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Testimony Submitted for the Record

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Thank you, Chairman Leahy and Ranking Member Grassley, for the opportunity to submit testimony regarding the scientific and medical perspective on why so many state laws regulating the provision of abortion care in the name of women's health and safety, promote neither health nor safety, and why the American Congress of Obstetricians and Gynecologists (ACOG) strongly supports S. 1696, the Women's Health Protection Act.

ACOG represents 57,000 board-certified ob-gyns and partners in women's health. A large part of our work is the development and dissemination of clinical guidelines and quality improvement tools to help our members provide the highest quality care, including abortion care, to our patients. This testimony provides you and the Committee with several examples of restrictive state laws that do nothing to further women's health and safety, and which in fact can have the exact opposite effect. These include laws that:

- 1) Require health care providers to practice according to outdated, rather than the best and most current, medical guidelines;
- 2) Prohibit use of telemedicine advancements for abortion, technology that is especially important in underserved and rural areas;
- 3) Require abortion providers to maintain admitting privileges at local hospitals, a business arrangement that only serves to reduce the number of providers, not to improve patient safety; and
- 4) Require health care providers to perform tests and procedures on our patients that are not medically necessary.

All these types of laws put physicians in the terrible predicament of either adhering to medical ethics by providing high quality care that's in the best interest of their patients, or facing legal punishments which may include fines, loss of licensure, and even jail time.

1) Laws Mandating the Use of Outdated Clinical Protocols for Medication Abortions

There are several reasons why a woman may opt for a medical abortion over a surgical abortion:

- It is less invasive,
- It avoids anesthesia, and
- It takes place in the privacy of her home, a consideration that may be especially important now that the US Supreme Court has ruled against safe perimeters protecting women entering abortion clinics.

In 2000, the FDA approved use of mifepristone, together with misoprostol, to end early pregnancies. Barring any medical contraindications, there are several evidence-based protocols for medication combinations to induce termination, including use of mifepristone. During the initial office visit, a woman will receive counseling about her options. If a woman is certain that she wants to terminate the pregnancy, and she is early in her pregnancy, meaning no later than 63 days of gestation as determined by clinical evaluation or ultrasound, she may be a candidate for a medical abortion. Medical abortion requires no special pretreatment lab tests beyond those generally needed for assessment of any early pregnancy. A nurse at the medical facility can give

the patient an initial dose of mifepristone, and misoprostol will be taken at home to complete the abortion.¹

Science and clinical evidence show that medical abortion works well for the majority of patients. Like all drugs, mifepristone carries some risks, but it is as safe, or safer, than many other drugs used today, including Tylenol and Viagra. Rates of infection and serious complications following a medical or surgical abortion procedure are extremely low. In the US, between 2001 and April 2011, there have been eight infection related deaths following the use of mifepristone and misoprostol. All were due to rare infections which have also been reported following childbirth, both vaginal and by c-section, and pelvic, abdominal or orthopedic surgery. According to FDA adverse report data, approximately 1.52 million women used mifepristone in the US, resulting in a fatality rate due to infection of 0.0005%, which is extremely low.² In fact, medical abortions can have safety advantages over surgical abortions for women who are extremely obese, have large uterine fibroids, certain uterine malformations, or a stenotic (narrow) cervix.³⁴ However, in an attempt to scare women and further restrict access to the medication, three states have passed laws which require physicians to prescribe an inferior regimen established 14 years ago, over newer, well-researched protocols.⁵

Since FDA approval in 2000, and as a result of continued medical research, a number of evidence-based regimens have emerged that make medical abortion safer, faster, and less expensive, and that result in fewer complications compared to the 2000 protocol. In March 2014, ACOG issued *Practice Bulletin Number 143 on the Medical Management of First-Trimester Abortion*. The conclusions are premised on recent studies that have shown the superiority of evidence-based regimens as compared to the 14 year old regimen set forth on the FDA-approved label.⁶⁷⁸ Practice Bulletin No. 143 concluded that:

- Based on efficacy and adverse effect profile, evidence-based protocols for medical abortion are superior to the FDA-approved regimen. Vaginal, buccal, and sublingual routes of misoprostol administration increase efficacy, decrease continuing pregnancy rates, and increase the gestational age range for use as compared with the FDA-approved regimen.
- Lower doses of mifepristone (200 mg) have similar efficacy and lower costs compared to those regimens that use mifepristone at 600 mg.
- Women can safely and effectively self-administer misoprostol at home as part of a medical abortion regimen, eliminating the need for women to return to a health care facility for the administration of misoprostol as outlined on the FDA-approved label.

In addition to these conclusions, data also indicate that the overall risk of serious infection with medical abortion is very low and that buccal administration of misoprostol may result in a lower risk of serious infection compared with vaginal administration.⁹ In fact, evidence-based regimens through at least 63 days of gestation are safer and more effective than the regimen described on the FDA-approved label when used up to 49 days of gestation.¹⁰ As with any medical care, treatments that are safer and more effective are medically preferable.

The FDA does not require label updates for new protocols unless there are new safety concerns, which there aren't in this case. So, physicians' use of the most recent evidence-based protocols

for mifepristone is considered “off-label”. The FDA allows “off-label” use of registered products when updated medical evidence supports such use.¹¹ In fact, “[u]p to 20% of all drugs are prescribed off-label and among some classes of cardiac drugs, off-label use can be as high as 46%.”¹² Laws, such as Arizona’s which mandates physician conformance with the out-of-date protocol on the FDA final printing labeling (FPL) instructions, are based on a complete misunderstanding of the role of the FDA in approving medications.

An FPL is an informational document meant to provide physicians with guidance about how to use a drug, as of the time of FDA approval. It is common for sound medical practice to advance beyond what is described on FDA drug labels. The FPL does not impose binding obligations on physicians or restrict the medical profession’s ability to develop new uses for the approved drug. The FDA has, itself, noted that “[g]ood medical practice and the best interests of the patient *require* that physicians use legally available drugs, biologics, and devices to their best knowledge and judgement.”¹³

A drug manufacturer needs only to demonstrate the safety and efficacy of a drug for a particular use in order to earn initial FDA approval for marketing the medication. Manufacturers are not required to seek FDA approval for additional uses.¹⁴ Indeed, the FDA itself has observed that “[t]he term ‘unapproved uses’ is, to some extent, misleading.”¹⁵ The FDA has regulatory authority over the manufacturers of drugs and medical devices; it does not—and cannot—regulate physicians and the practice of medicine.

So, to be clear: there is no medical basis to prohibit a physician’s use of the most up-to-date, evidence-based medication abortion protocol. Laws mandating protocols that are contrary to best medical practice are dangerous to our patients’ health. Even laws that mandate a protocol that is valid at the time of the law’s enactment are a bad idea. Medical knowledge continues to advance after a law’s passage.

2) Laws Restricting Use of Telemedicine for Medical Abortion

The 15 states’ laws that bar the use of telemedicine in the provision of medical abortion on the pretext of safety concerns related to medication abortion, are simply unwarranted.¹⁶ Telemedicine is already used successfully in cardiac care and the treatment of post-traumatic stress disorder, and is a useful tool in ensuring access to reproductive care for many women. ACOG encourages the effective use of telemedicine to expand access to the full array of high quality health care services for women, especially those in traditionally underserved areas.¹⁷

One such telemedicine program for medical abortion in Iowa helps ensure women in rural areas access to this care. In this program, a woman has an in-person visit with a nurse who collects necessary clinical information, provides detailed counseling regarding pregnancy options including the potential risks and benefits of each, and engages with the patient in the informed consent process. An ultrasound is performed by a trained technician to document gestational age. A physician at another site reviews the patient’s medical history and ultrasound images, and meets with the woman via video teleconference. If the physician and patient agree that she is eligible for a medical abortion, the physician enters a computer password remotely, which unlocks and opens a drawer in front of the patient and her nurse containing the medication. The

woman takes the first dose in the nurse's presence, and the remaining medications at home. The woman is scheduled for a follow-up visit in two weeks.

A recent study of this telemedicine program, published in ACOG's *Obstetrics and Gynecology* journal¹⁸, found that women participating in this setting were no more likely to have a complication than women who saw a doctor in person. Laws that restrict access to this care interfere with the provider-patient relationship, chip away at women's access to care, and isolate reproductive care from other needed care.

3) Laws Requiring Hospital Admitting Privileges for Abortion Providers

Another set of harmful laws are Targeted Regulation of Abortion Providers (TRAP) laws. These laws single out abortion providers for regulations, with a goal of forcing abortion providers out of practice. A typical example is requiring abortion providers to obtain admitting privileges at local hospitals.

First, it's important to know that abortion is one of the safest surgical procedures performed in the United States. The overall risk associated with childbirth is approximately fourteen times higher than abortion.¹⁹ Over 90% of abortions in the United States are performed in outpatient settings²⁰ and almost all complications that arise after an abortion can be, and are, treated on an outpatient basis. Hospitalization due to an abortion is rare. There is a less than 0.3% risk of major complications following an abortion that might need hospital care²¹ and a recent study found that the risk of major complications from first trimester abortions by aspiration is even less, 0.05%.²²

Having to obtain admitting privileges imposes a stricter requirement on abortion providers than on physicians that perform much riskier out-of-hospital procedures, including those that use general anesthesia. For example, the mortality rate associated with a colonoscopy is more than 40 times greater than that of abortion^{23,24}, yet gastroenterologists do not have to secure admitting privileges to local hospitals.

In the rare instance when a woman experiences a complication after an abortion and needs hospital care, emergency room physicians or, if necessary, the hospital's on-call specialist, are trained to evaluate such situations the same way they are trained to deal with complications arising from any other medical procedure. In fact, the transfer of care from the abortion provider to an emergency room physician is consistent with the developments in medical practice dividing ambulatory and hospital care in the medical field more broadly.²⁵ That is, throughout modern medical practice, often the same physician does not provide both outpatient and hospital-based care; rather, hospitals increasingly rely on "hospitalists" that provide care only in a hospital setting. Continuity of care is achieved through communication and collaboration between the health care providers which does not depend on all providers having hospital privileges.²⁶

Hospital privileges establish a business relationship between the hospital and the physician, in part based on the number of procedures and admissions the physician is expected to bring to the hospital annually. Given the safety margin of abortion, including the very slim chance of complications, it's rare that an abortion provider may have to admit a patient. Privileges often also require the physician to live or practice in close vicinity to the hospital, further limiting

access to care for women in remote areas.

4) Laws that Mandate Medically Unnecessary Ultrasounds Prior to Abortion

Twelve states have active laws on the books requiring providers to perform ultrasounds before an abortion can be performed, and in some cases forcing the provider to show and describe to women the image, often under the pretext that these laws protect and enforce a patient's right to informed consent.²⁷ In reality, these laws are medically unnecessary, contrary to medical ethics, and in violation of our patients' right to informed consent.

North Carolina's Woman's Right to Know Act, for example, includes a Display of Real-Time View Requirement, requiring a physician to perform an ultrasound on a pregnant woman at least four hours (and not more than 72 hours) prior to an abortion procedure, to place the image in the woman's view, and to provide a detailed description of the image—even if the woman asks the physician not to display and describe the image, and even if the physician believes that forcing this experience on the patient would harm her. The district court, in a case brought to overturn the Act, correctly found that this requirement serves no medical purpose and should be invalidated, recognizing it as antithetical to principles of informed consent and unduly interfering with the patient-physician relationship.

Informed consent

The principles of informed consent forbid physicians from acting over the objections of competent patients, and ensure that a patient has the freedom to determine the information she does—and does not—wish to hear, particularly where the information provides no medical benefit. It is contrary to good medical practice and to the ethics of informed consent to force physicians to convey information that will harm their patients. Informed consent is rooted in the concepts of self-determination and autonomy, and is based on the principle, fundamental in medicine and jurisprudence, that patients have the right to make decisions regarding their own bodies.²⁸ Informed consent ensures that each patient is provided the information she needs to meaningfully consent to medical procedures.^{29,30} Informed consent includes freedom from external coercion, manipulation, or infringement of bodily integrity. Informed consent has two essential elements: (1) comprehension and (2) free consent.³¹ Both of these elements together constitute an important part of a patient's "self-determination." "Comprehension" requires that the physician give the patient adequate information about her diagnosis, prognosis, and alternative treatment choices, including the option of no treatment.^{32,33}

Yet mandatory ultrasound laws force a physician to perform the procedure and deliver mandated information even over the patient's objection and even when the physician believes in his or her medical judgment that it is against the best interests of the patient to receive the information. These laws require that this information must be delivered when a patient is at her most vulnerable: in the midst of a medical procedure while the patient lies undressed on an examination table, with a probe on her abdomen or inserted into her vagina. Most informed consent discussions occur with the patient fully dressed sitting in the physician's office. And no other procedure in medicine requires that the physician show a patient images from her own body in order for her to comprehend her diagnosis and treatment options. For example, performing an angiogram before the placement of a stent is a medically appropriate preoperative procedure, but

there is no requirement that the patient view the screen before consenting to the operative procedure. Some patients choose to view medical images, others prefer not to. So too with abortion, there are simply no circumstances in which a patient's viewing of the fetus is medically necessary, and forcing her to do so unquestionably violates her autonomy and the physician's medical ethics. "Free consent" requires that the patient have the ability to choose among options; it is incompatible with being coerced or unwillingly pressured by forces beyond oneself.³⁴

As an ethical doctrine, informed consent is a process of communication whereby a patient is enabled to make an informed and voluntary decision about accepting or declining medical care. A core principle of informed consent is that it is the patient that decides how much, or how little, information he or she wants to receive. It has long been recognized that patients can still provide informed consent while declining to receive certain information, so long as their declination is a result of free choice. If a patient chooses not to consider certain information, that is a decision a physician should respect. Advocates for the North Carolina law argued that women in their state have the ability to not see or hear the ultrasound image or the physician's words, that they can wear earplugs or close their eyes. This argument lays bare the absurdity of these requirements and clarifies that they are truly not passed to help women be better informed.

Therapeutic Privilege

In some cases, forcing a woman to view and hear these images may actually do her harm. Therapeutic privilege is the limited privilege of a physician to withhold information from a patient when, in the physician's best medical judgment, the information about the patient's medical condition and options will seriously harm the patient. For example, a physician may decline to show a cancer patient a positron emission tomography ("PET") scan showing the advanced developmental stage of the cancer because, in the physician's best medical judgment, the image would cause the patient unnecessary distress and anxiety.

Similarly, some patients seeking abortions may be seriously harmed by seeing an ultrasound image and hearing a description of it. Some women make the difficult decision to have an abortion after learning that they are carrying a fetus with severe abnormalities; having to listen to a physician explain the details of the fetus' deformities could be extremely upsetting. Others become pregnant as the result of rape. To subject those women to a forced narrative script describing the ultrasound after having already been physically assaulted and traumatized would be cruel and unnecessary. In these cases, the physician— not the State—is best positioned to determine what's best for his or her patient based on the particular circumstances of each case.

Not Medically Necessary

Many patients who have decided to have an abortion have already had at least one ultrasound performed. Most women undergo an ultrasound as part of their initial obstetric appointment; high risk patients or those carrying a fetus with abnormalities invariably undergo ultrasound to better assess fetal viability. State laws forcing physicians to perform another ultrasound on their patients are medically unnecessary. In no other area of medicine are physicians required to breach medical ethics by subjecting a patient to a medical procedure that the patient does not want to undergo and which is not medically appropriate or necessary. In fact, in any other area of medical practice, forcing an unnecessary medical procedure upon an unwilling patient would constitute medical malpractice.

Protect the Patient-Physician Relationship from Legislative Interference

This and other laws focused on limiting women's access to safe and legal abortions puts government between a patient and her physician. A physician's primary mission is to serve as a patient's advocate, exercising all reasonable means to ensure that the most appropriate care is provided to each individual patient based on his or her specific needs and circumstances. Serving the best interests of the patient also means respecting the right of individual patients to make their own choices about their health care. Laws that for no medical reason treat abortion providers or abortion facilities differently than others – or restrict the ability of women to access safe, legal abortion care are unacceptable public policy, leaving physicians with a terrible choice: Follow their ethical obligation to provide the best possible care for their patients using their sound medical judgment OR comply with the law by treating their patients according to the flawed judgment of their state legislatures. Physicians who choose to provide the best possible care for their patients in these cases may be faced with fines, jail time, and loss of licensure.

We urge the Senate Judiciary Committee and the US Congress to protect the patient-physician relationship from unnecessary government intrusion and pass S. 1696, the Women's Health Protection Act. Laws that require physicians to give, or withhold, specific information when counseling patients, or that mandate which tests, procedures, treatment alternatives, or medicines physicians can perform, prescribe, or administer harm our patients, are detrimental to the patient-physician relationship, and are a wholly inappropriate expansion of government's reach into the personal lives and health care of Americans.

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- ¹ American College of Obstetricians and Gynecologists, Practice Bulletin No. 143, *Medical Management of First-Trimester Abortion* (March 2014)
- ² Food and Drug Administration, *Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2011*
- ³ Schaff et al., *Methotrexate and Misoprostol When Surgical Abortion Fails*, 87 *Obstetrics & Gynecology* 450, 450-452 (1996)
- ⁴ Creinin, *Medically Induced Abortion in a Woman With a Large Myomatous Uterus*, 175 *Am. J. Obstetrics & Gynecology* 1379, 1379-1380 (1996)
- ⁵ Guttmacher Institute State Policies in Brief Fact Sheet, *Medication Abortion*, (July 1, 2014)
- ⁶ Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121 *Obstetrics & Gynecology* 166 (Jan. 2013)
- ⁷ Ngo et al., *Comparative Effectiveness, Safety and Acceptability of Medical Abortion at Home and in a Clinic: A Systematic Review*, 89 *Bull. World Health Org.* 360 (May 2011)
- ⁸ Schaff, *Mifepristone: Ten Years Later*, 81 *Contraception* 1, 1-7 (January 2010)
- ⁹ Cleland et al., 121 *Obstetrics & Gynecology* at 166-171; Mary Fjerstad et al., *Rates of Serious Infection after Changes in Regimens for Medical Abortion*, 361 *N. Eng. J. Med.* 145, 145-51 (2009)
- ¹⁰ After 49 days of gestation, the efficacy of the regimen described on the FDA-approved label declines significantly, and the likelihood of continuing pregnancy increases. Creinin & Spitz, *Use of Various Ultrasonographic Criteria to Evaluate the Efficacy of Mifepristone and Misoprostol for Medical Abortion*, 181 *Am. J. Obstetrics & Gynecology* 1419, 1419-1424 (1999). However, regimens using vaginal, sublingual and buccal misoprostol provide efficacy rates up to 63 days of gestation that exceed the approximately 92% efficacy of the regimen described on the FDA-approved label up to 49 days of gestation. Spitz et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, 338 *N. Eng. J. Med.* 1241, 1241-1247 (1998); Regina Kulier et al., *Medical Methods for First Trimester Abortion (Review)*, *Cochrane Collaboration* (John Wiley & Sons, Ltd. ed. 2011); Schaff, 81 *Contraception* at 1-7; Cleland et al., 121 *Obstetrics & Gynecology* at 166-171
- ¹¹ FDA Drug Bulletin, Vol. 12, No. 1, *Use of Approved Drugs for Unlabeled Indications*, 5 (Apr. 1982) (off-label use “may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature”)
- ¹² AMA National Task Force on CME Provider/Industry Collaboration Fact Sheet, Vol. 2, Issue 3, *On-Label and Off-Label Usage of Prescription Medicines and Devices, and the Relationship to CME*, available at https://cme.wustl.edu/forms/On_Label_and_Off_Label_Usage_of_Prescription_Medicines_and_Devices_and_the_Relationship_to_CME.pdf
- ¹³ FDA Information Sheet, “*Off-Label*” and *Investigational Use Of Marketed Drugs, Biologics, and Medical Devices*, available at <http://www.fda.gov/regulatoryinformation/guidances/ucm126486.htm> (emphasis added).
- ¹⁴ FDA Drug Bulletin, Vol. 12, No. 1, *Use of Approved Drugs for Unlabeled Indications*, 5 (April 1982) (noting that “without the initiative of the drug manufacturer whose product is involved” new use regimens may never be added to approved drug labeling)
- ¹⁵ *Ibid.*
- ¹⁶ Guttmacher Institute State Policies in Brief Fact Sheet, *Medication Abortion*, (July 1, 2014)
- ¹⁷ American College of Obstetricians and Gynecologists, Committee Opinion No. 586 *Health Disparities in Rural Women* (March 2009)
- ¹⁸ Grossman D, Grindlay K, Buchacker T, Lane K, Blanchard K. *Effectiveness and acceptability of medical abortion provided through telemedicine*. *Obstet Gynecol* 2011;118:296–303
- ¹⁹ Elizabeth G. Raymond & David A. Grimes *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 *Obstetrics & Gynecology* 215, 215 (February 2012)
- ²⁰ Rachel Jones & Kathryn Kooistra, *Abortion Incidence and Access to Services in the United States, 2008*, 43 *Persp. on Sexual & Reprod. Health* 41, 46 (2011)
- ²¹ Stanley K. Hensha;-v., *Unintended Pregnancy and Abortion: A Public Health Perspective*, in *A Clinician's Guide to Medical and Surgical Abortion I* 1, 21 (Maureen Paul et al., eds., 1999).
- ²² Tracy A. Weitz et al., *Safety of Aspiration Abortion Performed by_ Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under a California Legal Waiver*, 103 *Am. J. Pub. Health* 454, 458 (March 2013). Similarly,

the risk of hospitalization from a medical abortion is 0.06%. Kelly Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121 *Obstetrics & Gynecology* 166, 169 (January 2013)

²³ Cynthia W. Ko et al., *Complications of Colonoscopy: Magnitude and Management*, 20 *Gastrointestinal Endoscopy Clinics of N. Am.* 659, 659-71 (October 2010)

²⁴ Raymond, *supra* note 5 at 216 (finding mortality rate of 0.6 per 100,000); Karen Pazol et al., Centers for Disease Control and Prevention, *Abortion Surveillance- United States, 2009*, *Morbidity and Mortality Weekly Report* 61: 1-44, Table 25 (Nov. 23, 2012); available at <http://www.cdc.gov/mmwr/pdf/ss/ss6108.pdf> (last visited Jul. 12, 2014) (finding national legal induced abortion case fatality rate for 2003-2009 of 0.67 per 100,000).

²⁵ ACOG, Committee on Patient Safety & Quality Improvement, Opinion No. 459, *The Obstetric Gynecologic Hospitalist* (July 2010).

²⁶ Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* (March 2001)

²⁷ Guttmacher Institute State Policies in Brief Fact Sheet, *Requirements for Ultrasound*, (July 1, 2014)

²⁸ Laurie, *Recognizing the Right Not to Know: Conceptual, Professional, and Legal Implications*, 42 *J. L. Med. Ethics* 1, 54 (2014) (“[C]onsent and refusal serve as a means to control what happens to our bodies and, by extension, our tissues and data as intimate adjuncts to ourselves and our sense of personal identity.”); see also Minkoff & Marshall, *Government-Scripted Consent: When Medical Ethics and Law Collide*, *Hastings Center Report* 39, No. 5 (2009), at 21 (Informed consent “is grounded in the principle of respect for persons, which affirms an individual’s consequent right to autonomous decision-making.”)

²⁹ ACOG Committee on Ethics, Committee Opinion No. 439 *Informed Consent*, (August 2009)

³⁰ AMA Code of Medical Ethics, *Opinion 8.08 - Informed Consent* (“Physicians should sensitively and respectfully disclose all relevant medical information to patients. The quantity and specificity of this information should be tailored to meet the preferences and needs of individual patients.”).

³¹ ACOG Committee on Ethics, Committee Opinion No. 439 *Informed Consent*, (August 2009)

³² AMA Code of Medical Ethics, *Opinion 8.08 - Informed Consent*

³³ *Whitlock v. Duke Univ.*, 637 F. Supp. 1463, 1467 (M.D.N.C. 1986) (In order for informed consent to be valid, it must be “competent, voluntary, and understanding.” (internal citations omitted)).

³⁴ ACOG Committee on Ethics, Committee Opinion No. 439 *Informed Consent*, (August 2009)