No. 05-380

IN THE

Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL,
Petitioner,

v.

LEROY CARHART, *et al.*,
Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR STEPHEN CHASEN, M.D., MARK I. EVANS, M.D., CASSING HAMMOND, M.D., MARC HELLER, M.D., TIMOTHY R.B. JOHNSON, M.D., GERSON WEISS, M.D., CAROLYN WESTHOFF, M.D., M.SC., AND NATIONAL ABORTION FEDERATION AS *AMICUS CURIAE* SUPPORTING RESPONDENTS

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INTEREST OF AMICI[1]

Amici are plaintiffs in *National Abortion Federation* v. *Gonzales*,[2] an action brought in the United States District Court for the Southern District of New York challenging the same statute under review here, the Partial-Birth Abortion Ban Act of 2003, 18 U.S.C. § 1531 (the "Act"). *Amici* submit this brief in support of Respondents and in support of affirmance.

Amici include seven individual physicians who are all practicing obstetrician-gynecologists, fellows of the American College of Obstetricians and Gynecologists ("ACOG"), and professors in, or chairs of, the Obstetrics and Gynecology Departments of leading teaching hospitals throughout the country. Collectively, they have published over 600 peer-reviewed articles, served as editors of numerous medical journals, and received tens of millions of dollars in competitive research grants from the National Institutes of Health. These physician-plaintiffs perform and teach abortion procedures that are banned by the Act:

- **Stephen Chasen, M.D.**, is Associate Professor of Obstetrics and Gynecology at the Weill Medical College of Cornell University and Director of High-Risk Obstetrics at New York Presbyterian-New York Weill Cornell Medical Center.

- **Mark I. Evans, M.D.**, is Professor of Obstetrics and Gynecology and Director of Comprehensive Genetics at Mount Sinai School of Medicine in New York; he is

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[1] No counsel for a party authored this brief in whole or in part, and no person or entity other than *amici* and their counsel made any monetary contribution toward the preparation or submission of this brief. Letters indicating the parties' consent to the filing of this *amicus* brief have been submitted to the Clerk of this Court.

[2] *National Abortion Fed'n* v. *Ashcroft*, 330 F. Supp. 2d 436 (S.D.N.Y. 2004), *aff'd National Abortion Fed'n* v. *Gonzales*, 437 F. 3d 278 (2d Cir. 2006).

also President of the Fetal Medicine Foundation of America.

- **Cassing Hammond, M.D.**, is Assistant Professor in Obstetrics and Gynecology and Director of the Program and Fellowship in Family Planning and Contraception at the Northwestern University School of Medicine.

- **Marc Heller, M.D.**, is the Medical Director of Planned Parenthood Mohawk Hudson in Schenectady, New York, and a part-time Associate Clinical Professor at the College of Physicians and Surgeons of Columbia University, through his association with its affiliate, Bassett Healthcare.

- **Timothy R. B. Johnson, M.D.**, a maternal-fetal medicine specialist, is the Bates Professor of the Diseases of Women and Children and Professor and Chair of the Department of Obstetrics and Gynecology at the University of Michigan Medical School.

- **Gerson Weiss, M.D.**, is Professor and Chair of the Department of Obstetrics, Gynecology, and Women's Health at the UMDNJ-New Jersey Medical School and Chief of Service of Obstetrics and Gynecology at the UMDNJ-University Hospital.

- **Carolyn Westhoff, M.D., M. Sc.**, is Professor of Obstetrics and Gynecology in the College of Physicians & Surgeons of Columbia University, as well as Professor of Epidemiology and of Population & Family Health in the Mailman School of Public Health, also at Columbia University.

Amicus **National Abortion Federation** ("NAF"), a non-profit organization founded in 1977, is the medical professional association of abortion providers in North America. Its members include over 400 non-profit and private clinics,

women's health centers, hospitals, and private physicians' offices in 47 states. NAF's members care for over half the women who obtain abortions each year in the United States, and they perform and teach abortion procedures that are banned by the Act. NAF is the lead plaintiff in *NAF* v. *Gonzales*.

INTRODUCTION AND SUMMARY OF ARGUMENT

Amici, plaintiffs in *NAF* v. *Gonzales* ("Plaintiffs"), challenged the Act because it is constitutionally deficient on numerous grounds, including that it bans an array of safe abortion procedures. But even if the Act prohibited only second-trimester surgical abortions in which the fetus is removed intact—as the government sometimes claims—it would still unconstitutionally endanger women's health. *Amici* refer to these procedures as intact dilation and evacuation ("intact D&E"), because they are among the variants of dilation and evacuation ("D&E"), which collectively account for the vast majority of second-trimester abortions.

Essentially ignoring the Act's other flaws, the government's defense of the Act relies almost entirely on Congress's finding that intact D&Es are "never medically indicated to preserve the health of the mother." *See* Pet. Br. 2. This claim—and Congress's findings—were discredited by overwhelming evidence presented at three separate federal-court trials held simultaneously in the Spring of 2004. At those trials, eminent experts from the faculties of leading medical schools, who have years of experience both performing abortions and treating women facing high-risk pregnancies, testified that D&E with intact removal offers significant safety advantages over alternative methods of terminating a pregnancy in the second trimester. These witnesses testified to the considerable health benefits of removing the fetus as intact as possible, and to the particular benefits of doing so for women in compromised medical states. After hearing this evidence, all three district courts concluded that banning such procedures without a health exception violates the Constitution and this Court's clear commands.

The New York district court, like the Nebraska and California courts whose decisions are under review, concluded that Congress's legislative findings cannot withstand even the most deferential review. *NAF*, 330 F. Supp. 2d at 488. The New York court found that there is "no consensus that D&X is never medically necessary," *id.* at 482, and that, in fact, "there is a significant body of medical opinion that holds the contrary," *id.* The New York court's conclusions were based on a substantial record amassed from over twenty witnesses, from twelve of the most acclaimed medical and academic institutions in the country, during a three-week trial. The record in New York comports fully with those under review in this case[3] and in *Planned Parenthood Federation of America* v. *Ashcroft*, 320 F. Supp. 2d 957 (N.D. Cal. 2004) ("*PPFA*").[4] That the New York court did not credit certain of Plaintiffs' evidence does not undermine that court's central and dispositive finding: that there is substantial medical authority supporting the proposition that prohibiting intact D&E endangers women's health. This finding adds considerable further weight to support affirmance.

STATEMENT OF RELEVANT FACTS FROM NEW YORK RECORD

Procedural History of the New York Litigation

In November 2003, roughly simultaneously with the filing of the two cases currently under review by this Court, Plaintiffs brought suit in the United States District Court for the Southern District of New York challenging the Act. On November 6, 2003, the New York court issued a temporary restraining order and, with the consent of the government, later extended the TRO pending final resolution of the

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[3] *Carhart* v. *Ashcroft*, 331 F. Supp. 2d 805 (D. Neb. 2004), *aff'd Carhart* v. *Gonzales*, 413 F.3d 791 (8th Cir. 2005), *cert granted* 126 S. Ct. 1314 (2006).

[4] *Aff'd Planned Parenthood Federation of America, Inc.* v. *Gonzales*, 435 F.3d 1163 (9th Cir. 2006), *cert. granted* 126 S. Ct. 2901 (2006).

case. During a three-week trial in March and April 2004, the court heard testimony from sixteen witnesses in person and six by deposition. On August 26, 2004, the court issued a decision permanently enjoining the Act as unconstitutional under this Court's precedents because it lacks a health exception. On January 31, 2006, the Second Circuit affirmed, holding that "the lack of a health exception renders the Act unconstitutional." *NAF*, 437 F.3d at 281. The Second Circuit deferred ruling on the appropriate remedy until supplemental briefs could be filed addressing this Court's recent ruling in *Ayotte* v. *Planned Parenthood*, 126 S. Ct. 961 (2006). That briefing was thereafter stayed pending the outcome of this case.

Expert Witnesses in the New York Case

The New York court recognized seven of Plaintiffs' witnesses (including the five Plaintiffs who testified at trial) as experts in obstetrics and gynecology and abortion practice and procedures. These experts are all professors in the obstetrics and gynecology departments at leading medical schools. *See NAF*, 330 F. Supp. 2d at 458-62. Dr. Timothy Johnson is department chair at the University of Michigan; Dr. Gerson Weiss is department chair at UMDNJ-New Jersey Medical School; Drs. Amos Grunebaum and Stephen Chasen teach at Cornell University; Drs. Cassing Hammond and Marilynn Frederiksen teach at Northwestern University; and Dr. Carolyn Westhoff teaches at Columbia University. Collectively, they have extensive experience both performing and teaching the abortion methods at issue in this case. They have all performed first- and second-trimester abortions, and have used both of the procedures commonly used to terminate pregnancies in the second trimester, D&E and induction. Each of these experts has either performed, or personally observed, the variant of D&E involving intact removal of the fetus. *See* Tr. 210:8-213:12, 307:17-308:4, 312:1-7 (Grunebaum); Tr. 526:1-530:8, 533:9-20 (Hammond); Tr. 742:5-751:4 (Westhoff); Tr. 1043:5-1046:2 (Frederiksen); Tr. 1311:1-1316:25, 1338:12-1340:11, 1341:7-21 (Weiss); Tr. 1551:12-1555:13 (Chasen); *see also* Tr. 396:4-400:11 (John-

son).[5] These experts teach an array of obstetric and gynecological procedures, including abortion; most of them teach D&E with intact removal.[6]

Five experts testified at trial for the government. Each of the government's experts had limited, if any, experience with abortion practice. Tr. 1788:25-1789:21 (government's witness Lockwood); Tr. 2399:19-24 (government's witness Clark) (testifying that he considers himself only "moderately skilled" in performing abortions); Tr. 2093:2-6 (government's witness Sprang) (testifying that he has performed abortions "exceedingly rarely"); Tr. 1967:16-17 (government's witness Anand) (testifying that he has never performed any type of abortion); Tr. 2487:21-2488:15 (government's witness Cook) (testifying that he has performed abortions by methods other than induction only on "rare occasions" and that most of the abortions he performed were to remove dead fetuses). Not one of the government's experts had any experience with D&E involving intact removal. None had even personally observed such a procedure. *NAF*, 330 F. Supp. 2d at 462-64.

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[5] The portions of the trial transcript cited in this brief are reproduced in the accompanying Appendix.

[6] The New York record also included deposition testimony of Drs. Mitchell Creinin and Maureen Paul, both of whom have extensive experience in obstetrics, gynecology, and abortion practice; Dr. Watson Bowes, whom the government had designated as an expert but did not call at trial; and representatives from three medical organizations opposing the Act: Joanna Cain, M.D., chair of the ethics committee of the American College of Obstetricians and Gynecologists ("ACOG"); Meghan Kissell, Director for Communications and Advocacy for the American Medical Women's Association ("AMWA"); and Alan Baker, Chief of Staff for the American Public Health Association ("APHA"). In addition, Dr. Rebecca Baergen of Cornell-Weill Medical School testified for Plaintiffs as an expert in pathology and perinatal pathology, Tr. 1096:23-1097:3; Dr. Sherwin Nuland of Yale University, a Pulitzer Prize-winning author and expert on medical and surgical history, testified as an expert in the evolution of surgical procedures, Tr. 69:8-14; and Dr. Joel Howell, Director of the Robert Wood Johnson Clinical Scholars Program at the University of Michigan, testified in rebuttal as an expert in evaluation of medical research, Tr. 2673:13-25.

New York Testimony on Abortion Methods

As the undisputed testimony showed and the New York district court found, approximately 90% of all abortions occur during the first trimester of pregnancy, and approximately 10% during the second. *NAF*, 330 F. Supp. 2d at 464. During the second trimester (which begins at thirteen to fourteen weeks from the first day of the woman's last menstrual period before she became pregnant ("LMP")), approximately 95% of abortions are performed using the D&E method. Tr. 779:7-8, 802:9-14 (Westhoff).

D&E consists of dilating the cervix and evacuating the uterus. Tr. 1552:19-21 (Chasen). Both Plaintiffs' and the government's witnesses testified that the physician's goal in any D&E is to empty the uterus in the safest way possible for the woman. *See e.g.*, Tr. 2701:5-2703:13 (government's expert Bowes); Tr. 1363:21-1364:1 (Weiss).

In a D&E, the physician first dilates and softens the cervix so that the uterus can be safely evacuated. *NAF*, 330 F. Supp. 2d at 464 (quoting trial testimony). To achieve adequate dilation, physicians typically place osmotic dilators in the cervix, which expand slowly as they absorb moisture from the cervix, thereby gradually opening it. *Id.* at 464-65. Once dilation is adequate, the physician inserts instruments or his or her fingers through the dilated cervix and into the uterus, to grasp the fetus. The physician then uses traction (*i.e.*, pulling) to remove the fetus from the uterus. Tr. 786:22-787:18 (Westhoff).

As the New York record demonstrates, during a D&E, the fetus may be removed intact or in parts. Both parties' experts testified that physicians performing D&Es seek to minimize the number of times they insert instruments into the uterus. They therefore try to remove as much of the fetus as possible with each pass of an instrument. *See* Tr. 1849:23-1850:3 (government's expert Lockwood); Tr. 2709:6-2710:6 (government's expert Bowes); Tr. 794:11-16 (Westhoff); Tr. 479:18-23 (Johnson). In some cases, depending on factors such as the degree of cervical dilation achieved, the tensile strength of the fetal tissue, and the position of the

fetus, the physician is able to remove the fetus intact or relatively intact with the first pass of instruments.[7] *See* Tr. 1572:19-1574:4 (Chasen); *see also* Tr. 791:17-792:6, 786:22-787:10 (Westhoff); Tr. 2696:4-10 (government's expert Bowes). The experts in New York testified, however, that despite attempts to remove the fetus as intact as possible, the process often results in removal of the fetus in parts, with the physician reinserting instruments—and extracting as much of the fetus as possible with each instrument pass—until the evacuation is complete.[8] *See* Tr. 786:22-787:10 (Westhoff); Tr. 1454:14-19 (Paul); Tr. 1503:11-24 (Creinin); Tr. 1573:23-1574:4 (Chasen).

A variety of terms—such as "intact D&E" or "D&X"—were used throughout the New York trial to describe second-trimester surgical abortions in which the fetus is removed intact or largely intact. Regardless of the term employed, the New York experts testified that such a procedure is "a variation of . . . D&E." Tr. 1065:6 (Frederiksen); *see also* Tr. 212:4-6, 231:23 (Grunebaum); Tr. 1450:8-10 (Paul); Tr. 665:22-666:3 (Hammond).[9]

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[7] The testimony in New York showed that physicians do not use a different dilation protocol to achieve an intact extraction. Rather, the same standard protocol may result in more dilation with a given patient, increasing the possibility of a relatively intact extraction. *See* Tr. 597:10-14 (Hammond) (physicians "do nothing differently before [their] intact procedures"); *see also PPFA*, 320 F. Supp. 2d at 965 (physicians "cannot . . . ascertain[]" the "potential for a largely intact removal" until the dilators are removed and "the surgical procedure has already begun").

[8] The fetal skull is the largest part of the normally developed fetus and is typically too large to pass through the cervix during a D&E. As a result, whether the fetus is dismembered or removed intact, the physician must reduce the size of the skull to complete the delivery. *See* Tr. 796:11-12, 797:25-798:14 (Westhoff); Tr. 643:8-11 (Hammond); Tr. 1573:7-13 (Chasen).

[9] The Act's findings, and the government, attempt to define D&Es with intact removal as if they were an entirely distinct procedure from D&Es involving dismemberment. However, the record evidence in New York showed that physicians who perform them "consider all D&E's [sic] part and parcel of the same procedure." Tr. 597:10-15 (Hammond); *see also PPFA*, 320 F. Supp. 2d at 966 ("[t]he only physicians who referred

The testimony in New York showed that virtually all of the remaining second-trimester procedures (five percent) are performed using the induction method. In an induction abortion, which can last anywhere from fewer than twelve hours to more than forty-eight hours, pre-term labor is initiated with medication, the cervix dilates, and the fetus is generally expelled through the labor process. *NAF*, 330 F. Supp. 2d at 467. In some induction abortions, however, the physician must intervene with surgical steps to complete the evacuation as safely as possible for the woman. When this happens, the physician uses the surgical techniques of D&E to complete the procedure. *Id.* at 468-69.

The uncontested evidence presented in the New York trial established that any D&E or induction—whether used to induce abortion or to treat pregnancy loss (sometimes called "miscarriage")—may fall within the definition of "partial-birth abortion" contained in the Act. *See* Tr. 298:21-299:8 (Grunebaum); 639:2-644:17 (Hammond); 854:3-862:20 (Westhoff); *see also* Tr. 1877:22-1878:18 (government's expert Lockwood).

The remaining procedures for pregnancy termination in the second trimester, hysterectomy (removal of the uterus) and hysterotomy (essentially a pre-term cesarean section), are rarely used to terminate pregnancies because of their inherent risks and consequences for future reproduction. They nonetheless remain legal and can be used in those unusual circumstances in which they may be the safest method for a given patient with a critical medical condition. *NAF*, 330 F. Supp. 2d at 467 (quoting trial testimony).

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to" intact procedures "as . . . separate . . . were witnesses who had never performed the[m]"). Despite the fact that both variants are used at the same point in pregnancy, the government seeks to stigmatize one as aberrant and to embrace the other as "standard." Pet. Br. 11.

ARGUMENT

LIKE THE TWO RECORDS BEFORE THIS COURT, THE NEW YORK RECORD SHOWS THE IMPORTANCE OF INTACT D&E TO WOMEN'S HEALTH.

The extensive evidence presented in New York is entirely consistent with that presented in the Nebraska and California cases under review. The New York court heard "more evidence during its trial than Congress heard over the span of eight years," including testimony from a greater number of physicians on the safety of D&E involving intact removal. *NAF*, 330 F. Supp. 2d at 482. In addition to Plaintiffs' highly credentialed experts, who testified to the significant safety advantages of intact D&E, several of the government's experts acknowledged that such procedures may reduce the risk of dire complications and provide safety advantages for some patients. *Id.* at 461-73. That evidence demonstrated that intact D&E is well within the standard of care; that it is becoming ever more widely used as greater numbers of physicians learn this approach to D&E and read about its benefits in the medical literature; and that a ban on its use would harm women's health.

Accordingly, like the courts whose decisions are under review, the New York trial court found that "[t]here is no consensus that D&X is never medically necessary, but there is a significant body of medical opinion that holds the contrary." *Id.* at 482. This conclusion, affirmed by the Second Circuit, places the New York decision in an unbroken line that has struck down laws banning intact D&E since this Court's decision in *Stenberg* v. *Carhart*, 530 U.S. 914 (2000).

A. On the Basis of Abundant Evidence, the New York Court Rejected Congress's Demonstrably Incorrect Findings.

Like the courts in Nebraska and California, the New York court concluded that Congress's findings were belied by both the congressional record itself and abundant trial evidence. Having observed that "[e]ven the government's own experts disagreed with almost all of Congress's factual

findings," *NAF*, 330 F. Supp. 2d at 482, the court held that those findings cannot satisfy even the highly deferential standard the government urged. The court, that is, found that the findings do not even reflect "reasonable inferences based on substantial evidence." *Turner Broad. Sys., Inc.* v. *FCC*, 512 U.S. 622, 666 (1994).

1. Contrary to Congress's Findings, the New York Record Established That There is No Medical Consensus Against Intact D&E.

The New York court rejected Congress's finding that there is a "consensus" that D&E with intact removal "is never medically necessary and should be prohibited." Act § 2(1). In fact, as the court found, "[t]he congressional record itself undermines this finding." *NAF*, 330 F. Supp. 2d at 488. The court likewise rejected the related findings that Congress made in an attempt to circumvent *Stenberg*. As the court observed, "[t]he face of the congressional record [itself] rebuts" Congress's finding "that D & X is a disfavored medical procedure that is not embraced by the medical community, 'particularly among physicians who routinely perform other abortion procedures.'" *Id.* at 490 (quoting Act § 2(2) and citing *id.* §§ 13, 14(O)); *see also id.* §§ 13, 14(O) (procedure "lies outside the standard of medical care" and "is unrecognized as a valid abortion procedure by the mainstream medical community"). The court found that:

> First, the [congressional] record includes the statements of nine associations, including ACOG and APHA, which opposed the ban because they believe that the procedure offers safety advantages .... Second, the congressional record contains letters from numerous individual physicians—whose practices include performing abortions—stating that maternal health would be jeopardized under the Act. Third, medical textbooks, which were included in the congressional record, discuss D&X as a medically recognized means to terminate a pregnancy.

330 F. Supp. 2d at 490 (citations omitted); *see also Hearing on H.R. 760: Hearing Before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 108th Cong. 186-88 (2003); *Partial-Birth Abortion: The Truth: Joint Hearing on S.6 and H.R. 929 Before the Senate Comm. on the Judiciary and the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 105th Cong. 23-35 (1997) (medically-based opposition to Act of Plaintiff NAF and of Planned Parenthood, representing physicians who perform an array of abortion procedures).

In addition to the congressional record, the New York court found that the "[t]estimony adduced at trial bolsters this conclusion" that Congress was "unreasonable to conclude that a consensus within the medical community" opposes intact D&E. 330 F. Supp. 2d at 489. That testimony includes the concessions of the government's own witnesses that no such consensus exists. *Id.* at 443; *see also* Tr. 2700:2-11, 2714:14-23 (government's expert Bowes).

Abundant trial evidence likewise disproved Congress's other "findings." For example, Congress asserted that intact D&E was not taught at any medical schools, Act § 2(14)(B). Yet, "[t]estimony at trial adduced that, contrary to Congress's finding, the procedure is taught at leading medical schools," *NAF*, 330 F. Supp. 2d at 490, including, as experts for both sides testified, Columbia, Cornell, New York University, Northwestern, and Albert Einstein College of Medicine. *Id.* at 479, 490 (citing testimony of, *inter alia*, government's experts Lockwood and Sprang). Dr. Lockwood, a witness for the government and Chair of the obstetrics and gynecology department at Yale Medical School, testified that intact D&E was taught under his chairmanship at New York University, Tr. 1794:4-1795:8, and that he "intends to develop a program at Yale which would teach the procedure." *NAF*, 330 F. Supp. 2d at 479. Currently, at least six additional medical schools, including Yale, provide instruction on this surgical technique. The record likewise reflects that authoritative medical textbooks discuss intact D&E and its safety benefits. *See id.* at 471

(citing A CLINICIAN'S GUIDE TO MEDICAL & SURGICAL ABORTION 136 (Maureen Paul *et al.*, eds. 1999)); *see also* WILLIAMS OBSTETRICS 243 (F. Gary Cunningham *et al.* eds., 22d ed. 2005); 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).

The New York record similarly refuted Congress's claim that intact D&E has not been the subject of peer-reviewed studies and articles. *See* Act § 2(14)(B). The record includes the testimony of *amicus* Dr. Stephen Chasen—Director of High-Risk Obstetrics at New York Presbyterian-New York Weill-Cornell Medical Center, where he also teaches—as well as the first of two articles Dr. Chasen has published in an authoritative peer-reviewed journal comparing D&E involving intact removal to D&E involving dismemberment. *See* Stephen T. Chasen *et al.*, *Obstetric outcomes after surgical abortion at ≥ 20 weeks' gestation*, 193 Am. J. of Obstetrics & Gynecology, 1161-64 (2005); Stephen T. Chasen *et al.*, *Dilation and evacuation at ≥ 20 weeks: Comparison of operative techniques*, 190 Am. J. of Obstetrics & Gynecology, 1180-83 (2004). *See* discussion *infra* at 18-19. Other peer-reviewed articles also discuss intact D&E and its safety advantages. *See, e.g.*, Phillip G. Stubblefield *et al.*, *Methods for Induced Abortion*, 104 Obstetrics & Gynecology 174-85 (July 2004); David A. Grimes, *The Continuing Need for Late Abortions*, 280 JAMA 747-50 (Aug. 26, 1998).

2. Evidence at the New York Trial Disproved Congress's Findings Regarding the Health Risks of Intact D&E.

The New York trial court correctly concluded that the evidence presented at trial refuted Congress's assertion that "overwhelming evidence" demonstrates that D&E involving intact removal presents serious increased risks to women. Act § 2(14)(A). The court concluded, for example, that "[e]xperts for both sides labeled . . . inaccurate" Congress's finding that intact removal increases the risk of uterine rup-

ture, abruption, amniotic fluid embolus, and trauma to the uterus. *NAF*, 330 F. Supp. 2d at 489; *see also*, *e.g.*, Tr. 2419:3-2420:13 (government's expert Clark); Tr. 2706:19-2707:17 (government's expert Bowes); Tr. 1831:18-1832:10 (government's expert Lockwood). Similarly, the trial court found that experts for both sides agreed that intact D&E "does not involve the capricious and erratic use of instruments," thus undercutting Congress's finding that the procedure poses an increased risk of maternal laceration and bleeding. 330 F. Supp. 2d at 489-90. The government's own experts agreed at the New York trial that there is simply no evidence that performing a D&E with intact removal poses greater safety risks than performing one involving dismemberment. *See* Tr. 2706:19-2707:17 (government's expert Bowes); Tr. 1880:2-5, 1880:23-1881:4; 1881:5-7 (government's expert Lockwood); Tr. 2151:23-25 (government's expert Sprang).[10]

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[10] Evidence presented at the New York trial also contradicted Congress's finding that removing the fetus intact in a D&E increases a woman's risk of cervical incompetence, which can lead to pre-term birth in subsequent pregnancies. *See NAF*, 330 F. Supp. 2d at 467 (citing Westhoff). The district court incorrectly suggested that Dr. Chasen's original study indicates an increased risk of subsequent pre-term birth: as experts from both sides explained, this difference between the two groups—women who had received intact D&Es and women who had received D&Es with more dismemberment—was statistically insignificant because there were so few patients in this part of the study. 330 F. Supp. 2d at 467; Tr. 1629:15-1631:9 (Chasen); Tr. 2679:18-2680:11 (Howell); Tr. 2425:1-25, 2429:16-2430:13 (government's expert Clark) (conceding that "one can reach no conclusions" from the Chasen study about the procedure's impact on risk of subsequent pre-term birth). No less important, as the government's experts conceded, women in the intact group in the study had *pre-existing* risk factors for pre-term delivery to a far greater degree than did women in the dismemberment group. *See* Chasen *et al.*, *Dilation and evacuation at ≥20 weeks: Comparison of operative techniques*, 190 Am. J. of Obstetrics & Gynecology, 1180, 1183 (2004); *see also* Tr. 2412:8-11, 2427:12-2429:1 (government's expert Clark); Tr. 2614:15-2615:6 (government's expert Cook). Indeed, each of the two women from the intact group who delivered a subsequent pregnancy pre-term had undergone the abortion in the study specifically because she had begun to lose that earlier pregnancy through premature rupture of the membranes or prema-

B. The New York Trial Record, Like the Nebraska and California Records, Amply Demonstrates the Safety Advantages of Intact D&E.

The New York trial record supports the safety advantages of intact D&E based on three demonstrated facts: (1) D&Es of all variations have safety advantages over induction abortions, (2) D&Es with intact removal have safety advantages over D&Es with dismemberment, and (3) these safety advantages are especially important for women who are particularly vulnerable to catastrophic complications by virtue of their already compromised medical states.

First, it is uncontested that prohibiting D&Es in general would endanger women's health. At the New York trial, all parties' experts agreed that, while D&E and induction are both extremely safe procedures, D&E is generally safer than induction at certain stages of pregnancy. *NAF*, 330 F. Supp. 2d at 467-68 (citing testimony of government's experts Lockwood, Sprang, and Clark, and Plaintiffs' expert Frederiksen). It was also undisputed that for numerous women, induction is dramatically less safe than D&E. These patients include, for example, women at high risk of uterine rupture during an induction, due to prior scarring from procedures such as high (also known as "classical") cesarean sections or from the surgical removal of uterine fibroids. *See* Tr. 1817:24-1818:8, 1818:19-22 (government's expert Lockwood); Tr. 2358:22-2359:17, 2407:21-2408:7, 2408:18-24 (government's expert Clark); Tr. 1584:22-1585:9 (Chasen); Tr. 1080:1-4 (Frederiksen); Tr. 223:25-224:16 (Grunebaum).

Second, the evidence presented in New York showed that numerous physicians believe that, among D&E vari-

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ture cervical dilation. Both those events are known risk factors for preterm delivery in future pregnancies. *See* Chasen *et al.*, *Dilation and evacuation at ≥ 20 weeks: Comparison of operative techniques*, at 1183. For this reason, the California and Nebraska courts both found that the Chasen study does *not* support the claim that intact D&E may increase the risk of subsequent pre-term birth. *See Carhart*, 331 F. Supp. 2d at 1022; *PPFA*, 320 F. Supp. 2d at 1001.

ants, D&E involving intact removal may be the *safest* way—although not the only way—to terminate a pregnancy in the second trimester. *See, e.g.*, Tr. 1588:23-1589:5, 1632:3-1633:4 (Chasen); Tr. 563:15-23 (Hammond); Tr. 824:12-17, 840:4-12, 841:20-22 (Westhoff); Tr. 1439:1-6, 1445:10-21, 1451:9-1452:9 (Paul); Tr. 1321:10-16, 1338:1-11, 1345:23-1346:2, 1421:2-12 (Weiss); Tr. 453:19-21 (Johnson); Tr. 1053:7-20, 1161:21-24 (Frederiksen); Tr. 1503:25-1504:2 (Creinin). Even the government's experts agreed that there are intuitive advantages to intact removal. Tr. 1828:4-14 (government's expert Lockwood); Tr. 2708:19-22, 2709:6-2710:6 (government's expert Bowes). Indeed, government witness Dr. Lockwood conceded that, compared to dismembering the fetus, intact removal might carry lower risks of injury to the woman. Tr. 1880:6-8. This is so for several reasons, as the evidence presented in New York showed:

- By reducing the number of times a physician must insert instruments through the cervix and into the uterus, intact removal reduces the risk of what government expert Dr. Lockwood called the most feared complication of D&E with dismemberment—uterine perforation. 330 F. Supp. 2d at 471 (citing testimony of government's experts Lockwood and Cook and of Plaintiffs' experts); Tr. 1765:21-1766:1, 1822:16-1823:1, 1823:14-1824:6 (government's expert Lockwood); Tr. 2548:5-23 (government's expert Cook). The government's experts agreed that it is medically appropriate to attempt to make as few instrument passes as possible, Tr. 1825:12-16 (government's expert Lockwood); Tr. 2708:19-22, 2709:18-2710:6 (government's expert Bowes), and Dr. Lockwood testified that making fewer passes with instruments also reduces the risk of infection. Tr. 1825:9-20 (government's expert Lockwood). Testimony from ACOG (presented by deposition of its representative, Dr. Joanna Cain) showed that ACOG viewed reduced instrumentation as a significant reason why D&E with intact removal may be the best or most appro-

priate abortion method to save the life or preserve the health of a woman. Tr. 185:2-18 (Cain).

- Removing the fetus intact virtually eliminates the risk that fetal tissue will be left in the uterus. Retained tissue increases the likelihood of infection, hemorrhage, and infertility. *NAF*, 330 F. Supp. 2d at 472; Tr. 248:13-249:9 (Grunebaum); Tr. 570:8-571:18 (Hammond); Tr. 824:18-825:7 (Westhoff); Tr. 1045:13-22, 1053:7-20, 1060:8-1064:18 (Frederiksen); Tr. 1322:25-1324:3, 1421:2-12 (Weiss); Tr. 1441:10-16 (Paul); Tr. 1590:21-24, 1593:2-9 (Chasen). The government's expert Dr. Lockwood agreed that intact removal logically lowers the risk of retained tissue. Tr. 1769:3-4.

- D&E with intact removal takes less operating time than D&E with dismemberment, and may thus reduce bleeding, the risk of infection, and exposure to anesthesia. 330 F. Supp. 2d at 472 (citing trial testimony of government's experts Bowes and Lockwood and Plaintiffs' experts Grunebaum, Hammond, Westhoff, Weiss, and Chasen). The government's experts agreed that a shorter procedure time is medically advisable for these reasons. Tr. 1825:21-1826:9 (government's expert Lockwood); Tr. 2709:6-16 (government's expert Bowes).[11]

[11] Contrary to the New York district court's suggestions and the government's claims here, *see* Pet. Br. 37 n.12, Dr. Chasen's original comparison study of D&E variants does not belie this evidence. While the procedure times for the two study groups was the same, the intact D&E group was, on average, two weeks further along in pregnancy, meaning that their procedure times were expected to be longer than the times for the group that had D&Es with dismemberment. *See* Tr. 1628:13-1629:19, 1634:5-16, 1680:2-6 (Chasen); Tr. 884:17-885:21 (Westhoff); Tr. 289:14-291:14 (Grunebaum). The fact that they were not longer indicates that the intact approach does reduce procedure time for D&E.

- Intact removal is less likely to expose the uterus and cervix to sharp fetal bone and skull fragments. 330 F. Supp. 2d at 471; Tr. 1825:17-20 (government's expert Lockwood); Tr. 447:4:-448:19 (Johnson); Tr. 565:7-566:2, 568:19-570:7, 592:2-9 (Hammond); Tr. 1053:11-18, 1058:10-1059:10 (Frederiksen); Tr. 1330:25-1332:8 (Weiss); Tr. 1590:1-17, 1592:9-15, 1611:11-1612:2 (Chasen); Tr. 793:2-794:5, 824:18-825:2 (Westhoff). The government's experts agreed that cervical laceration and uterine perforation are risks of dismemberment D&E. Tr. 2411:9-12 (government's expert Clark); Tr. 1825:9-20 (government's expert Lockwood); Tr. 2548:5-23 (government's expert Cook). And the evidence showed that sharp fetal fragments are the leading cause of this complication. Tr. 1058:10-23 (Frederiksen).

The New York record also included testimony regarding Dr. Chasen's original study, the first peer-reviewed study specifically comparing dismemberment and intact removal in D&Es. *See* Chasen *et al.*, *Dilation and evacuation at ≥ 20 weeks: Comparison of operative techniques*, 1180-83, *supra* at 13. Experts testified that the study demonstrated that intact removal is at least as safe as, and probably safer than, dismemberment in a D&E. Tr. 1612:22-1614:13, 1625:21-1629:14, 1632:3-1633:4, 1634:3-16, 1679:12-1681:8, 1694:18-1695:16 (Chasen); Tr. 838:18-25, 884:17-885:21 (Westhoff); Tr. 289:14-291:14 (Grunebaum); *Carhart*, 331 F. Supp. 2d at 962 (government's expert "Dr. Lockwood testified that the Chasen study 'suggests [the intact D&E method of abortion is] safe'" (alteration in original)).

The two patient groups in the study—those who had relatively intact procedures at a median gestational age of 23 weeks LMP, and those who had dismemberment procedures at a median gestational age of 21 weeks LMP—experienced comparable bleeding, procedure times, and complication rates (although all of the serious complications occurred in the dismemberment group). Chasen *et al.*, *Dilation and evacuation at ≥ 20 weeks: Comparison of operative tech-*

niques, at 1182-83 *supra* at 13. The fact that the complication rates were comparable was significant because, as Dr. Chasen and other experts testified, the patients in the intact group were at greater risk of complications because they were two weeks further along in pregnancy and the risks of abortion increase as pregnancy advances. Tr. 805:2-7 (Westhoff). Thus, the intact group would have been expected to have *worse* outcomes. Tr. 1625:21-1630:1, 1632:3-1633:4, 1634:3-16, 1679:12-1681:8, 1694:18-1695:16 (Chasen); Tr. 884:17-885:21 (Westhoff); Tr. 289:14-291:14 (Grunebaum). The fact that they did not "provide[s] medical support for the conclusion that intact D&E is a safe, and sometimes necessary, procedure." *PPFA*, 320 F. Supp. 2d at 1034.

Third, the New York record also included abundant evidence that intact removal may be the safest option for women with certain medical conditions who are terminating their pregnancies. In such cases, the benefits described above are particularly important given the patient's already compromised medical state and increased vulnerability to catastrophic complications. These conditions include, for example, being prone to or having infection, *NAF*, 330 F. Supp. 2d at 473; Tr. 1826:16-1827:9 (government's expert Lockwood); experiencing, or being at risk for, chorioamnionitis, a potentially deadly infection of the amniotic fluid and membranes that, among other things, increases the risk of uterine perforation, *NAF*, 330 F. Supp. 2d at 473; Tr. 1825:9-20, 1826:16-1827:20 (government's expert Lockwood); Tr. 588:19-590:7 (Hammond); being otherwise at risk of hemorrhage, *NAF*, 330 F. Supp. 2d at 473 (citing Hammond); having compromised immune systems, *id.*; and being prone to perforation or having uterine scarring, *id.* (citing *inter alia* government's expert Lockwood); Tr. 1335:18-1336:5 (Weiss); *see also* Tr. 1056:14-24 (Frederiksen). In addition, ACOG's expert panel pointed to numerous such conditions that make intact D&E the safest abortion method for certain patients. *See, e.g.*, Tr. 153:10-20, 154:16-23, 158:13-21, 185:2-18 (ACOG representative Cain). In addition to these conditions, there was also testimony in New York that D&E with intact removal could benefit women carrying fetuses with certain

anomalies, such as hydrocephaly (which greatly enlarges the fetal head), *NAF*, 330 F. Supp. 2d at 473 (citing government's and Plaintiffs' experts), and that it may also help in the post-abortion pathological diagnosis of certain fetal conditions. *See id.* (citing Westhoff).

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In sum, there was ample evidence in New York from highly credentialed experts on both sides to support the conclusion that banning intact D&E without a health exception creates "unnecessary risk of tragic health consequences." *Stenberg*, 530 U.S. at 937. The evidence showed that the unique advantages of intact removal—reduction of instrument passes, fetal fragmentation, and procedure time—minimize the likelihood of complications that, while perhaps infrequent in an absolute sense, are potentially catastrophic in the very real cases when they do occur. The potential consequences of these complications include hemorrhage, overwhelming and systemic infection, and infertility. *NAF*, 330 F. Supp. 2d at 471-72; *supra* at 16-18 Such potentially catastrophic complications are no less constitutionally cognizable simply because they are, fortunately, rare.[12]

C. The New York District Court's Characterization of Some of the Evidence Does Not Undermine Its Central Conclusion That Substantial Medical Evidence Supports the Safety Advantages of Intact D&E.

Contrary to the government's suggestion, *see* Pet. Br. 40-41, the New York court did not reject the essential safety benefits on which Plaintiffs' case rested. While the court opined that certain of Plaintiffs' proffered reasons for their belief in the safety advantages of intact D&E were "not credible" or even "false," the court did not so characterize

[12] This court's precedent offers no support for the suggestion in Chief Judge Walker's Second Circuit concurrence that procedures that reduce such complications offer only "marginal" and constitutionally insignificant benefits. *NAF*, 437 F.3d at 291.

the health benefits described above. Moreover, the court also found that Congress was "unreasonable" in concluding that there is "no credible medical evidence" that intact D&Es offer safety advantages. 330 F. Supp. 2d at 489. In so holding, the court necessarily found that *credible* medical evidence disproved Congress's false "findings."

The New York court did not state that any specific reason Plaintiffs offered in support of the medical advantages of intact procedures was "false" or "not credible." Instead, it merely noted that these advantages were "theoretical" or "hypothetical" because they were based on physician experience, and had not yet been proven by controlled studies—studies this Court has made clear are not necessary to support the need for a health exception.

As this Court held in *Stenberg*, the "absence of controlled medical studies" cannot defeat the need for a health exception. *See* 530 U.S. at 936-37. This Court, and lower courts, have never required that medical benefits be proven through studies as a prerequisite to invalidating bans on abortion procedures. In fact, banning a procedure would perversely preclude such studies ever being conducted. As this Court explained in *Stenberg*, "[m]edical treatments and procedures are often considered appropriate (or inappropriate) in light of *estimated* comparative health risks (and health benefits) in particular cases." *Id.* at 937 (emphasis added); *see also Planned Parenthood* v. *Danforth*, 428 U.S. 52, 77-78 (1976) (invalidating ban on saline abortions despite absence of studies demonstrating comparative benefits of saline versus prostaglandin induction);[13] *Planned Parent-*

[13] The trial court in *Danforth* heard testimony from two plaintiff-physicians and from four physicians who supported the ban. *See* Brief of John C. Danforth, Attorney General of Missouri, *Danforth*, 428 U.S. 52 (1976) (No. 74-1151, 74-1419), at 58-68; Brief for Planned Parenthood of Central Missouri, David Hall, M.D., and Michael Freiman, M.D., *Danforth*, 428 U.S. 52 (1976), (No. 74-1151, 74-1419), at 123-25; *see also* Brief as *Amici Curiae* for Planned Parenthood Federation of America, Inc., Association of Planned Parenthood Physicians, Inc. and Certain Medical School

hood v. *Taft*, 444 F.3d 502, 513 (6th Cir. 2006) (invalidating ban on alternative protocol for administering abortion drug after concluding that "studies are not necessary where there is expert testimony that a restricted procedure is safer than the alternatives"); *Wynn* v. *Scott*, 449 F. Supp. 1302, 1326 (N.D. Ill. 1978) (invalidating saline abortion ban on the basis of physician affidavits and drug manufacturer's description without studies in the record).

Evidence presented in the New York trial explained why requiring definitive controlled studies of intact D&E at this point would be unreasonable and at odds with the way medical innovations typically develop. Dr. Sherwin Nuland, formerly a practicing surgeon and now a professor of bioethics and medical history at Yale Medical School, testified that innovative surgical techniques such as intact D&E arise through a "process of evolution," proceeding from the initial flash of insight, then spreading within the profession by word of mouth, and moving gradually to scientific study with retrospective peer-reviewed reports and case studies (the current status of research relating to intact D&E), and only much later (and only if possible) to controlled experimentation. Tr. 69:21-73:2. Controlled studies require a sufficient sample size, which might be difficult to achieve here given the relative infrequency of second-trimester abortion by any method, and, in particular, the relative rarity of complications. *Id.* at 79:25-80:7. This limitation exists for any study of second-trimester abortion. *See*, *e.g.*, Tr. 1822:12-15 (government's expert Lockwood).[14] Given this limitation, the New York court's criticism of Plaintiffs' failure to provide controlled studies demonstrating that D&E with intact re-

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Deans, Professors and Individual Physicians, *Danforth*, 428 U.S. 52 (1976), (No. 74-1151, 74-1419), at Point II.

[14] For example, the government's expert Dr. Lockwood was unable to identify any randomized, controlled studies supporting his opinion that there may be safety advantages to induction abortion over surgical abortion after 20 weeks LMP.

moval lessens the risk of already-rare complications is misplaced.

The New York court also inappropriately relied on the views of a single government witness, Dr. Clark, to discredit Plaintiffs' experts' testimony supporting the safety advantages of intact D&E. Dr. Clark, who admitted to being only moderately skilled in performing abortions, Tr. 2399:19-24, contended that certain specific health conditions would not "necessitate" a D&E with intact removal. However, the conditions on which his testimony focused were not among those Plaintiffs had offered to support the greater safety of intact D&E. Instead, they included conditions Plaintiffs had offered as examples of why women obtain second-trimester abortions generally, or of why surgical D&E offers advantages over induction abortion.[15] Even the government's own witness, Dr. Lockwood, agreed that there may be advantages to intact removal over dismemberment in some cases. Dr. Lockwood specifically noted such potential advantages for women suffering from chorioamnionitis, a potentially deadly infection of the amniotic fluid and membranes that, among other things, increases the risk of uterine perforation. Tr. 1826:16-1827:18 (government's expert Lockwood). Dr. Clark's testimony notwithstanding, the New York court clearly recognized that the evidence demonstrated "a division of medical opinion" regarding the advantages of intact D&E for women with certain health conditions, such as "uterine scarring, placenta previa, preeclampsia, bleeding disorders, and infections"—a division that requires an exception to preserve women's health. *NAF*, 330 F. Supp. 2d at 481.

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[15] *See e.g.*, Tr. 1017:11-21 (Westhoff) (peripartum cardiomyopathy as example of condition that prompts some women to terminate pregnancy in the second trimester); Tr. 594:10-17 (Hammond) (Von Willebran's disease as example of condition that makes surgical approach (*i.e.*, D&E) far preferable to induction abortion); Tr. 2332:20-2334:5; 2349:24-2350:14 (government's expert Clark opining that that neither peripartum cardiomyopathy nor Von Willebran's disease necessitates intact D&E).

Finally, the Nebraska and California courts, both of which heard the same evidence, were untroubled by the absence of controlled studies or the consequently "theoretical" nature of the proffered health advantages of intact D&E, which advantages they found compelling. After hearing the testimony of substantially the same witnesses who testified in New York, both the California and Nebraska courts "f[ou]nd[] that intact D&E is in fact the safest medical option . . . in some circumstances and is significantly safer than induction, hysterotomy, or hysterectomy for terminating a second trimester pregnancy, and under certain circumstances, also significantly safer than D&E by disarticulation." *PPFA*, 320 F. Supp. 2d at 1002; *see also Carhart*, 331 F. Supp. 2d at 1018. Both courts also found that Plaintiffs' witnesses' "expertise in recommending and performing D&E and intact D&Es is unassailable . . . ." *PPFA*, 320 F. Supp. 2d at 1001 ("[T]he court accepts their testimony over that of the government witnesses, who . . . were not qualified to testify as experts on the practice."); *see also Carhart*, 331 F. Supp. 2d at 1025 ("In order to find that" D&E with intact removal does *not* bring safety advantages, "one would have to dismiss the views of highly trained and very experienced physicians . . . who have detailed knowledge of the surgical methods under discussion [and] would have to accept the contrary views of doctors . . . who have virtually no experience with abortions. Choosing . . . this nadir of inexperience . . . would be plainly unreasonable.") These contrary findings cast serious doubt on the New York court's view of some aspects of the evidence.

CONCLUSION

For the reasons set forth above, and in the Brief for the Respondents, the Court should affirm the judgment of the court of appeals.

Respectfully submitted,

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