is that less instrumentation reduces risk to women. This is countered by several factors. First, doctors who do D&X "do not count or keep track of how may instrument passes they use." NY TR 1206 (Frederiksen); NY TR 678 (Hammond). Second, none of the large retrospective studies on D&E (let alone D&X) have actually studied

[65] See e.g., Creinin deposition testimony read into the record, NY Day 9 ("when looking at the risks and the benefits of the different procedures, a procedure which is designed to remove the fetus intact could have a lower risk of complications or difference, a change in the ratio of risks to benefit"); SF TR 839-840 (Westhoff) ("possibility that those boney fragments can lacerate," have observed laceration from instrumental passes; "blind use of instruments which has more potential for perforation"); NY TR 252-54 (Grunebaum) (D&X "offers advantages over D&E"); NY TR 691 (Hammond) (D&X "offers advantages" to women).

[66] NY TR 261 (Grunebaum); NY TR 444, 491 (Johnson); NY TR 1369 (Weiss).

whether the introduction of instrumentation affects risk. Third, there are no studies published comparing D&E and D&X on the number of instrument passes. NY TR 678 (Hammond); NY TR 1461 (Paul); NY TR 1411 (Weiss). Fourth, practitioners of D&X only observe women for a very short time and do no long-term follow-up. NE TR 1527 (Shadigian).[67]

Respondents' second intuition claim is that an intact delivery will eliminate dismemberment in the uterus, thereby reducing the risk of lacerations or puncture. Plaintiffs' expert Frederiksen was aware of no studies that support this theory in the case of D&E or D&X. NY TR 1214.[68] Judge Straub concluded that the trial evidence showed that "plaintiffs failed to establish that D&X lessened the chance of retained fetal parts," (*National Abortion Federation v. Gonzales*, 437 F.3d 278, 308 (2d Cir. 2006)), and concluded "the plaintiffs were unable to 'explain the medical reasons supporting' the proposition that D&X is medically necessary." 437 F.3d at 300 (quoting 330 F.Supp. 2d at 479).

The district court in *NAF* concluded that expert witnesses "reasonably and effectively refuted Plaintiffs' proffered bases for the opinion that D&X has safety advantages over other second-trimester abortion procedures." 330 F.Supp.2d at 479. The court in *NAF* did "not

[67] NE TR 1527 (Shadigian: "hard . . . to understand how abortion providers . . . know their complications, if they don't even see their patients back later" (citing Picker Institute, *From the Patient's Perspective: Quality of Abortion Care* (1999) (found that only about 29% of women actually follow up with their abortion provider afterwards))).

[68] See also NY TR 1527 (Weiss); NY TR 2114-15 (Sprang) (called laceration from bony fragments is a "very, very theoretic possibility").

believe that many of Plaintiffs' purported reasons for why D&X is medically necessary are credible; rather they are theoretical or false." 330 F.Supp.2d at 480, and found that the "Government's experts, especially Dr. Clark, demonstrated that some of the Plaintiffs' reasons necessitating D&X are incoherent; other reasons were shown to be merely theoretical." 330 F.Supp.2d at 479-80.

If intuition is to be considered, intuition supports multiple possible dangers from D&X, as much as it does its theoretical safety, for several reasons: heightened risk of placenta previa and preterm birth (prematurity) in future pregnancies,[69] heightened risk of maternal laceration from crushing the fetal skull or puncturing the fetal neck, increased risk of infection from extended dilation,[70] and heightened risk of uterine trauma from internal rotation (version) of the fetus during D&X.[71] First, to the extent that D&X requires that the cervix is more dilated, it logically could entail greater risk. *NAF*, 330 F.Supp.2d at 466.[72] The Chasen study suggests a nearly "threefold

[69] NY TR 1752-53 (Lockwood) (citing studies).

[70] NE TR 1098-1174 (Sprang); SF TR 1083-85 (Sprang).

[71] NY TR 1766-67 (Lockwood); SF TR 444 (Doe) (potential risk of perforation or laceration of cervix or lower uterine segment from getting forceps around the fetal skull during D&X); SF TR 1085-87 (Sprang) (increased risk from internal podalic version, "basically forcing [the fetus] to do a somersault within the uterine cavity"); SF TR 1411 (Cook)

[72] NE TR 1148 (Sprang) (dilating the cervix over two days); NE TR 1530-32 (Shadigian) (D&X requires a greater degree of cervical dilation than D&E, involving longer multiple-day dilations; "D&X procedure uses those laminaria or osmotic dilators whereas in the medical induction procedure, it's only medications that actually have the woman's body start the physiological process of contraction . . . the concerns are how many times the woman's cervix is dilated over so many days and how far it's dilated with the number of laminaria"); SF TR 744 (Creinin).

increased risk of premature birth [for women undergoing D&X] along with a plausible biologic explanation for why that might occur, namely, twice the cervical dilation. . . . " NY TR 2386 (Clark).[73] Second, there was significant testimony, from experts on both sides, that internal podalic version of the fetus carries risks of uterine rupture, abruption, and trauma to the uterus.[74] Thus, contrary to this Court's statement in *Stenberg v. Carhart*, 530 U.S. 914 (2000), that "division of medical opinion . . . signals the presence of risk, not its absence. . . . " (*Id*. at 937), a division of medical opinion based on intuition, in the absence of empirical evidence, signals uncertainty as to *whether D&X involves a greater or lesser risk* than well-established procedures for abortion.

B. No empirical data demonstrate the safety of D&X.

All of Respondents' evidence about the safety of D&X amounted to assertions of the intuitive safety of the procedure from the few who do it; no reliable empirical evidence was presented, with the sole exception of the Chasen study, published after the trials, which is seriously flawed (as outlined below). Several of Respondents' experts conceded the lack of any empirical studies testing the

[73] See also NY TR 1752-54, 1844 (Lockwood) (concerned about prematurity after D&X, needs additional study); NY TR 2121 (Sprang); NY TR 2546-47 (Cook) (Chasen study showed a disturbing trend toward increased risk of preterm deliveries specifically as a result of [D&X]").

[74] NY TR 375 (Grunebaum); NY TR 508 (Johnson); NY TR 1766-67 (Lockwood); NY TR 2108 (Sprang); NY TR 1415-16 (Weiss); NY TR 2545-46 (Cook).

providers' intuition.[75] Frederiksen could identify no studies comparing blood loss or risk of injury from "bony parts" between D&X and D&E. *Carhart*, 331 F.Supp.2d at 928.[76] The Government's experts also emphasized that no empirical data existed.[77] Even if (as Respondents claim) it is *generally* true that the safety for each particular woman depends on her individual circumstances *when two procedures are statistically similar in terms of risk*, there is no data indicating that D&X can be so compared because there is no data to show that it *is* statistically similar in terms of risk.[78]

The absence of empirical evidence to support the safety of D&X is reflected in the three papers on which Respondents rely for all their "data" to support D&X:

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[75] NY TR 1523 (Creinin) (no published peer reviewed studies); NY TR 1408 (Weiss) (no published studies evaluating the potential risks or benefits). Of the Government's experts, see NY TR 1751-1752, 1885 (Lockwood).

[76] 331 F.Supp.2d at 935 (citing Clark (no studies concerning relative risk of D&X)); NY TR 2386 (Clark) (risks of D&X are "absolutely unknown").

[77] "Since the D&X has never been studied in a formal away in peer review literature, there is no basis to say that D&X is safer than any other procedure." NE TR 1513 (Shadigian). "[T]here is no sound basis on which to conclude the D&X is safer than medical induction." *Id.* NE TR 932 (Bowes) (claims of safety can't be supported by evidence-based medicine) NE TR 922 (no published peer reviewed studies evaluating safety of an intact D&E versus a disarticulation D&E and none comparing safety of intact D&E with labor induction abortion); NE TR 1352 (Cook) (no peer-reviewed studies).

[78] NE TR 1523 (Shadigian) (the short-term complications are not known, the long-term complications are not known; "no studies that tell us what the correct indication [the reason why the procedure would be performed over other procedures] should be for a D&X"; "and because it hasn't been studied at all, we can't really even compare it to a D&E or to a medical induction of labor . . . when something is so unstudied. . . . ").

Haskell's (not peer-reviewed), McMahon's (not peer-reviewed), and Chasen's.[79] Haskell's 1992 paper was neither peer-reviewed nor controlled; it was simply a compiled series of his own personal experience.[80] Back in 1997, when Respondents' expert Westhoff testified in court against state prohibitions on D&X and relied on the Haskell and McMahon papers, she believed that D&X "deserved formal clinical comparative evaluation as the best way to evaluate its risks and benefits for the future." NY TR 964-965, 967-68 (Westhoff). There is no evidence that Haskell or McMahon ever "followed up with patients to determine complications." NE TR 1528 (Shadigian);[81] NE TR 1343 (Cook). By contrast, in a related context – regarding the utility of administering "parenteral or additional oral antibiotic therapy" – Haskell himself noted that "*there are no data to confirm the necessity of this*

[79] There is evidence in the record that women undergoing D&X never received informed consent for this untested procedure by D&X practitioners or by Haskell, McMahon, and Chasen in their papers. Informed consent specifically for D&X was required by the serious risk to the mother from increased cervical dilation, internal podalic version, and the insertion of scissors in the back of the fetal skull, which are not components of D&E.

[80] NE TR Defendant's Exh. 580. There was "no comparison comparable or concurrent control group. They simply stated their results but didn't compare it to a group that they had matched with similar kinds of patients . . . so it's a case series and it was not peer reviewed, so we don't know whether there was selection bias in selecting the patients for the study; don't know how many patients were lost to follow-up." NE TR 923-24 (Bowes).

[81] "[S]elf-reported case reviews" are "not sufficient." NE TR 1528 (Shadigian). "[I]t's the very first step in evaluating procedures" to discuss the procedure with others who do it. "After that happens, there is a series of evidence-based studies that need to happen for us to make any conclusions about the general safety or unsafety of a procedure." NE TR 1529 (Shadigian). See also SF TR 1233, 1236-38 (Shadigian); SF TR 895 (Bowes).

practice."[82] Likewise, McMahon's paper was self-reported and not peer-reviewed.[83] Respondents' expert Westhoff admitted that McMahon's data was self-reported and testified that McMahon admitted that his results were "inconclusive." NY TR 965-967.[84]

The only peer-reviewed study on D&X ever published is the Chasen study,[85] an observational, retrospective cohort study which compared a group of women who had D&E abortions (263) with a group that had D&X abortions (120) at or beyond 20 weeks gestation. NY TR 1624-26. All were performed in the same hospital, not an outpatient clinic. NY TR 1628 (Chasen).[86] The Chasen study has

[82] Maureen Paul, *A Clinician's Guide to Medical and Surgical Abortion* 129 (1999) (Chapter 10) (emphasis added) (a book developed by the National Abortion Federation, NY TR Day 4 (April 1, 2004) (Hammond)).

[83] JT McMahon, *Intact D&E: the first decade*, Presented at the NAF conference, New Orleans, April 2, 1995 (NE TR Defendant's Exhibit 608; cited in *Carhart*, 331 F.Supp.2d at 1021 n.149.

[84] See also NY TR 2513, NE TR 1343 (Cook critique of study); NE TR 1343 (Cook critique of McMahon); NE TR 924 (Bowes critique of McMahon).

[85] ST Chasen, RB Kalish, M Gupta, JE Kaufman, WK Rashbaum, FA Chervenak, *Dilation and evacuation at > or = 20 weeks: comparison of operative techniques*, 190 Am. J. Ob. Gyn. 1180 (2004). There was no pre-existing published data addressing the comparison of D&E and D&X before Chasen's. NY TR 1614-15. Judge Casey found Chasen to be the only study to compare D&E and D&X. *NAF*, 330 F.Supp.2d at 476. NY TR 370-371 (Grunebaum) (other than Chasen study, no published studies of D&X).

[86] After criticism from a peer-reviewer at the ACOG journal *Obstetrics & Gynecology*, which rejected the study for publication, Chasen changed his paper. NY TR 1658-1660. The reviewer criticized Chasen's original conclusion that "[d]ilation and evacuation with intact extraction is as safe as dilation and extraction with disarticulation after 20 weeks gestation," on the basis that the retrospective study showed only that there were no obvious differences between the two procedures,

(Continued on following page)

several limitations that render it unreliable for assessing the relative safety of D&X and D&E. First, there were so few patients that no conclusions could be reached with any statistical validity. *Carhart*, 331 F.Supp.2d at 962 (citing criticism by Bowes, Sprang, Lockwood); NY TR 2126 (Sprang); NY TR 2689 (Howell). Second, the authors did not document their follow-up procedure, preventing them from reliably documenting complications.[87] Third, the patients in the two groups were not randomized and were very different in important characteristics: in age, in gestational duration of pregnancy at which the procedures were done, and in the indications for which the abortions were performed. No regression analysis was employed to take account of these differences and adjust for them. The authors did not identify the criteria for deciding which patient would have what procedure; thus, the operators were inherently "biased" in determining what procedures they would use. NY TR 1523-24 (Creinin). On the critical issue of subsequent pre-term birth (PTB), the authors followed only 62 pregnant women (of 363 patients) who happened to return to that hospital for prenatal care. NY TR 1662. The study suggests greater cervical and genital tract trauma with D&X (though not

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not that D&X was safe. NY TR 1659. Chasen then made two changes to his paper: changing his abstract conclusion to state that "outcomes appear similar between patients undergoing dilation and evacuation and dilation and extraction after 20 weeks gestation," and changing the conclusion from "[o]ur data affirmed that D&E, after 20 weeks gestation with intact extraction when performed by experienced physicians, is as safe as D&E with disarticulation," to "[o]ur data affirmed that abortion after 20 weeks gestation with intact D&X appears to have similar complication rates as dilation and evacuation when performed by experienced physicians." NY TR 1660-61.

[87] SF 752 (Creinin); SF 1794 (Chasen).

statistically significant due to the lack of statistical power).[88] These trends contradict the study's conclusion that the outcomes are similar in the two groups.[89]

Chasen admitted, based on the data in his retrospective study, that (1) he could not state that one technique is superior to the other (D&X v. D&E) (NY TR 1661) and (2) that the major complications that occurred in the D&E group could not have been avoided by doing a D&X abortion. NY TR 1665. The Chasen study does not show any improvement in outcomes between D&E and D&X. NY TR 2393-94 (Clark).[90] The district court in *NAF* concluded that "the Chasen Study itself found no difference between D&X and D&E in procedure time or estimated blood loss. . . . " 330 F.Supp.2d at 472. No additional data on D&X has been published in the two years since the Chasen study.[91]

For all these reasons, the claims of D&X's safety cannot be supported by evidence-based medicine. NE TR

[88] Genital tract lacerations occurred in 3.3% of the D&X cases and 1.5% of the D&E cases; cervical lacerations occurred in 2.4% of the D&X cases and in 0.8% of the D&E cases. NY TR 2124 (Sprang).

[89] NY TR 2125 (Sprang); NE TR 926-33 (Bowes).

[90] See also NE TR 1595 (Shadigian critique of Chasen); NE TR 1158-61, 1222-26 (Sprang critique).

[91] A follow-up study by Chasen et al., looking at obstetric outcomes after D&E or D&X at >20 weeks gestation, was published in 2005, using the previous dataset but somehow finding twice as many prenatal patients. Chasen, et al., *Obstetric Outcomes After Surgical Abortion at (greater than or equal to) 20 weeks' gestation*, 193 Amer. J. Ob. Gyn. 1161 (2005). 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.

932 (Bowes).[92] Six years after *Stenberg v. Carhart*, "[n]o studies support the contention that the D&X abortion method is safer than other abortion methods." *Stenberg*, 530 U.S. 914, 966 (2000) (Kennedy, J., dissenting).

C. There is substantial, reliable evidence that there are well-established alternatives to D&X.

For women seeking abortion, there are two well-established alternatives to D&X: medical induction and D&E. They have been the subject of many peer-reviewed studies over the past 20 years, and these are widely considered to be "safe." SF TR 103 (Paul); SF TR 846 (Westhoff); SF TR 430 (Doe); SF TR 705, 718, 748-49 (Creinin); SF TR 194 (Sheehan); SF TR 1819 (Chasen). No empirical evidence exists that these are less safe than D&X.

For the pregnant woman who develops a medical emergency, there are safe alternatives. Maternal-fetal medicine has established alternative procedures to treat all maternal medical conditions and fetal anomalies. NY TR 1760, 2311, 2313-14 (Clark). Several experts from both

[92] The 8th Circuit concluded that, after the Chasen study, "there are still no medical studies addressing the medical necessity of the banned procedures." *Carhart v. Gonzales*, 413 F.3d 791, 803 (8th Cir. 2005) ("There is a dearth of studies on the medical necessity of the banned procedures."). ACOG acknowledged that "ACOG is unaware of any comparative maternal morbidity studies specifically evaluating Intact D&E procedures with other methods of abortion." *NAF*, 437 F.3d at 307 (quoting ACOG President that "there is no data to say that one of the procedures is safer than the other"). As Judge Straub noted, "it is undisputed that no peer-reviewed studies or data exists [sic] showing that D&X is either safe or safer than abortion procedures." 437 F.3d at 307.

sides testified that at 20-24 weeks gestation, medical induction and D&E are comparable for safety and are established alternatives to D&X.[93] NY TR 1632-33 (Chasen). As Judge Walker noted, the district court in *NAF* concluded, from a review of the Congressional and trial record, that there is "substantial evidence that, even if the D&X procedure is wholly prohibited, a woman can obtain a safe abortion in almost every conceivable situation." 437 F.3d at 296. Although Respondents give the impression that D&X *just might* be useful in *some emergency*, the truth is quite opposite: because the dilation required for D&X takes so long to complete, D&X can never be used properly in a true emergency to treat a woman.

Because there are well-established alternatives to D&X, the Act imposes no "substantial obstacle," *Casey*, 505 U.S. at 877, and imposes no "significant threat to the life or health of a woman." *Id.* at 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*.

[93] NY TR 1743, 1749-50 (Lockwood); NY TR 2306 (Clark); NY TR 541 (Hammond); NY TR 810 (Westhoff) (both induction and D&E "are very safe"); NY TR 1426 (Weiss); NY TR 422, 423, 500-501 (Johnson); NE TR 1534 (Shadigian); NE TR 1174, 1213 (Frederiksen); NE TR 504, 579-80 (Broekhuizen); NE TR 2306 (Clark); NE TR 1423 (Cook); NE TR 1129 (Sprang). See *Carhart*, 331 F.Supp.2d at 941-42 (surveying testimony).

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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APPENDIX A

INDEX TO TRIAL TESTIMONY

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SF Day Three, April 1, 2004 (vol. 3, pp. 374-477)

SF Day Four, April 5, 2004 (vol. 4, pp. 478-696)

APPENDIX B

Excerpt from ACOG Practice Bulletin No. 67 (included in all ACOG Practice Bulletins):

"Studies were reviewed and evaluated for quality according to the method outlined by the US Preventive Services Task Force:

I Evidence obtained from at least one properly designed randomized controlled trial.

II-1 Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A – Recommendations are based on good and consistent scientific evidence.

Level B – Recommendations are based on limited or inconsistent scientific evidence.

Level C – Recommendations are based primarily on consensus and expert opinion."

American College of Obstetricians and Gynecologists, Medical management of abortion, ACOG Practice Bulletin No. 67, 106 Obstetrics & Gynecology 882 (October 2005) (reprinted in ACOG, 2006 Compendium of Selected Publications 705 (2006))

U.S. Preventive Services Task Force,
***Guide to Clinical Preventive Services* (2005)**

"*The USPSTF grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor).*

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcome.

Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes."

U.S. Preventive Services Task Force, *Guide to Clinical Preventive Services: Recommendations of the USPSTF* 164 (2005) (Appendix A).

The current *Guide to Clinical Preventive Services 2005: Recommendations of the USPSTF* is available on the Web at http://www.ahrq.gov/clinic/pocketgd.pdf.