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Hearing on S. 1696, "The Women's Health Protection Act"

My name is Dr. Monique Chireau, and I am Assistant Professor in the Division of Clinical and Epidemiological Research in the Department of Obstetrics & Gynecology at Duke University Medical Center. I appreciate the opportunity to testify today regarding the impact that S. 1696 would have on the regulation of abortion in the United States.

S.1696 could be reasonably interpreted to invalidate virtually any type of current state laws which place restrictions or regulations on abortion. It would also endanger healthcare providers' freedom of conscience. It would also prohibit the future enactment of any of these laws. The purpose of the bill is given as "protect[ing] women's health by ensuring that abortion services will continue to be available and that abortion providers are not singled out for *medically unwarranted restrictions* that harm women by preventing them from *accessing* safe abortion services" (emphasis added).

Implicit in this stated purpose are the following four assumptions: abortion is good and safe for women; state abortion restrictions and regulations are "medically unwarranted;" access to abortion is important to women's health; and, that the state has no interest in protecting unborn children. I will address each in turn.

The Centers for Disease Control (CDC) defines an induced abortion as "an intervention performed by a licensed clinician…that is intended to terminate a suspected or known intrauterine pregnancy and produce a nonviable fetus at any gestational age" (*Morbidity and Mortality Weekly Report*, November 29, 2013, volume 16:8). The United States Supreme Court has repeatedly acknowledged that "abortion is inherently different from other medical procedures, because no other procedure involves the purposeful termination of a potential life." *Harris v. McRae*, 448 U.S. 297, 325 (1980). The Court has also held that the "abortion decision has implications far broader than those associated with most other kinds

of medical treatment." *Bellotti v. Baird* (*Bellotti II*), 443 U.S. 622, 649 (1979). The Court recently held that "[s]evere depression and loss of esteem can follow" the abortion decision. *Gonzales v. Carhart*, 550 U.S. 124, 159 (2007).

I. Assumption A: Abortion is Good for Women.

A substantial body of literature indicates that induced abortion is associated with significant risks and potential harms to women. While abortion is stated to be very safe at early gestational ages, it carries specific risks. These include infection, bleeding, uterine perforation with damage to bowel or bladder, and the significance of these risks is underlined by the need to document them when obtaining informed consent from patients prior to performing this procedure. This is especially noteworthy given that induced abortion is an elective procedure.

A number of studies have documented these risks in detail in the peer-reviewed scientific literature. For example, a study by Niinimaki et al of all women who underwent induced abortion (42,000 women) in the nation of Finland noted that 20% of patients undergoing medically induced abortion (*i.e.* with medications) and 5.6% of women undergoing surgical abortion experienced an adverse event (including bleeding, hemorrhage, injury). 16% of women undergoing medical abortion, and 2% of women undergoing surgical abortion, experienced hemorrhage, while 2% of either surgical or medical abortion were complicated by infection. These statistics represent a significant burden of disease; if applied to the United States, where 1.3 million abortions are performed annually, this translates to 260,000 adverse events per year. While these statistics are troubling, they are impossible to verify in the United States, where abortion surveillance is incomplete and inadequate. CDC stated in their most recent report on abortion in the United States that California, Maryland and New Hampshire did not report data, and that incomplete data were available for a number of other analyses including the age and ethnicity of women undergoing abortion.

Other research has demonstrated that the risks associated with abortion increase dramatically with gestational age. An important study on abortion mortality and morbidity by Bartlett *et al* found that the risk of mortality "increased exponentially by 38% with each additional week of gestation". When the risk for death from

abortions performed at greater than 21 weeks was compared with the risk of death from abortion at 8 weeks or less, this study noted that women at later gestational ages were 77 times more likely to die from the procedure. These findings not only emphasize that abortion is not a benign procedure, but also provide support for establishing regulations regarding ultrasound dating of pregnancy. Use of the last menstrual period date to establish the gestational age of the pregnancy is notoriously unreliable (as is physical examination), especially in adolescents, and the use of ultrasound for dating pregnancy is part of the standard of care.

Other complications can occur following abortion. Bhattacharya et al, 2012 found that induced abortion in a first pregnancy increased the risk of preterm birth. Surgical abortion increased the risk of subsequent preterm delivery compared with medical abortion (Bhattacharya et al, 2012. Reproductive outcomes following induced abortion: a national register-based cohort study in Scotland, *British Medical Journal*). Klemetti et al, in a study of abortion in Finland, found increased odds for very preterm birth (<28 weeks) in all subgroups of women who underwent abortion: 1.19 after 1, 1.69 after 2, and 2.78 after 3 abortions. Increased odds for preterm birth and low birthweight were seen with > 3 abortions. Most abortions were surgical (88%) and done for social reasons (97%). These statistics are of special interest in the United States, since African American women not only undergo abortion more than three times as often as Caucasian women, but also experience preterm birth at 1.6 times the rate of Caucasian women.

A robust literature exists on mental health problems following abortion. Coleman (2011) performed a meta-analysis which included 22 studies and 877,181 women. An 81% increase in mental health problems including depression, anxiety, substance abuse and suicide was noted in women who had induced abortion. The risk for mental health problems was increased 55% in women who had induced abortion compared with those who gave birth. Therefore, any assertions that there are no significant risks to abortion, either medical or surgical, are contradicted by data.

I believe the lack of oversight, reporting, data collection and monitoring of the abortion industry in the United States has caused the true extent of harm to women caused by this procedure to be understated. No other commonly performed procedure, which is potentially associated with injury or death to a patient, receives

so little scrutiny. This lack of accountability in abortion service provision has contributed to other social ills such as enabling the cover-up of the sexual abuse of minors, human trafficking, rape and the exploitation of women.

If abortion is "good" for women and essential to women's health and central to women's ability to participate equally in the economic and social life of the United States as stated in the first finding of Senate bill 1696, one would naturally be led to ask why abortion should not be subject to the same oversight, monitoring and accountability as procedures considered to be "medically comparable."

S. 1696 provides that someone challenging a law need only show that the law "impedes women's access to abortion services" based on one or more of an extensive list of factors. In other words, even a state law, for example, that includes abortion clinics in a list of medical facilities required to meet ambulatory surgical standards would likely be in violation of this act if abortion clinics closed as a result of failing to meet these standards.

II. Assumption B: State abortion restrictions and regulations are "medically unwarranted".

With this backdrop, it is important to note that States have a compelling interest in protecting the health of their citizens when it comes to abortion, and they have the authority to do so within regulatory frameworks including state medical boards and departments of health. States traditionally regulate the practice of medicine, provide health surveillance and enforce public health standards. These principles are well established in law and should apply to abortion; but unfortunately, in some states they do not.

S. 1696 would undermine State efforts to protect the health of women by exempting abortion from the most basic common-sense regulations that could be interpreted as making abortion "more difficult to access" and it would preclude states from giving abortion the breadth of oversight which the United States Supreme Court has recognized is allowed for this unique procedure.

It should go without saying that the promulgation of regulations requiring clinics to meet certain basic health and safety standards is essential for the health and safety

of citizens. Historically, states have regulated medical procedures by establishing standards for the proper training and credentialing of medical care providers, both physician and non-physician. In addition, states have established health and safety standards of facilities in order to ensure safe conditions not only for the procedures being performed in the facilities but to accommodate any emergent response which may be required.

These standards protect patients from injury and death. Even simple procedures such as laser hair removal are regulated. A recent article in the Widener Law Review noted that liposuction, a procedure performed in physician offices, which does not enter any body cavities and which is routinely performed for outpatients, is associated with mortality. The point is that all medical procedures involve varying levels of risk and it is no less true for abortion. It is important to note that induced abortion differs significantly from dilation and curettage in a non-pregnant patient for a variety of reasons, including differences between the pregnant and non-pregnant uterus, the presence of the fetus, increased risk for perforation, bleeding and infection, and the consequences of incomplete evacuation of the uterus.

In addition, states have the responsibility for oversight of the collection of vital statistics on individuals undergoing procedures so that complications and trends can be analyzed and systems improved. Abortion should be subject to the same regulation and oversight, and Congress should not preempt the ability of the states to discharge their traditional regulatory functions. This is especially important since, as noted above, abortion surveillance is deeply flawed and inadequate.

Abortion regulations protect women's health by preventing serious consequences including death, which are potential complications of abortion. Abortion is not necessarily a routine or safe procedure; it has known risks and consequences as noted above. These risks have not been defined on a large scale due to the fact that large-scale accurate statistics on abortion complications are not collected.

Recent publicized deaths due to abortion include Lakisha Wilson who died in March 2014 at a Cleveland, Ohio clinic; Tonya Reaves, who died following a late term abortion in a Chicago Planned Parenthood Clinic in 2012; Jennifer Morbelli who died following a late term abortion in 2013; and an unknown patient, died

after abortion at Nova Women's Healthcare, Fairfax, VA, 2013. These cases are only the more notorious examples of the risks – including mortality – associated with legal abortion.

To the extent some studies on abortion safety cite low morbidity and mortality, it is because these procedures are carried out in clinical settings where health and safety policies and procedures are in place. The fact that morbidity and mortality rates are lower in these settings is clear evidence that regulation is needed and protects women.

At a minimum, health and safety standards allow for proper oversight, facilities and procedures. For example, parking lot, hallway and door width regulations facilitate access by emergency personnel in case of a complication requiring transport to a hospital. It is difficult to overstate the importance of these most basic facility regulations.

A prime example of their importance can be found in the Report of the Grand Jury investigating the Kermit Gosnell case, in which he was found guilty of manslaughter in the death of Karnamaya Mongar. Among other things, at page 129 of its Report, the Grand Jury cited doorways and narrow, substandard hallways as factors contributing to the inability of emergency personnel to save her: "Mrs. Mongar's slim chances of survival were seriously hampered because it was exceedingly difficult for responders to get her to the waiting ambulance. The emergency exit was locked. Gosnell sent Ashley to the front desk to look for the key, but she could not find it. Ashley told us that a firefighter needed to cut the lock, but "It took him awhile… because the locks is old." She testified that it took "twenty minutes, probably trying to get the locks unlocked." After cutting the locks, responders had to waste precious more minutes trying to maneuver through the narrow cramped hallways that could not accommodate a stretcher.

Also significant for patient health and safety standards are regulations regarding instrument cleaning and processing to prevent disease transmission and requirements for resuscitation equipment to allow emergency personnel the opportunity to provide timely and appropriate care.

Because complications from abortion (especially at later gestational ages) can and do occur, policies and procedures must be in place to provide emergency follow up care for women. It is a maxim within medicine that a provider has an obligation to provide follow up care and to manage the complications caused by any procedures they have performed, or to arrange for follow up care. Hence if a provider is performing abortions, they should either be able to admit a patient who is experiencing complications to the hospital, or have an arrangement in place to provide these services.

It is also worth noting that within states, the scope of practice for different types of clinicians is carefully defined. As noted above, physicians are responsible for managing complications for their patients, and are held accountable to standards of care for their specialties. States' scope of practice laws prevent these responsibilities from being casually delegated to another practitioner (such as a nurse practitioner or physician assistant) and prevent the practice of medicine by unqualified individuals.

This situation is already occurring in various states; in an effort to circumvent medical board regulations, non-physicians are being trained to perform medical and surgical abortions outside their scope of practice in violation of State law. "…in a number of states, including those with physician-only laws, APCs [advanced practice clinicians] with additional training are providing medication and, in some cases, aspiration [surgical] abortions as a result of Attorney General opinions, regulatory clarifications, and other mechanisms…"This demonstrates that even in states where abortion is restricted by law to licensed physicians, nonlegislative strategies have provided APCs with opportunities to incorporate abortion services into their practices." (see apctoolkit.org).

This is willful violation of state regulations designed to protect patients. Under this illegal scenario, since the provider is essentially practicing outside of the law, patients with complications are told to "go the emergency room, but don't tell them you had an abortion, just that you're miscarrying". Emergency department physicians in this predicament not only lack critical clinical information from the provider who performed the abortion (since management of miscarriage is quite different from that of complicated abortion) but are also unable to elicit an accurate history from patients, who are often too fearful or ashamed to tell what really

happened. These women are victimized twice – first through abortion, and again through emotional blackmail. This shows disregard for patient welfare through patient abandonment as well as refusal to take responsibility for women's care. It is ironic that the current generation of abortionists, who decry the "back-alley butchers" of the past, have adopted the same tactics, performing clandestine abortions and forcing women to lie about their real reason for coming to the hospital with complications.

Nightmare situations such as Kermit Gosnell's filthy, dangerous and ultimately homicidal "women's health clinic", where untrained staff gave anesthesia and performed procedures, provide irrefutable evidence that health and safety standards for abortion clinics are mandatory.

III. Assumption C: Access to abortion is important to women's health.

Abortion is an elective procedure which is not medically indicated, since pregnancy is not a disease. In point of fact, abortion does not prevent, treat or palliate any disease. It is not a procedure which contributes to a woman's health or to women's health *per se*.[1]

Abortion alone, and in and of itself, does not provide "care" for the health of a pregnant woman. While in rare circumstances the termination of pregnancy as part of medical care for the mother can be lifesaving, this occurs in the context of a *program* of treatment for the woman, not as an isolated procedure where the sole intent is the death of the fetus.[2]

[1] Examples of interventions which improve women's health include cancer prevention; smoking cessation; treatment of hypertension, diabetes and other diseases; and pain control in terminal stages of cancer.

[2] This is an example of the ethical principle of double effect—When a physician terminates a pregnancy because continuing pregnancy poses a risk to the life of a pregnant women, the physician expects the death of, but does not intend to kill, the fetus. This motivation can be tested by the question, "if the fetus does not die as a result of my intervention, will I have failed to accomplish what I intended to do?"

Abortion is also not necessarily a panacea when a woman is carrying a baby with a significantly life-limiting condition. Studies show that aborting a child with a fetal anomaly can cause great psychological harm for some parents.[3] Researchers have stressed the importance of adequate psychological support and guidance from the woman's caregiver during the decision-making process.[4]

A more compassionate option for women in these circumstances is perinatal hospice, a multidisciplinary approach that helps parents experience the life of their child to the fullest extent possible before and after birth. When presented with this option, more than 80 percent of parents choose perinatal hospice.[5] Physicians in one study reported that 87 percent of their patients diagnosed to be carrying a child with a lethal congenital disorder choose to continue pregnancy in this environment of care.[6]

Yet, S. 1696 would invalidate any laws that require abortion providers to educate their patients about the availability of perinatal hospice.

Ultimately, the overwhelming majority of abortions (78%) are done because "having a baby would change my life drastically." An unwanted pregnancy is for many women a very difficult and life-changing circumstance, but not a life-threatening health problem.

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[3] In 2004, one study revealed that maternal grieving after such abortions continued for over six months and included pathological anxiety and depression. A. Kersting et al., *Grief after termination of pregnancy due to fetal malformation*, J. PSYCHOSOM. OBSTET. GYNAECOL.25:163 (2004). In 2005, a study by Korenromp et al. revealed that a substantial number of the participants (17.3 percent) showed pathological scores for posttraumatic stress. Korenromp et al., *supra.* A follow-up study in 2009 revealed that at 14 months post-abortion, 16.7 percent of women were diagnosed with a psychiatric disorder. A. Kersting et al., *Psychological impact on women after second and third trimester termination of pregnancy due to fetal anomalies versus women after preterm birth: A 14-month follow up study*, ARCH. WOMEN'S MENTAL HEALTH 12:193 (2009).

[4] Korenromp, *supra*.

[5] M. D'Almeida et al., *Perinatal Hospice: Family-Centered Care of the Fetus with a Lethal Condition*, J. AMER. PHYSICIANS & SURGEONS 11:52 (2006);

[6] B.C. Calhoun et al., *Perinatal Hospice: Comprehensive Care for the Family of the Fetus with a Lethal Condition* (2005).

IV. Assumption D: The State has no interest in protecting unborn life.

S. 1696 utterly fails to acknowledge the state's compelling interest in protecting unborn life. In fact, there is no mention of unborn children at all, in spite of the fact that the purpose of the bill is to eliminate most regulations or restrictions on abortion.

The Supreme Court has recognized since *Roe v. Wade* that the state has an interest in the "potentiality" of unborn life that increases through the pregnancy. Further, the vast majority of Americans support many regulations of abortion because they understand that abortion ends a human life—71% of Americans believe abortion should never be legal or be legal only in certain circumstances (Gallup, May 2014). 64% believe that it should be illegal in the second trimester; 80% in the third (Pew, Jan. 2014.

Unborn children and their mothers are vulnerable to injury, exploitation and social and economic disadvantage. This interest underlies state programs to provide health insurance and food assistance to pregnant women. Other examples are efforts to prevent women from taking medications that might harm a fetus; protecting women from occupational exposures such as radiation (e.g. radiology technicians, power plant workers) and chemotherapy (e.g. nurses). It is noteworthy that substance abuse, intimate partner violence, sexual exploitation and mental health problems are risk factors for abortion, suggesting that abortion may be a marker for these social comorbidities. Thus, women seeking abortion are likely a vulnerable population, who need special protections. It is therefore clear that for practical, medical and legal reasons states have an interest in pregnant women and unborn life because of their need for these protections.

Undergirding this interest is the need to define when pregnancy begins. Traditionally, OB/GYN physicians were tasked with this definition. For generations pregnancy was assumed to begin at conception. The decision as to when pregnancy began later became a pragmatic one based upon basic science research and clinical diagnostics – upon implantation the embryo sends out a detectable hormonal signal, human chorionic gonadotropin (hCG), which is the basis for current pregnancy testing. This is an arbitrary way to define the onset of pregnancy since it is based on detecting an event – implantation – rather than when

the embryo came into existence at fertilization, 8-10 days earlier. The distinction is important because embryonic and fetal vulnerability to certain environmental exposures is high at early gestational ages. However, because laboratory studies could only detect implanted embryos, the pragmatic definition prevailed. Recent research has focused on diagnostic markers which may identify very early pregnancies.

Similarly, neonatologists are pushing back the boundaries of neonatal viability (currently at approximately 23-24 weeks). Scientific advances such as surfactant and antenatal steroid therapy have markedly increased survival rates for even the most premature infants, increasing a fetus' likelihood of surviving a late abortion and the need for resuscitation Much recent research has focused on prenatal treatment of Down Syndrome (61-93% of Down Syndrome fetuses are aborted in the US). We are moving closer to being able to treat Down Syndrome and prevent its complications. If this becomes possible, couples may likely choose to carry these pregnancies to term rather than aborting them. S. 1696 ignores these scientific advances by removing restrictions on abortion at various gestational ages.

Conclusion

S. 1696 is a measure that seeks to overturn longstanding state restrictions on abortion that have been supported in the courts. It ignores not only widely supported policies and scientific evidence, but also prior Supreme Court rulings, and clearly targets state regulations which protect the health of our most vulnerable citizens – pregnant women and their unborn children -- and undermines states' compelling interest in the health of the unborn. It does not merit support based on these findings. Thank you.