

**SCIENTIFIC AND MEDICAL ADVANCES IN THE
FIELD OF IN UTERO SURGERY**

HEARING

BEFORE THE

SUBCOMMITTEE ON SCIENCE, TECHNOLOGY,
AND SPACE

OF THE

COMMITTEE ON COMMERCE,
SCIENCE, AND TRANSPORTATION
UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

SEPTEMBER 25, 2003

Printed for the use of the Committee on Commerce, Science, and Transportation



U.S. GOVERNMENT PRINTING OFFICE

87-755 PDF

WASHINGTON : 2014

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512-1800; DC area (202) 512-1800
Fax: (202) 512-2104 Mail: Stop IDCC, Washington, DC 20402-0001

SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

JOHN McCAIN, Arizona, *Chairman*

TED STEVENS, Alaska	ERNEST F. HOLLINGS, South Carolina,
CONRAD BURNS, Montana	<i>Ranking</i>
TRENT LOTT, Mississippi	DANIEL K. INOUE, Hawaii
KAY BAILEY HUTCHISON, Texas	JOHN D. ROCKEFELLER IV, West Virginia
OLYMPIA J. SNOWE, Maine	JOHN F. KERRY, Massachusetts
SAM BROWNBACK, Kansas	JOHN B. BREAUX, Louisiana
GORDON H. SMITH, Oregon	BYRON L. DORGAN, North Dakota
PETER G. FITZGERALD, Illinois	RON WYDEN, Oregon
JOHN ENSIGN, Nevada	BARBARA BOXER, California
GEORGE ALLEN, Virginia	BILL NELSON, Florida
JOHN E. SUNUNU, New Hampshire	MARIA CANTWELL, Washington
	FRANK R. LAUTENBERG, New Jersey

JEANNE BUMPUS, *Republican Staff Director and General Counsel*

ROBERT W. CHAMBERLIN, *Republican Chief Counsel*

KEVIN D. KAYES, *Democratic Staff Director and Chief Counsel*

GREGG ELIAS, *Democratic General Counsel*

SUBCOMMITTEE ON SCIENCE, TECHNOLOGY, AND SPACE

SAM BROWNBACK, Kansas, *Chairman*

TED STEVENS, Alaska	JOHN B. BREAUX, Louisiana, <i>Ranking</i>
CONRAD BURNS, Montana	JOHN D. ROCKEFELLER IV, West Virginia
TRENT LOTT, Mississippi	JOHN F. KERRY, Massachusetts
KAY BAILEY HUTCHISON, Texas	BYRON L. DORGAN, North Dakota
JOHN ENSIGN, Nevada	RON WYDEN, Oregon
GEORGE ALLEN, Virginia	BILL NELSON, Florida
JOHN E. SUNUNU, New Hampshire	FRANK R. LAUTENBERG, New Jersey

CONTENTS

Hearing held on September 25, 2003	Page 1
Statement of Senator Brownback	1
WITNESSES	
Armas, Alex, Parent, Villa Rica, Georgia	4
Prepared statement	6
Armas, Julie, Parent, Villa Rica, Georgia	3
Prepared statement	4
Clancy, Michael, Photographer, Roscoe, Illinois	10
Prepared statement	11
Thorp, M.D., James A., Associate Director, Regional Perinatal Center, Sacred Heart Women's Hospital and Clinical Professor, Department of Obstetrics and Gynecology, University of Florida at Pensacola	8
Prepared statement	9
APPENDIX	
Lautenberg, Hon. Frank R., U.S. Senator from New Jersey, prepared state- ment	21
Response to written questions submitted by Hon. Frank R. Lautenberg to:	
James A. Thorp, M.D.	21
Michael Clancy	22

SCIENTIFIC AND MEDICAL ADVANCES IN THE FIELD OF IN UTERO SURGERY

THURSDAY, SEPTEMBER 25, 2003

U.S. SENATE,
SUBCOMMITTEE ON SCIENCE, TECHNOLOGY, AND SPACE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:38 p.m. in room SR-253, Russell Senate Office Building, Hon. Sam Brownback, Chairman of the Subcommittee, presiding.

OPENING STATEMENT OF HON. SAM BROWNBACK, U.S. SENATOR FROM KANSAS

Senator BROWNBACK. Good afternoon. The hearing will come to order. I apologize for my lateness. I had another appointment that I had to attend to before getting over here. Thank you all for being here.

During the hearing today, I would like to examine some of the most recent advances in the fields in utero surgery and fetal medicine. In particular, we will hear the remarkable story of a family who chose to undergo surgery for the benefit of an unborn child, Samuel Armas. Samuel underwent fetal surgery to treat spina bifida. Samuel is with us here today, along with his parents, Alex and Julie.

The ability to treat and cure diseases for the benefit of a young child who has yet to be born is an amazing advance that will help alleviate the suffering of many young children, and, in fact, is already doing so. These are advances that all people, regardless of their political views, can embrace as a positive step. I'm heartened by these advances and look forward to hearing from the respective witnesses.

Let me also say that this hearing is not about abortion; rather, it is about advances in therapeutic interventions that are effectively treating people suffering from diseases before they are born. There is little debate about whether the child in utero is alive; but whether it is a life, a life worthy of protecting, that is the debate, and we will continue to have that on another day.

Today, I would like to focus primarily on the testimony of the family that chose to undergo this remarkable intervention, and the reasons they chose to do so given the risks associated with a surgery of this nature, as well as the amazing results of this intervention.

Finally, I would like to close by quoting from a recent article that appeared detailing the advances in ultrasound technology that

show, quote, "An unborn child can smile, yawn, blink, suck his fingers, and cry as early as the 26th week of pregnancy."

We've got those blown up, and I'll submit into the record an article that appeared in the Sunday Herald Sun, September 14, of a 4-D, four-dimensional, picture, sonograms, showing—and this a child pictured at 24 weeks of age—and we'll have those to hand out to people so that they can see. It's really quite remarkable. You can't see it much in this detail of the picture, but the smiling child here is really quite remarkable to see.

[The information referred to follows:]



Senator BROWNBACK. These advances are amazing. These new scientific discoveries continue to help illuminate the public policy debate on the importance of life when it begins.

Now I'd like to turn to our panel of witnesses. We have an exciting set of witnesses here today with us. Mr. Alex Armas, he's a parent from Georgia, delighted to have you here with us today, parent of Samuel. And his wife, Julie, is here. Glad to have you here, and, I think, expecting another one when?

Ms. ARMAS. Three weeks.

Senator BROWNBACK. Three weeks. So just barely here and able to travel well. Mr. Michael Clancy is a photographer that was involved in taking some of the pictures that—they were involved in this particular surgery. And Dr. James Thorp, Medical Doctor, a Clinical Professor of Obstetrics and Gynecology at the University of Florida, Pensacola, and Associate Director of the Regional Perinatal Center at Sacred Heart Women's Hospital, in Pensacola, Florida, who was involved in these surgeries, as well. NIH is doing some initial reviews of these surgeries and their efficacy. We will hear some about that, as well.

But let's start with the witnesses and the testimony, and I believe we'll start with Mr. and Mrs. Armas. If you'd be willing to start in your testimony, we would certainly appreciate that.

First, let me say thank you and welcome for coming. We had to do some delays because of Isabel, it wasn't cooperating quite as much, but delighted that you could still make it with us here today.

STATEMENT OF JULIE ARMAS, PARENT, VILLA RICA, GEORGIA

Mrs. ARMAS. Good afternoon.

My name is Julie Armas, and I am honored to be invited here today to tell you of our experience with fetal surgery.

In the spring of 1999, my husband and I were thrilled to learn that after two miscarriages and numerous infertility treatments, we were finally expecting a baby. By the 15th week of my pregnancy, our unborn son was diagnosed with spina bifida. The first words my doctor said were, "Well, this is really bad."

We learned that the opening in our baby's spine caused permanent nerve damage that could prevent him from walking and using the bathroom normally. More importantly, the damage to the spine had also caused his brain to begin forming in an abnormal way, which could ultimately lead to hydrocephalus, causing mental deficit, as well.

In light of this grim diagnosis, we were told that at least half of all babies with spina bifida are aborted. But abortion was never an option for us. Instead, we began educating ourselves about spina bifida, and learned of an experimental procedure to close the spinal lesion in utero, rather than after birth, which is what is traditionally done. We were excited that there was someone somewhere interested in preventing some of the problems caused by spina bifida.

Despite the reservations of my physician, my husband and I traveled to Vanderbilt University and underwent an intensive two-day consultation with surgeons, social services, and medical ethicists. We were immediately told that fetal surgery was not a cure for our son, whom by now we had named Samuel.

Senator BROWNBACK. I'm kind of partial to that name. I like that one.

[Laughter.]

Mrs. ARMAS. The greatest potential benefit of surgery before birth was that in many cases the brain malformation had improved, thus decreasing the changes of hydrocephalus and the subsequent mental issues.

We were asked why we would consider such a life-threatening procedure when spina bifida itself is typically not life-threatening. And our answer was that Samuel was not a hypothetical; he was already a member of our family, our son, and deserved our best efforts to improve his life.

After much prayer and support from family and friends, Samuel and I had maternal fetal surgery at Vanderbilt on August 19, 1999. I was 21 weeks pregnant, and he weighed about a pound.

Thankfully, no complications arose following the surgery, and Samuel was born by scheduled Cesarean on December 2, 1999, 15 weeks after our surgery. He never went to the intensive care nursery, and came home with me 4 days after birth. Today, he is an

active—as you may learn—walking three-year-old who attends preschool, and is age appropriate developmentally.

In conclusion, I am grateful for the attention that this Committee is giving to fetal surgery. Though it's not without significant risk, it provided a ray of hope when we were in a very dark place.

Thank you.

[The prepared statement of Mrs. Armas follows:]

PREPARED STATEMENT OF JULIE ARMAS, PARENT, VILLA RICA, GEORGIA

Good afternoon.

I am honored to be invited here today to tell you of our experience with fetal surgery.

In the spring of 1999, my husband and I were thrilled to learn that after two miscarriages and numerous infertility treatments, we were finally expecting a baby. By the fifteenth week of my pregnancy, our unborn son was diagnosed with spina bifida. The first words my doctor said were, "This is really bad". We learned that the opening in our baby's spine caused permanent nerve damage that could prevent him from walking and using the bathroom normally. More importantly, the damage to the spine had also caused his brain to begin forming in an abnormal way, which could ultimately lead to hydrocephalus causing mental deficits as well. In light of this grim diagnosis, we were told that at least half of babies with spina bifida are aborted.

Abortion was never an option for us. Instead, we began educating ourselves about spina bifida, and learned of an experimental procedure to close the spinal lesion in utero, rather than after birth. We were excited that someone, somewhere, was interested in preventing some of the problems caused by spina bifida. Despite the reservations of my physician, my husband and I traveled to Vanderbilt University and underwent an intensive two day consultation with surgeons, social services, and medical ethicists. We were immediately told that fetal surgery was not a cure for our son, who by now we had named Samuel.

The greatest potential benefit of surgery before birth was that in many cases, the brain malformation had improved, thus decreasing the chances of hydrocephalus and subsequent mental issues. We were asked why we would consider such a life-threatening procedure when spina bifida itself is typically not life-threatening. Our answer was that Samuel was not a hypothetical, he was already a member of our family, our son, and deserved our best efforts to improve his life.

After much prayer and support from family and friends, Samuel and I had maternal-fetal surgery at Vanderbilt on August 19, 1999. I was 21 weeks pregnant, he weighed about a pound. Thankfully, no complications arose following surgery, and Samuel was born by scheduled Cesarean on December 2, 1999, fifteen weeks after our surgery. He never went to the intensive care nursery, and came home with me four days after birth. Today he is an active, walking, three year old who attends preschool and is age-appropriate developmentally.

In conclusion, I am grateful for the attention this committee is giving to fetal surgery. Though not without significant risk, it provided a ray of hope when we were in a very dark place.

Senator BROWNBACK. Thank you, Mrs. Armas.

Mr. Armas, love to hear your testimony.

STATEMENT OF ALEX ARMAS, PARENT, VILLA RICA, GEORGIA

Mr. ARMAS. Good afternoon.

My name is Alex Armas, and I'm the father of a three-year-old child with spina bifida who underwent corrective fetal surgery at Vanderbilt University in 1999. Thank you for the opportunity to be here today and to share with you the impact that this fetal surgery process had on our family.

In early 1999, my wife and I learned that we were expecting our first child. Although we were thrilled at the hope of finally having a baby, our happiness was soon overshadowed when we were told that our baby had spina bifida.

As it was initially explained to us, our baby would likely suffer from brain malformations, hydrocephalus, which is excess fluid pressure on the brain, incontinence, inability to walk, learning deficiencies, and perhaps even problems swallowing or breathing. The doctor painted a grim picture for us and stopped just short of suggesting an abortion.

It is every parent's worst nightmare to learn that something's wrong with your child, and we were initially devastated. However, our view was that after years of trying to conceive, this was the baby that God chose to give us. In our mind, this was not a 15-week-old fetus; but, rather, was our new son, Samuel Armas. Thus, abortion was never an option for us. To the contrary, my wife and I set out to learn about spina bifida and what options were available to us and Samuel.

We soon heard about the maternal fetal surgery program for spina bifida that was offered at Vanderbilt University. After being presented with details of the procedure, including past successes, inherent risk of prematurity, my wife and I had a difficult decision to make. After weighing the substantial risks and the possible life-long benefits, past surgery successes, and after much prayer, we decided to go ahead and have the surgery. In our minds, we would not have deprived an already-born son of a similar life-improving procedure with similar risks.

We were particularly struck during this process by those who ethically challenged us on risking our baby's life for a life-improving procedure, while we would have been supported should we have elected to legally end his life.

When our son underwent fetal surgery, he was 21 weeks old gestationally. His brain was not developing correctly due to a Chiari malformation, and had enlarged ventricles due to worsening hydrocephalus. Immediately after the surgery, the hydrocephalus stopped increasing and started to slowly decrease. By the time Samuel was born, 15 weeks later, his brain malformation had reversed, and the hydrocephalus had mostly disappeared. He did not require a shunt to drain fluid from his brain, which is very common among children with spina bifida. This was of considerable benefit to Samuel, because shunts are commonly plagued with blockages, with infections, and can require a child to have multiple brain surgeries in the first year of life.

The benefit of the in utero procedure was that it allowed continued development inside the womb, where conditions are ideal for problems to stabilize, or, in Samuel's case, even reverse, to some degree. This was particularly evident in neurological benefit to Samuel.

We've learned that children with spina bifida have an average shunt rate of approximately 70 to 95 percent, depending on the level of the lesion. With corrective fetal surgery for spina bifida, this average drops by half and is between 20 to 50 percent. Fetal-surgery children also exhibit less kidney damage, lower bladder infection rates, and, in some cases, improved leg function by up to two neurologic levels, or spine levels.

Currently, the National Institute of Health is conducting trials, as you mentioned, to evaluate corrective fetal surgery for spina bifida. It's our hope that further clinical studies will be supported

so that future parents facing circumstances such as we did will be better equipped to make educated decisions about medical alternatives for birth defects.

Continued studies and increased awareness of intrauterine surgical intervention will also increase acceptance among insurance companies. We were fortunate, in that our insurance provider, at the time, had investigated the economic benefits of fetal surgery and had decided to cover all of our costs. However, many other insurance companies are still reluctant to cover fetal surgery. And, subsequently, this leaves an enormous financial burden on families who are already struggling with what to do with their pregnancy.

Increased awareness and supportive advances in fetal surgery are critical to future families and their unborn babies. Progress in this field is not only improving lives, but it is also saving lives by representing an option, an alternative, a hope for parents who may otherwise choose to end their pregnancy. Most people think, "This could never happen to me." But it can, and it did for us. Having options like fetal surgery can turn a family's initial perception of hopelessness into an outlook of hope where the little victories of life are celebrated. We've seen living proof of this in our son.

Today, Samuel is nearly 4 years old and has not had to endure the surgeries that are normally common for most children with spina bifida. He is walking with leg braces, is cognitively normal, and loves looking for bugs. We're very grateful for his progress and for the obvious benefits that he's had from fetal surgery.

We're also very thankful for the Subcommittee's consideration of advances in this field and hope that it'll see the true value in its progress.

Thank you.

[The prepared statement of Mr. Armas follows:]

PREPARED STATEMENT OF ALEX ARMAS, PARENT, VILLA RICA, GEORGIA

Good afternoon. My name is Alex Armas and I am the father of a 3 year old child with spina bifida who underwent corrective fetal surgery at Vanderbilt University in 1999.

Thank you for the opportunity to be here today and share with you the impact fetal surgery has had on our family.

In early 1999, my wife and I learned that we were expecting our first child. Although we were thrilled at the hope of finally having a baby, our happiness was soon overshadowed when we were told that our baby had spina bifida.

As it was initially explained to us, our baby would likely suffer from brain malformations, hydrocephalus (excess fluid pressure on the brain), incontinence, inability to walk, learning deficiencies, and perhaps even problems swallowing or breathing. The doctor painted a grim picture for us and stopped just short of suggesting an abortion.

It is every parent's worst nightmare to learn that something is very wrong with your child and we were initially devastated. However, our view was that after years of trying to conceive, this was the baby God chose to give us. In our mind, this was not a 15 week old fetus, but rather was our new son, Samuel Armas. Thus, abortion was never an option for us. To the contrary, my wife and I set out to learn about spina bifida and what options were available to us, and Samuel.

We soon heard about the maternal-fetal surgery program for spina bifida that was offered at Vanderbilt University. After being presented with details of the procedure including past successes and inherit risks of prematurity, my wife and I had a difficult decision to make. After weighing the substantial risks, the possible life-long benefits, past surgery successes and much prayer, we decided to have the surgery. In our minds, we would not have deprived an already-born son of a similar life-improving procedure with similar risks.

We were particularly struck by those who ethically challenged us on risking our baby's life for a life-improving procedure, while we would have been supported should we have decided to legally end his life.

When our son underwent fetal surgery, he was 21 weeks old gestationally. His brain was not developing correctly due to a Chiari malformation and had enlarged ventricles due to worsening hydrocephalus. Immediately after surgery, the hydrocephalus stopped progressing and started to slowly decrease.

By the time Samuel was born, fifteen weeks later, his brain malformation had reversed and the hydrocephalus had mostly disappeared. He did not require a shunt to drain fluid from the brain, which is very common among children with spina bifida. This was of considerable benefit since shunts are commonly plagued with problems such as blockages and infections which may require multiple brain surgeries during the first years of life.

The benefit of the in utero procedure was that it allowed continued development inside the womb where conditions are ideal for problems to stabilize, or as in Samuel's case, even reverse to some degree. This was particularly evident in neurological benefit.

We have learned that children with spina bifida have an average shunt rate of approximately 70 percent to 95 percent, depending on lesion level. With corrective fetal surgery for spina bifida, this average drops by half and is between 20 percent to 50 percent. Fetal surgery children also exhibit less kidney damage, lower bladder infection rates, and in some cases improved leg function by up to two neurologic levels.

Currently the National Institute of Health (NIH) is conducting trials to evaluate corrective fetal surgery for spina bifida. It is our hope that further NIH studies will be supported so that future parents facing circumstances such as we did, will be better equipped to make educated decisions about medical alternatives for birth defects.

Continued studies and increased awareness of intrauterine surgical intervention will also increase acceptance among insurance companies. We were fortunate in that our insurance provider at the time had investigated the economic benefits of fetal surgery and decided to cover all of our medical costs. However, many other insurance companies are still reluctant to cover fetal surgery. This leaves an enormous financial burden on families who are already struggling with what to do with their pregnancy.

Increased awareness and support of advances in fetal surgery are critical to future families and their unborn babies. Progress in this field is not only improving lives, but is also saving lives by representing an option, an alternative, a hope for parents who may otherwise choose to end their pregnancy. Most people think "this could never happen to me", but it can, and it did for us. Having options in fetal surgery can turn a family's initial perception of hopelessness into an outlook of hope and a life where little victories are celebrated and cherished.

We have seen living proof of this in our son. Today Samuel is nearly 4 years old and has not had to endure the surgeries that are normally common for most children with spina bifida. He is walking with leg braces, is cognitively normal, and loves looking for bugs. We are very grateful for his progress and for the obvious benefits he has had from fetal surgery.

We are also thankful for the Subcommittee's consideration of advances in intrauterine medical procedures and hope it will see the value in its progress.

Senator BROWNBACK. Well, I'm thankful for you to be here to testify today, because hopefully you will help give hope to a number of parents who are caught in a very similar circumstance.

I'll have some more questions for you a little bit later on.

Dr. Thorpe, would you describe for us the procedure that we're talking about here and the nature of it and the progress that's being made?

**STATEMENT OF JAMES A. THORP, M.D., ASSOCIATE DIRECTOR,
REGIONAL PERINATAL CENTER, SACRED HEART WOMEN'S
HOSPITAL AND CLINICAL PROFESSOR, DEPARTMENT OF
OBSTETRICS AND GYNECOLOGY, UNIVERSITY OF FLORIDA
AT PENSACOLA**

Dr. THORP. Senator Brownback, other Members of the Committee, and members and guests, thank you very much for the privilege of presenting my testimony in the U.S. Senate.

My name is Jim Thorp. I'm 50 years old. I am a maternal fetal medicine specialist, and am privileged to have worked with unborn children as my patients for many years. A maternal fetal medicine specialist is an obstetrician/gynecologist who has completed 2 to 3 years of additional formal education and clinical experience with an American Board of Obstetrics and Gynecology approved maternal fetal medicine fellowship. Members of our Society for Maternal Fetal Medicine, SMFM, have advanced knowledge of the obstetrical, medical, genetic, and surgical complications of pregnancy and their effects on both the mother and the fetus. My career has been focused on the child within the womb as a patient.

I completed my fellowship in maternal fetal medicine in 1988, and began practice at St. Luke's Hospital of Kansas City, affiliated with the University of Missouri, Kansas City. In 2001, I relocated to practice at Sacred Heart Women's Hospital, affiliated with the University of Florida at Pensacola.

Now, my particular expertise involves what I would refer to as closed maternal fetal surgical procedures. That is, procedures that do not involve a major maternal surgery that opens the womb. During my maternal fetal medicine career, I have performed in excess of 250 such procedures, including fetal blood samplings, fetal transfusions, decompressions of certain bodily cavities, such as the urinary tract, among others. I have also directed clinical research and published extensively in my specialty.

The first fetal surgery should be and is credited to Sir Albert William Liley in 1963. He developed the technique for diagnosing and treating fetuses suffering from anemia as a result of Rh disease. He is known as the "Father of Fetology," and was an ardent advocate of the rights of the child within the womb. Dr. Liley said, "As a doctor, I regard the unborn child as my patient, and protect and respect his life as I would the life of any other patient." From my clinical experience, I am convinced that unborn children are individuals and human beings who are capable of receiving and responding to medical care and who should have legal protection.

It is extremely difficult not to see the fetus as a child before birth with the same value as a child after birth, especially after one sees her smiling, grimacing, moving, sleeping, yawning, urinating, stretching, sucking a thumb, as well as responding to pain from needle sticks.

When a fetus is suspected of having severe anemia, the operating team and I use an ultrasound to guide a needle through the mother's abdomen, through the uterus, into the one of the baby's small blood vessels. If severe fetal anemia is confirmed by immediate blood testing within the operating room, I will transfuse the baby with donor blood, specially prepared. Without such a transfusion, the fetus will likely die or deliver severely premature, with signifi-

cant ramifications. I've done this as early as 19 weeks gestation, with perfect outcomes.

As endoscopic and laser technology increases, the surgical correction of other problems, including twin-twin transfusion syndrome, is now being performed and has been for some years. The NIH is currently funding the so-called MOMS study, which is a \$25 million project at three centers, which is looking at the repair of spina bifida, as Samuel had, in a controlled prospective trial.

Another technique that is currently under investigation, repair, includes diaphragmatic hernia, congenital defect in the diaphragm, removal of many fetal tumors, and even balloon angioplasty of certain valves within the fetus within the womb. Near scar-free repair of cleft palate and lip can also be performed.

Thomas Jefferson said, "The care of human life, and not its destruction, is the first and only legitimate object of a good government." The United States is a world leader in advanced medical study, and this includes research for the youngest and the most innocent of our patients, those still within the womb. I believe nations, societies, and governments will ultimately be judged by the way that they treat their weakest, their most vulnerable, their most innocent, including the child within the womb.

I will close with a quote from just this past June 9, the lead article in *Newsweek* by Claudia Kalb. And I quote, "No matter what legislatures, activists, judges, or even individual Americans decide about fetal rights, medicine has already granted unborn babies a unique form of personhood, as patients."

Thank you.

[The prepared statement of Dr. Thorp follows:]

PREPARED STATEMENT OF JAMES A. THORP, M.D., ASSOCIATE DIRECTOR, REGIONAL PERINATAL CENTER, SACRED HEART WOMEN'S HOSPITAL AND CLINICAL PROFESSOR, DEPARTMENT OF OBSTETRICS AND GYNECOLOGY, UNIVERSITY OF FLORIDA AT PENSACOLA

Thank you very much for the privilege of presenting my testimony in the United States Senate. My name is Jim Thorp and I am 50 years of age. I am a Maternal-Fetal Medicine Physician Specialist and am privileged to have worked with unborn children as my patients for many years. A Maternal-Fetal Medicine specialist is an obstetrician/gynecologist who has completed two to three years of additional formal education and clinical experience within an American Board of Obstetrics and Gynecology approved Maternal-Fetal Medicine Fellowship Program. Members of the Society for Maternal Fetal Medicine (SMFM) have advanced knowledge of the obstetrical, medical, genetic, and surgical complications of pregnancy and their effects on both the mother and fetus. My career has focused upon the child within the womb as a patient. I completed my Fellowship in Maternal Fetal Medicine in 1988 and began practice at St. Luke's Hospital of Kansas City, affiliated with the University of Missouri at Kansas City. In 2001 I relocated to practice at Sacred Heart Women's Hospital, affiliated with University of Florida at Pensacola. My particular area of expertise involves closed maternal fetal surgical procedures, that is, procedures that do not involve a major maternal surgery to open the womb. During my Maternal Fetal Medicine career I have performed in excess of 250 such procedures including fetal transfusions, urinary decompressions, fetal blood samplings and others. I have also directed clinical research and published extensively in my specialty.

The *first* fetal surgery is credited to Sir Albert William Liley in 1963. He developed the technique for diagnosing and treating fetuses suffering from anemia as a result of Rh disease. He is known as "the father of fetology", and was an advocate for the rights of the child within the womb. Dr. Liley said, "As a doctor I regard the unborn child as my patient and protect and respect his life as I would the life of any other patient. From my clinical experience I am convinced that unborn children are individuals and human beings who are capable of receiving and responding to medical care and who should have legal protection."

It is extremely difficult *not* to see the fetus as a child before birth with the same value as a child after birth, especially after one sees her smiling, grimacing, moving, sleeping, yawning, stretching, sucking a thumb, as well as responding to pain from needle sticks. When a fetus is suspected of having severe anemia the operating team and I use an ultrasound to guide a needle through the mother's abdomen into one of the baby's blood vessels. If severe fetal anemia is confirmed by immediate blood testing in the operating room, I will transfuse the baby with donor blood. Without such a transfusion, the fetus will die. I have done this as early as 19 weeks gestation with perfect outcomes.

As endoscopic and laser technology increased, the surgical correction of twin-to-twin fetal transfusion syndrome is now being performed. The NIH is currently funding the MOMS trial, which is investigating the repair of spina bifida within the womb. Another technique that is currently under investigation includes repair of diaphragmatic hernia, removal of fetal tumors, and even balloon angioplasty of valves *within* the fetal heart. Near scar free repair of cleft palate/lip may also be possible.

Thomas Jefferson said, "The care of human life, and not its destruction is the world first, and only legitimate object of good government". The United States is the world leader in advanced medical study and this includes research for the youngest and most innocent of our patients, those still within the womb. I believe nations, societies and governments will ultimately be judged by the way that they treat their weakest, their most vulnerable and their most innocent, including the child within the womb. I will close with a quote from the June 9th *Newsweek* article by Claudia Kalb: "No matter what legislators, activists, judges or even individual Americans decide about fetal rights, medicine has already granted unborn babies a unique form of personhood-as patients."

Senator BROWNBACK. Thank you very much, Dr. Thorp. Powerful testimony. I didn't realize we could do all those things and those are taking place. I look forward to probing into those various surgeries that are occurring now.

Mr. Clancy, you're a photographer. We don't usually have photographers testify in front of the Senate, although——

Mr. CLANCY. How about photojournalists?

Senator BROWNBACK. Particularly photojournalists. But you've got some interesting photographs that you wanted to share with us.

STATEMENT OF MICHAEL CLANCY, PHOTOGRAPHER, ROSCOE, ILLINOIS

Mr. CLANCY. Well, like you said, my name is Michael Clancy, and I appreciate having the opportunity to take part in the legislative process of our great country.

As a veteran photojournalist in Nashville, Tennessee, I was hired by *USA Today* to photograph a spina bifida corrective surgical procedure. It was to be performed on a child 21 weeks in utero, at Vanderbilt University Medical Center. At that time, in 1999, 21 weeks in utero was the earliest that the surgical team would consider for surgery. The worst possible outcome would be that the surgery would cause premature delivery, and no child born earlier than 23 weeks had survived.

The tension could be felt in the operating room as the surgery began. A typical C-section incision was made to access the uterus, which was then lifted out and laid at the junction of the mother's thighs. The entire procedure would take place within the uterus, and no part of the child was to breach the surgical opening. The position of the child was adjusted by gently manipulating the outside of the uterus.

The entire surgical procedure on the child was completed in 1 hour and 13 minutes. When it was over, the surgical team

breathed a sigh of relief, as did I. As the doctor asked me what speed of film I was using, out of the corner of my eye I saw the uterus shake, but no one's hands were near it. It was shaking from within. Suddenly, an entire arm thrust out of the opening and pulled back, until just the little hand was showing. The doctor reached over and lifted the hand, which reacted and squeezed the doctor's finger. As if testing for strength, the doctor shook the tiny fist. I took the picture. Wow. It happened so fast that the nurse standing next to me asked, "What happened?" "The child reached out," I said. "Oh, they do that all the time," she responded.

The surgical opening to the uterus was closed, and the uterus was then put back into the mother, and the C-section opening was closed.

It was 10 days before I knew if the picture was even in focus. To ensure no digital manipulation of images before they see them, *USA Today* requires that film be submitted unprocessed. When the photo editor finally phoned me, he said, "It's the most incredible picture I've ever seen."

When I first saw the picture I took that day, I said to myself, "I have captured the earliest interaction ever recorded," proof that at 21 weeks in utero a child is a reactive human being. Four years later, the story of Samuel Armas has become legend and can no longer be ignored. The picture originally known as "Fetal Hand Grasp" has been renamed by the people as "The Hand of Hope," hope for a generation that will embrace the knowledge that new technology brings, a generation that will demonstrate the courage to acknowledge a living human being's struggle to survive.

Samuel Armas had made more of an impact on the world before he was born than most of us make in a lifetime.

Thank you very much.

[The prepared statement of Mr. Clancy follows:]

PREPARED STATEMENT OF MICHAEL CLANCY, PHOTOGRAPHER, ROSCOE, ILLINOIS

"STORY OF THE 'FETAL HAND GRASP' PHOTOGRAPH"

As a veteran photojournalist in Nashville, Tennessee, I was hired by *USA Today* newspaper to photograph a spina bifida corrective surgical procedure.

It was to be performed on a child, twenty-one weeks in utero, at Vanderbilt University Medical Center. At that time, in 1999, twenty-one weeks in utero was the earliest that the surgical team would consider for surgery. The worst possible outcome would be that the surgery would cause premature delivery, and no child born earlier than twenty-three weeks had survived.

The tension could be felt in the operating room as the surgery began. A typical C-section incision was made to access the uterus, which was then lifted out and laid at the junction of the mother's thighs. The entire procedure would take place within the uterus, and no part of the child was to breach the surgical opening. The position of the child was adjusted by gently manipulating the outside of the uterus. The entire surgical procedure on the child was completed in 1 hour and thirteen minutes. When it was over, the surgical team breathed a sigh of relief, as did I. As a doctor asked me what speed of film I was using, out of the corner of my eye I saw the uterus shake, but no one's hands were near it. It was shaking from within.

Suddenly, an entire arm thrust out of the opening, then pulled back until just a little hand was showing. The doctor reached over and lifted the hand, which reacted and squeezed the doctor's finger. As if testing for strength, the doctor shook the tiny fist. Samuel held firm. I took the picture. Wow!

It happened so fast that the nurse standing next to me asked, "What happened?" "The child reached out," I said. "Oh, they do that all the time," she responded. The surgical opening to the uterus was closed and the uterus was then put back into the mother and the C-section opening was closed. It was ten days before I knew if

the picture was even in focus. To ensure no digital manipulation of images before they see them, *USA Today* requires that film be submitted unprocessed. When the photo editor finally phoned me he said, "It's the most incredible picture I've ever seen."

Senators, when I first saw the picture I took that day, I said to myself, I have captured the earliest interaction ever recorded. Proof that at twenty-one weeks in utero the child is a reactive human being. Four years later, "The Story of Samuel Armas" has become legend, and can no longer be ignored. The picture originally known as, "The Fetal Hand Grasp," has been renamed by the people as, "The Hand of Hope." Hope for a generation that will embrace the knowledge that new technology brings. A generation that will demonstrate the courage to acknowledge a living human being's struggle to survive.

Samuel Armas had made more of an impact on this world before he was born, than most of us make in a lifetime.

Thank you.

MICHAEL CLANCY,
Roscoe, Illinois.

Senator BROWNBAC. That's beautiful testimony. Do you have a picture, one of the pictures that you took?

Mr. CLANCY. There's a poster in the—I have some right behind you.

Senator BROWNBAC. Was that the one that appeared in—I remember, in *USA Today*, seeing a picture in—

Mr. CLANCY. It's been in *USA Today* now four times. It was in the June 9 issue of *Newsweek*. It's been around the world. It's been on television shows. It's been embraced by the pro-life community, the religious community. And—

Senator BROWNBAC. And this is the picture?

Mr. CLANCY. That's the picture. When I first took the picture, most of the picture agencies said, "It's too graphic for the United States, but it'll be great overseas."

[Laughter.]

Mr. CLANCY. And that's kind of what's happened. It took 4 years for it to run in a secular publication, in *Newsweek*.

Senator BROWNBAC. In the United States it took—

Mr. CLANCY. It took 4 years for that picture—

Senator BROWNBAC.—four years before anybody would run it?

Mr. CLANCY. Right.

Senator BROWNBAC. Why? They said it—

Mr. CLANCY. Because of the story of Samuel. It has become legend. People are e-mailing the story about Samuel reaching out and squeezing the doctor's finger, and they're saying, "You've got to see this picture." And it's like it can't be ignored any longer. It has been amazing to me. I created a website, because I felt that I needed to do the right thing with this picture, it's so powerful. I give it to pro-life groups, religious groups, and church groups. Anyway, it has just been phenomenal.

In the last year, I've had 250,000 visitors to the Website. I answer e-mails. Every night I go home, I have 20 or 30 e-mails about the picture. People are asking me to come speak somewhere. And I don't feel that I'm worthy to go speak somewhere. I just promote the picture. It has just been an amazing moment.

And I'm still in shock that at 21 weeks in utero, the child was a reactive human being. And we see what we want to see. The political climate just, you know, allows you to see what you want to see and not do something about it. I think each person has to take it into their own hand and do something about it.

Senator BROWNBAC. When did this picture first appear in publication, then, overseas?

Mr. CLANCY. It was published January 7—January 9 in the *Tennessean* and in *USA Today*. Then it ran overseas in October in France. They ran a four-page layout in a French magazine. And then it took off like wildfire, and you could see it go country to country. It was pretty amazing.

It's gone around the world, like, three or four different times. Whenever it hits a new country, I get e-mails in languages I can't read.

[Laughter.]

Mr. CLANCY. I go to *translate.com*. I cut and paste, and I get a crude translation of what they're trying to ask me. Most people are wanting a copy of the picture, how can they find out more about it. It has just been an amazing thing for me.

Senator BROWNBAC. That is an amazing picture.

Mr. CLANCY. Thank you.

Senator BROWNBAC. Let's see Samuel? Is he here? Is he willing to come forward and testify?

Hi, Samuel. How are you today?

SAMUEL ARMAS. Fine.

Senator BROWNBAC. Do you like to look for bugs?

SAMUEL ARMAS. Yes, sir.

Senator BROWNBAC. I'll bet you're good at catching those. And butterflies?

SAMUEL ARMAS. Caterpillars.

Senator BROWNBAC. What's that?

Mrs. ARMAS. Caterpillars.

Senator BROWNBAC. Caterpillars, yes. I'll bet you like those. You don't eat them, do you?

SAMUEL ARMAS. No.

Senator BROWNBAC. No. We don't want to do anything like that. What do you like to play?

SAMUEL ARMAS. The cars.

Senator BROWNBAC. With cars? Oh. And what do you have on your shirt? You've got several things on your shirt there. What do you have?

SAMUEL ARMAS. A butterfly.

Senator BROWNBAC. Oh, that looks nice.

SAMUEL ARMAS. A grasshopper.

Senator BROWNBAC. Oh.

SAMUEL ARMAS. A lunar moth.

Senator BROWNBAC. A lunar moth. Well, we're going to get scientific on me, aren't you.

[Laughter.]

Senator BROWNBAC. You're not just going to let me slide with a regular—

Mr. ARMAS. And that one, what's that one?

SAMUEL ARMAS. A spider.

Senator BROWNBAC. And a spider.

Mr. ARMAS. Do we touch spiders?

SAMUEL ARMAS. No.

Senator BROWNBAC. You don't touch any spiders? Why don't you touch spiders?

SAMUEL ARMAS. They might bite.

Senator BROWNBAC. Yes. Those can be pretty rough, can't they?
Now, how old are you?

SAMUEL ARMAS. Three.

Senator BROWNBAC. You're three?

SAMUEL ARMAS. Yes, sir.

Senator BROWNBAC. Oh. Have you seen this picture of you?

SAMUEL ARMAS. Yes, sir.

Senator BROWNBAC. Well, you're offering a lot of hope to people.

Mrs. ARMAS. Tell him about that picture.

Mr. ARMAS. Who's in that picture?

SAMUEL ARMAS. I'm Samuel.

Senator BROWNBAC. And what did they do? What did they fix?

SAMUEL ARMAS. They fixed my boo-boo.

[Laughter.]

Senator BROWNBAC. And you feel much better now that they fixed your boo-boo?

SAMUEL ARMAS. Yes.

Senator BROWNBAC. Thank you very much. Thank you very much. That is remarkable.

And tell me, Dr. Thorp, you've been in this field for a number of years now, what's the state of play in this field, and what have you seen over the last 5, 10 years? What the Armas's have done, is this a radical surgery now within the field, or is this—or is it we're getting this one down and it's moving on forward?

Dr. THORP. Well, sir—

Senator BROWNBAC. Pull that microphone up, if you would.

Dr. THORP.—in my specialty, in the Society of Maternal Fetal Medicine, what we've witnessed over the last 10 years is unheralded incredible opportunities to treat the fetus in the womb, as you've seen in front of you. I think that this is still investigational, and that's why we're so grateful that our government has provided such resources through the NIH to actually do the study, where many children will actually be randomized in utero before the surgery to either standard after-birth repair versus the in utero repair. But the opportunities in the future are unlimited for treating and fixing the fetus in utero.

Senator BROWNBAC. Now, tell me, where would Samuel be today if they had not gone through the in utero surgery?

Dr. THORP. Quite honestly, it's very difficult to say, Senator, because we're looking at one case. He could be the same, or he could be better, or he could be worse. And that's why the NIH is conducting the trial that they're doing.

It's a moving target, Senator, because as time progresses and institutions get more experienced, their control changes. So to use a historical control is very dangerous in this type of a situation where there's a moving improvement in outcomes.

Senator BROWNBAC. But we generally think, in medicine, the sooner you can catch something and deal with it, the better off you are, and I don't know if that holds as well in in utero surgery.

Dr. THORP. Absolutely, it does. Theoretically, there's a tremendous plasticity of fetal cells, in terms of inflammation and scarring. The two-hit hypothesis with spina bifida is that the initial problem that causes the defect is the initial insult, but then the ongoing in-

sult is the exposure to the nerve cells of the brain and spinal cord to amniotic fluid, which is thought to cause more damage. So the theory then is that if that nerve tissue, the spinal cord, is protected and closed in the uterus, then it won't take that second hit, the so-called second-hit hypothesis. But that's yet to be proven in prospective trials.

Senator BROWNBAC. We had a witness in here—this has been a couple of months ago—of a young man that was cured of sickle cell anemia. He was 17 years old. What was his name? Keone Penn. Keone Penn was a young man, 17 years old, and the physician that was here claimed that if they can catch the sickle cell anemia even in the womb, that they were going to have a much greater chance of being able to deal with developmental problems. Now, they didn't catch his until much later, and he, of course, had a lot of developmental problems because of the lateness that they caught it. But with umbilical cord blood transfusion, he was cured of it.

Dr. THORP. Yes, sir.

Senator BROWNBAC. Are you familiar with those taking place, as well?

Dr. THORP. I'm familiar with those cases. And we're in the embryonic stage. But you're absolutely correct. There are a number of diseases that have the potential of being completely cured by putting stem cells from cord blood into a fetus at 18 or 19 weeks, and that fetal immune system will actually empower it to be part of itself and will grow clones of normal blood cells throughout the life, instead of sickle cell. Also, a similar type of disease with severe combined immunodeficiency has also, I understand, been successfully performed.

Senator BROWNBAC. At what age are we looking at for the youngest treatment in the womb? What do you see? The child's going to have to develop to a certain level before you can detect and work on issues that come forward. I mean, you mentioned angioplasties being done, and cleft palates being fixed without a sign. What ages in the womb are we talking about that will be probably the youngest age that we will get to in performing different types of surgeries?

Dr. THORP. I don't know that there will be a limit. Technically, with ultrasound capability right now and with, for example, the standard needles that I use in my surgery, I've done a procedure as early as 19 weeks gestation successfully that otherwise the baby would have died. Now, that's merely limited by the physical size of the umbilical vessel and also the size of the needle. But as new technologies, nanotechnologies—there's a new da Vinci robotic device which is being tested, I understand, in Tennessee—great potential to lower that age.

Senator BROWNBAC. That is amazing.

The Armas family, this was quite a thing for you to do. When this first hit you that your child has spina bifida, and you described that situation, how much information was available to you that this surgery was a possibility at those early steps?

Mrs. ARMAS. I am a labor and delivery nurse, and I live in a large city. We live just outside of Atlanta, and we didn't know anything about it. My mother stumbled across Vanderbilt's website

after we knew something was wrong. We didn't quite know what it was. And my mother actually found their website, and that's how we knew to ask about it. It wasn't something that was commonly known to us.

Senator BROWNBAC. So you just thought your options are to go ahead and have the child, and the child will be born with spina bifida, or abort the child, is the options that you were——

Mrs. ARMAS. Yes.

Senator BROWNBAC.—that you were generally provided at that time?

Mrs. ARMAS. Yes, the traditional repair is done immediately after birth.

Senator BROWNBAC. Now, this is 3 years ago, going on four?

Mrs. ARMAS. August 19—was four years ago was the——

Senator BROWNBAC. Four years ago.

Mrs. ARMAS.—surgery. Yes. Samuel will be four in December.

Senator BROWNBAC. He was throwing me off, because I thought he was four, and then when he said three.

What about the situation now? My guess is you get contacted by a number of parents with similar problems. Are they getting more information—what's available, what options are out there for them?

Mrs. ARMAS. I think we are getting—and one of the reasons we agreed to have *USA Today* in the surgical suite was that we wanted to increase awareness of this surgery, because, like I said, we didn't know anything about it, and we are getting some contacts from people who have seen the picture, and then even later found out they were carrying a child with spina bifida and remembered it and called us.

But I still think, in talking to friends, it's not widely accepted as a viable alternative.

Senator BROWNBAC. Just not widely accepted as a viable alternative?

Mrs. ARMAS. What I'm thinking of is, I have a co-worker who was diagnosed with a child with spina bifida. He's less than a year old. And she talked to me, and I told her about fetal surgery. She came back, and she said, "Well, my doctor doesn't think that's a good idea." And, you know—and so she subsequently didn't look into it any further.

In general, I think it's still considered very risky and experimental, which is one reason we're very grateful that they're conducting trials now to bring some validity to the outcomes.

Senator BROWNBAC. That would be the case, Dr. Thorp, on spina bifida. What about these other issues, like cleft palate, the angioplasty? My guess is you don't have a—there isn't another option available when you're doing something like that on a child in the womb.

Dr. THORP. There are no clinical trials, sir. This is only anecdotal, totally investigational, and it's very possible at this point in time that we're doing more harm than good.

Senator BROWNBAC. On an angioplasty or a cleft palate repair?

Dr. THORP. With all of these.

Senator BROWNBAC. Because you just—you don't have the standardized trials yet?

Dr. THORP. Absolutely correct. And, you know, as Julie mentioned, there are some significant drawbacks. She took significant risk to herself to try to help Samuel within the womb. Forty percent of the babies of the mothers that undergo this surgery will actually deliver prematurely, before 32 weeks. And, in many cases, that could actually be detrimental to the baby. So then not only will the baby have spina bifida at birth, but it will also have a double hit with the significant ramifications of extreme prematurity. So that's a very serious thing.

So when we're looking at the risks, there's also significant risks to mom. When you make a large incision in the uterus, her uterus could rupture and put her life at risk, as well. Not only for the last pregnancy, with Samuel, but also with this pregnancy, with Ethan. So before—our government, our NIH, our medical system is approaching this the right way, absolutely correct, we don't want this widely available to everybody until we know for sure that we are doing no harm. *Primum non nocere* is part of our Hippocratic oath. That is, first do no harm.

And it may that fetal surgery is here to stay and it's only going to get better and better, but it may be that making a large incision in the uterus is not the way to go because it's so dangerous for mother and baby. It may be that when we are developing our laser, our endoscopic technology, that this can all be done through a scope. And, in fact, it is being done investigational at this time, attempted through a scope.

Senator BROWNBACK. That would seem to me to be a way that it would be likely that this would develop, because that big incision in the womb is a—

Dr. THORP. Very dangerous.

Senator BROWNBACK.—dangerous procedure and dangerous thing to do. Are we seeing that developing? The laparoscopic surgeries?

Dr. THORP. Yes, sir, absolutely. There is a laparoscopic laser surgery that is now available for twin-twin transfusion syndrome. And twin-twin transfusion syndrome, for those of you who are not familiar with it, is a very common complication of identical twins. In fact, 10 or 15 percent of identical twins, as early as 15 to 20 weeks gestation, will have vascular connections which will cause severe complications in both twins. And there are at least, I believe, three centers that are actually going in and actually lasering the vascular connections between those two babies. Now, again, that's controversial, it's investigational, but it's being done, and done successfully.

Senator BROWNBACK. Mr. and Mrs. Armas, when you first saw the picture, how—I guess this was several days after the surgery that you first saw the picture—what did you think?

Mr. ARMAS. Like Mr. Clancy, the first time we saw the photo was a good bit later, weeks later. And, in fact, we were planning, "OK, tomorrow morning is the *USA Today*. You need to get it at work." And I got a copy, and her parents and our family got copies, and that's the first time we saw it. And we were told that—basically what the picture entailed and about the hand, but it—without too much detail, we didn't realize what had been captured on film until we saw it in the newspaper, and it was pretty significant to us.

Senator BROWNBAC. What did you feel at that time when you saw it? I mean, did you feel like this is a significant picture, as what Mr. Clancy described, this has made it around the world and touched lives and gave hope? I mean, you called the picture "The Hand of Hope."

Mr. CLANCY. Well, the people have kind of renamed it. That's what it goes around now as an e-mail. It's kind of like being mass e-mailed to people, and they titled it "The Hand of Hope."

Mr. ARMAS. What I first thought was, "That's my boy." Like we said, this was from very early on—we had wanted Samuel for so long, and he was finally here, and we were going to have him no matter what problems he came with. We were prepared, and the Lord was going to help us deal with that. But there he was, and that's my first thought, is, you know, not only have we named him or come to know him or love him without even meeting him yet, but there he was on the film. And it was pretty amazing.

Sometimes we are taken aback—as we went through this process, we got caught up in the process and kind of got used to it, but every once in awhile we would step back and think, "Can you believe we're having fetal surgery?" And these are things that we might see on TV or read about, but we were actually participating in this. And the picture kind of brought that home to us.

Do you have anything to add to that?

Mrs. ARMAS. No.

Senator BROWNBAC. What did you think when you first saw the hand of your child?

Mrs. ARMAS. I was at home, on bedrest. He's at work. My family is out. And they're all calling me, telling me about the picture, and I hadn't even seen it. I think it was sort of surreal, because the whole process—like he said, we were, sort of, concerned about our life and how it was going to change with just this child with this special need. And then seeing that I was put to sleep for this surgery, so, you know, there wasn't a lot of that anxiety in the middle of the surgery. And it was almost easy to pretend that I had had my tonsils out or something. And then seeing that, you know, it was awesome.

Senator BROWNBAC. Dr. Thorp, you mentioned you do a lot of actions not breaching into the womb, but drawing blood, other items, with the fetus. With a young child—what reaction do you get from that young child when you stick it with a needle?

Dr. THORP. Senator, there's no question that this is a human baby in the womb. It does all the things that I said in my testimony as early as 20 weeks. I will often have to paralyze a fetus because if there's motion I will lose complete visibility of the target that I'm putting the needle at. So I will need to paralyze a fetus, much like you would be paralyzed in an operating room so that a surgeon and anesthesiologist could operate on you.

So it's very difficult to give that baby a shot. And I will usually try to give the baby a shot in the buttock with a smaller gauge needle. And it's the exact same reaction that—if you have children or that Samuel has when they go to the doctor's office and they have to get a shot. They pull away, and then you have to chase them in the womb with the needle.

[Laughter.]

Senator BROWNBACk. He's kind of——

Dr. THORP. There's no question they feel it.

Senator BROWNBACk. He's kind of confined in there. I mean——

Dr. THORP. Yes, sir.

Senator BROWNBACk.—you can catch him.

Dr. THORP. There's absolutely no question. It's the same way that you would expect a child, a newborn, in a doctor's office. It's the same to me. It always has been. And to those of us who see the ultrasounds, and to the parents—I would dare say that Mr. and Mrs. Armas have absolutely no difference in their perception of Samuel outside of the womb and Ethan, who is in the womb. It's the same precious life.

Senator BROWNBACk. Does it vary on age? When you're giving that child a shot, does it vary on age or at any of the age that you're operating in there, the same pull-back reaction, pain being felt, sensations?

Dr. THORP. The pull-back gets stronger beyond 19 weeks, but the first—the earliest I've transfused a fetus is 19 weeks, and I've gotten the same reaction. It's—that baby will move away from the needle. It's painful, just like we don't like needles.

Senator BROWNBACk. Our two youngest ones are both five, and we just did two shots to them for childhood diseases prevention, and it took five of us holding, shooting, to get all that done. I don't suppose you have five—maybe you have to have five, but when you're in that type of situation that would take a lot. But there's a pain sensation that's clearly there.

I want to thank all of you for coming and for presenting this. This is a short hearing, but this is a powerful picture. And just like pictures like Iwo Jima, others that have changed the course of history when you see them, where they evoke a powerful emotion within us, and I like to think they evoke that powerful spirit within us that just says, "This is something," that it touches.

And I think, Mr. Clancy, what you're seeing with this is just one of those. This is one of those powerful images that touch, and it touches people everywhere.

And to the Armas family, thank you for being—for staying in there. I'm sure you didn't think Samuel was going to be quite this famous this early. Maybe later on, but maybe not quite this early that he would be so famous.

Did anybody else have anything else they wanted to add?

Dr. Thorp?

Dr. THORP. Sir, I would just say that Julie and Alex are really heroes. They're really much—and Samuel—much like astronauts doing a first thing. They took a lot of risk for themselves, and they took a lot of risk, and it was the right thing to do. And only by the risk that they took can the rest of us be benefited, and they are to be congratulated and thanked for that.

Senator BROWNBACk. Absolutely. Absolutely. You're quite the heroes. And I think of all the parents out there that would be in a similar situation and looking for hope and now, you know, here's a couple that have gone before them to give them hope.

We have five children, and my wife has had miscarriages, too, and it's—you give a lot of people a lot of hope in situations that

they can look at as being pretty dark and pretty difficult. So thanks for doing that. God bless you all.

Thank you all for joining us here today. I appreciate particularly witnesses and the distances you've traveled and what you've shared.

The hearing is adjourned.

[Whereupon, at 3:25 p.m., the hearing was adjourned.]

A P P E N D I X

PREPARED STATEMENT OF HON. FRANK R. LAUTENBERG,
U.S. SENATOR FROM NEW JERSEY

In utero surgery—also known as fetal surgery—provides a real opportunity to improve the lives of children. Fetal surgery can offer hope to women who might otherwise give birth to children with potentially deadly or debilitating conditions such as spina bifida. It can save lives.

Medical advances in fields such as fetal surgery are very positive developments, especially when they help women *who want to bear children*.

There are exciting developments in another field that, like fetal surgery, could alleviate congenital birth defects and similar problems: *stem cell research*.

That is why I have cosponsored Senator Feinstein's bill that would prohibit human *reproductive* cloning—which just about everyone agrees is abhorrent—but would allow *therapeutic* cloning—that is, the cloning of cells for medical research, including stem cell research.

I hope that Congress will continue to support the development of lifesaving treatments.

The best way for Congress to show its support is to keep increasing the funding for the National Institutes of Health (NIH) by 8 to 10 percent each year, which is what the research community recommends.

Of course, that will become increasingly difficult now that we are running budget deficits again but if we *truly* view the NIH and the research conducted under its auspices as a national priority, we will find a way to get it the money it needs.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. FRANK R. LAUTENBERG TO
JAMES A. THORP, M.D.

Background

Question 1. As fetal surgery becomes more routine and medical technology continues to advance, there are concerns that doctors will make the fetus a patient at the expense of the mother's autonomy. Thus far, the pre-viable fetus has been deemed a patient according to the woman's decision to continue a pregnancy to viability and thus, to term. However, as medical technology makes the fetus more accessible to pediatric surgeons, perceptions of the fetus may change as the fetus begins to make serious claims for a right to nutrition, to protection, and to therapy.

Should a fetus have the right to receive surgical treatment independently of the mother's self-interest and legal rights?

Answer. NO, under no circumstances should a fetus have the right to receive surgical treatment independently of the mother's self-interest. A surgical intervention against the mother's desire should never be done and in fact is considered a criminal offense (assault and battery). Even if future studies show that some fetal surgeries are life-saving (to the fetus) it will always involve risk to the mother. For this reason no mother should ever be coerced into a fetal surgical procedure that she refuses. Interestingly, even cesarean section to save a normal fetus cannot be imposed upon a mother against her will. It is my understanding that this has been tested in court.

Question 2. Does a mother have the right to refuse a surgery because she is afraid of the risk such a surgery poses to herself?

Answer. YES. Absolutely and unequivocally YES. At the present time the "open maternal-fetal surgery" which includes a large incision into the pregnant uterus poses significant risk to the mother (potentially life-threatening). In contrast, although the benefits to the fetus are promising, they remain unproven. Indeed, the surgery also poses significant risks to the fetus, including fetal death and prematurity. About 40 percent of mothers undergoing "open maternal-fetal surgery" will deliver 8 weeks or more premature, thus adding additional risk. Thus, at the

present time, many educated and wise couples may elect NOT to have open maternal-fetal surgery.

RESPONSE TO WRITTEN QUESTION SUBMITTED BY HON. FRANK R. LAUTENBERG TO
MICHAEL CLANCY

Question. Does the doctor who performed the surgery (Dr. Joseph Bruner) share your account of the events that took place during the surgery?

Answer. Thank you for your inquiry as to Dr. Bruner's comments regarding the surgical procedure performed on Samuel Armas.

Dr. Bruner's first account of the events were published in the Tennessean Newspapers Sunday January 9, 2000 Issues Section. <http://www.tennessean.com/sii/00/01/09/vandyfeta109.shtml>

His statement:

"Depending on your political point of view, this is either Samuel Armas reaching out of the uterus and touching the finger of a fellow human, or it's me pulling his hand out of the uterus . . . which is what I did."

Three months later Dr. Bruner told Maj McKenna, (reporter) at the *Atlanta Journal Constitution*:

"When Samuel's hand appeared in the uterine opening, I impulsively reached out and lifted it," he said. "It was a very human thing to do, to reach out and take someone's hand." <http://www.nrlc.org/news/2000/NRL05/sam.html>
(Could not access the original article)

Dr. Bruner reportedly told *Time* magazine Europe that when his finger was grasped it was the most emotional moment of his life, and that for an instant during the procedure he was just frozen, totally immobile: <http://www.armybarmy.com/sam-hand.html> (Could not access the original article)

My credibility and integrity as a journalist has been severely challenged by Dr. Bruner's comments, but my version of the event has never changed.

