IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

LEROY CARHART, M.D., et al.,	)	
Plaintiffs,	)	
v.	)	No. 4:03CV3385
JOHN ASHCROFT, in his official capacity as Attorney General of the United States,	)	
Defendant.	)	

DEFENDANT'S TRIAL BRIEF

Dated: March 26, 2004

PETER D. KEISLER
Assistant Attorney General, Civil Division

MICHAEL G. HEAVICAN
United States Attorney

PAUL D. BOESHART
Assistant United States Attorney

SHANNEN W. COFFIN
Deputy Assistant Attorney General

ANTHONY J. COPPOLINO
Special Litigation Counsel

TERRY M. HENRY
PREEYA M. NORONHA
ANDREW I. WARDEN
Attorneys
U.S. Department of Justice
P.O. Box 883
Washington, D.C. 20044
(202) 514-4107

Counsel for Defendant

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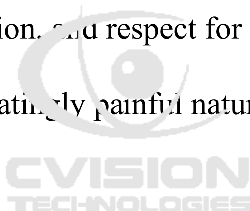
DEFENDANT'S TRIAL BRIEF

INTRODUCTION

As the Court is well aware, this case concerns the constitutionality of the Partial-Birth Abortion Ban Act of 2003, Pub. L. 108-105, § 3(a), 117 Stat. 1201 (to be codified at 18 U.S.C. § 1531) (hereinafter, the "Act"). The Act prohibits a specific late-term abortion procedure which it defines as "partial-birth abortion," but which has also been referred to as "dilation and extraction" ("D&X"), "intact dilation and extraction," or "intact D&E" (intact dilation and evacuation). Congress found on the basis of an extensive record, compiled over many years of legislative hearings and inquiry, that the procedure is not only "gruesome and inhumane," but is never medically necessary to preserve the health of the mother. Act, § 2(1), (2). Indeed, Congress found that the procedure "in fact poses serious risks to the long-term health of women and in some circumstances, their lives." Id., § 2(2). Congress therefore prohibited this procedure in order to promote the health and well-being of pregnant women, the integrity of the medical profession, and respect for infant human life in face of the gruesome, inhumane, and excruciatingly painful nature of the partial-birth abortion procedure. Id., § 2(14)(G)-(N).



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Plaintiffs challenge the Act on two principal grounds. First, they maintain that the Act defines the term "partial-birth abortion" so broadly as to prohibit the dilation and evacuation (D&E) procedure most commonly used to perform abortions during the second trimester of pregnancy, thus unduly burdening a women's ability to choose an abortion. Relatedly, plaintiffs contend that the Act's definition of "partial-birth abortion" is so vague and ambiguous that it deprives physicians of fair warning as to which abortion procedures are prohibited, in violation of the Due Process Clause of the Fifth Amendment. Supplemental Complaint, dated November 14, 2003, ¶¶ 4, 42, 46, 61. Second, plaintiffs contend that the Act unduly burdens a women's right to choose by failing to include an exception where partial-birth abortion, in appropriate medical judgment, is necessary to preserve the health of the mother, or is the most medically appropriate procedure for a particular woman. Id., ¶¶ 3, 21, 49, 52-55, 59(c).

As will be shown at trial, plaintiffs' constitutional challenges to the Act lack merit. Plaintiffs' charges of vagueness and overbreadth are belied by the terms of the Act itself, which bars, and only bars, the deliberate and intentional delivery of a *living* fetus until it is largely *outside* the body of the mother -- either head first, or in breech position to at least the navel -- for the purpose of then committing a separate, deliberate, and overt act to kill the fetus before delivery is completed. By so narrowly and precisely defining the prohibited abortion procedure, the Act avoids the fatal shortcoming of the Nebraska statute invalidated in Stenberg v. Carhart, 530 U.S. 914 (2000), which, unlike the Act, was susceptible of a construction encompassing dismemberment of the fetus prior to delivery outside the woman's body, the dominant characteristic of the D&E procedure. The legislative record before Congress reveals that the

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procedure barred under the Act differs markedly from other common abortion procedures such as D&E, or induction of labor, and the testimony at trial will confirm this to be the case.

Plaintiffs also claim that the Act, like the Nebraska statute in Stenberg, is constitutionally flawed for failure to include an exception for the health of the mother. As will be shown at trial, this contention is factually unfounded. Supreme Court precedent, both prior to and including Stenberg, requires that laws regulating access to abortions contain a maternal health exception only where necessary in appropriate medical judgment. See infra at 7-9. Plaintiffs assert that partial-birth abortion may be necessary in cases involving severe fetal abnormalities, to avoid health risks brought about or exacerbated by pregnancy, or simply where partial-birth abortion, in the physician's judgment, would be the safest and most medically appropriate procedure for a given patient. Supplemental Complaint,¶¶ 13, 21, 30, 32, 49. The expansive record compiled by Congress shows, however, that partial-birth abortion is never needed in cases of fetal anomalies, or maternal complications. Congress' inquiry also revealed a complete lack of credible medical evidence to support the claim that partial-birth abortion represents a safer alternative to accepted abortion procedures. To the contrary, Congress found that partial-birth abortion actually "poses serious risks to a woman's health." See Act §§ 2(2), (13), (14)(A), (B), (O).

Review of the legislative record will show that Congress' findings concerning the lack of any credible medical justification for partial-birth abortion are (at the very least) reasonable, and based on substantial evidence. The expert testimony to be presented at trial will also substantiate Congress' finding that partial-birth abortion is never medically necessary. In addition, the legislative record, and the testimony at trial, will show that Congress also drew reasonable inferences when it concluded that the banned abortion procedure inflicts intense and unnecessary

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pain on unborn infants. Under Turner Broadcasting Sys., Inc. v. FCC, 520 U.S. 180 (1998), and other precedents, those findings are entitled to the respect and deference of this Court. So long as they are reasonably based on substantial evidence, these findings must be accepted by the Court out of due regard for the role of Congress as a co-equal branch of government to which the Constitution assigns responsibility for exercise of the legislative power, and which possesses superior fact-finding capabilities where controversial medical, scientific, and social issues are concerned. When the matter is viewed against the record amassed by Congress, and the evidence this Court will receive at trial, it becomes clear that the Constitution imposed no obligation on Congress to provide for a health exception when banning the unnecessary procedure defined by the Act as partial-birth abortion. Accordingly, plaintiffs' challenge to the Act must fail.

DISCUSSION

I. THE ACT COMPORTS WITH CONSTITUTIONAL REQUIREMENTS.

A. "Partial-Birth Abortion" Is Narrowly and Precisely Defined and Is Distinct from Other Abortion Procedures.

The Act prohibits a physician from "knowingly perform[ing] a partial-birth abortion," defined by the Act as:

> "(A) deliberately and intentionally vaginally deliver[ing] a living fetus until . . . the entire fetal head is outside the [mother's] body" (or, in the case of a breech presentation, until "any part of the fetal trunk past the navel is outside the [mother's] body") for the purpose of performing an "overt act that the [physician] knows will kill the partially delivered living fetus";

and, thereafter,

> "(B) perform[ing] the overt act, other than completion of delivery, that kills" the partially delivered fetus.

Act, § 3 (to be codified at 18 U.S.C. § 1531(a), (b)(1)).

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Plaintiffs characterize the statute's definition of partial-birth abortion as impermissibly vague and overbroad, potentially encompassing other methods of abortion, most notably D&E. Supplemental Complaint, ¶ 42. Defendant has previously shown, however, that the Act cannot be faulted on constitutional grounds as imprecise. Defendant's Opposition to Plaintiffs' Motion for a Temporary Restraining Order, dated November 4, 2003, at 37-47. A vagueness claim is based on the due process concern that a statute or regulation provide fair notice as to what contemplated conduct falls within the scope of a prohibition. See Grayned v. City of Rockford, 408 U.S. 104, 108 (1972). The Court must look to whether a statute or regulation defines an offense "with sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement." Kolender v. Lawson, 461 U.S. 352, 357 (1982). A statute cannot be summarily invalidated as vague, however, simply because it is difficult to determine whether certain imaginable but marginal offenses would fall within its language. See Jordan v. DeGeorge, 341 U.S. 223, 231 (1951); United States v. Petrillo, 332 U.S. 1, 7 (1947). "Statutes should not be declared unconstitutionally vague by speculating about possible hypothetical applications." Planned Parenthood of Minnesota v. State of Minnesota, 910 F.2d 479, 482 (8th Cir. 1990).

The Act allows little room for uncertainty when it comes to describing the abortion procedure that Congress meant to ban. To violate the Act, it is quite apparent that a physician must set out, deliberately and intentionally, to deliver a living fetus intact, to a point where the fetus's head (or, in the case of a breech presentation, the navel) is outside the mother's body. The physician must do so, moreover, for the purpose of killing the fetus by a separate, overt act, other than delivery itself (usually puncturing the back of the child's skull and suctioning out its

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brains). Finally, the physician must then knowingly and intentionally perform that separate and over act, killing the fetus before completing the delivery. Thus, the procedure to which the Act is directed "is plainly within its terms," and the statute cannot be struck down as vague even if "marginal cases could be put where doubts might arise" as to its application. United States v. Harriss, 347 U.S. 612, 618 (1954).

Moreover, as shown by the legislative record, and as trial testimony will confirm, the procedure banned by the Act, whether referred to as partial birth abortion, intact D&E, or D&X, is unmistakably dissimilar to the D&E procedure. Plaintiffs are engaged in an effort to define away the procedure that Congress banned by subsuming it into the "D&E" label. Previously, the D&E procedure has been consistently characterized, by plaintiffs and others, as the surgical dismemberment of the fetus through the introduction of forceps, which the physician uses to grasp and dismember fetal parts. By contrast, the procedure targeted by the Act is designed to be utilized late in the second trimester, when fetal parts are larger, greater dilation is required, and specific steps are taken to attempt to deliver the fetus as intact as possible at least to the head, which is then reduced in size -- either through evacuation of cranial contents or compression with an instrument -- in order to complete delivery. See, e.g., Partial-Birth Abortion Ban Act of 2002: Hearing Before the Subcommittee on the Constitution of the House Committee on the Judiciary, 107th Cong., 2d Sess. 7 (July 9, 2002); Partial-Birth Abortion --The Truth: Hearing on S. 6 and H.R. 929 Before the Subcommittee on the Constitution of the House Committee on the Judiciary and the Senate Committee on the Judiciary, 105th Cong., 1st Sess. 120-124 (Mar. 11, 1997). However labeled, the evidence will show that the procedures are distinct.

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Plaintiffs' arguments that D&E cannot be distinguished from partial-birth abortion are unpersuasive. Plaintiffs take *elements* of the Act's definition and argue that, where some of these elements exist in another procedure, that method of abortion may be banned by the Act. But the fact that, *during the course of* a D&E, 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 unlawful. Under the Act, the specific action taken to kill the fetus must occur at a particular time: after the fetus is intentionally delivered outside the mother *for the purpose of then* performing a separate act to kill. 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 question is whether a separate act to kill was performed *after* the fetus was removed from the mother to a specific anatomical point.

B. The Act May Be Sustained Under Existing Precedent Concerning the Regulation of Abortion.

In Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833 (1992), the Supreme Court reaffirmed that the government "has legitimate interests from the outset of the pregnancy in protecting the health of the woman and the life of the fetus that may become a child." Given these legitimate government interests, not all abortion-related regulations are invalid. Id. at 876. Prior to fetal viability, women have the right to have an abortion "and to obtain it without undue interference" from the government. Id. at 846. The government thus may not, prior to viability, impose an "undue burden" on a woman's decision to terminate her pregnancy; that is, the government may not place "a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus." Id. at 877. After fetal viability, the government "'in promoting its interest in

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the potentiality of human life may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother.'" Id. at 879 (quoting Roe v. Wade, 410 U.S. 113, 164-65 (1973)).

In Stenberg v. Carhart, 530 U.S. 914 (2000), the Supreme Court considered the constitutionality of a Nebraska statute which -- while defining the banned procedure very differently from the federal statute at issue in this case -- sought to regulate the performance of partial-birth abortions. The Court held that, following the framework established in Casey, "the governing standard requires an exception 'where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother,'" but only when "substantial medical authority supports the proposition that banning a particular abortion procedure could endanger women's health." Id. at 931, 938 (citations omitted). Ultimately, because "Nebraska ha[d] not convinced [the Court] that a health exception is never necessary to preserve the health of women," the Court held that the lack of a health exception was fatal to the constitutionality of the Nebraska statute. Id. at 937-38 (internal quotation marks omitted).

The Court's decisions in Casey and Stenberg stand for the proposition that whether a regulation of a particular abortion procedure imposes an undue burden turns on whether the regulation poses a "*significant threat* to the * * * health of a woman." Casey, 505 U.S. at 880 (emphasis added). Accord Women's Medical Professional Corp. v. Taft, 353 F.3d 436, 446 (6th Cir. 2003) ("[t]aken together, Casey and Carhart stand for the proposition that states may restrict an abortion procedure except when the procedure is necessary to prevent a significant health risk."). Indeed, in Casey, the Court expressly rejected the notion that "any regulation touching upon the abortion decision must survive strict scrutiny, to be sustained only if drawn in narrow

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terms to further a compelling state interest," since that formulation could not "be reconciled with the holding in Roe itself that the State has legitimate interests in the health of the woman and in protecting the potential life within her." 505 U.S. at 879. As the Court explained, "[t]he very notion that the State has a substantial interest in potential life leads to the conclusion that not all regulations must be deemed unwarranted." Id. In determining that the Nebraska statute was constitutionally infirm because it lacked a health exception, the Court relied on the "medically related evidentiary circumstances" that were developed in the record of that case. Id. at 932.

In enacting the Partial-Birth Abortion Ban Act of 2003, Congress amassed its own evidentiary record and reached a different conclusion, finding that "partial-birth abortion * * * is a gruesome and inhumane procedure that is never medically necessary and should be prohibited." Act, § 2(1). Congress' findings were "informed by extensive hearings held during the 104th, 105th, 107th, and 108th Congresses," and "reflect the very informed judgment of the Congress that a partial-birth abortion is never medically necessary to preserve the health of a woman, poses serious risks to a woman's health, and lies outside the standard of medical care, and should, therefore be banned." Act, § 2(13); see also id., § 2(1), (2), (14)(O).

Congress also specifically found that "[t]here is no credible medical evidence that partial-birth abortions are safe or are safer than other abortion procedures." Act, § 2(14)(B) (citing, *inter alia*, the lack of studies and articles in peer-reviewed journals demonstrating the procedure's safety compared to other abortion methods). Congress relied on medical opinion that "the relative advantages and disadvantages of the procedure in specific circumstances remain unknown," and that "no consensus [exists] among obstetricians about its use." Act, § 2(14)(C). Congress also concluded that, by late in the second trimester of pregnancy, "unborn infants . . .

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can feel pain when subjected to painful stimuli," and that partial-birth abortion inflicts excruciating pain on the partially delivered infant. Act, § 2(14)(M). This case, therefore, presents a controversy that is distinguishable from that presented in Stenberg, for here, the Court must take account of the specific findings Congress made, the legislative record on which they rest, and the evidence offered at trial -- including findings and information that may run contrary to the record in Stenberg in various respects.

Although the task of interpreting the substantive reaches of the Constitution falls within the domain of the federal courts, the Supreme Court has repeatedly emphasized that when Congress exercises its legislative powers, its conclusions related to the need for legislation, and the factual bases for the laws Congress enacts, fall plainly within its independent, institutional prerogatives. The Judiciary owes "substantial deference" to the findings of its co-equal branch, both "out of respect for [Congress'] authority to exercise the legislative power," and because Congress "is far better equipped than the judiciary to amass and evaluate the vast amounts of data bearing upon legislative questions." Turner Broadcasting Sys., Inc. v. FCC, 520 U.S. 180, 195-96 (1997) ("Turner II") (internal quotation marks and citations omitted).

For these reasons, the Court has stated that, "[i]n reviewing the constitutionality of a statute, . . . [o]ur sole obligation is 'to assure that, in formulating its judgments, Congress has drawn reasonable inferences based on substantial evidence.'" Turner II, 520 U.S. at 195 (quoting Turner Broadcasting Sys., Inc. v. FCC, 512 U.S. 622, 665-66 (1994) ("Turner I")). "The question is not whether Congress, as an objective matter, was correct," but rather "whether the legislative conclusion was reasonable and supported by substantial evidence. . .." Id. at 211. Substantial evidence "does not mean a large or considerable amount of evidence, but rather 'such

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relevant evidence as a reasonable mind might accept as adequate to support a conclusion,'" Pierce v. Underwood, 487 U.S. 552, 565 (1988) (citation omitted), regardless of whether the evidence may be in conflict. Turner II, 520 U.S. at 211.

To ascertain whether a "substantial basis" exists "to support Congress' conclusion[s]," courts "examine first the evidence before Congress and then [any] further evidence presented to the District Court" by the government. Turner II, 520 U.S. at 196. See id. at 204 ("[a]dditional evidence developed on remand supports the reasonableness of Congress' predictive judgment"); id. at 200 (citing the "evidence before Congress, supplemented on remand"). Courts, however, "are not to reweigh the evidence de novo, or to replace Congress' factual predictions with [their] own;" they "are not at liberty to substitute [their] judgment for the reasonable conclusion of a legislative body." Id. at 211-12. "The Constitution gives to Congress the role of weighing conflicting evidence in the legislative process." Id. at 199.

The Court has explained, moreover, that deference to Congress' factual findings is particularly appropriate when the legislation at issue has the indicia of careful lawmaking, such as when Congress studies the issue at length, holds numerous hearings, and makes express legislative findings. See Turner II, 520 U.S. at 199. Congress' factual findings are also due particular deference in cases involving medical and scientific judgments, even in circumstances in which there might be some disagreement in professional opinion. As the Supreme Court has made clear, "[w]hen Congress undertakes to act in areas fraught with medical and scientific uncertainties, legislative options must be especially broad and courts should be cautious not to rewrite legislation, even assuming, arguendo, that judges with more direct exposure to the

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problem might make wiser choices." Marshall v. United States, 414 U.S. 417, 427 (1974); Lambert v. Yellowley, 272 U.S. 581 (1926).

In hearings held over a period of eight years, Congress obtained testimony and other information from highly credentialed and experienced practitioners in the fields of Obstetrics and Gynecology, and Maternal-Fetal Medicine (high-risk obstetrics), among them physicians who will testify before this Court, including Drs. Curtis R. Cook, Watson A. Bowes, and M. LeRoy Sprang. These and other experts testified that, given the alternatives to intact D&E or D&X, partial-birth abortion is never required to preserve the health of the mother, whether a pregnancy must be terminated because of maternal complications, or due to fetal abnormalities. They also testified to the lack of acceptable scientific evidence establishing the procedure's safety, the potential risks of maternal injury, even fatality, as well as future infertility, and the terrible pain the procedure inflicts on the unborn infant before it dies. As defendant will set forth in post-trial briefing, this testimony and information provided substantial evidence to support Congress' findings and conclusions. These findings are accordingly entitled to substantial deference from the Court, and form a compelling basis for legislative action on which the Act must be sustained.

II. THE EVIDENCE AT TRIAL WILL FURTHER SUBSTANTIATE CONGRESS' FINDINGS IN SUPPORT OF THE ACT.

In addition to the abundant medical evidence in the legislative record that supports Congress' findings, defendant intends to offer the testimony of eight medical experts at trial, several of whom, as noted above, provided medical evidence to Congress. "The reasonableness of Congress' conclusion[s] [will also be] borne out by the evidence" these highly experienced and well regarded medical professionals will provide. Turner II, 520 U.S. at 200. Their

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testimony will reinforce, first, that the procedure defined by the Act is of so particular a nature that it cannot be taken to comprise routine dilation and evacuation, or other common abortion procedures; and, second, that Congress' conclusions concerning the medical necessity, safety, and potential risks of partial-birth abortion, as well as its gruesome and inhumane nature, are reasonable and well-grounded in medical fact. Defendant's experts will testify as follows.

1. Dr. George V. Mazariegos. Dr. Mazariegos is a pediatric liver and intestine transplant surgeon at Children's Hospital of Pittsburgh and the Thomas Starzl Transplantation Institute. He also serves as an Associate Professor of Surgery, Anesthesiology, and Critical Care Medicine at the University of Pittsburgh Medical School. He is a Fellow of the American College of Surgeons and a member of the American Society of Transplant Surgeons, the Society of University Surgeons, and the Association for Academic Surgery. He is board-certified in Surgery and Surgical Critical Care. As a result of his 17 years of post-graduate experience as a transplant surgeon, his 10 years' experience teaching surgery and critical care at a major teaching hospital, and the rapidly changing nature of the transplant field, he has expertise in the development of innovative surgical techniques and the commonly accepted procedures for review and assessment of new techniques.

Dr. Mazariegos will testify in connection with the anticipated testimony of plaintiffs' expert, Dr. Howell, that while the *history* of surgery includes many examples of techniques developed through trial-and-error, and individual innovation, *current* practice is moving toward a more scientific approach to the development of new surgical techniques, to ensure optimal patient care and safety. For example, in the mid-1990s the American College of Surgeons adopted guidelines for the development and adoption of innovative surgical procedures that

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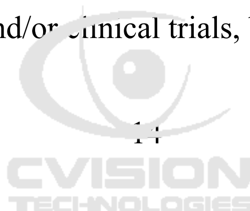
require scientific assessment of a new procedure's safety, efficacy, and need. While clinical trials may be difficult to carry out in the surgical arena, other methods of obtaining objective data and information about the risks and benefits of new surgical procedures, such as monitored observational studies, or retrospective reviews, are both practicable and expected in the current medical environment.

2. Dr. Watson A. Bowes. Dr. Bowes is an Emeritus Professor of Obstetrics and Gynecology in the School of Medicine at the University of North Carolina, where he served as a Professor in the Division of Maternal-Fetal Medicine from 1982 to 1999. From 1969 to 1982 he was a faculty member of the Department of Obstetrics and Gynecology at the University of Colorado Health Sciences Center. In addition to his teaching experience, Dr. Bowes has more than 30 years' experience in the practice of Obstetrics and Gynecology, including the performance of medical and surgical abortions for patients with life-threatening medical conditions. He is board-certified in Obstetrics and Gynecology and Maternal-Fetal Medicine, and is a member of the American College of Obstetricians and Gynecologists. He has published 141 scholarly articles, and currently serves as Editor of the *Obstetrical and Gynecological Survey*. At the request of Representative Charles Canady and Senator Orrin Hatch, he prepared an analysis of the Partial Birth Abortion Act of 1995, which is now part of the legislative record before Congress, and has since followed the issue of partial-birth abortion closely.

Dr. Bowes will principally explain, consistent with the opinions of Dr. Mazariegos, that during the last 15-20 years the medical community has placed an increasing emphasis on evidence-based medicine, requiring the objective evaluation and study of a new procedure, whether through controlled studies and/or clinical trials, before it can be accepted as a safe and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effective medical technique. There are, however, no peer-reviewed studies in the published medical literature evaluating the safety and effectiveness of partial-birth abortion, or its risks and benefits as compared to other procedures for terminating pregnancy after the first trimester. Additionally, there is no valid scientific evidence substantiating the asserted advantages of partial-birth abortion. Dr. Bowes will testify that, in the absence of such evidence, claims that the procedure is superior to alternative procedures for terminating pregnancy do not comport with prevailing standards of evidence-based medicine, and are unfounded.

Dr. Bowes will also testify that, in his opinion, partial-birth abortion is never medically necessary to preserve the health of a pregnant woman, because there are commonly used and safe alternatives to the procedure that are readily available. After 37 years as a treating physician, and 32 years teaching, he is aware of no maternal condition or fetal anomaly that has required, or would require, a partial-birth abortion involving a live fetus to save the life or preserve the health of the mother.

3. Dr. M. LeRoy Sprang. Dr. Sprang is an Associate Clinical Professor of Obstetrics and Gynecology at the Feinberg School of Medicine at Northwestern University in Chicago, Illinois, teaching courses in high-risk obstetrics, and related surgical techniques. He is also a Senior Attending Physician in the Department of Obstetrics and Gynecology at Evanston Northwestern Healthcare, and a Consulting Physician in the Department of Obstetrics and Gynecology at St. Francis Hospital, both located in Evanston, Illinois. He is a Fellow of both the American College of Obstetricians and Gynecologists and the American College of Surgeons. He has been board-certified in Obstetrics and Gynecology since 1977.

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In 1997, Dr. Sprang served on a special committee of the American Medical Association appointed to review the matter of late-term abortions, which issued a report (contained in the legislative record) concluding that no circumstances exist in which partial-birth abortion would be the only safe means to terminate a pregnancy. Dr. Sprang also co-authored an article, "Rationale for Banning Abortions Late in Pregnancy," that was published in the *Journal of the American Medical Association* in August 1998, and which also formed part of the record before Congress when it passed the Act.

Dr. Sprang will testify that the common D&E procedure is readily distinguished from the intact D&E or D&X procedure banned by the Act, in terms of the extent to which the cervix is dilated, and the technique applied for removing the fetus from the uterus. Dr. Sprang will also testify that, in his opinion, the use of intact D&E is never required to preserve the health of a pregnant woman, because it is never the sole procedure available to safely handle maternal health conditions, or fetal conditions, during pregnancy. Moreover, the partial extraction of a living fetus would never be medically necessary, because the physician can always bring about fetal demise before extraction by first injecting the amniotic sac with a chemical agent such as digoxin, injecting the fetal heart with potassium chloride, or simply by cutting the umbilical cord, none of which methods presents any significant risk to the life or health of the mother. Dr. Sprang will also explain that, because fetuses experience acute stress in response to noxious stimuli beginning at approximately 18 weeks' gestation, bringing about fetal demise before partially delivering a fetus, puncturing its skull, and suctioning out its brains, is a step that also spares the unborn infant needless pain and suffering.

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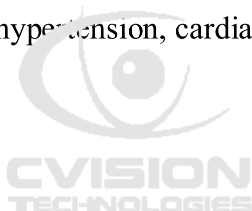
Dr. Sprang will also address the relative safety of partial-birth abortion. He will explain that partial-birth abortion presents several significant risks to the health and future fertility of the pregnant woman. These include the risk of cervical incompetence (a weakening of the cervix that threatens the woman's ability to carry a subsequent pregnancy to term) due to prolonged and excessive dilation of the cervix. Additional risks are presented when the physician instrumentally converts the fetus to a breech position within the uterus in preparation for the procedure. Puncturing the fetus's skull with a sharp instrument, while the skull is still inside the uterus, also presents as yet unquantified risks of lacerating the uterus, and the cervix. Dr. Sprang will testify, in addition, that the purported benefits of intact D&E are unsupported by any studies or other published data establishing the procedure's safety, and do not account for its potential risks. He will also attest to his conclusion that, due to recent medical developments, induction of labor is, in general, the safest method of abortion beyond 20 or 22 weeks' gestation.

4. Dr. Curtis R. Cook. Dr. Cook is a board-certified specialist in Maternal-Fetal Medicine, currently serving as Associate Clinical Professor at the Michigan State University College of Human Medicine, and as Associate Director of Maternal-Fetal Medicine at Butterworth Hospital in Grand Rapids, Michigan. In these capacities, he teaches clinical obstetrics, perinatology, and high-risk obstetrics (including medical and surgical options for managing complications during all stages of pregnancy), and provides clinical care to complicated obstetrical patients referred to him from throughout the State of Michigan. In addition, Dr. Cook maintains a practice in Maternal-Fetal Medicine, providing care exclusively to women with complicated pregnancies, including those suffering from preeclampsia, diabetes, hypertension, cardiac disease, cancer, respiratory ailments, and other disorders, and those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carrying fetuses with suspected abnormalities. His practice involves termination of pregnancy when necessary due to fetal or maternal complications. Dr. Cook testified twice before Congress on medical issues implicated by proposed legislation to ban partial-birth abortion.

Concerning the differences between partial-birth abortion and routine dilation and evacuation (D&E), Dr. Cook will testify that partial-birth abortion is a procedure the physician must deliberately plan to undertake in advance that varies from D&E in significant respects. In particular, the intact D&E or D&X procedure requires additional dilation of the cervix, with the insertion of numerous osmotic dilators well in excess of the number used in D&E.

Dr. Cook will also testify that partial-birth abortion is not medically necessary to preserve the health or future fertility of women undergoing complicated pregnancies. He will recount that never, in more than a decade of providing prenatal care to women with complicated pregnancies, has he ever encountered a situation, or heard of one, where partial-birth abortion has been required, or even considered as clinically superior. While, in his experience, it is sometimes necessary to terminate a pregnancy because of maternal complications, such as a cardiac or renal disorder, or preeclampsia, partial-birth abortion is never necessary because other methods for safely ending pregnancy are readily available. Likewise, in the case of fetal abnormalities, there are alternatives to partial-birth abortion that do not threaten a woman's health or fertility. For example, in the case of hydrocephaly (enlarged head due to intra-cranial fluid), the physician can first drain the excess fluid from the fetal skull (a procedure known as cephalocentesis), and reduce the size of the fetal head to ensure that it does not become entrapped.

Dr. Cook will also address the relative safety of partial-birth abortion. He will explain that partial-birth abortion has never been shown to be medically safer than other abortion

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procedures through the kind of controlled studies that are usually performed before new surgical techniques or advances are accepted as safe and efficacious by the medical community. Indeed, Dr. Cook will testify that, as compared to other abortion techniques (in particular, induction of labor) partial-birth abortion presents a number of risk factors, including an increased potential for uterine injury, bleeding, and infection due to the introduction of surgical instruments to convert the fetus to a feet-first position, and the potential for cervical incompetence as a result of excessive cervical dilation.

5. Dr. Elizabeth Shadigian. Dr. Shadigian is a Clinical Associate Professor of Obstetrics and Gynecology at the University of Michigan Medical Center in Ann Arbor, Michigan, who, in addition to her teaching duties, treats patients with high-risk and complicated pregnancies, performs obstetrical and gynecological surgery, and provides specialty gynecological care. She is board-certified in Obstetrics and Gynecology, and is a Fellow of the American College of Obstetricians and Gynecologists.

Dr. Shadigian will testify to the distinctions between D&E and intact D&E or D&X, and, based on her own experience teaching and practicing at a large medical facility that cares for pregnant women with complex medical problems, and fetal abnormalities, she will attest that it is never medically necessary for physicians to perform partial-birth abortions. She will testify, principally, that even where a pregnancy must be terminated due to maternal or fetal conditions, termination can be safely accomplished through delivery of the fetus by induction, or D&E, methods that are available, studied, and safe.

Concerning the relative safety of the partial-birth abortion procedure, Dr. Shadigian will explain that, based on the available literature, there is no sound basis for concluding that the

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banned procedure is any safer than other abortion methods. Indeed, there are risks associated with the procedure, such as uterine perforation, cervical laceration, and other cervical trauma, that are not presented by a procedure such as induction, which involves no surgery whatsoever. Dr. Shadigian will also explain, like Dr. Sprang, that induction of labor has become more effective, and safer for women, and is now, in fact, the safest method of performing an abortion in the mid- to late-second trimester.

6. Dr. Charles J. Lockwood. Dr. Lockwood is currently Chairman of the Department of Obstetrics, Gynecology, and Reproductive Science at the Yale University School of Medicine. From 1995 to 2002, he was Chairman of Obstetrics and Gynecology at New York University School of Medicine. He is board-certified in both Obstetrics and Gynecology and Maternal-Fetal Medicine. His expertise on matters concerning abortion is based on 10 years' experience overseeing and supervising abortion services at two major teaching hospitals, oversight of residency training programs, and his own practice in Maternal-Fetal Medicine. During his last year at New York University, for example, he oversaw approximately 300 second trimester abortions, approximately 200 of which involved dilation and evacuation (D&E), and 75-100 of which involved intact dilation and extraction (D&X), with potassium chloride injections performed beforehand to terminate the fetus prior to beginning the procedure.

Dr. Lockwood will also testify on the distinct nature of partial-birth abortion, the medical necessity of the procedure, and its relative safety. So far as the first of these issues is concerned, Dr. Lockwood will explain that partial-birth abortion differs from D&E in that the fetus is not removed piecemeal from the uterus by dismemberment, but is removed intact until the fetal head

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is caught on the inner edges of the cervix, at which point the skull is crushed or punctured with surgical instruments and the contents removed.

Regarding medical necessity, Dr. Lockwood will attest that partial-birth abortion is never necessary to preserve the health of a woman after the fetus reaches viability (at approximately 23 weeks' gestation). Prior to viability, there are circumstances relating to the health of the mother that may require termination of pregnancy, including severe preeclampsia, congestive heart failure, certain cancers, or a septic uterus. Dr. Lockwood will testify, however, that he has considered these and other complications of pregnancy that plaintiffs have raised, and, in such cases, a physician would have a number of alternatives from which to choose, including medical induction, and D&E, as well as the option of injecting potassium chloride into the fetal heart, or digoxin into the amniotic sac, to bring about fetal death prior to beginning a D&X procedure.

On the subject of relative safety, Dr. Lockwood will testify that, notwithstanding arguments that intact D&E or D&X is intuitively safer than D&E because it involves fewer instrument passes into the women's uterus, the relative safety of intact D&E or D&X cannot be established without hard data, and, preferably, randomized trials. In addition, while intact D&E or D&X may theoretically reduce risks of uterine perforation as a result of fewer instrument passes, it presents a risk that sharp instruments used to puncture the back of the fetus's head may tear the cervix. Furthermore, Dr. Lockwood will testify that conversion of the fetus to a breech position during intact D&E or D&X may also create risks to the woman of uterine trauma.

7. Dr. Steven L. Clark.[1/] Dr. Clark is a Professor of Obstetrics and Gynecology at the University of Utah School of Medicine. He is board-certified in Obstetrics and Gynecology

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[1/] Dr. Clark's testimony may be presented through trial testimony in another proceeding.

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and in Maternal-Fetal Medicine. In addition to his academic appointments, he maintains an active practice in Maternal-Fetal Medicine, and has developed special expertise, based on 20 years' experience, in critical care obstetrics -- the treatment of women who experience serious and potentially fatal medical conditions and complications during pregnancy. He has also developed expertise in pregnancies involving fetal anomalies.

Dr. Clark will also address the medical necessity of partial-birth abortion to protect the health of pregnant women, and claims made about the relative safety of the procedure. He will testify, having spent his entire professional life caring for the most seriously ill of pregnant women, that he is not aware of any circumstance in which partial-birth abortion would be necessary to preserve the health of a woman experiencing medical complications during pregnancy. He has considered the various complications of pregnancy identified by plaintiffs, and other known complications such as cardiac conditions, preeclampsia, and diabetic retinopathy, and will testify that D&X would never be necessary to preserve women's health in these circumstances. That is so because the pregnancies could be safely terminated using other procedures such as medical abortion (induction) or D&E. In any event, fetal demise could be achieved beforehand by intracardiac injection of potassium chloride. Dr. Clark will testify, in addition, that most fetuses with anomalies can be terminated either by medical abortion, or D&E, with cases of hydrocephaly addressed by means of cephalocentesis.

Secondly, Dr. Clark will testify that the use of a new and invasive procedure such as intact D&E or D&X cannot be justified on the ground that it is "intuitively" safer without rigorous scientific proof establishing its safety. He will add that he disagrees, in any event, with the notion that intact D&E or D&X is intuitively safer than D&E. The literature concerning

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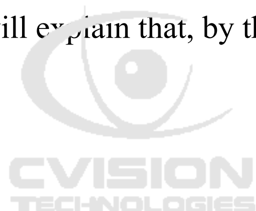
D&E demonstrates that trauma resulting from instrument passes into and out of the cervix is extremely rare, whereas the forced dilation of the cervix to deliver an intact fetus, as is done in intact D&E or D&X, has a long history of causing serious maternal complications.

8. Dr. Kanwaljeet S. Anand. Dr. Anand is a pediatrician specializing in the care of critically ill newborns and children, who for more than 20 years has conducted intensive research and study on the development of pain and stress in the human newborn and fetus. He received his medical degree from Mahatma Gandhi Memorial Medical College in Indore, India. After post-doctoral training in Pediatrics, he was awarded a Rhodes Scholarship to study at the University of Oxford, where he received a Ph.D. from the Faculty of Medicine for research performed on surgical pain and stress in premature and full-term newborns. Following additional post-doctoral training at Oxford, Dr. Anand completed a fellowship in pediatric critical care at Massachusetts General Hospital.

Dr. Anand has held academic appointments at the University of Oxford, Harvard Medical School, and Emory University School of Medicine. He has authored or co-authored more than 200 published articles, and is currently Professor of Pediatrics, Anesthesiology, Pharmacology and Neurobiology at the Arkansas University for Medical Sciences. He also serves as Director of the Pain Neurobiology Laboratory at the Arkansas Children's Hospital Research Institute, where he studies the immediate and long-term effects of pain in premature newborns and full-term infants, the development of a functional pain system during fetal and neonatal life, and the treatment of pain at these ages.

Dr. Anand will testify at trial on the subject of fetal pain experienced during partial-birth abortion. He will explain that, by the 20th week of gestation, if not earlier, human fetuses have



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reached the level of anatomical development necessary to feel pain, and have been observed to exhibit physiological responses to painful stimuli from as early as 16 weeks of gestation. Indeed, the highest density of pain receptors per square inch of skin in human development occurs in utero at 20 to 30 weeks' gestation, while fibers that dampen and modulate the experience of pain do not begin to develop until 32-34 weeks' gestation. Consequently, a 20-32 week fetus would experience a much more intense level of pain than older infants, children, or adults subjected to the same or similar stimuli. Dr. Anand concludes, therefore, as he will attest at trial, that at 20 weeks' gestation or more, the forcible extraction of the fetus through the cervix, followed by surgical incision of the fetal cranium, and vacuum suctioning of the fetal brain, causes prolonged and intense pain to the unborn infant. Moreover, the local or regional anesthesia that is routinely applied to the mother would offer the fetus no protection against this pain. To ensure that the fetus experiences no pain during a surgical procedure would require doses of general anesthesia at levels that would be toxic to the mother.

CONCLUSION

In sum, the legislative record, together with the record in this case, will furnish substantial evidence to support the reasonableness of Congress' judgment that the separate and distinct procedure defined by the Act as partial-birth abortion is never necessary to preserve the health of the mother. Congress therefore has acted within the constraints of the Constitution in banning this particular procedure, and has not imposed an undue burden on a woman's right to obtain a medically safe abortion. Accordingly, plaintiffs' constitutional claims based on the asserted scope and vagueness of the Act, and its failure to incorporate a maternal health exception, should be dismissed, with prejudice.

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Dated: March 26, 2004

Respectfully submitted,

PETER D. KEISLER
Assistant Attorney General, Civil Division

MICHAEL G. HEAVICAN
United States Attorney

PAUL D. BOESHART
Assistant United States Attorney

487 Federal Building
100 Centennial Mall North
Lincoln, Nebraska 68508
Tel. (402) 437-5241

SHANNEN W. COFFIN
Deputy Assistant Attorney General

/s/ Anthony J. Coppolino
ANTHONY J. COPPOLINO
Special Litigation Counsel

/s/ Terry M. Henry
TERRY M. HENRY
PREEYA M. NORONHA
ANDREW I. WARDEN
Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Avenue, N.W.
Room 7144
Washington, DC 20530
Tel.: (202) 514-4107
Fax: (202) 616-8470
e-mail: terry.henry@usdoj.gov

Counsel for Defendant John Ashcroft,
Attorney General of the United States

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CERTIFICATE OF SERVICE

I hereby certify that on March 26, 2004, I served the foregoing document by electronic mail, on counsel for plaintiffs, as follows:

Priscilla J. Smith, psmith@reprorights.org

Suzanne Novak, snovak@reprorights.org

Nan E. Strauss, nstrauss@reprorights.org

Janet L. Crepps, jcrepps@reprorights.org

Jerry M. Hug, jhug@qwest.net

/s/ Terry M. Henry
TERRY M. HENRY

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