own witnesses. Indeed, as medical practice has evolved in the nine years since ACOG first formulated its policy on intact D&E, and in the six years since this Court decided *Stenberg*, the medical consensus about these safety advantages has grown.

Against this backdrop, the consequences of the Act's failure to include an exception for procedures necessary to protect a woman's health are clear. The Act prevents physicians from providing the care that is most likely to avoid potentially catastrophic health outcomes. It thus imposes a risk of increased harms on those women for whom intact D&E would be the safest option.

Moreover, the Act prohibits more than just intact D&Es. The Act's broad scope and vague terms would chill physicians from performing any second-trimester abortion. And the Act would hinder medical advancement by preventing physicians from using their clinical experience to develop safer procedures.

Like all physicians, ACOG's members must both "recognize responsibility to patients first and foremost" and "respect the law." Amer. Med. Ass'n, *Principles of Medical Ethics: Preamble* (June 2001).[3] Because the Act impermissibly forces physicians to choose between those two duties, the decisions of the Courts of Appeals should be affirmed.

STATEMENT OF FACTS

Every time a physician performs an induced abortion or treats a patient experiencing a miscarriage, the goal is the same: to empty the uterus using the safest techniques for the woman. A physician uses the same techniques

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[3] *Available at* http://www.ama-assn.org/ama/pub/category/2512.html.

whether treating a miscarriage or inducing an abortion. Physicians have continuously improved their techniques, such that in the United States an induced abortion is "one of the safest [surgical] procedures in contemporary practice." David A. Grimes & Mitchell D. Creinin, *Induced Abortion: An Overview for Internists*, 149 Annals Internal Med. 620, 623 (2004). Indeed, an induced abortion is many times safer for a woman than continuing a pregnancy through to childbirth. *See, e.g.*, David A. Grimes, *Estimation of Pregnancy-Related Mortality Risk by Pregnancy Outcome, United States, 1991 to 1999*, 194 Am. J. Obstetrics & Gynecology 92, 92-93 (2006). But the risks of abortion increase as pregnancy advances. *See, e.g.*, Linda A. Bartlett et al., *Risk Factors for Legal Induced Abortion-Related Mortality in the United States*, 103 Obstetrics & Gynecology 729, 732 (2004).

A. Abortion Procedures

1. First-Trimester

Almost 90% of induced abortions are performed in the first trimester of pregnancy. *See* Lilo T. Strauss et al., Nat'l Ctr. for Chronic Disease Prevention, *Abortion Surveillance—United States, 2002*, Morbidity and Mortality Wkly. Rep. Surveillance Summaries, Nov. 25, 2005, at 1, 21 tbl. 6. The first trimester runs through the first 13 weeks of pregnancy, measured from the first day of the last menstrual period ("LMP") before the woman became pregnant.

The great majority of first-trimester abortions are performed using a method called vacuum aspiration (sometimes called suction curettage). *See id.* at 31 tbl. 18. In these procedures, the physician dilates the cervix and inserts a tube called a cannula through the vagina and cervix and into the uterus. Once the cannula is in the uterus, the physician uses suction to empty the uterus.

See A Clinician's Guide to Medical and Surgical Abortion 111-112 (Maureen Paul et al. eds., 1999) ("*Clinician's Guide*").

2. Second Trimester

Dilation and Evacuation. In the second trimester of pregnancy (approximately 13-26 weeks LMP), when vacuum aspiration is no longer effective, over 95% of induced abortions are performed using the method known as dilatation and evacuation ("D&E"). *See* Strauss et al., *supra*, at 31 tbl. 18. Although individual physicians' techniques may vary somewhat, physicians generally begin by dilating the cervix with dilators, which absorb moisture from the woman's cervix and thus widen the opening of the cervix. These dilators are inserted hours to days prior to the evacuation portion of the procedure. The amount of time required for adequate dilatation varies based on factors including the duration of the pregnancy and the number of prior vaginal deliveries. Some physicians also use medications to facilitate dilation. In some cases of miscarriage, the cervix dilates on its own before the physician sees the patient, eliminating the need to initiate dilation before evacuating the uterus.

After the cervix is sufficiently dilated, the patient returns to the physician for the evacuation procedure. *See* Phillip G. Stubblefield et al., *Methods for Induced Abortion*, 104 Obstetrics and Gynecology 174, 179-180 (2004). After suctioning out the amniotic fluid, the physician reaches through the dilated cervix, generally with a clamp or forceps; grasps the fetus with the instrument; and then pulls the fetal part grasped within the instrument out through the cervix and vaginal canal. *See Clinician's Guide*, *supra*, at 133-36. At this point, when the physician starts to withdraw the forceps from the woman's body, the fetus is usually intact. Often, especially earlier in the second trimester, disarticulation

(or dismemberment) occurs as the physician delivers the fetal part grasped in the instrument and pulls it through the opening of the cervix. The physician then reinserts the forceps, and repeats this step until all fetal material has been removed from the uterus. *See id.* The fetus dies sometime during the process of disarticulation.

Physicians try to minimize the number of times they insert instruments into the woman's uterus, and therefore attempt to remove as much of the fetus as possible each time they insert the instrument. In some D&Es, little or no disarticulation occurs, and the physician removes the fetus relatively intact. This reduces instrumentation and therefore reduces the risk of injury to the woman's uterus. Any D&E can result in relatively intact removal of the fetus.

However, as the pregnancy advances, the fetal skull will become too large to pass through the cervix—especially later in the second trimester. Hence, whether the D&E involves extensive disarticulation or relatively intact removal, the fetal skull usually must be compressed to allow it to pass through the cervix without injuring the woman. *See* Warren M. Hern, *Abortion Practice* 199-200 (1984). And in many D&Es, the physician extracts part of the fetus while it retains a heartbeat or other indicia of life, such as a pulsating umbilical cord.

Starting at approximately the mid-point of the second trimester, some physicians more routinely perform D&Es in which the fetus is removed intact (sometimes known as "intact D&E" or the "intact variant"). In one technique, the physician brings the fetus through the cervix intact in a breech position. If the head then lodges in the uterus, it must be compressed to complete the extraction. ACOG has referred to this procedure as intact dilatation and extraction. *See* ACOG Statement of Policy, Abortion

Policy (July 2004), *reprinted in* ACOG, *2006 Compendium of Selected Publications* 1059-61 (2006) (reaffirming Jan. 1997 and Sept. 2000 revisions). In another technique, the physician begins by compressing the skull of a fetus that is presenting head-down—while it is entirely within the uterus. Once the head will fit through the cervix, the physician removes the fetus intact.

Because greater dilation generally increases the likelihood of intact extraction, whether intact extraction will be possible in any given case often depends on how far the cervix has dilated. But physicians cannot predict in which cases they will be able to remove the fetus intact or relatively intact. In most cases, physicians perform dilation on all of their patients the same way and hope to achieve enough dilation to facilitate intact extraction.

Induction. Other than D&E, almost all other induced abortions after the first trimester are performed by the method known as induction. In an induction abortion, the physician induces pre-term labor with potent medications, the cervix dilates, and the fetus is generally expelled through the labor process. The procedure requires constant monitoring and must be performed in a hospital. An induction lasts anywhere from fewer than twelve hours to more than forty-eight hours.

Induction poses specific risks to women with certain medical conditions, and may be entirely contraindicated for others. For example, induction abortions are relatively or absolutely contraindicated for women who have had a previous hysterotomy or cesarean section with a classical (vertical) scar, because they can lead to uterine rupture, hemorrhage, and even death. *See* P. Boulout et al., *Late Vaginal Induced Abortion after a Previous Cesarean Birth: Potential for Uterine Rupture*, 36 Gynecologic & Obstetric Investigation 87, 88 (1993).

In some circumstances in which the induction results in a breech delivery, the fetal skull may be too large to fit through the partially dilated cervix. In such cases, the physician generally must compress the skull to complete the delivery and reduce the likelihood of serious injury to the woman. In the case of an incomplete or unsuccessful induction, the physician must complete the abortion using D&E techniques. *See* Stubblefield et al., *supra*, at 180-81; *Clinician's Guide, supra*, at 151.

Abdominal Surgery. In rare instances, physicians perform abortions via abdominal surgery: hysterectomy (removal of the uterus) or hysterotomy (essentially a pre-term cesarean section). *See Williams Obstetrics* 245 (F. Gary Cunningham et al. eds., 22d ed. 2005) ("*Williams Obstetrics 2005*"). These procedures entail far higher risks for the woman than do either D&E or induction. Compared to the type of incision used for term cesarean deliveries, the incision in the uterus used for a second trimester abortion by hysterotomy has a higher risk of rupture in subsequent pregnancies. Such a rupture in a subsequent pregnancy can cause hemorrhage, loss of the uterus, fetal death, and even the woman's death. And a hysterectomy eliminates a woman's ability to bear children in the future. *See* P. Diggory, *Hysterotomy and Hysterectomy as Abortion Techniques, in Abortion and Sterilization: Medical and Social Aspects* 317, 331 (Jane E. Hodgson ed., 1981).

B. ACOG's Statement of Policy on Intact D&E

In October 1996, ACOG's Executive Board, the governing body that sets policy for the organization, embarked on an effort to develop a policy statement concerning the so-called "partial birth abortion" procedure. A task force convened by the Executive Board reviewed the medical facts surrounding the issue and

drafted a proposed policy statement. The task force consisted of practicing obstetrician-gynecologists, who were "carefully select[ed] . . . based on their expertise and viewpoint"—ACOG "chose task force members from diverse backgrounds." *Carhart* Pet. App. 424a-25a. Members included, among others, specialists in treating high-risk pregnancies and physicians who regularly performed or oversaw abortions, including intact D&Es. *See id.* at 425a-26a. The task force also included at least one physician who opposed abortion. *See id.* at 425a.

The task force members reviewed materials sent to them in advance and then met over a two day period to review the background literature and discuss specific cases in which the intact variant of D&E might be employed. *See id.* at 426a-33a. As one task-force member testified, there were "multiple circumstances that an expert panel could identify at the time of the task force where [intact D&E] was clearly the best choice, including . . . where the other options led to a higher likelihood of death or recurrence of disease." *Carhart* J.A. 502 (Cain Dep. Test.); *PPFA* J.A. 859 (same). Therefore, the task force concluded that intact D&E could be the safest or most appropriate procedure for a given patient, and that the decision whether to choose such a procedure should be left to a woman and her physician. *See Carhart* Pet. App. 436a. The task force presented this conclusion to ACOG's Executive Board in a draft Statement of Policy.

The Executive Board includes, among others, nationally elected officers, and elected representatives from each of ACOG's nine geographic districts and one district made up of members of the Armed Forces. At the time that ACOG's Executive Board considered the draft Statement of Policy, there were 19 members. The Executive Board approved the draft Statement of Policy, but determined that it should explicitly state the task

force's conclusion that an intact D&E may be the best or most appropriate procedure under certain circumstances.

The Executive Board inserted that conclusion (emphasized below) into its final policy statement which states, in relevant part:

> A select panel convened by ACOG could identify no circumstances under which [intact D&X] . . . would be the *only* option to save the life or preserve the health of the woman. ***An intact D&X, however, may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman, and only the doctor, in consultation with the patient, based on the woman's particular circumstances can make this decision.*** The potential exists that legislation prohibiting specific medical practices, such as intact D&X, may outlaw techniques that are critical to the lives and health of American women.

Carhart J.A. 975-976 (second emphasis added). Despite routine turnover of its membership, the ACOG Executive Board reaffirmed the Statement of Policy in September 2000 and again in July 2004. *See* ACOG Statement of Policy, *supra*.

ARGUMENT

I. INTACT D&E IS NECESSARY TO PREVENT SERIOUS HARM.

Over 95% of women terminating a pregnancy in the second trimester undergo a D&E procedure. *See* Strauss et al., *supra*, at 31 tbl. 18. Among D&E procedures, those

in which the fetus is delivered intact, or relatively intact, offer potentially significant safety advantages.

A. Intact D&E Reduces The Risk of the Most Serious Complications of Non-intact D&E.

The intact approach reduces the risk of the most severe complications of D&Es involving dismemberment by minimizing instrumentation and reducing the chances of retained fetal tissue.

First, the intact variant of D&E "minimize[s] instrumentation within the uterine cavity." *Clinician's Guide, supra*, at 136. It thus "facilitates extraction and minimizes uterine or cervical injury from instruments or fetal bones." *Williams Obstetrics 2005*, *supra*, at 243.

Fewer instrument passes and fewer fetal-bone fragments means less risk of uterine perforation—the most serious and feared complication of D&E. "[A] perforation occurring with second-trimester D&E may lead to bowel injury and will likely require laparotomy [open abdominal surgery]." Stubblefield et al., *supra*, at 180. A perforation that reaches the uterine artery, which is engorged during pregnancy, may cause catastrophic hemorrhage. "Uterine perforations that involve injury to major blood vessels or other organs . . . require in-hospital surgical management." *Clinician's Guide*, *supra*, at 178. Some uterine perforations can also reach the gastrointestinal tract, risking contamination of the abdominal cavity with bacteria (peritonitis) or entry of bacteria into the blood stream (sepsis). By causing tissue and organ damage, including damage to the brain and

other vital organs, both hemorrhage and sepsis can have long term effects on the woman's health.[4]

Second, removing the fetus intact also eliminates the possibility that fetal tissue will be retained in the uterus, a cause of hemorrhage or infection in non-intact D&E procedures. *See* Stubblefield, et al., *supra*, at 180 ("[h]emorrhage during or after D&E can be caused by an incomplete procedure"); *Clinician's Guide, supra*, at 201 (retained fetal tissue can cause bleeding, infection of the uterus and fallopian tubes, and sepsis). Long-term complications of retained fetal tissue also include infertility.

Third, intact removal increases the physician's control over the procedure. Increased control minimizes the likelihood of complications that are present in other forms of D&E. For example, removing the fetus intact reduces the likelihood that the physician will have to locate the last piece of fetal tissue remaining in the uterus by grasping repeatedly with the forceps—a process that risks injuring the woman. *See* Hern, *supra*, at 194-95.

Finally, emerging study data, confirmed by clinical experience, suggests that intact removal is faster than other methods used at comparable stages of pregnancy. A recent study measured the procedure time for both the intact and non-intact variants. The women who received the intact variant were two weeks later in pregnancy, and

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[4] "Obstetric hemorrhage can be of a volume large enough to precipitate a state of generalized circulatory failure, resulting in . . . irreversible tissue damage." Am. Acad. of Pediatrics & ACOG, *Guidelines for Perinatal Care* 180 (5th ed. 2002). Lungs, kidneys, and the pituitary gland are particularly susceptible to damage from hemorrhagic shock during pregnancy. *See Critical Care Obstetrics* 555 (Gary A. Dildy et al. eds., 4th ed. 2004). Sepsis can result in lung, liver, and kidney failure, damage to the brain and other organs, and even death. *See id.* at 329-31; *Williams Obstetrics 2005, supra*, at 994-95.

thus were expected to require longer procedures. But the intact procedures performed on the later-term women took no longer than the non-intact procedures performed on the earlier-term women—that suggests that all things being equal, intact D&Es are quicker. *See* Stephen T. Chasen et al., *Dilation and Evacuation at ≥ 20 Weeks: Comparison of Operative Techniques*, 190 Am. J. Obstetrics & Gynecology 1180, 1180-03 (2004). The shorter the procedure lasts, the less the blood loss, trauma, exposure to anesthesia, and risk of serious complications.

B. Intact D&E Is Safest For Women With Certain Conditions.

Intact removal offers particularly significant benefits for women suffering from certain medical conditions that make the potential complications of non-intact D&E especially grave. Hemorrhage, infection, and prolonged surgical intervention present particular risks for women with chronic medical conditions such as bleeding disorders, heart disease, or compromised immune-systems. The intact variant is also significantly safer for women with certain pregnancy-related conditions.

1. Intact D&E is Safest for Women with Placenta Previa and Accreta.

For some women with placenta previa, the intact variant minimizes the chance of hemorrhage. In this condition, the placenta partially or entirely covers the cervical opening, creating a risk of excessive bleeding when the cervix is dilated. *See Emergency Medicine: Concepts and Clinical Practice* 2377 (Peter Rosen et al. eds., 1998); *Williams Obstetrics 2005*, *supra*, at 819-820. Bleeding occurs when the placenta separates from the cervix and the uterine wall, and the bleeding cannot be controlled until after the uterus is emptied. While a

woman with placenta previa will begin to bleed in any D&E procedure when the cervix is dilated, causing the placenta to begin to separate, intact removal minimizes the risk of excessive bleeding and hemorrhage by reducing instrumentation and manipulation near the bleeding placenta. *See Carhart* J.A. 523 (Broekhuizen Trial Test.); *PPFA* J.A. 266-267 (same); *Carhart* J.A. 888 (Westhoff Trial Test.). In addition, because the intact variant can be performed more quickly than the non-intact technique, the bleeding can be controlled sooner and the risk of excessive bleeding is lower. Induction is absolutely contraindicated in cases of placenta previa because the lengthy process of the labor and delivery would result in life-threatening hemorrhage.

The intact variant may also be safest for women suffering from placenta accreta. Women with placenta accreta, which occurs when the placenta abnormally invades the wall of the uterus, may benefit from a procedure that minimizes the use of instruments in the uterine cavity. Such a procedure is less likely to disrupt the placenta and cause life-threatening hemorrhage. *See PPFA* J.A. 511-514 (Chasen Trial Test.).

2. Intact D&E is Safest for Women with Chorioamnionitis.

Intact D&E reduces the risk of harm to a patient with chorioamnionitis, a bacterial infection of the fetal membranes. The infection spreads rapidly to the fetus, placenta, and uterine wall, and eventually spreads to other pelvic organs, resulting in peritonitis and sepsis.

Even in the early stages of this condition, antibiotics cannot effectively treat the condition unless the uterus is also emptied of the pregnancy tissue. Thus, because it allows the physician to remove the fetus more quickly, the intact variant allows physicians to treat the infection

earlier and prevent its spread. The intact variant's lower risk of uterine perforation likewise helps prevent the infection from spreading beyond the uterus. Indeed, intact removal is also preferable if the woman has other infections because, as ACOG's Dr. Cain testified, "any increase in instrumentation might increase the ability of the bacteria to enter the blood stream." *Carhart* J.A. 507; *PPFA* J.A.1110.

These advantages were recognized even by one of the Government's experts. Dr. Lockwood testified that intact D&E might be advantageous for women with chorioamnionitis because the infection may have thinned or damaged the uterus. See *Carhart* J.A. 424-25. Other witnesses agreed that in those circumstances, "an intact D&E would be the optimal way to empty the uterus," because it decreases the risk of cervical laceration and hemorrhage, which are among the most common complications of D&E. *Carhart* J.A. 711-13 (Frederiksen Trial Test.); *see also id.* at 768, 770-71 (Hammond Trial Test.); *id.* at 124-25 (Vibhakar Trial Test.) (induction abortion is contraindicated for a woman with chorioamnionitis).

3. Intact D&E is Safest for Women with Certain Fetal Abnormalities.

Intact D&E may also be the safest procedure for a woman whose fetus has certain abnormalities—such as severe hydrocephalus, a greatly enlarged head—that make extraction difficult. The intact variant allows a doctor to reduce the size of the abnormally large head before it passes through the cervix—thereby reducing the risk of injury to the cervix. *See Carhart* J.A. 595 (Chasen Trial Test.). As recognized by the AMA task force—whose members included the Government's expert Dr. Sprang—intact D&E may be preferred "when the fetus has been diagnosed with hydrocephaly or other anomalies

incompatible with life outside the womb." *PPFA* J.A. 670-671 (Sprang Trial Test.).

C. The Safety Benefits of Intact D&E Are Significant.

The Government repeatedly and incorrectly asserts that the medical benefits of D&E involving intact removal are insignificant, and thus that the risks imposed by banning such procedures are "marginal." *See Carhart* Pet'r Br. iv, 10, 14, 37, 39, 40, 42; *PPFA* Pet'r Br. 10, 24, 27-29. This argument misunderstands how doctors evaluate risk. It is a significant safety advantage where a procedure reduces the risk of a potentially catastrophic complication. And a ban on that procedure correspondingly places patients at significant risk by depriving them of the treatment that is most likely to help them avoid a tragic outcome.

Likewise, though complications from the non-intact variant are (fortunately) rare, the Government "cannot prohibit a person from obtaining treatment simply by pointing out that most people do not need it." *Stenberg v. Carhart*, 530 U.S. 914, 934 (2000). Denying women access to a procedure that could reduce those infrequent disastrous outcomes—especially women faced with the medical conditions described above—subjects them to real increased risk of serious harm.

It is thus medically incorrect to dismiss, as the Government does, the safety advantages of the banned procedures as "marginal."

II. A MEDICAL CONSENSUS RECOGNIZES THAT INTACT D&E OFFERS HEALTH BENEFITS.

The safety advantages of intact D&E are widely recognized—in medical texts, peer-reviewed studies, clinical practice, and even by some of the Government's own witnesses. This broad collection of medical authority contradicts the Government's claim that only a "minority of medical professionals" recognize that a ban on intact D&E would subject women to significant health risks. *Carhart* Pet'r Br. 9; *PPFA* Pet'r Br. 10. These safety advantages are even more widely accepted today than they were six years ago, when this Court decided *Stenberg*. And they were apparent in the record that Congress considered in passing the Act.

A. Authoritative Texts and Peer-Reviewed Articles

The intact variant and its safety advantages are recognized in authoritative medical texts and articles in peer-reviewed journals. A leading textbook on abortion methods describes the intact variant and suggests that it is safer because it reduces the need for insertion of instruments into the uterus. *See Clinician's Guide*, *supra*, at 136-37; *see also* Phillip G. Stubblefield, *First and Second Trimester Abortion*, *in Gynecologic, Obstetric, and Related Surgery* 1033, 1043 (David H. Nichols & Daniel L. Clarke-Pearson eds., 2d ed. 2000) (confirming that intact D&E is a recognized variant of D&E). The year after this Court decided *Stenberg*, *Williams Obstetrics*, another authoritative text in the field, recognized that the intact D&E is a variant of the D&E procedure. *See Williams Obstetrics* 871 (F. Gary Cunningham et al. eds., 21st ed. 2001). In 2005, *Williams Obstetrics* observed that the intact variant "facilitates extraction and minimizes uterine or cervical

injury from instruments or fetal bones." *Williams Obstetrics 2005*, *supra*, at 243.

Articles in leading, peer-reviewed medical journals also describe the intact variant of D&E and confirm the benefits of this "further evolution" of the D&E technique. Stubblefield et al., *supra*, at 179. For instance, a peer-reviewed study published in 2004 by Dr. Stephen T. Chasen of Cornell University suggests that intact D&E is safer than its alternatives. Dr. Chasen compared women who underwent non-intact procedures with those who underwent relatively intact procedures. *See* Chasen et al, *supra*, at 1181. Though the overall complication rates in the two groups were comparable, all of the serious complications were suffered by women who underwent the non-intact variant. *See id.* at 1182.

Moreover, the patients in the intact group had been pregnant longer. *See id.* at 1183. As the Government's Dr. Lockwood testified, the patients with longer pregnancies would have been expected to suffer higher rates of more serious complications. *See Carhart* J.A. 435, 440. That the women in the intact D&E group did not suffer such higher rates of more serious complications suggests that the intact procedures were at least as safe as, and likely safer than, the non-intact alternative.

B. Medical Schools

Since this Court decided *Stenberg*, even more leading medical schools have started to teach the intact method of D&E. Among the schools that now teach the intact variant are Columbia, Cornell, Yale, New York University, Northwestern, University of Pittsburgh, University of Pennsylvania, University of Rochester, and University of Chicago. This evidence flatly contradicts Congress's finding that "no medical schools . . . provide

instruction" in D&E with intact removal. *Carhart* Pet. App. 595a (Act § 2(14)(B)).

Even the Government's expert, Dr. Lockwood, testified that he intended to establish a program that would teach intact D&E at Yale, where he chairs the Department of Obstetrics and Gynecology. *See Carhart* J.A. 406-07 (Lockwood Trial Test.). Yale now teaches the intact variant.

C. Medical Associations

The intact variant's safety advantages are also recognized by leading medical associations. ACOG's own position on the intact variant, as reflected in its 1997 Statement of Policy, reaffirmed most recently in July 2004, belies the Government's claim that only a small minority of physicians assert the safety advantages of intact removal in a D&E. ACOG, which represents more than 90% of all board-certified obstetricians and gynecologists practicing in the United States, has concluded that intact D&E "[m]ay be the best or most appropriate procedure to save the life or preserve the health of a woman." *Carhart* J.A. 976 (1997 ACOG Statement of Policy).[5]

That ACOG "could identify no circumstances under which this procedure . . . would be the *only* option to save the life or preserve the health of the woman," *see id.* at 975-976 (emphasis in original), is in no way inconsistent with the proposition that intact D&E may be medically necessary in some cases to avoid significant risks to the

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[5] *See also Partial-Birth Abortion Ban Act of 2003: Hearing on H.R. 760 Before the House Subcomm. on the Constitution of the Comm. on the Judiciary*, 108th Cong. 197 (2003) (2002 ACOG statement) ("there are circumstances under which intact D&X would be the most appropriate and safest procedure to save the life or health of a woman").

woman. While other abortion techniques may be available to terminate a particular woman's pregnancy, the intact variant may be the *safest* method for that woman.

Other leading medical associations agree. The American Medical Women's Association has concluded that D&E with intact removal is "in some circumstances . . . the safest and most appropriate alternative available to save the life and health of the woman." *See Partial-Birth Abortion Ban Act of 2003: Hearing on H.R. 760 Before the House Subcomm. on the Constitution of the Comm. on the Judiciary*, 108th Cong. 201 (2003) ("*2003 Hearing*"). The American Public Health Association takes a similar position. *See* 149 Cong. Rec. S12931 (daily ed. Oct. 21, 2003) (statement of Sen. Boxer).

D. Congress's "Findings" Are Contradicted by Its Own Record and the Medical Evidence.

Despite this medical consensus and the inclusion of intact D&E within mainstream care, the Government argues that this Court must defer to Congress's "findings" that intact D&E is never medically necessary. After reviewing the medical evidence before Congress, ACOG agrees with the District Court in *Carhart* that "the congressional record disproves the Congressional Findings." *Carhart* Pet. App. 464a.

Congress claimed that the procedure is disfavored "particularly among physicians who routinely perform other abortion procedures." *Id.* at 590a (Act §2(2)). Precisely the opposite was true: The National Abortion Federation, Planned Parenthood, and ten physicians with recent surgical-abortion experience all described the safety advantages of an intact approach to D&E. For example, Dr. Anne R. Davis stated that "there is no

question that intact D&E is a safe abortion procedure that may well be the safest procedure for some women in certain circumstances." 2003 Hearings, *supra*, at 191-195. Dr. J. Courtland Robinson stated that "sometimes it is necessary to deliver the fetus intact to perform the safest method of abortion." *Carhart* Pet. App. 69a. And Dr. Samuel Edwin stated that intact D&E "is the safest option for many women faced with medical emergencies during pregnancy," 141 Cong. Rec. S18192 (daily ed. Dec. 7, 1995) (statement of Sen. Levin). A chorus of other doctors echoed these statements.

Also squarely contradicted is Congress's finding that the intact variant actually harmed the health of women. Even the Government's experts conceded that there was no evidence to support Congress's finding that the intact variant increased the risk of "uterine rupture, abruption, amniotic fluid embolus, and trauma to the uterus." *See, e.g.*, *PPFA* J.A. 727 (Shadigian Trial Test.); *id.* at 781 (Cook Trial Test.).

The medical evidence also fails to support Congress's finding that intact D&E increases a woman's risk of cervical incompetence, which can cause pre-term birth in subsequent pregnancies. *See Carhart* Pet. App. 594a-95a (Act § 2(14)(A)). Two different studies have found that dilation in a non-intact D&E procedure is not associated with cervical incompetence. *See* Kalish et al., *Impact of Mid-Trimester Dilation and Evacuation on Subsequent Pregnancy Outcome*, 187 Am. J. Obstetrics & Gynecology 882 (2002); Schneider et al., *Abortion at 18-22 Weeks by Laminaria Dilation and Evacuation*, 88 Obstetrics & Gynecology 412 (1996). The dilation protocol is the same for both intact and non-intact procedures. Moreover, Dr. Chasen's follow-up study in 2005 concluded that, contrary to the findings of Congress and the testimony of some of the Government's witnesses, those who received intact D&E did not suffer higher rates of spontaneous, preterm

birth in future pregnancies. *See* Stephen T. Chasen et al., *Obstetric Outcomes After Surgical Abortion at ≥ 20 weeks' gestation*, 193 Am. J. Obstetrics & Gynecology 1161, 1163 (2005).

The Government's own witness perhaps best sums up the reliability of the congressional findings. Dr. Watson A. Bowes, Jr., who supports the ban and has never opposed any abortion restriction, testified at trial that had anyone in Congress sought his opinion, he would have advised Congress that the findings were inaccurate. *See PPFA* Pet. App. 195a. As Dr. Bowes stated, Congress's findings "cannot be supported by evidence-based medicine." CA8 App. 285.

III. THE ACT WILL CHILL DOCTORS FROM PROVIDING SECOND-TRIMESTER ABORTIONS.

Because the Act is both vague and broad, it will chill doctors from providing a wide range of procedures used to perform induced abortions or to treat cases of miscarriage. This chill will extend well beyond those procedures that the Act purports to target.

First, the terms of the Act are ambiguous and foreign to the actual practice of medicine. As Dr. Carolyn Westhoff of Columbia testified at trial in *National Abortion Federation v. Ashcroft*,[6] another lawsuit challenging the constitutionality of the Act, "it's really difficult for me to tell when I am actually doing a case exactly whether I would be violating the ban." S.A. 11a. Confirming the validity of Dr. Westhoff's concerns, the Government's expert Dr. Lockwood conceded that before

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[6] 330 F. Supp. 2d 436 (S.D.N.Y. 2004), *aff'd*, 437 F.3d 278 (2d Cir. 2006).

speaking to "counsel for the government, [he] believed that the Act's language was so imprecise that it just doesn't prohibit intact D&Es but also threatens all abortions." *Id.* at 12a.

For one, "partial-birth abortion" is not a medical term: neither medical textbooks nor physicians use the term to define any particular procedure. *See 2003 Hearing*, *supra*, at 1. The Act exacerbates this problem by defining "partial-birth abortion" with terms that are themselves confusing. "Overt act," for example, could describe many of the steps that physicians take in any D&E or induction, such as severing the umbilical cord, separating a fetal part from the remainder, or compressing a part of the fetus that cannot otherwise pass through the cervix.

Moreover, though the Government asserts that the Act targets intact D&Es, the word "intact" does not appear in the Act. Remarkably, the Government has defended that omission on the grounds that including the word "intact" would create an "obvious loophole." S.A. 7a. Physicians cannot confidently treat their patients given these mixed signals.

This confusion is amplified by discrepancies between the Act's "Findings" and its operative language. For example, the Findings state that in a so-called partial-birth abortion, the physician "deliver[s] all but the head out of the womb." *Carhart* Pet. App. 597a (Act § 2(14)(J)). But to trigger the ban, the physician need deliver from the womb only "any part of the fetal trunk past the navel." *Id.* at 599a (Act § 3(a)). The Findings also refer to "converting" the fetus to a "breech position"; state that "labor is induced"; and describe "the doctor blindly forcing a sharp instrument into the base of the" fetal skull. *Id.* at 594a, 596a (Act § 2(14)(A) & (H)). But the ban includes no such elements, or anything like them. *See id.* at 599a

(Act § 3(a)). As one doctor explained, "I don't know if what is banned necessitates that I do those actions listed in the findings or not." S.A. 10a.

Second, the Act's scienter requirements only compound its vagueness. For example, the Act purports to target only procedures in which the physician delivers a certain portion of the fetus "for the purpose of performing an overt act the [physician] knows will kill the . . . fetus." *Carhart* Pet. App. 599a (Act § 3(a)). But the state-of-mind identified in the Act is not limited to intact D&Es. To the contrary, a physician begins a D&E with the intent of removing the fetus as intact as possible—but does not know whether intact removal will be possible or when fetal demise will occur.

Similarly, a physician begins every D&E intending to perform acts necessary to evacuate the uterus in a way that is safe for the woman. The physician also knows that such acts, which include cutting the umbilical cord or dismembering or compressing a fetal part, will result in fetal demise. Thus, in any D&E or induction procedure where part of the fetal trunk past the navel is outside the uterus, the physician will commit an "overt act" if necessary to complete the safe evacuation of the uterus.

As a result of these ambiguities, the Government's expert Dr. Lockwood testified that the Act could well be construed to "outlaw all D&Es." CA8 App. 489.[7] Even the Government essentially concedes that any D&E procedure might be covered by the Act. *Carhart* Pet'r. Br. 47 ("Where . . . a physician delivers . . . any part of the trunk past the navel . . . and then performs a discrete act that aborts the fetus, the procedure constitutes a 'partial-

[7] Another Government witness, Dr. Cook, recognized that Congress could have more narrowly tailored the Act to reach only intact D&E procedures. *See Carhart* Pet. App. 515a; CA8 App. 419-20.

birth abortion,' in the literal sense of the phrase, rather than a [non-intact D&E] regardless of whether the ultimate lethal act is . . . dismemberment.").

Indeed. when beginning any D&E, the physician knows that the safest way to proceed may well be to perform each of the steps in the Act's definition. *See Carhart* J.A. 52-53 (Doe Trial Test.), *id.* at 143 (Vibhakar Trial Test.), *id.* at 205-208 (Knorr Trial Test.). In every D&E and induction abortion, the physician "deliberately and intentionally" extracts the fetus from the uterus through the vaginal canal. *See Carhart* J.A. 108-09 (Fitzhugh Trial Test.). Likewise, the first time the physician inserts instruments into the woman's body, grasps part of the fetus, and withdraws the instrument, the physician may remove the fetus until part of the fetal trunk past the navel is outside the woman's body. Or, on the first pass with instruments, the physician may disjoin a leg from the rest of the fetus, and then, on the second pass, remove the fetus until part of the fetal trunk past the navel is outside the woman's body. In either of the previous two scenarios, these steps may occur—for a "living fetus" need not be intact. *See id.* at 109-11; *Carhart* Pet. App. 517a. Finally, in either scenario, if the remainder of the fetus within the uterus obstructs continued extraction, the physician would commit an "overt act," such as disjoining the part of the fetus outside the uterus, or compressing the fetal part that is obstructing delivery. In either scenario, that may occur before fetal demise.

The Act could also extend to inductions. For example, sometimes during an induction, the fetus is not fully expelled within a reasonable time, or the woman develops health complications (including hemorrhage and infection) before the procedure can be completed. In these situations, the physician must complete the fetal evacuation using instruments, and may violate the Act for

all the same reasons that a physician might violate the Act while performing a D&E. *See* Carhart J.A. 467-468 (Lockwood Trial Test.). In other instances, such as when the fetus has severe hydrocephalus, the fetal head is too large to pass through the woman's cervix. In this circumstance, the physician must reduce the size of the head to extract the fetus, and thus must perform an "overt act" that may kill the fetus. *See Carhart* J.A. 110-111 (Fitzhugh Trial Test.). One Government witness acknowledged that a doctor in that situation would face "the possibility of being charged." CA8 App. 363 (Sprang Trial Test.).

The Act's chilling effect is manifest. As Drs. Michael Greene and Jeffrey Ecker explained soon after the passage of the Act, physicians who performed non-intact D&Es feared "that the wording of the current bill is sufficiently imprecise that the procedures they are now doing could be construed to meet the criteria of the banned procedure." Michael Greene & Jeffrey Ecker, *Abortion, Health and the Law*, New Eng. J. Med. 350:2, Jan. 8, 2004, at 178. Dr. Paul Blumenthal similarly warned:

> None of my colleagues know or could state whether the abortion procedures they now perform are covered under this law. Indeed, as I read the definition of the banned procedures, any of the safest, most common abortion methods used throughout the second-trimester of pregnancy could proceed in such a manner as to be outlawed.

Paul Blumenthal, *The Federal Ban on So-Called "Partial-Birth Abortion" is a Dangerous Intrusion into Medical Practice*, Medscape Gen. Med., June 25, 2003, http://www.medscape.com/viewarticle/457581.

To so chill the provision of the only safe options for second-trimester abortion—D&E and induction—places an "undue burden" on the right to reproductive choice. It also gravely endangers the health of women in this country.

IV. THE ACT WILL HINDER IMPROVEMENTS IN PATIENT SAFETY.

The Act also stifles physicians' ability to develop and vary techniques to increase safety for women. Such exploration and variation of known techniques led to the most common, safest abortion methods used today. *See Carhart* J.A. 163-164 (Howell Trial Test.). This Court has long recognized that "present medical knowledge" changes, *see City of Akron v. Akron Ctr. for Reprod. Health, Inc.*, 462 U.S. 416, 437 (1983), and that bans on abortion methods threaten to stymie medical advancement. Thus, in *Planned Parenthood v. Danforth*, the Court invalidated a broad ban on saline instillation because, among other things, the statute threatened to preclude "methods that may be developed in the future and that may prove highly effective and completely safe." 428 U.S. 52, 78 (1976). The Act at issue here also interferes with medical evolution and thus violates a guiding principle of this Court's prior abortion rulings.

For instance, physicians developed the vacuum-aspiration procedure as a safer alternative to dilatation and curettage ("D&C"), which was slower, less thorough, and caused more complications. *See* Pak Chung Ho, *Termination of Pregnancy Between 9 and 14 Weeks, in Modern Methods of Inducing Abortion* 54, 56-57 (David T. Baird et al. eds., 1995). Although vacuum aspiration had been described in medical literature for over a hundred years, it was not until abortion was legalized nationwide in 1973 that physicians were able to develop and perfect these techniques. *See Clinician's Guide*, *supra*, at 5-6,

107-08. Vacuum aspiration is now by far the most common method of first-trimester abortion. *See id.* It is also incredibly safe.

Later, the D&E procedure was developed when physicians experimented with ways to extend first-trimester surgical techniques to the second trimester. Physicians did so in the 1970s and 1980s, seeking an option safer than induction abortions, which were then the only method of second-trimester abortion short of abdominal surgery. In addition to requiring hospitalization, often over days, the induction method known at the time did not work before 16 weeks LMP. This meant that any woman past 12 weeks LMP had to wait—up to four weeks—until an induction was feasible. *See* Eugene Glick, *Surgical Abortion* 46-48 (1998).

Today, D&Es account for 95% of second-trimester abortions, and D&Es have essentially eclipsed inductions. Most of the credit for the rapid improvement in D&E techniques belongs to physicians who, over the years, have tested slightly varying techniques and have shared their discoveries with their colleagues. *See id.* And as this Court has recognized, the development of D&E was ultimately responsible for the remarkable improvements in the safety of post-first-trimester abortion that have occurred since *Roe*. *See Akron*, 462 U.S. at 435-37. One of the reasons D&E safety has itself improved so markedly is that physicians continue to innovate, using slightly varying techniques, and have taught the improved techniques to colleagues. *See, e.g.*, Glick, *supra*, at 47.

The growing prevalence of intact D&Es represents the continued evolution of the longstanding D&E method. Physicians have long recognized the safety advantages of minimizing the number of times they insert instruments into the patient's body, and physicians have long known

that intact extraction sometimes occurs. Through the intact variation, physicians simply try to increase the likelihood that this will occur for any given procedure, and they do this for one reason and one reason only: to minimize medical risk for their patients. *See Clinician's Guide*, *supra*, at 136.

If physicians are permitted to perform and improve the variant through clinical experience, these improvements may further advance medical knowledge and make abortion safer. If allowed to stand, the Act would stifle clinical progress, prevent further, peer-reviewed study of intact D&E, and cause immeasurable loss to women and their families.

CONCLUSION

For the preceding reasons, the judgments of the Courts of Appeals should be affirmed.

Respectfully submitted,

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APPENDIX

UNITED STATES DISTRICT COURT, D. NEBRASKA

LEROY CARHRAT, M.D., WILLIAM G. FITZHUGH, M.D., WILLIAM H. KNORR, M.D., AND JILL L. VIBHAKAR, M.D., *Plaintiffs*,

v.

JOHN ASHCROFT, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE UNITED STATES, *Defendant*.

No. 4:03CV3385.

November 4, 2003.

Defendant's Opposition to Plaintiffs' Motion for a Temporary Restraining Order

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[EXCERPT]

a) The Partial-Birth Abortion Procedure is Plainly Distinct from the Dilation and Evacuation Method of Abortions.

Plaintiffs present a series of assertions that deliberately intermix the terms of the Act, such as "living" fetus, "outside" the mother, and "overt act" to kill in an effort to demonstrate that the terms, individually and taken together, are confusing and could encompass procedures undertaken during a D&E or induction. They state that "[d]uring the course of all D&Es, all of the products of conception will be drawn or expelled through the cervical os and 'outside the body' of the woman." Pls' TRO Mem. at 12. They also state that, "during the course of" a D&E or induction, several routine steps may cause fetal demise- such as rupturing the amniotic sac, dismembering part of the fetus, compressing or making an incision in the skull- but that "there is no way to know the precise cause or timing of fetal demise." *Id.* at 19; *see also id.* at 34 ("during the course of" a D&E or induction abortion, different steps may cause fetal demise "but not immediately").

What such assertions overlook is (i) the definition of partial birth abortion in the Act is structured and worded to encompass a specific procedure performed sequentially and after the fetal head or torso is already outside the body of the mother and (ii) the D&E method of abortion has been repeatedly characterized as an internal dismemberment procedure and readily distinguished from the D&X procedure on which Congress focused. Read as the statute is plainly written, and viewed in the light of established descriptions of D&E, plaintiffs' vagueness claim should be rejected.

First, a partial-birth abortion under the Act requires a specific time and place for the killing of the fetus- in the middle of "delivery" and outside the body of the mother. The Act narrowly and specifically defines a partial delivery as one in which the provider

> (A) deliberately and intentionally vaginally delivers a living fetus until, in

> the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother, for the purpose of performing an overt act that the person knows will kill the partially delivered living fetus; and
>
> (B) performs the overt act, other than completion of delivery, that kills the partially delivered living fetus . . .

Act, § 3 (to be codified at 18 U.S.C. § 1531 (b)(1)(A), (B)) (emphasis added). Congressional findings in support of the Act likewise describe a partial-birth abortion as

> an abortion in which a physician deliberately and intentionally vaginally delivers a living, unborn child's body until either the entire baby's head is outside the body of the mother, or any part of the baby's trunk past the navel is outside the mother and only the head remains inside the womb, for the purpose of performing an overt act (usually the puncturing of the back of the child's skull and removing the baby's brains) that the person knows will kill the partially delivered infant, performs this act, and then completes delivery of the dead infant . . .

Act, § 2(1). The intentional- and sequential- nature of the partial-birth abortion procedure is apparent. First, the physician must deliberately and intentionally partially deliver a living fetus. Second, the delivery is then stopped mid-course. Third, before delivery is completed, the living fetus, which is now largely outside the mother, is then

killed by a separate overt act (usually the removal of cranial matter). Finally, the delivery of the fetus is completed. Moreover, the living fetus must be delivered to a certain anatomical extent outside the body of the mother before it is killed – either its head must be outside the body of the mother, or, in the breech position, the fetus must be removed to a precise anatomical point, the navel.

What plaintiffs have done is taken elements of the definition, such as "living fetus," "outside" the body, and "overt act" to kill and argued that, where these elements exist in other procedures, that method of abortion may be banned by the Act. The fact that, during the course of a D&E or induction, the "products of conception" are removed to a point "outside the mother," or some "overt act" is taken to kill a living fetus, or that the fetus may show signs of life thereafter outside the body, does not render D&E or induction a banned procedure. Under the Act, the specific act to kill the fetus must happen at a particular point and place in time: after the fetus is intentionally delivered outside the mother for the purpose of then inflicting a separate act to kill. The concern that a physician would not know the "precise time" of fetal demise during a D&E, or that a dismembered fetus has a heartbeat after a D&E, is irrelevant. The relevant question is whether a separate act to kill a was inflicted after it was removed from the mother to a specific anatomical point.

Beyond this, the D&E method of abortion has been repeatedly characterized by medical experts on both sides of the debate as an internal dismemberment procedure. Dr. Haskell, who authored the monograph that first alerted Congress and the American public to the use of the partial-birth abortion procedure, distinguished his procedure from "classic D&E in that it does not rely upon dismemberment to remove the fetus . . . . Rather, the surgeon grasps and removes a nearly intact fetus through

an adequately dilated cervix." HJC 7/9/02 at 127. Dr. Carhart testified in *Stenberg* that the D&E procedure requires the doctor to use instruments to grasp a portion (such as a foot or hand) and use the traction created by the opening between the uterus and vagina to dismember the fetus, tearing the grasped portion away from the remainder of the body. *Stenberg*, 530 U.S. at 925-26. Dr. Carhart further testified that, during a D&E, "dismemberment occurs between the traction of . . . my instrument and the counter-traction of the internal os of the cervix . . ." *Id.* At the conclusion of a D&E abortion, Dr. Carhart described the fetus as reduced to "a tray full of pieces." *Id.* at 959.

Indeed, the problem found by the Supreme Court with the definition of the procedure invalidated in *Stenberg* was that it could be construed to encompass vaginal dismemberment of limbs under the D&E procedure. The Nebraska statute held unconstitutional in *Stenberg* prohibited "deliberately and intentionally delivering into the vagina a living unborn child, or a substantial portion thereof, . . . " 530 U.S. at 938 (citing Neb. Rev. Stat. Ann. § 28-326(9)). The Supreme Court concluded that the Nebraska law prohibited D&E abortions because a "D&E will often involve a physician, pulling a 'substantial portion' of a still living fetus, say, an arm or leg, into the vagina prior to the death of the fetus." *Id.* at 939.

The Supreme Court's concerns over the language expressed in *Stenberg* are not implicated here. The language crafted by Congress no longer provides that the procedure is performed inter-vaginally, but on a living fetus that is outside the mother's body. Congress also replaces the language that a "substantial portion" of the fetus is pulled into the vaginal area, with language that the fetus is removed outside the body to at least a specific anatomic landmark – either the "entire fetal head" is outside the mother or, in the breech presentation, any

part of the fetal trunk past the navel. This language is unquestionably much more specific than the language in Stenberg.

For these reasons, various scenarios raised by plaintiffs in which a D&E abortion might fall under the language of the Act, such as because the cervix has prolapsed into alignment with the vaginal introitus, do not render the Act unconstitutionally vague. In light of the clearly structured definition in the Act, and the established description of the D&E procedure, plaintiffs' self-serving and untested affidavits cannot be credited at this initial stage. Unverified assertions about what could happen during a D&E or induction not only confuse the elements of the partial-birth abortion procedure, but miss the key overall point – the Act is intended to prohibit a procedure by which a living fetus is intentionally drawn partially outside the body of the mother for the purpose of killing it in the middle of delivery. Also, "[t]hat there may be marginal cases in which it is difficult to determine the side of the line on which a particular fact situation falls is no sufficient reason to hold the language too ambiguous to define a criminal offense." *Petrillo*, 332 U.S. at 7 (citation omitted). When it is abundantly clear from eight years of legislative history containing substantial medical evidence that Congress intended to prohibit a specific procedure in which a partially-born fetus is killed in the middle of delivery, the existence of some borderline situations does not rise to a level of vagueness that justifies invalidating the Act. *See United States v. Harriss*, 347 U.S. 612, 618 (1954) ("[I]f the general class of offenses to which the statute is directed is plainly within its terms, the statute will not be struck down as vague even though marginal cases could be put where doubts might arise.") (citing *Petrillo*, 332 U.S. at 7).

> The Constitution has erected procedural safeguards to protect against conviction for crime except for violation of laws

> which have clearly defined conduct thereafter to be punished; but the Constitution does not require impossible standards. The language here challenged conveys sufficiently definite warning as to the proscribed conduct when measured by common understanding and practices. The Constitution requires no more.

Petrillo, 332 U.S. at 7.

Finally, plaintiffs' critique the Act for not containing a viability line, not demarcating specific abortion procedures that are not affected, not including the word "intact," or not describing procedures regarding the suctioning of skull contents. *See* Pls' TRO Mem. at 32 n.31. These points are easily addressed. Congress' decision not to legislate these distinctions does not render the Act it did write impermissibly vague. Congress could justifiably find that the precise point of viability may change, and that the destruction of a late term, living fetus outside the womb is just as objectionable, even if the fetus quite near, but not yet past, viability. Also, utilizing the term "intact" in the Act would presents an obvious loophole that would allow the virtually identical procedure to occur where a single fetal toe had been dismembered. Lastly, defining the specific overt act to kill as solely suctioning of brain content again would permit the identical procedure – the killing of a living fetus outside the body and inches from a complete birth – to proceed through some other means of killing. The point of the legislation was to prohibit the destruction of a living fetus inches from an autonomous existence. That Congress chose not to legislate the limitations plaintiffs' cite in no way renders the Act unconstitutionally vague.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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03 Civ. 8695 (RCC)

NATIONAL ABORTION FEDERATION; MARK I. EVANS, M.D.; CAROLYN WESTHOFF, M.D., MSC; CASSING HAMMOND, M.D.; MARK HELLER, M.D.; TIMOTHY R.B. JOHNSON, M.D.; STEPHEN CHASEN, M.D.; GERSON WEISS, M.D., ON BEHALF OF THEMSELVES AND THEIR PATIENTS,

Plaintiffs,

v.

JOHN ASHCROFT, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE U.S., ALONG WITH HIS OFFICERS, AGENTS, SERVANT, EMPLOYEES, AND SUCCESSORS IN OFFICE,

Defendants.

New York, N.Y.
Before:
HON. RICHARD CONWAY CASEY
District Judge

TRIAL TRANSCRIPT EXCERPTS

Cassing Hammond, M.D. (619:5 – 620:9)

Q. Doctor, I am referring back to the first topic you raised as opposed to the second. The second one was your opinion that the ban is broad and vague. The first was that you, I believe, stated that the findings contained different information than the definition that is contained in the Act's ban. Am I understanding your testimony correctly?

A. You are.

Q. Can you explain what you mean by that.

A. There are several things that are discussed in the fmdings that aren't actually included in the ban itself. If you would like, I can identify some of those.

Q. That would be great.

A. If you go back to the beginning of the findings section -- again. this is section 2, findings -- let me look here and make sure I am referring to the right place.

THE COURT: Are you saying, Doctor, that some of these things you are talking about that are effects are not in the ban? Would you expect the effects to be in the ban? I know you are not a lawyer, but isn't it rather obvious?

THE WITNESS: No, I don't think I am talking about effects, your Honor.

THE COURT: You have been through all of those and you have noted those you agree with and disagree with,

but I don't know that your statement makes any sense to me.

THE WITNESS: There is some language that is used to define or describe partial-birth abortion in the findings that doesn't appear in the ban at all. So I don't know if what is banned necessitates that I do those actions listed in the findings or not. They are different. They describe partial-birth abortion in different ways.

Carolyn Westhoff, M.D., MSc. (845:2 – 846:1)

Q. Dr. Westhoff, without enumerating them, have you perceived any differences between language that describes a certain abortion procedures in the findings of the statute and language that appears in the text of the ban in Section 1531(b) (1)?

A. Yes. The ban is more general than the findings.

Q. Mindful of the Court's ruling I'm not going to take you through those differences but instead will ask you this: What impact, if any between those differences, between the text of the ban in Section 1531(b) (1) and the text in the findings, have on your ability as a physician to determine what conduct is prohibited by the ban?

A. The language –

THE COURT: Doesn't your question presume a fact that hasn't been established?

MR. HUT: I said what difficulty if any, your Honor. What impact, if any -- at least I certainly intended to.

THE COURT: All right.
Can you answer that question?

THE WITNESS: Reading the ban, the language is more general and brief than in the findings. And it appears that it could apply to a broader range of D&Es that I perform including D&Es that involve dismemberment because it doesn't say anything about intact. And, therefore, it's really difficult for me to tell when I am actually doing a case exactly whether I would be violating the ban.

Charles Lockwood, M.D. (1877:7 – 1878:18)

Q. In December you found distressing the Act's imposition of penalties on doctors, right?

A. Still do.

Q. You think that the imposition of criminal penalties unravels the physician's social contract with his or her patients, right?

A. Correct.

Q. Because part of that contract is a right of patients to expect doctors to do their very best for them, right?

A. Correct.

Q. You also thought in mid December 2003 that it was entirely unconscionable for Congress to incur civil suits, right?

A. Very much so.

Q. And you still do, right?

A. Very much so.

Q. In December, before you spoke with counsel for the government, you believed that the Act's language was so imprecise that it just doesn't prohibit intact D&E is but also threatens all abortions, right?

A. Correct.

Q. So when you first read the Act as a practicing physician without conferring with government lawyers, you believed it was written in a way that threatened all abortions, right?

A. I wrote what I wrote.

Q. And you did believe that, right?

A. Correct. To be fair to all sides, I had reviewed the expert reports of your plaintiffs, and that may have added to my sense of urgency and concern.

Q. In fact, in your opinion, the wording of the Act is such that you can certainly understand why the plaintiffs' experts opined as they did concerning the Act's threat, right?

A. Correct.

Q. You still agree, don't you, Dr. Lockwood, that if the Act is not interpreted the way you believe appropriate, it is not only vague but worse, right?

A. If it is interpreted in a way that leads to a lack of acces. to pregnancy terminations, that would be a problem.

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 MEDICAL WOMEN'S ASSOCIATION, AMERICAN PUBLIC HEALTH ASSOCIATION, ET AL. IN SUPPORT OF RESPONDENTS

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September 20, 2006

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	iii
INTEREST OF *AMICI CURIAE*	1
SUMMARY OF ARGUMENT	2
ARGUMENT	4
I. INTACT D&E HAS EVOLVED IN A MANNER CONSISTENT WITH OTHER SURGICAL TECHNIQUES AND ITS SAFETY AND HEALTH BENEFITS HAVE BEEN EQUALLY WELL DEMONSTRATED	4
A. Contrary To Congress's Findings, Surgical Techniques Develop Without Reliance On Controlled Trials	4
B. The Evolution Of Intact D&E Comports With The Standards For Safety And Efficacy In Surgical Advancement	12
II. THE HEALTH BENEFITS OF INTACT D&E MANDATE THAT IT BE CONSTITUTIONALLY PROTECTED	18
A. Women's Health Is Primary To, If Not Dispositive Of, The Constitutional Analysis	20
B. Banning An Intact Approach To D&E Denies Women A Potential Health Benefit By Increasing The Health Risks They Face	22
III. ADOPTING THE GOVERNMENT'S POSITION WOULD MARK A SEA CHANGE IN THIS COURT'S ABORTION JURISPRUDENCE	26

TABLE OF CONTENTS—continued

Page

A. This Court Should Reject The Claim That Preventing Abortion Which "Resembles Infanticide" Is A Compelling Interest Sufficiently Strong To Overcome Women's Interest In Access To The Safest Abortion Procedure 26

B. This Court Rightly Has Never Held That A Restriction On Abortion May Survive Even Though It Would Increase Risks To Women 29

CONCLUSION 30

TABLE OF AUTHORITIES

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Page

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INTEREST OF *AMICI CURIAE*

Amici curiae are medical and public health organizations and institutions, as well as individual physicians and academicians who oppose the Partial Birth Abortion Act of 2003 because it jeopardizes women's health by criminalizing safe and effective abortion procedures, and further restricts the study and advancement of such procedures. *Amici* and their members believe that their insight and hands-on experience with the methods by which surgical procedures evolve and surgeons determine whether procedures are safe and beneficial for their patients will assist the Court in construing Congress's findings and the impact of the statute in this case.

Amici include 41 individual physicians, surgeons, medical ethicists, medical historians and the following entities: **American Medical Women's Association** (national organization of 10,000 women physicians, surgeons, and physicians-in-training dedicated to promoting women's health); **American Public Health Association** (oldest, largest, and most diverse organization of public health professionals in the world; has a long standing commitment to reproductive rights and reproductive choice); **Medical Students for Choice** (organization of nearly 10,000 medical students and residents seeking comprehensive medical education including abortion training); **National Family Planning & Reproductive Health Association** (represents clinicians, administrators, researchers, educators, advocates and providers in the family planning field who provide reproductive health care services at nearly 4,500 clinics to more than 5 million women annually); **New York Obstetrical Society** (a 140-year-old regional organization of obstetrician-gynecologists and gynecological surgeons who are leaders in the field of women's health care); **Physicians for Reproductive Choice** (national organization of physicians of various specialties that exists to promote,

educate and advocate about the importance of comprehensive reproductive healthcare and to ensure that all people have the knowledge, access to quality services and freedom to make their own reproductive health decisions); **University of Chicago Hospitals, Department of Obstetrics and Gynecology** (physicians and surgeons, including maternal-fetal medicine specialists, practicing at a top ranked hospital, affiliated with a leading academic institution).[1]

SUMMARY OF ARGUMENT

Through the Partial Birth Abortion Ban Act of 2003 (the "Act"), Pub. L. No. 108-105, 117 Stat. 1201 (codified at 18 U.S.C. § 1531), Congress has attempted to prohibit some of the most common and safest methods of abortion in the second trimester, without providing an exception to preserve a woman's health. Congress attempted to justify this attack on women's health by "finding" that so-called "partial birth abortion" is never medically necessary because "[t]here is no credible medical evidence that partial-birth abortions are safe or are safer than other abortion procedures." *Id.* § 2(14)(B), 117 Stat. at 1204.[2] Congress based that conclusion in substantial part on the fact that no controlled or comparative studies or peer-reviewed articles had demonstrated the safety and efficacy of such procedures. See *id.*; but see Br. *Amicus Curiae*, American College of Obstetricians and Gynecologists 17-18 (collecting peer-reviewed literature on intact D&E).

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[1] Letters of consent have been filed with the Clerk. Pursuant to Rule 37.6, *amici* state that no counsel for a party authored any part of this brief, and no person or entity other than *amici* and their counsel made a monetary contribution to the preparation or submission of this brief.

[2] "[P]artial birth abortion" is not a medical term and does not refer to any procedure. But, since the Government sometimes asserts that it is the same as surgical abortions in which the physician succeeds in removing the fetus intact or largely intact (referred to herein as the intact variation of dilation and evacuation abortion, or "intact D&E"), *amici* address the safety and evolution of intact D&E procedures.

Congress's conclusion is built on a false premise. Controlled or comparative studies are common in the pharmaceutical context, and are certainly a valuable method of evaluating safety and efficacy in medicine in general. However, they have never been the method surgeons have used to determine whether new surgical procedures, or variations on familiar procedures, are safe to employ and provide health benefits to their patients. Surgery, by its nature, does not fit the randomized control trial ("RCT") paradigm. When a new technique is first developed, there is simply no way to create a sufficient number of "trials" to conduct a controlled study. Even after a new surgical technique has reached a level of acceptance in the surgical community, circumstances often continue to preclude such evaluation. However, despite substantial impediments to controlled studies, the level of knowledge and skill in the surgical profession has exploded in the past century because the surgical community has developed a field-specific approach: it engages in widespread communication regarding common problems, theoretical approaches and ultimately practical solutions. When a surgeon finds a technique that represents an improvement over prior techniques, he or she records the results and shares them with others, who then begin to perform the new technique and share their experience.

This is the way numerous now familiar procedures were introduced and evaluated when they were new and untested. The safety and health benefits of intact D&E have been demonstrated in the same manner. Accordingly, as each of the lower courts to have addressed Congress's findings has concluded, "credible medical evidence" does, in fact, exist to show that intact D&E is not only safe and effective, but it is often safer than alternative methods of terminating pregnancy in the second trimester.

When viewed in light of these standards, this Court's longstanding abortion jurisprudence renders the Act

unconstitutional. The Act places women's health in jeopardy. This Court has *never* held that *any* government interest is strong enough to outweigh the combined interest of the state and the woman in her health.

Neither can the Act be saved by the availability of other abortion procedures that the Government claims are "safe enough." This artificial standard of safety is foreign to surgical practice. Surgeons seek to maximize the safety and health benefits for each patient for whom they care. They do not merely conclude that a procedure is "safe enough" and then decline to take further steps or make additional innovations to advance their patients' health interests. Nor would any patient want his or her physician to follow such a minimalist approach. An ongoing effort to reduce patient risk is a paramount obligation for surgeons—an obligation that cannot, consistent with this Court's precedent, be undermined where, as here, it would increase risks to women's health.

ARGUMENT

I. INTACT D&E HAS EVOLVED IN A MANNER CONSISTENT WITH OTHER SURGICAL TECHNIQUES AND ITS SAFETY AND HEALTH BENEFITS HAVE BEEN EQUALLY WELL DEMONSTRATED.

A. Contrary To Congress's Findings, Surgical Techniques Develop Without Reliance On Controlled Trials.

The development of new surgical techniques responds to surgery's unique demands and differs markedly from the way new therapies are developed in other areas of medicine. Initial development of surgical techniques and procedures rarely, if ever, depends on prospective research. Instead it evolves based on practitioner experience, observation and innovation. Surgical advancement commonly occurs when, in the course of performing an existing procedure, a physician

conceives of a way to improve the procedure through modification, tries the new method, and if successful, continues to employ it. See, *e.g.*, *Gonzales* v. *Carhart*, No. 05-380 (U.S.), Pet. App. 397a;[3] Sherwin B. Nuland, *Doctors: The Biography of Medicine* 410 (1988) (describing development of radical mastectomy; the procedure combined "the best features of all previous approaches" and took them one step further).

After a surgeon finds that his or her innovation appears to benefit patients, the surgeon informs others through a variety of means, ranging from formal conference presentations to more informal training sessions for institutional colleagues or communication with other physicians. Other surgeons then attempt the refined procedure, relaying to others word of their experiences with the technique and its safety and efficacy. Through these innovations and adaptations, the procedure evolves to the point that it is either discarded, or surgeons gain sufficient confidence to put it into regular practice and to determine whether it is the best and safest approach for a particular patient. See *e.g.*, Nuland, *supra*, at 410, 448-49 (discussing the spread of knowledge concerning various surgical procedures); *Carhart* Pet. App. 468a (citing William H. Frist & D. Craig Miller, *Repair of Ascending Aortic Aneurisms and Dissections*, 1 J. Cardiac Surg. 33, 45-46 (1986) (describing now-Senator Frist's view that surgeons rely on clinical experience to determine whether a surgical technique is appropriate)). Surgeons who, based on skill and experience, believe that a new surgical approach provides advantages for particular patients will not wait for the results of a large scale controlled study before putting the new approach into practice. *Carhart* Pet. App. 341a.

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[3] Hereafter, *amici* refer to the Petitioner's Appendix in *Gonzales* v. *Carhart* as "*Carhart* Pet. App." and the appendices in *Gonzales* v. *PPFA* as "App." and "Pet. App."

Consistent with this approach to surgical innovation, the first published articles about a surgical innovation are likely to be retrospective and observational. *Id.* For example, a physician might publish outcomes of a particular procedure for one or more patients in a case study or series. In this situation, the physician has not treated patients in conformance with a predetermined study design. Instead, he or she has exercised his or her best clinical judgment at the time of treatment, carefully observed the outcomes, and reported the experience for the benefit of other experts in the field. The case study or series is a common way of sharing early individual experience, especially in the surgical community. Robin S. McLeod, *Issues in Surgical Randomized Controlled Trials*, 23 World J. Surg. 1210, 1213 (1999); Eric K. Fung, et al., *Randomized Controlled Trials for Evaluating Surgical Questions*, 128 Arch. Otolaryagol. Head Neck Surg. 631, 631 (2002); Pet. App. 143a. After treating a larger number of patients with a new surgical approach, a physician might publish a retrospective cohort study based on chart review. This type of study allows the researcher to compare and evaluate outcomes for two groups ("cohorts") of patients based on information contained in their medical charts. Pet. App. 109a.

Only much later—and only if an adequate sample size exists and medical ethics permit—can the modification be subjected to a prospective controlled trial.[4] See Claus Bartels et al., *Cardiopulmonary Bypass: Evidence or Experience Based?*, 124 J. Thorac. Cardiovasc. Surg. 20, 24-25 (2002). In prospective RCT research, patients are randomly assigned to either a group which will receive new treatment, or a

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[4] It would be inappropriate to begin a controlled trial too soon after the introduction of a new surgical procedure. Among other reasons, the new procedure must be in existence long enough to be sufficiently familiar to surgeons so they may enroll an adequate number of participants, and the surgeons must be sufficiently experienced that operator variation can be controlled enough to satisfy scientific norms. McLeod, *supra*, at 1211.