Approved: 05/05/10
Date

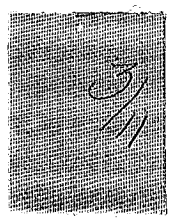
MINUTES OF THE SENATE PUBLIC HEALTH AND WELFARE COMMITTEE

The meeting was called to order by Chairman Jim Barnett at 1:30 p.m. on March 11, 2010, in Room 546-S of the Capitol.

All members were present.

Committee staff present:
Nobuko Folmsbee, Office of the Revisor of Statutes
Renae Jefferies, Office of the Revisor of Statutes
Iraida Orr, Kansas Legislative Research Department
Terri Weber, Kansas Legislative Research Department
Amanda Nguyen, Kansas Legislative Research Department
Jan Lunn, Committee Assistant

Conferees appearing before the Committee:
Senator Mary Pilcher-Cook
Jennnifer Lahl, BSN, MA, National Director, Center for Bioethics and Culture Network
Alexandra Fraser, PhD, private citizen
David Pauls, MD, Manhattan, Ethics Committee Member of Mercy Regional Health Center, Board President for the Center for Bioethics and Culture
Bruce Tjaden, DO, FACOG, The Center for Reproductive Medicine, Wichita
Peter Bath, D Min, Vice President of Spiritual Wellness and Human Development, Shawnee Mission Medical Center
Sarah Meyer, private citizen
Thomas Witt, Chair, Kansas Equality Coalition
David A. Grainger, MD, MPH, Associate Dean for Research, Profession, Division of Reproductive Endocrinology and Infertility, University of Kansas School of Medicine, Wichita



Senator Barnett welcomed students and parents from Mrs. Yvonne Barnett's fifth grade class, Blue Valley Sunrise Point Elementary:
Hayden Richardson and her Mother, Christy Richardson
Landon Ginther and his Mother, Lashelle Ginther
Doug Gould and his Mother, Leslie LaPlace
Gracie Salts and her Mother, Peggy Salts
Drew Schifman and his Father, Ken Schifman
Maggie Manning
Dominic Legato
Ryan Schmidt
Evan Phillips
Analiese Lahey
Luke Killman

Senator Barnett announced today would be Terri Weber's last day as a staff member of the Public Health and Welfare Committee. Ms. Weber is retiring from the State of Kansas at the end of the month. Chairman Barnett expressed appreciation to Ms. Weber and, on behalf of committee members and staff, presented her with a Legislative Pin.

SB 509 - Establishing the women's health and embryo monitoring program act

Renae Jefferies briefed **SB 509** to those attending. The bill would require the State's fertility clinics to electronically report data required under the act to the Department of Health and Environment. Ms. Jefferies detailed the contents of the legislation: definitions, fees, confidentiality, responsibilities, liability, evaluation, and penalties for failing to submit information.

Senator Pilcher-Cook, the originator of this legislation, spoke about importance of this legislation that addresses outdated laws related to biotechnologies, and specifically, those concerning egg and sperm donation and invitro fertilization (Attachment 1). She indicated these fertility clinics lack information, oversight, health and safety measures, and consumer protection. The intent of this legislation is to provide the information to better protect and inform consumers of the risks and benefits of fertility medicine. Senator Pilcher-Cook encouraged favorable passage of **SB 509**.

Jennifer Lahl began her testimony by establishing her credentials and expertise relevant to fertility medicine (Attachment 2). She supports **SB 509** as the means to address concerns related to fertility medicine that are dangerous to women, dangerous to children, unregulated and lacking adequate oversight. She provided statistics and examples to substantiate these concerns. She indicated that political leaders must protect constituents who have been ignored by the fertility industry.

Alexandra Fraser, shared her personal experience concerning egg donation which resulted in a health crisis. She indicated had this type of legislation been in place, she might have made a more informed decision thus eliminating the torsioned ovary, intestinal failure, and infection (Attachment 3). Ms. Fraser asked those attending to favorably consider this legislation as a means to protect women, children, and the public.

Dr. David Pauls, encouraged favorable consideration of this legislation (Attachment 4). He indicated his concerns regarding the egg donation industry and suggested that passage of this legislation would provide the data and follow-up necessary to evaluate the safety of egg donation.

Dr. Bruce Tjaden testified as a medical doctor specializing in reproductive endocrinology. He provided information concerning the five centers in Kansas that provide reproductive medicine care (Attachment 5). He indicated that those in reproductive medicine are required by the Center for Disease Control to submit data on an annual basis and are monitored more closely than any other field of medicine. He requested Senators vote against **SB 509**.

Dr. Peter Bath provided comments related to Shawnee Mission Medical Center's commitment to serving as one of the four reproductive medicine facilities in Kansas. He reported that his facility reports annually to the Center for Disease Control and the Food and Drug Administration all statistics concerning assisted reproductive technology similar to those outlined in **SB 509** (Attachment 6). He indicated **SB 509** duplicates surveillance efforts being conducted at the national level and encouraged a vote against this legislation.

Sarah Meyer spoke against **SB 509** (Attachment 7). She shared her experience with seeking medical care from a reproductive endocrinologist. Ms. Meyer cited the physician/patient relationship will be impacted if this legislation is passed. She expressed doubtful concern that her privacy would be protected and criticized the fact that criminal investigation and penalties could result.

Thomas Witt, Chair, Kansas Equality Coalition, encouraged Senators to vote down or amend **SB 509** (Attachment 8) because it creates a mechanism for tracking/reporting gay and lesbian Kansans to state agencies. The legislation requires amendment to provide greater protection for private medical records, to prevent unauthorized disclosure, and to create severe sanctions for those who violate provisions.

Dr. David Grainger, University of Kansas School of Medicine (Wichita) spoke in opposition to **SB 509** (Attachment 9). He commented that the bill is intrusive, duplicative, expensive, and unnecessary. He indicated the bill provides no "opt-out" clause for data collection; provides public access to medical information of infertility patients; and increases costs at a time when the State is fiscally challenged

Senator Barnett asked Senators to evaluate the written testimony provided by:

Sindy Wei-mester, MD, PhD, private citizen, in favor of **SB 509** (Attachment 10)
Barbara Atkinson, MD, Executive Vice Chancellor, Executive Dean, School of Medicine and Paul Terranova, PhD, Vice Chancellor for Research, Senior Associate Dean, School of Medicine, Kansas University, in opposition to the legislation (Attachment 11)
Dr. Jason Eberhart-Phillips, MD, MPH, State Health Officer and Director of the Division of Health, Kansas Department of Health and Environment, offering comments from a neutral position (Attachment 12)

Chairman Barnett adjourned the meeting at 2:30 p.m.

PUBLIC HEALTH AND WELFARE
GUEST LIST
March 11, 2010

NAME	AFFILIATION
Drew Schifman	Sunrise Point Elementary
Dominic Legato	Sunrise Point Elementary
Landon Ginther	Sunrise Point Elementary
Ryan Schmidt	Surise Point Elementry
Luke Killman	Sunrise Point Elementary
Hayden Richardson	Sunrise Point Ele.
Gracie Salts	Sunrise Point Elementary
Analiese Lahey	Sunrise Point Elementary
Maggie Manning	Sunrise Point Elementary
EVAN PHILLIPS	SPE
Douglas Gould	Sunrise Point Elemetary
Leslie La Place	Sunrise Point Elementary
Yvonne Barnett	Sunrise Point Elementary
Ken Schifman	SPE
Christy Richardson	SPE
LaShelle Ginther	SPE
Peggy Salts	SPE
PETER BATH.	SHAWNEE MISSION MEDICAL CENTER
Melissa Ness	Shawnee Mission Medical Center
Marlee Carpenter	KAHP
BRUCE TJADEN	Wichita. KS
David Grainger	Wichita KS
Jackson Lindsey	Stein Law
Chad Austin	KHA
Dena Winegarner, DO.	none
Marilyne Winegarner	—
Becky Winegarner	—
Sara Haworth	Intern - Sen. Vicki Schmidt
Linda Kaesen	KDHE
Kari Presley	Kearney & Associates

Holly Smith	Kansas Liberty
Jeanne Gawdun	ICFL
Michael Schuttloffel	Kansas Catholic Conference
Sarah Meyer	citizen
Jamal Jones	United Health Group
Sarah Gillooly	PPKM

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Testimony by Senator Mary Pilcher Cook
Senate Health Committee – **SB 509**
Thursday, March 11, 2010

Chairman Barnett and members of the committee:

Thank you for the hearing on the Women's Health and Embryo Monitoring Act (WHEMA). Technology is changing at breakneck speed in many fields, and it is bringing with it some issues that need careful consideration by legislators in regards to women's health and the monitoring of embryos.

Today, you will hear via testimony, some of it personal, that with egg and sperm donation, and *in vitro* fertilization and research facilities, we have:

- a lack of information,
- a lack of oversight,
- a lack of health and safety measures
- and therefore, a lack of consumer protection,
- which leads to shattered lives and long court battles.

Our laws have not kept up with these concerns, and the subjects involve biotechnologies which profoundly affect people's health and their lives in a multitude of ways. A few days ago I sent you an email with a bulleted list of links to stories on several of these subjects. I hope you had time to read some of them.

In addition to the impressive testimony you will hear from the individuals who gave up time from their private lives to be here today, I urge you to please consider the written testimony from Dr. Sindy Wei-Mester, who has an M.D. and a Ph.D. in Biology with a strong background in basic science research.

Dr. Wei-Mester assures us that in medical and research training there are certain important principles whenever attempting a procedure or study. In this health committee, we are constantly addressing these principles: **1) ethics, 2) subject safety, 3) informed consent, and 4) patient autonomy.**

HB 509 is a bill that, for the most part, just asks for information. It does not mandate clinical procedures – it simply asks what those clinical procedures are. The bill protects patient privacy.

After the testimony you hear today, I think you will agree Kansas Legislators need to have the ability to receive, and give the public, some general information about women's health and embryo monitoring in IVF and research facilities in Kansas.

Thank you for your consideration.

Senate Public Health & Welfare
Date: 03/11/10
Attachment: 1

Testimony in Support of Senate Bill 509, "Women's Health and Embryo Monitoring Program Act,"

Before the Public Health and Welfare Committee

By Jennifer Lahl

March 11, 2010

Members of the Senate, thank you for inviting me today to testify on behalf of the "Women's Health and Embryo Monitoring Program Act" and to submit my comments on the well-being of women and children.

My name is Jennifer Lahl. To establish my credentials and expertise relevant to this testimony, permit me to give you a brief overview of my background. I have a B.S. in Nursing and worked for over 20 years in pediatric nursing, specifically pediatric critical care nursing at UCSF, UCLA, and Children's Hospital in Oakland, CA. I was a member of the transport team at UCSF, where the majority of the flight and ground transports I did involved going out to smaller community hospitals and picking up critically ill children, specifically premature infants. I have contributed chapters in a nursing textbook on Maternal and Child Health and was three-time editor of *Facts and Comparisons*, a drug reference book for use by healthcare professionals. I have published peer-reviewed articles in the *American Journal of Bioethics*. Throughout my career, I have been a long-time patient advocate.

In 2000, I received my master's degree in bioethics and have been involved since that time as the national director of a non-profit educational organization, the Center for Bioethics and Culture. Since 2000, I have written and spoken extensively on reproductive technologies, the exploitation of women through various reproductive technologies, and the risks to the health and well-being of women and children. I have testified to members of the European Parliament in Brussels on the exploitation of women for their eggs by the international in vitro fertilization (IVF) industry. I have briefed members of the U.S. Congress on Capitol Hill three times on one of my organization's projects, titled "Trading on the Female Body." I am also a member of ISMAAR, the International Society for Mild Approaches in Assisted Reproduction, and attended ISMAAR's Second World Congress in London. I have been interviewed by numerous media outlets, including a PBS program dealing with egg donation, and *The Montel Williams Show* on "Extreme Baby-making." And I gave a Technology Talk on the Google Campus in Mountain View, CA, on these same issues.

The concerns that bring me before you today are threefold.

Fertility medicine as currently practiced in the United States is:

1. Dangerous to women
2. Dangerous to children
3. Woefully unregulated and lacking proper oversight

I encourage you to support this bill in that it seeks to address all three of these problems by beginning the important task of collecting data which can be used to provide the information needed to better inform consumers of the risks and benefits of fertility medicine and protect all of the stakeholders involved in fertility practice.

Senate Public Health & Welfare
Date: 03/11/10
Attachment: 2

Dangerous to Women

25 years of reproductive technology addressing human infertility have lured us into thinking that ovarian stimulation, and egg harvesting and retrieval procedures are safe. Since 1978, when Louise Brown was born as the first "test tube baby," the reproductive industry has grown. In America alone, it is a $6.5-billion, largely unregulated business.[1] But the view that these technologies are safe is far from reality, as we look at the many ways a woman's body can be harmed.

From the American Society of Reproductive Medicine publication, Assisted Reproductive Technology: Guide for Patients:

Ovarian stimulation carries with it a risk of hyperstimulation, where the ovaries become swollen and painful. Fluid may accumulate in the abdominal cavity and chest, and the patient may feel bloated, nauseated, and experience vomiting or lack of appetite. Up to 30 percent of patients undergoing ovarian stimulation have a mild case of ovarian hyperstimulation syndrome (OHSS) that can be managed with over-the-counter painkillers and a reduction in activity. In moderate OHSS, patients develop or accumulate fluid within the abdominal cavity, and gastrointestinal symptoms may occur. These women are monitored closely, but generally do very well with simple outpatient management. The condition tends to resolve without intervention unless pregnancy occurs, in which case recovery may be delayed for several weeks. Up to 2 percent of patients develop severe OHSS characterized by excessive weight gain, fluid accumulation in the abdomen and chest, electrolyte abnormalities, over-concentration of the blood, and rarely the development of blood clots, kidney failure, or death. It may be medically necessary to drain fluid from the abdomen with a needle if breathing becomes difficult. Patients with severe OHSS require hospitalization until the symptoms improve. If pregnancy occurs, OHSS can worsen. Occasionally, termination of pregnancy must be considered in the most severe cases. Although initial reports suggested that women who use fertility drugs have an increased risk for ovarian cancer, numerous recent studies support the conclusion that fertility drugs are not linked to ovarian cancer. Nevertheless, there is still uncertainty whether a risk exists and research continues to address this question.

Please consider the stories of a just a few women who have experienced short- and long-term risks:

Calla Papademas, while a Stanford student, suffered a severe brain stroke because of OHSS. Calla was being superovulated in order to "donate" her eggs to a man who wanted to have a child using a surrogate. Calla will never be able to have her own children.[2] Calla had an undiagnosed benign pituitary tumor, a condition that occurs in 25 percent of the general population.

Jaqueline Rushton died of Acute Respiratory Distress Syndrome as a direct result of OHSS. Her case was so severe that she suffered multiple organ failure, which included her lungs, thus requiring mechanical ventilation to assist respiration.[3]

Jessica Wing died at age 31 of colon cancer. It was only when Jessica's mother, a physician, started doing research and found other cases in the literature linking these drugs to colon cancer did she put two and two together. Her mother, Dr. Jennifer Schneider, has now joined me at two congressional

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[1] Sigrid Fry-Revere, "Funding Embryonic Stem Cell Research: Government Largesse is Not Always the Best Option," *Genetic Engineering and Biotechnologyy News*, Mar 15 2007 (Vol. 7, No. 6). http://www.genengnews.com/articles/chitem.aspx?aid=2061&chid=0

[2] The Calla Papademas Story Video http://www.thecbc.org/research_display.php?id=361

[3] "IVF Treatment Killed My Daughter" http://news.bbc.co.uk/1/hi/health/4635261.stm

briefings, speaking out for the need of an egg donor registry to begin tracking and monitoring these young donors so we can provide proper informed consent.[4]

Jane Doe, who had to tell her story anonymously as stipulated by her contract agreement with the fertility clinic, had an artery cut during the egg retrieval process, during which they extracted almost 60 of her eggs. The internal bleeding was not detected for several hours, until she almost died and had to be returned to the operating room for exploratory surgery to find and repair the source of her hemorrhage. She has ongoing health problems and is being treated for infertility now.[5] This incident occurred at a prestigious fertility facility in the San Francisco Bay Area.

One 33-year-old woman suffered a massive heart attack as a result of OHSS. Five days later her husband had to make the awful decision to remove his wife from life support.[6]

A review of the literature on strokes reported on 34 women following their ovarian stimulation. In 12 cases, stroke occurred in the cerebral arteries. One case had major retinal artery involvement. Six cases with occlusions in major peripheral vessels and two cases with mesenteric artery occlusions. Three women had myocardial infarctions and two had intracardiac thrombosis. The case review of these women showed the majority of them had no associated risk factors; several women were left with either residual paralysis or post stroke, two women required amputation, and one died.

Long-term risks are associated with increased incidence of cancers. Major studies suggest a link between cancer and ovarian stimulation. Results of a study published in the *American Journal of Epidemiology* show that the hormones used to induce ovulation appear to increase the overall risk of cancer.[7] One study showed that 567 women who had received drug treatment to induce ovulation had a 36 percent increased risk of developing cancers. This study also reports an increased risk of breast cancer by 42 percent; uterine cancer risk by more than threefold; and the risk of non-Hodgkin lymphoma by about 2.5-fold. Treatment with the ovulation-inducing drug Clomiphene was associated with an increased risk of uterine cancer by 4.6 times, and an increase the risk of malignant melanoma by 2.6 times. Most studies cite a limitation to their research, stating that longer studies with more women need to take place.

I could go on and tell countless more stories of women who I've personally met or read about in the media and scientific literature. Sadly, the IVF industry remains woefully unregulated, and what reporting is done by the Centers for Disease Control and Prevention (CDC) is largely success- and outcome-driven, with several years of lag time in reporting.

Dangerous to Children

One of the many ways that today's reproductive technologies are reckless—endangering the health of mothers and their babies—is by implanting multiple embryos at one time. It is said that multiple births associated with IVF have reached epidemic rates: currently 1 in every 4 IVF pregnancies results in a multiple birth. Because of the high risks and very real risks to the mother and her children, there is a

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[4] In Vitro Fertilization and Cancer, by Jennifer Schneider, MD
http://www.beforeyoutakethatpill.com/2008/10/schneider.html

[5] Interview with Jane Doe, "The Diary of a nameless, faceless, egg donor" http://cbc-network.org/research_display.php?id=379

[6] http://news.bbc.co.uk/2/hi/health/4440573.stm

[7] http://www.cancerpage.com/news/article.asp?id=13150

movement outside of the U.S. toward a practice known as eSET.[8] eSET stands for "elective single embryo transfer." One baby at a time is best for the mother, and certainly best for the child. Children of multiple births are at risk of low birth weight and of being born prematurely. Premature and low birth weight infants suffer both short- and long-term medical and developmental problems. They are often born with organs that are less developed and, therefore, not functioning properly; this requires high medical critical intensive care.

Also, the "vanishing twin" concept is very real for women carrying multiple children, as there is a real danger of miscarriage of one or of several of the embryos. A woman's womb is not meant for *litters,* and inadvertently, miscarriage happens with multiple births—that is, the twin *vanishes*.[9]

An independent consulting group's Executive Summary to the Human Fertilization and Embryo Authority in the United Kingdom said, "Multiple birth is the single biggest risk to the health and welfare of children born after in vitro fertilisation (IVF). It can be effectively reduced by transferring only one embryo to those women who are most at risk of having twins."[10] Since 1980, the rate of twins in the United States has risen 70 percent.[11] Twins and multiple birth children have a higher risk of birth defects than single births.

And there are also the risks that the fertility technologies place on these children. These technologies are not as safe as the public is led to believe.[12] Babies are at risk for:

- Heart defects (hole between the two chambers of the heart)
- Cleft lip or cleft palate
- Improperly developed esophagus
- Malformed rectum
- Increased risk for certain rare genetic disorders[13]
- Fourfold increased risk of stillbirth in IVF and ICSI babies
- Five percent to 10 percent chromosomal difference in IVF over naturally conceived children
- Neural tube defects
- Low birth weight later predisposing them to obesity, hypertension and Type 2 diabetes
- Autism

One study involved 9,584 babies with birth defects and 4,792 babies without. Among the mothers of babies without birth defects, only 1.1 percent had used IVF or related methods. In the other group, however, 2.4 percent of mothers of babies with birth defects had used IVF or related methods.

Recent U.S. data reports that of 140,795 IVF cycles, only 59,790 resulted in births, a 60 percent failure rate!

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[8] HFEA Statement of Elective Single Embryo Transfer http://www.hfea.gov.uk/en/1713.html
[9] Consequences of Vanishing Twins in IVF/ICSI Pregnancies
http://humrep.oxfordjournals.org/cgi/content/abstract/20/10/2821?eaf
[10] HFEA Executive Summary, http://www.hfea.gov.uk/docs/MBSET_executive_summary.pdf
"[11] Lowering Odds of Multiple Births,"
http://www.nytimes.com/2008/02/19/health/19mult.html?_r=3&oref=slogin
[12] "Birth Defects Tied to Fertility Techniques,"
http://www.nytimes.com/2008/11/18/health/research/18birth.html?_r=1
[13] "Picture Emerging on Genetic Risks of IVF," http://www.nytimes.com/2009/02/17/health/17ivf.html?_r=2

The first IVF children are only now entering adulthood; most are still under 20. And sadly, no long-term studies are being conducted to follow-up these children.

Woefully Unregulated and Lacking Proper Oversight

One news story reported, "Most fertility clinics break the rules."[14] This article reports that, "Fewer than 20 percent of U.S. clinics follow professional guidelines on how many embryos should be used for younger women." Dr. Bradley Van Voorhis, director of the fertility clinic at the University of Iowa, said, "Clearly, most programs are not adhering to the guidelines." The recent attention on Nadya Suleman and her octuplets, along with the 60-year-old, postmenopausal Canadian woman who gave birth to premature twin boys, has finally brought much-needed scrutiny to fertility practices.

Lack of controls and regulation have caused the infertility industry to be referred to as the "wild, wild west" and fertility doctors as the "cowboys," supported by stories such as these:

- Ben Ramaley, a fertility doctor in Connecticut, was accused of impregnating a female patient without her knowledge, let alone her consent, using his own sperm. The couple had doubts about the biological father when their twins were born with a "fair complexion." The patient's husband is African-American. DNA testing confirmed their suspicions.[15]
- Kirk Maxey, now 51, donated his sperm anonymously twice a week between 1980-1994. By his own estimation, he believes he could have fathered 400 children.[16]
- A legal puzzle when a baby has three biological parents.[17]
- "Building a Baby, with Few Ground Rules." Working mostly over the Internet, Ms. Kehoe handpicked the egg donor, the anonymous sperm donor, and a gestational carrier who would deliver her baby. Finally, she hired the fertility clinic, which put together her creation. A month after Bridget and Ethan were born, the surrogate who gave birth to them gained custody, as she had obtained a court order to retrieve them after learning that Ms. Kehoe was being treated for mental illness.[18]
- A high-profile case of Nadya Sulyman, a single mother by choice, who has 14 children by assisted reproductive technologies, eight of the children born at one time. Her physician, Michael Kamrava, has been expelled from the American Society of Reproductive Medicine and is under investigation by the Medical Board of California.[19]
- "For Sale: Human Eggs Become a Research Commodity." Offering up large sums of money for egg donation may be too good an offer for some women to pass up—especially those who might not qualify for paid fertility donation, which screens women based on intellectual and physical attributes. The financial incentives might also drive some to over-donate.[20]

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[14] "Most fertility clinics break rules," http://www.usatoday.com/news/health/2009-02-21-fertility-clinics_N.htm

[15] "Dr. Ben Ramaley: Fertility Doctor Accused Of Using Own Sperm To Artificially Inseminate Woman," http://www.huffingtonpost.com/2009/11/13/dr-ben-ramaley-fertility_n_357611.html

[16] "Mapping the God of Sperm," http://www.newsweek.com/id/227104

[17] "A Legal Puzzle: Can a Baby Have Three Biological Parents?," http://www.nytimes.com/2010/01/26/opinion/26tues3.html

[18] Building a Baby, With Few Ground Rules, http://www.nytimes.com/2009/12/13/us/13surrogacy.html?_r=1

[19] "Octomom Physician Accused of Gross Negligence," http://www.emaxhealth.com/1272/87/35042/octomom-physician-accused-gross-negligence.html

[20] "For Sale: Human Eggs Become a Research Commodity," http://www.scientificamerican.com/article.cfm?id=shelling-out-for-eggs

- Fertility clinic websites aren't explaining the risks of testing an embryo for genetic disorders before it's implanted in the womb, researchers found. The procedure, known as pre-implantation genetic diagnosis (PGD), can be used to test for 5,000 different genetic disorders and, more controversially, choose the sex of an infant. But it's not 100 percent reliable, and could, in rare cases, cause harm to the embryo or even destroy it.[21]

Outside of the U.S., some very positive trends and changes in fertility medical practice are occurring. Many European fertility experts have discovered that the powerful hormones and the aggressive ovarian stimulation practices are harmful to women, and that the epidemic of multiple births has significant health consequences. And so, European fertility practice is moving closer to a model of a natural cycle IVF and minimal stimulation procedures. The new model for the infertile woman is a women- child-friendly "less is more" approach.

Dr. Esther Baart, a leading expert in the field of embryology, has completed a randomized, controlled trial comparing mild-stimulation approaches with the conventional high-dose protocol. In her study, using pre-implantation genetic screening to compare the two approaches, she found that while mild stimulation reduced the total number of embryos retrieved, a significantly higher proportion of these embryos were chromosomally *normal*. Dr. Baart explains that during the natural menstrual cycle of a woman, normal levels of hormones that are naturally released allow the body to select the best-quality follicles to release eggs, which will then produce the healthiest embryos. However, with conventional, high-dose ovarian stimulation, a woman's natural hormones are unnaturally suppressed for two weeks, causing medically-induced menopause, and then she is switched to high-dose hormones to stimulate multiple eggs to release, The current aggressive approach to IVF results in abnormally high levels of estrogen. Dr. Baart suggests that this approach leads to more eggs of a *lower* quality. Mild approaches to IVF however, are conducted within the woman's own natural cycle and allow her body to select better-quality follicles, thus reducing the proportion of low-quality eggs.[22]

Women do much better and are much safer with minimal ovarian stimulation. Why? High-dose gonadotrophins, the synthetic hormones, have associated risks. With minimal stimulation, egg quality is higher and endometrial receptivity is better, which increases the success of embryo implantation, thus increasing the chances of a healthy pregnancy and the birth of a healthy baby.

Sadly, the IVF industry, the fertility specialist and fertility clinics—along with the brokers of eggs and sperm—have no vested interest in self-regulation. A *New York Times* article from February 23, 2009, which noted the pay of specialists at private universities, stated:

> *"Generally, fertility doctors are among the highest paid. . . Dr. James A. Grifo, a professor of obstetrics and gynecology at New York University, was paid $2,393,646, substantially more than the president of the university."*[23]

Dr. Grifo was recently quoted in a story on the octuplet birth. He said, "I don't think it's our job to tell them how many babies they're allowed to have. I am not a policeman for reproduction in the United

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[21] "IVF Websites Often Mum on Embryo Gene Test Risks," http://www.reuters.com/article/idUSTRE59D5FD20091014

[22] "Natural-cycle/Mild IVF: A Science-Based and Patient-Centered Approach for the Future," Dr. Geeta Nargund http://www.futuremedicine.com/doi/full/10.2217/17455057.4.4.327

[23] "Many Specialists at Private Universities Earn More Than Presidents, http://www.nytimes.com/2009/02/23/education/23pay.html

States. My role is to educate patients." Grifo was on the news praising the ASRM guidelines and objecting to laws that would regulate medical practice. Guidelines are currently ignored. The majority of fertility clinics *break* the rules. The health and well- being of women and children are endangered. And so, it is time for things to change. This bill will go a long way toward implementing corrective and sound policies.

Louise Brown, the first test-tube baby, fertilized in the lab and implanted by Drs. Patrick Steptoe and Robert Edwards, was the product of minimal stimulation IVF. Dr. Edwards, often referred to as the father of IVF, said in his published article discussing natural cycle, minimal stimulation, that the time has come to "rethink" IVF, and that the more natural approach needs to be the routine.[24]

The American Society for Reproductive Medicine has already announced its opposition to this bill and has engaged its local state members to help defeat it. But the political wind is changing, bringing a fresh political will, in some state legislators, to change the practice of reproductive medicine in their states. These leaders now see the need to protect constituents who have been ignored by the fertility industry: those left infertile, harmed, or dead; children who have a right to know who their biological parents are; and reproductive consumers who still have little or no access to much-needed studies detailing actual risks.

The fertility industry drivers do not want to check their practices. But even if they manage to temporarily block sensible legislation, eventually the facts will catch up with them, and they will have to answer to the public. As concerned citizens, we have the obligation to speak up and encourage our lawmakers to protect the defenseless by curbing the blatant excesses of an industry run rampant.

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[24] IVF, IVM, Natural Cycle IVF, Minimal Stimulation IVF—Time for a Rethink," http://www.ismaar.org/PDFs/RB2789-Edwards.pdf

Testimony by Alexandra Fraser, PhD to Kansas State Senate on Senate Bill 509, "Women's Health and Embryo Monitoring Program Act"

I would like to express my thanks to the Senators of my home state of Kansas for accepting my testimony on Senate Bill 509. I have a PhD in Biology from the University of Kansas. While I was pursuing this degree I decided to sell my eggs to help fund my graduate studies. The results were disastrous for my short-term and long-term health. Although I am a scientist, the purpose of my testimony is to tell my personal story of selling my eggs in the state of Kansas with the goal that in the future young women in Kansas will be spared significant dangers to their health. I believe that my story illustrates the need for a registry of egg donors, long-term studies to track the health of egg donors, and a decoupling of egg donation from monetary compensation.

The decision to sell my eggs: In 2002 I was 29 and all-but-dissertation for a PhD in biology at the University of Kansas. I had a job at the university making about $800 per month, which barely covered my living expenses. This research position kept me quite busy and I could not find time to write my dissertation and complete my degree. At this point I had been in graduate school for eight years, and I felt discouraged by the poverty and criticism that accompanies graduate study. I was in love with a young man who was waiting for me to join him another city, and I was desperate to complete my education and move on with my life. I calculated that three months of income would allow me to complete my degree. I looked into student loans, bank loans, and borrowing money from family but none of these options were feasible for me. I started looking for other ways to obtain $2400.

For years I had seen ads in the *Pitch Weekly*, a Kansas City area entertainment paper, advertising for egg donors. I figured, "Why not try to earn money from something I wasn't using?" I visited the university library and searched the medical journals for literature about the risks of egg donation and found nothing, thereby assuming it was not dangerous. After doing some online research I learned that I could work with either a local fertility clinic, or a broker who would arrange for me to sell my eggs to a couple in another city. I liked the idea of being seen and tracked by a local doctor. After finding the website for a reputable fertility clinic in the greater Kansas City area, I applied to sell my eggs. Money was my primary reason for selling my eggs, but my online research left me with a positive impression of the process: that I would be helping others, that the process involved a relatively low time commitment (that is, compared to working for $10 per hour), and that it was safe.

Screening and Informed consent: Through the fertility clinic, I went through a multi-stage screening process that included applications, review of information sheets, one meeting with the doctor who would perform the procedure, and multiple meetings with a nurse practitioner. The screening process focused on my genetic fitness, that is, my family history of disease, my sports and academic background, and photos of me as a child. The psychologist for the clinic also screened me for mental health issues.

I was selected to be the donor for two recipient couples who would share my eggs. I agreed that the process would be anonymous. I would not know the couples, nor would I know whether or not a child was conceived with my eggs. It was flattering to be selected, and I found the medical technology behind the process to be fascinating and exciting. I signed a contract to sell my eggs. The total compensation – which was described as a stipend for my time rather than payment for my eggs – would be $2750.

At the time I signed my contract, the nurse practitioner described the possible side effects. I was told that hyperstimulation could occur, and that infertility was possible but highly unlikely. I do not remember now whether or not she mentioned cancer as a possible risk. The list of risks was lengthy but they were presented as though they were remote. I found them to be similar to many of the potential side effects for birth control pills. I was told that the most dangerous thing about selling my eggs would be the frequent drive down K-10.

The donation and retrieval process: Over the next several weeks I took a series drugs: drugs to match my reproductive cycles to the recipient mothers, drugs to stimulate my ovaries, and drugs to ripen my eggs. Each evening for a couple of weeks I would inject myself in the thigh with a syringe, and each time I would pray for the health of the recipient mothers and that my body would make healthy eggs for them. I did know that I should have been praying for my own health.

In the week prior to the retrieval, my abdomen began to swell. I was gaining fluid and my ovaries were enlarged. I was told that my ovaries were mildly hyperstimulated, but that it was safe to move forward with the retrieval. On September 12, 2002 I underwent anesthesia, and the doctor removed 28 eggs from my right ovary using a trans-vaginal, ultrasound-guided needle. I went to a friend's house to rest and recover. Over the next several days the swelling went down. A few days after the retrieval, I was feeling pretty good. I visited the clinic again, was told I was doing fine, and we discussed the possibility of beginning another donor cycle the follow month. At this point, my experience with selling my eggs was very positive.

Ovarian hyperstimulation and torsioned ovary: A little more than a week after the retrieval, on September 21, 2002, I awoke with a searing pain in my abdomen. When I tried to walk into the bathroom I lost consciousness from the pain. It felt as though my insides were being tied tightly with a string. A friend drove me to the clinic. It was a Saturday so I saw the on-call doctor. She performed an ultrasound and said it was nothing more than my follicles shedding and that the pain would go away in a few days. She said, "If anything serious were wrong, you would know. You wouldn't have been able to walk into the clinic." Over the next three days my abdomen swelled, I was delirious with pain and fever, moving in and out of consciousness, and I couldn't move my bowels. Another friend drove me back to the clinic, where the nurse told me I needed an enema and to eat something and I would be fine. However, whenever I ate I would vomit. On the fifth day I couldn't stop vomiting. I spent an entire night vomiting stool.

The clinic agreed to see me again, yet another friend drove me to the clinic and I finally saw the doctor who had performed the retrieval. He went white when he saw my distended abdomen, and he had me on the operating table in thirty minutes. He removed my right ovary, which had swollen to the size of a grapefruit and become torsioned in my fallopian tube. I had an infection and was on the verge of peritonitis, and I had lost a lot of blood. I was admitted to the hospital — ostensibly for a day or two – but stayed two weeks because my bowels were still obstructed. For a week I had a nasogastric tube to apply suction to decompress my intestines. I had a port installed in my chest to receive liquid nutrition. Overall, I was confined to bed for almost four weeks. I lost more than twenty five pounds on my 135 pound frame, and I looked like a skeleton at the end of my hospital stay.

From the point at which I was diagnosed with the torsioned ovary, the clinic spared no expense. They got the best gastroenterologist to see me daily. The clinic put my mother up in a nice hotel near the hospital. The fertility doctor saw me daily. When I was discharged, they kept my mother and me at the hotel for another week so that they could check on me. I did not have health insurance but I never saw a bill from my surgery or my hospitalization.

I do feel that the clinic should have diagnosed my torsioned ovary earlier. Once they recognized the severity of my situation, I feel they did make a sincere effort to do the right thing. I am glad that I was working with local doctors who knew me and not an egg broker or a fertility doctor across the country that only saw me for the retrieval. Nonetheless, the donation made me very sick and I can never get my ovary back.

Since that time, I regained my strength, moved away, married the young man who was waiting for me, and got a great job. It seems ridiculous now that I was so desperate for $2400. I certainly regret selling my eggs, but I thought it was behind me.

Cancer: Almost five years to the day after my egg donation, I was diagnosed with stage II B breast cancer. I was only 34 years old and was otherwise vigorously healthy. I didn't have just a little bit of cancer: I had a three centimeter tumor tucked into seven centimeters of pre-cancerous cells. The disease was on (but not in) my chest wall. I also had pre-cancer throughout my other breast. I underwent a mastectomy, four months of chemo, followed by three more surgeries and twenty eight days of daily radiation treatments. A few months after finishing radiation I had another mastectomy. I feel very fortunate that I now show no signs of cancer. However, I am only 36 but I have lost both breasts and I have only a 65% chance of making it to age 45 free of cancer. Even if I survive, my doctors have informed me that the chemotherapy has fried my remaining ovary and I am not able to have children.

I believe that selling my eggs contributed to my breast cancer. Although I cannot prove this relationship, the following reasons suggest a link:

- My health has always been excellent with no major risk factors for breast cancer. I had no significant family history of breast cancer and do not carry either of the known breast cancer genes (BRCAI or BRCAII).
- Complications of selling my eggs are the only irregular conditions in my health history.
- Most breast cancers, including my tumor, are stimulated by hormones. Thus the mechanism exists by which ovarian stimulation could trigger tumor growth.
- The fertility drugs I took were originally developed to stimulate infertile women. Their effect on healthy, young, fertile women is likely to be different.
- Some studies indicate that the hormonal effects of pregnancy offset the risk of taking fertility drugs. Because egg donors do not become pregnant, they do not experience these benefits.
- Two doctors in the oncology field have told me that anecdotally, they see more breast cancer in women who have undergone IVF or egg donation.
- My support group for young women with breast cancer includes other women who were egg donors or experienced unsuccessful IVF cycles.

Conclusion: As a result of selling my eggs, I survived a torsioned ovary, intestinal failure, and a body cavity infection. I have also survived breast cancer, including having both of my breasts cut off, and eighteen months of harrowing chemotherapy and radiation treatments. I am grateful to be alive, but I believe that all of this could have been avoided if I had not sold my eggs – a procedure that I thought was safe. We native Kansans live proudly by our state motto, *Ad astra per aspera.* Although I survived, I believe that I suffered this adversity needlessly, and I hope that other women will not suffer as I did.

A registry of donors, including frequency of complications, would have led me to make a more informed choice. I fear that right now a young student at KU or Kansas State or another of our fine Universities is considering selling her eggs. She will not be provided with any real numbers about the risks she faces. Only long-term tracking and studies can adequately address cancer risk from egg donation. Most women who get cancer after selling their eggs will not be diagnosed for several or many years later – longer than the three to five years of data in most research studies. For example, my cancer diagnosis and my history as an egg donor do not appear in any medical literature or statistics about egg donor outcomes.

My mother, who rushed to my side when I was sick, sometimes cries that I sold her grandchildren away. She bemoans that I almost lost my life not once, but twice – all for only $2750 dollars. I think about how eager I was to move close to my boyfriend-turned-husband, and how selling my eggs has jeopardized our future together, and the possibility of having our own children. It caused me to have both of my breasts cut off, which affects my young marriage and my sense of femininity. I realize now how vulnerable I was when I was poor, frustrated, lonely and trying to finish my education. Everyday I have to live with the consequences of this stupid, ill-informed decision I made when I was 29. Eliminating the financial compensation for human eggs will spare other women from my fate.

TESTIMONY IN SUPPORT OF SENATE BILL 509
BEFORE THE PUBLIC HEALTH AND WELFARE COMMITTEE
BY DR. DAVID PAULS
MARCH 11, 2010

Members of the Kansas Senate, thank you for the opportunity to testify and submit comments on behalf of the "Women's Health and Embryo Monitoring Program Act." I am Dr. David Pauls, a practicing physician in Manhattan, KS. I was born, raised and educated here in the state of Kansas. I received my B.S. from Friends University in Wichita and my M.D. from KU. I did my residency training in general surgery in Wichita and have been in practice for the past seventeen years in Manhattan. In addition to this, I have a M.A. in bioethics from Trinity International University in Deerfield, IL. I am serving on the ethics committee for Mercy Regional Health Center in Manhattan and am the board president for the Center for Bioethics and Culture.

I come today to raise concerns regarding the egg donation industry. Unlike many other aspects of medical care, this three billion dollar industry is largely unregulated in this country, with the practice primarily occurring in private offices and clinics which fall outside the scrutiny of most regulatory agencies. In addition, most of these procedures are done on a cash basis since most insurance plans do not cover in-vitro fertilization. This places them outside the usual review that is done by insurers both private and governmental.

The continued expansion of egg donation, both for reproductive medicine and research purposes raises concerns regarding the safety of those women who are donors. The long-term effects of egg donation are still unclear. Medical literature suggesting links between fertility drugs and cancer are concerning but inconclusive. Ovarian hyperstimulation syndrome, or OHSS, is the most concerning immediate complication that can occur with stimulating the ovaries. The cause of this condition is unknown, but seems to be related to changes in the walls of the blood vessels around the ovaries, causing the vessels become leaky. In addition, the fluid from the ovary can leak out into the abdominal cavity where it is absorbed and can cause more generalized problems affecting the kidneys and lungs. Mild forms of OHSS, which can be treated as an outpatient, are estimated to occur from 8-23% of the time, while more severe forms which require hospitalization occur 2-5% of the time.

Long-term risks are more difficult to delineate due to the lack of data and follow-up. Concerns have been raised due to suggested links between ovarian stimulation and cancers of the uterus, ovary, and colon. There is controversy regarding these links which will persist unless efforts are begun to monitor women for an extended period of time following ovarian stimulation and egg donation. Efforts to further investigate these links are severely limited by the lack of any long-term monitoring in these women. While there is some reporting done by most IVF clinics through the Centers for Disease Control (CDC) and the Society of Assisted Reproductive Technology (SART), these reports only contain basic demographic data regarding the patients treated, the underlying cause of

infertility, and statistics regarding numbers and success rates for the procedures performed by that clinic. While this data is useful in looking at the clinics efficacy in achieving pregnancy and comparing it with other clinics, it provides no information regarding complications or surveillance information for egg donors. This lack of information significantly hampers the ability to delineate the risks regarding egg donation and its associated procedures. Longitudinal surveillance, which is simply a fancy term for long-term observation or follow-up, is currently done in other areas of medicine such as medical devices, treatment of cancer as well as certain infectious diseases. Long-term follow-up is the only way to accurately delineate the risks involved with ovarian stimulation procedures and protocols.

There are concerns that the ability to obtain informed consent, one of the ethical foundations in the professional practice of medicine, is constrained by the inability to accurately delineate the risks involved. Without knowledge of the long-term effects of these procedures, how can women make a truly informed decision regarding these procedures? A primary concern is that most egg donors are young adults, while diseases like cancer, a potential risk that raises particular concern, will usually not show up until years later. The lack of any long- term surveillance in this population leaves patients in the dark regarding potential problems they may face down the road.

Monitoring exists at this time in other areas of medicine. The treatment of cancer patients has long been a subject of surveillance by cancer centers across the country as part of their accreditation process. This has enabled us today to not only tell the patient what to expect in the immediate time regarding their treatment and complications, but also the long-term effects on other organ systems and the potential for problems in the future. Another area in which long-term surveillance is intensively carried out is organ transplantation. Because of this, not only do we know how well a transplanted organ is expected to work, but also the long-risks of having the immune system suppressed particularly with relation to cancers and heart disease. A third area is medical devices, such as heart valves, pacemakers, and breast implants. Long-term surveillance allows us to determine the life expectancy of these devices as well as the potential for serious complications down the road.

For these reasons, I would ask that you support and vote in favor of Senate Bill 509, the "Women's Health and Embryo Monitoring Program Act." With the data collected here, answers to some of the concerns raised regarding the safety of egg donation can be addressed in a more definitive manner which can only enhance patient safety.

THE CENTER FOR REPRODUCTIVE MEDICINE

DAVID GRAINGER, MD, MPH • BRUCE TJADEN, DO • TIFFANY VON WALD, MD • LAURA TATPATI, MD

March 10, 2010

Senator, James Barnett, MD
Public Health and Welfare Committee
State of Kansas

To the committee:

I am a reproductive endocrinologist. Like all reproductive endocrinologists, I have completed medical school, fours years of residency in OB/GYN and then completed a fellowship in reproductive endocrinology. That means seven (7) years of training after medical school.

I love my job; we are in the baby making business, we are in the family building business. There are very few things in life that we, as Americans, cherish more than our children. Those of us in reproductive medicine have the privilege of helping infertile couples become pregnant, have a baby and become a family.

In Kansas there are five centers that provide advanced reproductive medicine care, four in Kansas City and one in Wichita. Two of the programs are intimately related to medical education at the University of Kansas School of Medicine in Kansas City and Wichita, training medical students, residents in family medicine and residents in OB/GYN, as well as the physician assistant program at Wichita State University. Most of those providers stay in Kansas.

As you know those of us in reproductive medicine that provide ART are required to submit data on an annual basis to the Center for Disease Control (CDC). We are monitored more closely than any other field of medicine. I know of no statutes, rules, regulations or laws that mandate other specialist to report outcomes to the federal government, not cardiologist doing stents, nor gastro-enterologist doing colonoscopies nor plastic surgeons doing breast augmentations. None of them are required to provide information regarding how many cases they do, the age, the gender of their patients not to mention the outcome(s). Yet those of us in reproductive medicine are required to report our data annually. And we have reported our data, willingly, for many years. If the state of Kansas is interested in statistics regarding the utilization of reproductive medicine in Kansas or the outcomes of services provided, the data is already collected, already collated, and already published online. The data is currently available free to the state of Kansas, to any state or to anyone. There seems to me to be little reason for the state of Kansas to be in the duplicate data collection business. There seems to be plenty of fiscal need in the state of Kansas at this time. Schools, roads infra-structure, higher education and health care just to mention a few; needs that supersede data collection on reproductive medicine, especially redundant data collection.

The five centers in Kansas did more than 1000 cases of assisted reproduction in 2008. If we assume a 40% live birth rate (probably a conservative estimate) that means 400 babies were born that would not be here if it were not for assisted reproduction. Most of the clinics have done the same number of cases for the last five years. That would mean nearly 2000 babies have blessed Kansas families in the last five years alone. Blessings that would not exist if it were not for assisted reproduction.

Some states have laws that mandate insurance coverage for assisted reproduction. Kansas, is not one of them. Assisted reproduction is an expensive process. Most Kansans pay "out of pocket" for reproductive services. The state of Kansas does not provide support for the costs of assisted reproduction. While I understand that the cost of Women's Health and Embryo Monitoring Program is not supposed to be passed

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on to the reproductive medicine clinics. Each and every clinic will have to invest substantial resources to comply with the Act. These costs will ultimately be passed on to the patients of Kansas increasing their out of pocket costs. I think the state of Kansas has more pressing financial concerns than to pay for a redundant data collection system for reproductive medicine that will be maintained (and paid for) "in perpetuity".

I strongly opposed SB_509, the Women's Health and Embryo Monitoring Program as a superfluous program that will costs all Kansans money, will penalize those patients that need reproductive services and be of no benefit to the citizens of the state.

Thank you for your time and consideration.

Bruce Tjaden

Bruce Tjaden, DO, FACOG
Board Certified in Reproductive Endocrinology and Infertility
Associate Professor, Department of Ob/GYN
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SHAWNEE MISSION
MEDICAL CENTER

Senate Public Health and Welfare
SB 509 – Women's Health and Embryo Monitoring Program
March 11, 2010

Mr. Chairman and members of the committee I am Dr. Peter Bath, Vice President of Spiritual Wellness and Human Development with Shawnee Mission Medical Center. I am here today on behalf of Shawnee Mission to provide comments in opposition to the passage of SB 509.

Shawnee Mission Medical Center in Merriam Kansas was Johnson County's first hospital and has been caring for the health and well being of the Kansas City community since 1962. The Foundation for our Medical Center has encouraged philanthropy and focuses on improving the health of our community's residents – young and old, insured and uninsured, current and future patients. Through our community hospital and charitable work we have fostered and produced innovative approaches to community wellness and support. We strive to do this every day through effective, clinical proven best practice care that has at its center the trust and best interests of our thousands upon thousands of patients who seek us out every year.

Among the many services we offer is a comprehensive reproductive medicine program. SMMC is one of four in the state of Kansas. As an example of our services we have performed over 100 cycles of in vitro fertilization (IVF) in 2009 resulting in a pregnancy rate for all of our patients of over 50% per cycle.

As a faith based medical center, part of the Adventist Health System, we are intentionally cognizant of and supportive of a carefully articulated faith perspective in this field. We have an active Ethics Committee at SMMC that assists us in providing guidance about the use of new technologies in this area, once they become available and before they are embraced.

We are members of the American Society of Reproductive Medicine (ASRM), Society of Assisted Reproductive Technologies (SART) and report annually to the Center for Disease Control (CDC), and the Food and Drug Administration (FDA), number of cases, pregnancies, outcomes, all statistics of which are similar to what is outlined in the bill before you. As such we oppose the passage of SB 509 for the following reasons:

SB 509 requires reporting of information that is currently readily available

This bill duplicates efforts already done by the national surveillance programs. The data collected by CDC is freely accessible to everyone and has been available for a number of years.

It is unclear how the information required to be gathered by this bill would be used and for what specific purpose.

As an organization we take extreme caution in protecting information gathered from our patients and have protocols and policies in place that address the privacy concerns of our patients. SB 509 fails to define how and in what manner the information gathered as a result of the bill will be used other than a broad reference to "investigatory or evidentiary" purposes. We find the lack of specificity and safeguards troubling as we would not allow access to data of this nature without a clear understanding of its purpose.

The fiscal note is prohibitive and unnecessary.

Given the significant fiscal crisis facing the state and the increasingly challenging financial burden faced by all hospitals, it is neither prudent nor well advised to incur the additional cost for the state, estimated at $250,000. Not to mention the additional reporting costs and time for the hospital to inefficiently duplicate data and reporting structures that already exist and are well defined. Rather than establish a new structure and program, we encourage the state, if it so wishes, to review the data sources already in place.

In conclusion, we ask that after the committee considers the implications of the bill that you not support its passage, particularly in light of the level of duplication and significant resources this would unnecessarily entail for implementation.

Respectfully submitted on behalf of Shawnee Mission Medical Center,

Peter Bath, D Min.
Shawnee Mission Medical Center

Sarah Meyer
Testimony Against Senate Bill 509
March 11, 2010

Thank you for giving me this opportunity to speak. My name is Sarah Meyer. My husband and I have been married five years. We always knew we would want children, and like everyone else, just assumed it would happen for us. When it did not we saw a reproductive endocrinologist, at the urging of my physician. I was diagnosed with PCOS and later, a genetic blood clotting disorder. Both of these make conceiving a child difficult without treatment.

I am not very open with my friends, family and colleagues about my disease. I understand that more than one in eight couples in their child-bearing years suffers from infertility, so I am not alone. But few people talk about their disease. Not being able to have a child is painful, emotionally, physically and financially.

My husband I have to put up with intrusive questions into our personal lives. We know that people may mean well but this does not make their comments any less painful. Yes, we do know the proper way to have a baby. As a matter of fact, we have considered adoption but right now we want to focus on medical treatment. I would advise people to think about what they might say to someone with any other chronic disease and really think about what you are saying before making offhanded quips to your friend with infertility.

We have both been subjected to so many procedures and tests that I long ago lost count. Things like measuring the quantity and quality of my husband's sperm and numerous internal ultrasounds to measure the thickness of my uterine lining and number of follicles containing eggs. Countless blood draws. And one very sad miscarriage when I was four months into my pregnancy.

I cannot fathom why the state would want to track so much personal and private information about infertility patients. The legislation says it is so the state can track crimes. What crimes are these? I resent the fact that my doctors will have to provide another entity with these very intimate details about my family, my body and my disease. I resent the fact that my miscarriage, the private source of so much grief and pain for my family, could be used as the source for a criminal investigation. I am appalled at the number of people that will have access to my private medical information.

I also have to ask a question? Has there been an outcry from the infertility community for more government intervention? Have reproductive endocrinologists in practice asked our elected officials to keep this private information about their patients and add many more layers of bureaucracy?

I know that we go to great lengths to respect and protect the sanctity of the doctor/patient relationship. Are we now saying that in the case of treatment for the disease of infertility, that this is not a relationship deserving of that respect?

My husband and I are private citizens with a disease. We want to build out family in the state that we call home. We are deserving of our privacy.

I would like to thank everyone on the committee for your time and consideration.

Senate Public Health & Welfare
Date: 03/11/10
Attachment: 7

Kansas Equality Coalition

Our mission is to end discrimination based on sexual orientation and gender identity, and to ensure the dignity, safety, and legal equality of all Kansans

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Testimony Thomas Witt, Chair, Kansas Equality Coalition
Senate Committee on Public Health and Welfare
Statement in opposition to SB509
March 11, 2010

The Kansas Equality Coalition is a statewide not-for-profit organization with over one thousand members in nine chapters. We are a grass-roots group who works for full equality and fair treatment for gay and lesbian Kansans.

The Equality Coalition opposes SB509, and we do so for specific and narrow, but critical, reasons.

SB509 is written to add comprehensive reporting requirements to fertility clinics and fertility research facilities. According to the quarter-million dollar fiscal note attached to this bill, "[e]ach fertility clinic must report data to KDHE from a required list of 70 data items." Among those data items are the marital status of the fertility patient, whether male or female, and whether the clinic offers fertility services to "same sex couples."

Furthermore, SB509 permits the Kansas Department of Health and Environment to turn these reports over to a private company for retention and analysis, and while it provides for criminal penalties for unauthorized disclosure of private medical records, those penalties do not provide for any civil relief for those persons who may be damaged by a release of their medical records.

Finally, SB509 criminalizes any failure to report those 70 data items as a level 10, non-person felony.

The Kansas Equality Coalition opposes these specific provisions of SB509 for the following reasons:

- The provisions of this bill can be used to require the disclosure by fertility patients of their sexual orientation as a requirement for receiving treatment. It is currently legal for businesses to discriminate against Kansans on the basis of their sexual orientation; indeed, at least two of our members have come before this body to testify about employment discrimination, and returned home only to find they've been fired because their sexual orientation became public.
- The state of Kansas, through our constitution, explicitly bans recognition of same-sex couples. SB509 seeks to add same-sex couples to Kansas statutes for reasons that are unclear, and that have no impact on the efficacy and safety of fertility treatments.
- Since the state of Kansas does not recognize same-sex couples, and this bill requires reporting of the marital status of all patients, those unmarried same-sex partners seeking fertility treatments are further exposed to invasive questions that have no impact on the efficacy and safety of their medical treatment.
- SB509, through its provisions for disclosure to outside contractors, places in the hands of anonymous individuals some of the most intimate and sensitive information imaginable. There is little recourse for persons who have their information disclosed or misused, information that may then be used to legally discriminate against the patient.
- Criminalization of the reporting requirements will put fertility clinics in the business of inquiring about *all* their patient's sexual orientation, and will make that information part of their permanent record on file with the State of Kansas.

SB509 sets up a mechanism for tracking and reporting gay and lesbian Kansans to state agencies, one which we find incredibly abhorrent and offensive. We urge this committee, in the strongest possible terms, to strike these provisions from this bill before it moves forward. We also request that you amend this bill to provide much greater protection for private medical records to prevent their unauthorized disclosure, with severe sanctions for those who violate these provisions.

Senate Public Health & Welfare
Date: 03/11/10
Attachment: 8

The University of Kansas
School of Medicine-Wichita

Office of Research

March 11, 2010

Senator Jim Barnett
Chair
Senate Public Health and Welfare Committee
Kansas Legislature

RE: SB 509, Women's Health and Embryo Monitoring Program Act

Dear Chairman Barnett,

Thank you for the opportunity to provide comments today regarding my strong opposition to Senate Bill 509. This bill is intrusive, duplicative, expensive, and ultimately unnecessary and therefore one must question its intended purpose.

Senate Bill 509 proposes collecting and making public a vast array of personal and very private information about couples seeking infertility care. The bill provides no opportunity for the patient(s) or clinics to opt-out of this data collection. To my knowledge, there is no example of a medical illness that would have such surveillance and publication of the details of an individual's health condition. While the bill claims confidentiality (Section 5), it quickly provides at least four means by which sensitive, identifiable data could be obtained and used (Section 5, c1-3, d).

Reproductive data should be considered the most sensitive data that could possibly be collected on individuals by the government. It is certainly looked at that way at the Federal level. In fact, the CDC offers this type of data 308(d) protection – the highest level of protection that can be offered by the Federal Government. I will quote the language of 308(d) as it relates to HIV/AIDS data (such as would be collected under SB 509) and you can make the comparison to what is actually written in SB 509:

"...is collected with a guarantee that it will be held in confidence, will be used only for the purposes stated in this Assurance, and will not otherwise be disclosed or released without the consent of the individual or institution in accordance with Section 308 (d) of the Public Health Service Act (42 U.S.C. 242m(d)). This protection lasts forever, even after death."

If passed, SB 509 will provide public access to personal and private information of infertility patients. This fact will have a chilling effect on those seeking reproductive care in our state. Issues of privacy alone should dissuade a single vote for this bill in your committee.

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It should be noted that most of the data requested in this bill are already being provided to the federal government by infertility clinics. In 1992, Congress passed the Fertility Clinic Success Rate and Certification Act. This act was passed to provide protections and useful information to the consumers of assisted reproductive technologies, and ultimately provided a mechanism for fertility clinics to report data to the federal government about the outcomes of every cycle of assisted reproduction that occurred in the United States. This data is collected, validated, and published annually by the Center for Disease Control in conjunction with the Society for Assisted Reproductive Technology (SART). Over 120 data elements for each cycle are collected by clinics and submitted to the government. Most of what is asked for in SB 509 is duplicative of what clinics are already reporting to the CDC. What is not duplicative appears to be completely unnecessary (for example, the method of disposition of every egg retrieved in the assisted reproduction process, egg grading) and the method of disposition of every embryo created. This information is useful to the patient only; it serves no purpose to collect and report this data to a government agency. Moreover, SB 509 would require the collection of financial information of patients and how they pay for services. This bill is also over-reaching, attempting to address complex issues with vague plans (for example, the language on donor-conceived children and third party reproduction options).

Lastly, this bill is too expensive. The cost ascribed to this bill seems deceptively small. As the past president of SART, I am intimately aware of the costs of collecting and transmitting this data to the federal government. It is my opinion that these costs to the state have been grossly underestimated (software costs alone may exceed the overall budget, in my opinion). Furthermore, this bill would add a tremendous burden to the providers of infertility care of redundant reporting and record retention – in perpetuity, and make criminals of medical professionals who fail to report or fail to report accurately. This will drive the costs of IVF even higher, making this highly successful therapy even less available to the citizens of our state. Infertility patients already bear a huge burden in financing the costs of treatment that are routinely not considered a reimbursable medical expense by health insurers.

For these numerous reasons, I urge the members of the committee to vote NO on SB 509. Thank you for your consideration of my strong opposition to this unnecessary bill.

David A. Grainger MD, MPH
Associate Dean for Research
Professor, Division of Reproductive Endocrinology and Infertility
University of Kansas School of Medicine - Wichita

Testimony in Support of Senate Bill 509
Before the Public Health and Welfare Committee
By Sindy Wei-mester
March 11, 2010

My name is Sindy Wei-Mester. I have an M.D. and a Ph.D. in Biology with specialization in the field of real-time live imaging of the early immune response. With my strong background in basic science research and publications in top scientific journals such as *Nature* and *Science*, I have always been an avid supporter of biological research using live subjects and donated tissue, both animal and human. However, my experiences have taught me that at times, even a scrupulous medical scientist may be tempted to make erroneous assumptions, cut corners, or risk safety in order to save time or achieve success. In my medical and research training I have learned the importance of certain principles whenever attempting a procedure or study. These include: **1) ethics, 2) subject safety, 3) informed consent, and 4) patient autonomy. I am testifying today as a former egg donor on the dangers posed to women by the egg harvesting industry. I believe that all four of the above key principles had been violated in my case.** Even though I suffered immediate life-threatening complications from the process, it wasn't until many more years of medical training that I was able to understand the full scope of how I had been taken advantage of, mislead, and abandoned by the egg harvesting industry. As a medical professional it is still difficult to accept that such abuses are allowed to exist in my profession. Meanwhile, players "behind the scenes" such as the egg donation agency and the egg brokers have left the issues of ethics, health, and safety to the doctors, so that they can concentrate on profit. **It is my assessment that the egg donation industry cannot be allowed to continue without regulations aimed at preventing unethical recruitment, substandard practices, and inadequate monitoring of women for the purpose of egg harvesting.**

The goal of my testimony is to illuminate the importance of placing regulations on the way that the egg harvesting industry is run -- from ethical, legal, and medical standpoints. 1) The health and safety of women must be protected first and foremost in any procedure related to ovum production, and should never be superseded by concerns of profit, costs of screening and monitoring the subject, quantity of eggs produced, quantity of eggs retrieved, or completion of the cycle. 2) Furthermore, like any other industry, the egg harvesting industry must be held accountable for reporting adverse effects and for tracking the long-term health of donors. 3) Ethically, informed consent must be properly obtained, with an admission that more research is needed to illuminate the long-term risks to donors. It is also an ethical responsibility for those who profit from egg harvesting to track the health of donors, including conducting large scale research in order to study risks.

I will now relate my experience. In 2001, while still in the combined MD/PhD program, I signed up for egg donation after seeing a university newspaper advertisement for egg donors. The monetary compensation of $6500 seemed like a lot to me at the time, as I made barely enough to live on. Though I had a desire to help an infertile couple, money was definitely a major driving factor in my decision. Before I started, I searched the medical literature with a fine-tooth comb to verify that this procedure was indeed as harmless as advertised by the egg donation agency. I did not find any hard evidence in the literature of future infertility and cancers, and it seemed that the risks of other complications were extremely low. However, I was not told that the egg

donors were rarely followed after the donation, and that doctors were under no obligation to report adverse events[1]. Like many other women egg donors, I was bound by legal contracts to remain anonymous and therefore even if late complications occurred, they would be difficult to report.

At this point I had a normal gynecologic history, including normal age at first menses, regular menstrual cycles, and nothing significant on pelvic ultrasounds. It was assumed that I was healthy enough to undergo the egg harvesting protocol. Then I submitted my photographs, passed my genetic screening as a "quality assurance" for the tissue purchaser, and submitted myself to a psychological screen and IQ test administered by a psychiatrist. Based on these results I was chosen as the egg donor, from whom a "designer offspring" would be created.

The legal contract stated that the creation of these eggs were for the purpose of in vitro fertilization. The recipients of my eggs would retain all rights to my eggs and any subsequent embryos created from my eggs, "including but not limited to the ability to make all decisions regarding disposition of embryos." The literature given by the egg donation agency outlined the possible risks of ovarian hyperstimulation syndrome (OHSS), as well as some other theoretical risks that they assured me were rare. What I did not realize at this time was that there were other hidden players in the egg industry who could potentially make money off my eggs, and that there were no laws in place to discourage hyperstimulation of many more eggs than reasonably needed for the goal of helping the infertile couple. My contract did not guarantee that third parties would not be involved in the trading or selling of these eggs, though it specifically forbade donations to other infertile couples without the donor's consent. **My eggs could have been a high-value commodity for profiteers who had nothing to do with the infertile couple, and I was not made aware of this possibility in a forthcoming and direct manner.**
The below was part of the information provided to the public by the egg donation agency:

Q: How many eggs are removed during the retrieval?
A: The average is 10-15 eggs aspirated per cycle, but donors can produce 16 or more eggs.

Q: Can a donor <u>not</u> produce enough eggs in a stimulated cycle?
A: Yes, if the doctor cancels the cycle for poor response the donor will be compensated between $650.00-750.00.

According to my agency, failure to produce more than 4 eggs qualifies as "not enough eggs". Four is typically higher than the target for women who are receiving fertility treatment using oral medications. However, note that there is no upper limit for the number of eggs a donor may safely "produce", indicating that safety of ovum overproduction is being ignored. This illustrates that the drive to produce a higher number of eggs is extremely high, and failure to produce "adequate" eggs is linked with reduced financial compensation for the donor. Needless to say, this concept of "more is better" brings up ethical questions concerning the use of financial compensation for the recruitment of egg donors. This is especially alarming when no standards are in place to prevent an agency from overproducing eggs. The agency also told me that if I had a successful donation and become a proven donor, I may receive more compensation for future cycles, upwards of $8,000 (on paper) to $20,000 (verbally) – more than I would make in a year of intensive lab work. **When "successful" production cycles are linked to increased financial**

compensation and "failures" are linked to a decrease in financial compensation, women will become more likely to tolerate untoward side effects, including those of OHSS, for fear of losing this compensation. This payment structure poses an obvious ethical conflict.

After signing my legal contract I began to administer all the medications as directed by the egg donation agency. These medications arrived by mail. I already knew how to mix and administer the medications but I don't recall being instructed by medical personnel. At no point did they adjust my dosage. I remember receiving follow-up early on with a local doctor, and more exams after I travelled by plane to Northern California for the harvesting. **Imagine my surprise when they told me that I was producing approximately 60 egg follicles!** A mature follicle measures ~2 cm in diameter. The normal ovary measures approximately 4 x 2.5 x 1 cm, and is analogous to the testes. Therefore, you can imagine how 30 mature follicles of 2 cm diameter clustered within each gonad must look like and feel. **I was concerned, but the doctors and nurses assured me that this was within the reasonable range for a fertile young woman.**

A couple of days before the retrieval the nurse emailed me that my blood estrogen (estradiol) levels came back much higher than they had anticipated (~10,000 pg/ml). A woman in her 20s has an average estrogen level of ~150 pg/ml, with a peak of ~400 pg/ml prior to ovulation. In late pregnancy, the levels may rise 100-fold, but this rise normally occurs over a 6 month period. I asked the fertility specialist to consider altering the timing and course of this process. I was concerned because the drugs I received were probably tested on Caucasian women of average weight. I am a thin non-Caucasian woman. Studies have shown genetic differences in liver drug metabolism for ethnic populations; the examples are too many to reference and are beyond the scope of this topic. **Despite my concerns, the doctor told me that even though my hormone levels were extremely high, they would not make any adjustments to the protocol because they did not want to risk failure.** I continued to follow all their directions, as it stipulated in my legal contract that I "(understood) it (was) imperative" that I "not deviate from (the protocol) unless instructed to do so by the IVF physician." Therefore, I proceeded to finish my ovarian stimulation, finishing off with a shot of human chorionic gonadotropin (HCG) to help release the eggs for the harvesting. The next morning, I underwent transvaginal needle retrieval of the eggs.

What was unknown after the surgery was that the doctor had punctured an artery during the harvesting. When I woke from the anesthesia I became weak, nauseous, and dizzy. I was scheduled to catch a plane that afternoon, to return home. They told me that I looked good and was ready to go home, even though I had problems maintaining my blood pressure. At this point I refused to leave, because I could not stand without getting dizzy –orthostatic hypotension after an invasive procedure typically raises the suspicion of blood loss. A few hours later they started giving me intravenous fluids because they thought that the anesthesia was causing my low blood pressure. Then I developed pain and difficulty breathing. **An ultrasound showed that everything was fine except for fluid in my pelvis, which they said was normal (later, this was documented as "fluid pocket near the right kidney".** During this entire time the doctor and nurse persisted in trying to get me to leave, which would mean hours of traveling by car and plane. The pain in my belly became unbearable and I became convinced that I was bleeding internally; something was irritating and pushing on my diaphragm. **When I asked if I could be bleeding internally, they told me that it was unlikely.** My blood pressure was even lower at

this time, so they gave me medication to raise it. Unfortunately giving pressors in a bleeding patient increases the bleeding rate. **At 6pm, after 8 hours of slowly and painfully bleeding out, they FINALLY admitted me to the hospital. To me it seemed like they had done just about everything to get rid of me up until that point.** The fertility doctor ordered me to eat something. As soon as I sat up in bed to eat, I developed sudden distress and difficulty breathing. They took my blood pressure and called out "40/20". At that moment I feared that I going to die. In my medical records the blood pressure reported was 61/29. At this point they finally began to realize that something was terribly wrong, that I was going into shock from blood loss, so I was taken into the operating room for an emergency exploratory laparotomy to find the source of bleeding. The surgeons flipped through my bowels three times to ensure that no other organs were punctured.

During the harvesting of ~60 eggs, which I assume required 60 passes of the needle through my ovaries, the fertility doctor had punctured a high pressure artery in my right ovary. This tiny bleeder was easily fixed with a touch of electrocautery. I had an emergency blood transfusion to replace the 1.5 liters of blood lost. There is absolutely no reason why they should have waited so long to properly diagnose me, thus turning this into an emergency surgical situation when they could have done a small laparoscopic procedure to diagnose and fix a small bleeding artery. Had I followed their directions and gone home, I would have died. Unfortunately their disregard of the signs of OHSS, low index of clinical suspicion for post surgical complications, and their extremely slow response resulted in a horrific clinical outcome.

After the surgery, I had to be kept on a breathing machine in the intensive care unit (ICU) and treated for acidosis throughout the next day. After I was stabilized enough to move to the regular medical wards, the fertility doctor came to see me. She told me that the bleeding was probably due to a genetic bleeding disorder (i.e. my own fault) and that this has never happened before. Then she proceeded to checked me for rare genetic bleeding disorders - nothing. **I found the doctor's reluctance to accept that a simple, clear-cut complication had occurred to be highly disturbing.** A few days after I was admitted, the 9/11 attack had occurred and all the planes were grounded for a week. Despite not being able to walk or tolerate a 10 hour car ride home, the doctor told me I needed to free up medical resources and go home now. She tried to get me to leave by stating that when she had her C-section it only took her 3 days to start walking again. However, she neglected the fact that I had gone into prolonged shock caused by her own negligence, spent time in the ICU, underwent a massive surgical procedure, and had emergency blood transfusions. There were no apologies from beginning to end. **I was shocked by this dismissive attitude from a top doctor of a top fertility treatment center, a medical expert who has published many articles on safety evaluation and recommendations for egg harvesting.** At the same time, I was afraid to launch any complaints because I was a student in the same hospital system with plans to pursue the same field – Ob/Gyn; years later I decided on another medical specialty for unrelated reasons.

I am thankful to be alive, but I know that it was not because the doctor caught the post surgical complication. It was because I finally took a stand, and refused to go home when I knew that something was wrong. If I had died I would not be here to tell my story. I fear that cases like mine are buried deep by the fertility centers who do not want to lower their reputation. **While I**

was in the hospital the fertility doctor told me that she would write a case report on the complication I had. When I searched the medical literature for all of her publications some years later, I wasn't surprised to find that there was no such report. I have no way of knowing if this incident even made it into a statistical analysis somewhere in the medical literature. It makes sense that an industry thriving on profits and reputation has little incentive to report adverse events, for fear of driving away potential IVF clients and egg donors.

The $6,500 I was given has long since evaporated into medical treatments for multiple late complications caused by this incident. I developed an infection inside my incision site and required multiple steroid injections into the scar to stop it from growing out of control. I suffered from post traumatic stress for months because of my near-death incident, and was unable to work for two months due to both physical and mental deterioration. When I came off birth control a few years later I discovered that my previously normal menstrual cycles and hormone levels had become irregular. My previously normal ovaries took on a polycystic appearance, with more than 25 small follicles in each ovary. I developed occasional incontinence and pelvic pain likely as a consequence of the emergency surgery causing adhesions (fibrotic bands, analogous to scarring) around my organs.

The worst part of this is my current struggle with infertility, requiring continued exposure to the very same types of fertility drugs that I had already been overexposed to in the past – exposure whose link to cancer has not been adequately studied and may take decades to emerge[1]. I may need more surgeries in the future to determine if the emergency surgery that was done had damaged my reproductive organs. I fear that the procedure may have harmed the *quality* of my eggs, even if the fertility experts are certain (at least theoretically) that *quantity* of eggs remains unaffected. Because of the high hormonal exposure during my egg donation cycle and multiple anecdotes from other egg donors, the development of early cancer is always in the back of my mind. Though a large study has found no evidence linking IVF to ovarian cancer, there is a generalized, undeniable causal relationship between transient exposure to female hormones and transient risk of rapid-growth gynecologic cancer[2]. **I believe that is absolutely necessary for egg donors to be followed and studied, *especially if they had experienced hyperstimulation during the process.* No follow up has *ever* been offered to me.** Nobody from the egg donation agency, fertility clinics, or hospital has contacted me since, except to obtain my insurance information so that they could pass my hospital bill to my own health insurance company.

Summary and Conclusion:

1) Ethical considerations:

Financial compensation for eggs disproportionately targets college women with financial hardships. These women usually have long academic careers ahead of them and have not considered childbearing yet, so any infertility caused by the procedure would cause more psychological and physical damage to these women. Docked pay for failure to produce a target number of eggs and escalating pay scales for subsequent cycles are factors that may encourage underreporting of adverse side effects by the egg donor.

2) Subject safety:

Subject safety is variable, being highly dependent on the individual clinician's practice. This is why there needs to be standardized safety practices and mandatory reporting of complications. In the article "Assessing the Medical Risks of Human Oocyte Donation for Stem Cell Research: Workshop Report (2007)", one fertility expert advocated the following[3]:

> *"By working from such information as a patient's age, weight, and follicle count... a doctor can begin with an FSH dose based on those factors and then modify it as necessary. We monitor during the course of the stimulation to further decrease the dose if too many follicles are developing or the estradiol levels are too high."*

To reduce risk of hyperstimulation, these actions were also recommended:

- *Modify stimulation protocol*
  - *Decrease gonadotropin dosage*
  - *OCP/Lupron/Low dose gonadotropins*
- *Reduce the ovulatory dose of hCG*
- *Delay administration of hCG: "Coast"*
- *Cancellation of cycle eliminates the risk of OHSS*
- *Withhold hCG administration*

Basically the safety recommendations for egg donors include determining the initial dosing of these powerful drugs on the weight and age of the patient. If there is any evidence of producing more eggs or hormones than expected during routine monitoring, then the drug dosage should be reduced, the administration of stimulating medications delayed, or the cycle cancelled. None of these recommendations were followed in my case. **In fact, it was one of my own egg donation doctors who was consulted and quoted in the above article.**

Regarding the risk during surgical retrieval of the eggs, the perceived negligible risk of complications is likely due to incomplete data[3]:

"It is difficult to know, however, exactly how often such complications occur... Although excellent statistics are kept on such things as how many viable eggs each procedure produces, the statistics are not so complete on the complications that ensue during and after."

As my case illustrates, this perceived near-zero risk is inherently dangerous because it will not raise red flags when complications do occur, resulting in delayed intervention and a poorer-than-expected outcome. When a complication does occur, the denial of medical responsibility based on statistical rarity is a faulty and circular argument. This denial of responsibility would also prevent egg donors from obtaining monetary compensation for treatment of complications and appropriate follow-up. As my case illustrates, poor management of retrieval complications can be a problem even in the hands of the most experienced clinician.

Lastly, I received no follow up after my procedure. It is the ethical duty of the fertility industry to conduct timely follow-up and research studies in order to promote safety. This is true of any other industry especially pharmaceutical – so why make fertility an exception?

3) Informed consent:

Many are improperly informed about the risks of the egg harvesting process. Verbally I was told that risk was virtually non-existent and that studies have not linked the procedure to cancer and infertility. I should have been told that there were not enough studies or long-term follow up to determine risk.

It should be made abundantly clear if embryos or stem cells may potentially be secondarily sold, traded, or gifted. The amount of profit potentially generated from each transaction and the purpose of each transaction should be transparent to everyone involved, especially the donor. Without this information, the egg donor cannot possibly make an informed decision.

4) Patient autonomy:

I was hyperstimulated with approximately 60 eggs retrieved. During the procedure I expressed concerns about not using weight-based dosing of fertility medication, the excessive number of follicles produced, and skyrocketing estradiol levels. Nothing was done to personalize my procedure based on clinical findings, which is clearly incongruent with the standard of care. After the procedure my concerns about internal bleeding were not adequately acknowledged until I went into shock and had to undergo an emergency laparotomy. In my experience, the pressure to complete a successful cycle became stronger as I became more invested in the process, and thus I progressively lost my right to make decisions regarding my own body.

Final thoughts:

Even the tiniest risk of complication needs to be taken seriously especially when dealing with perfectly healthy young women, who have no need to undergo a potentially life-threatening

procedure. Procedures with risk are performed on sick patients with the understanding is that the benefits of the procedure outweigh the risks or the consequences of doing nothing. In egg donation there is no medical benefit, only risk. It represents a conflict of interest when the physician does not perceive the egg donor as a patient for whom they have the responsibility to minimize risk. This aspect must be considered when treating healthy young women with everything to lose.

References:

1. Nature. 2006 Sep 7;443(7107):26. Health effects of egg donation may take decades to emerge.

2. American Journal of Epidemiology Vol. 153, No. 11 : 1079-1084.

3. Assessing the Medical Risks of Human Oocyte Donation for Stem Cell Research: Workshop Report (2007).

KU THE UNIVERSITY OF KANSAS
Medical Center

March 11, 2010

Senate Public Health & Welfare Committee
Chairman
300 SW 10th
Topeka, KS 66612

Dear Mr. Chairman and Mr. Ranking Minority Member:

On behalf of the University of Kansas Medical Center (KUMC), I appreciate this opportunity to submit a letter in opposition to Senate Bill 509, the "Women's Health and Embryo Monitoring Program Act". As the state's only academic medical center, our mission is to promote health through excellence in education, research, and patient care. KUMC's Center for Reproductive Sciences pursues both basic and clinical research to increase fertility in both women and men, decrease the incidence of miscarriage, and reduce and prevent birth defects. These programs help thousands of Kansas families and discoveries could impact families across the globe. SB 509 would be extraordinarily cumbersome and have a detrimental effect on our patients, on our research, and on the translation of discoveries into cutting-edge patient care of the future.

Specifically, SB 509 raises several significant concerns. Those concerns include patient and donor privacy, duplicative and expensive reporting requirements, inconsistency in definitions with current clinical practice, implementation costs for reporting agencies and the state, criminal penalties for non-reporting (severity level 10, non-person felony), and most significantly, the creation of regulatory obstacles that may prevent the treatment and discovery of cures for infertility for Kansas patients and families.

SB 509 requires reporting of private patient and donor information that exceeds what is necessary for patient medical care or improved public health. Because some of this information is already reported to the U.S. Centers for Disease Control and Prevention (CDC) and/or the Society for Assisted Reproductive Technology (SART), it is unclear how this non-medically-necessary information is to be used (e.g., marital status; method of financial screening used to evaluate and ensure that future children's needs are met), and whether the privacy protections are sufficient. Much of the patient's financial information that would be made reportable is not accessible to the clinician or researcher and thus, it would be difficult to determine who the responsible reporting entity should be. Moreover, the expense of duplicative and unclear reporting requirements under threat of criminal prosecution may create an environment that will threaten access to health care services for those with infertility issues.

In addition, there are definitions in the bill which are inconsistent with scientific and physician terminology and would present compliance issues for clinicians and researchers. Current federal and state statutes, regulations, and guidelines that govern fertility patient care and research are

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the product of years of thoughtful, collaborative work by practitioners and organizations throughout the United States. Required changes to the system without a deliberate process from all interested stakeholders will create an unworkable system which will disadvantage Kansas patients, clinicians and researchers.

Finally, SB 509 creates considerable implementation costs for physicians and clinics that treat infertility as well as to the State of Kansas, without any apparent benefit to patients. The implementation of additional processes and procedures to try to remain compliant with SB 509 would not only create an economic drain, but would take away valuable time spent with patients or conducting research aimed at treating infertility, which impacts thousands of our citizens each year.

KUMC strives to attain the highest ethical standards, while providing the highest quality patient care and conducting world-class research. The statutes, regulations, and guidelines currently in existence generally strike a sufficient balance to address the concerns of this particular bill. We therefore oppose the passage of SB 509. Thank you for your time and consideration, and please let us know if we can answer any questions or provide additional information.

Sincerely,

Barbara Atkinson, MD
Executive Vice Chancellor
Executive Dean, School of Medicine

Paul Terranova, PhD
Vice Chancellor for Research
Senior Associate Dean, School of Medicine

KANSAS
DEPARTMENT OF HEALTH
AND ENVIRONMENT

Mark Parkinson, Governor
Roderick L. Bremby, Secretary

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Written Testimony on SB 509

Presented to
Senate Public Health and Welfare Committee

By
Jason Eberhart-Phillips, MD, MPH
State Health Officer and Director Division of Health,
Kansas Department of Health and Environment

March 11, 2010

Chairman Barnett and members of the committee, I am Dr. Jason Eberhart-Phillips, State Health Officer and Director of Health for the Kansas Department of Health and Environment. Thank you for the opportunity to provide you with additional information from the perspective of the KDHE regarding the implications of the program outlined in SB 509, the Women's Health and Embryo Monitoring Program Act.

As you are aware, the fiscal note provided to you by the Division of Budget specifies the items that would be required reporting under SB 509. The fiscal note also indicates estimates needed to support the data collection and program proposed. As deliberations are made regarding this program, KDHE wishes to point out the following that we believe will impact implementation:

Program implementation

- The definition for reporting agency could be interpreted as significantly broad. We had understood there would be a reporting requirement for the five ART facilities in Kansas. However, the definition of reporting agency (Sec. 2, q) could indicate that reporting would be required from "any agency, clinic, laboratory or business where IVF services are provided, infertile patients are treated....". Would this include physicians' offices and numerous other entities that might provide some of these services?
- Significant effort would be required to acquire documentation specified in the bill regarding informed consent, patient screenings, etc.

Data collection

- Assistive reproductive technology clinics are monitored by and currently report detailed, record-level data to three federal agencies and two professional societies; Centers for

Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Society for Reproductive Technology (SART), College of American Pathologists (CAP) and for the Centers for Medicare and Medicaid Services through Clinical Laboratory Improvement Amendments (CLIA).

- Data collection outlined in the bill involves over 70 items of interest, which may require as many as 300 data points to produce. These data cannot be collected in a de-identified manner, thus increasing KDHE's responsibility for security of health information.
- Software systems now in place are proprietary and are expected to be costly.

Thank you for the opportunity to provide these written comments.